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Report Run Date: 13-May-2021

Data Lock Date: 12-May-2021 18:30:08

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All UK spontaneous reports received between 4/01/21 And FOE /21 for COVID-19 vaccine Oxford Aniversity/AstraZeneca

Name: COVID-19 vaccine AstraZeneca analysis print

Date: 13-May-2021
Data Lock Date: 12-May-2021 18:30:08
Action Date: 03-Feb-1921
Data Lock Date: 12-May-2021 18:30:08
MedDRA Version: MedDRA 24.0 Report Run Date: 13-May-2021 Earliest Reaction Date: 03-Feb-1921

Reaction Name	<u>Total</u>	Fatal
Blood disorders		
Anaemia deficiencies		
Anaemia vitamin B12 deficiency	6	0
Iron deficiency anaemia	4	0
Pernicious anaemia	1	0
Anaemias NEC		
Anaemia	50	0
Blood loss anaemia	2	0
Microcytic anaemia	1	0
Normocytic anaemia	1	0
Anaemias haemolytic NEC		
Haemolytic anaemia	4	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	2	0
Anaemias haemolytic mechanical factor		
Atypical haemolytic uraemic syndrome	1	0
Red cell fragmentation syndrome	1	0
Bleeding tendencies		
Increased tendency to bruise	74	0
Spontaneous haematoma	4	0
Spontaneous haemorrhage	1	0
Coagulation factor deficiencies		
Hypofibrinogenaemia	2	0
Coagulopathies		
Abnormal clotting factor	5	0
Antiphospholipid syndrome	21	0
Coagulopathy	37	0
Disseminated intravascular coagulation	14	1
Hypercoagulation	17	1
Eosinophilic disorders		
Eosinophilia	15	0
Hypereosinophilic syndrome	1	0
Haematological disorders		
Blood disorder	5	0
Bone marrow disorder	2	0
Bone marrow oedema	1	0
Mast cell activation syndrome	5	0
Mastocytosis	1	0
Methaemoglobinaemia	1	0
Haemolyses NEC		
Haemolysis	4	0
Leukocytoses NEC		
Leukocytosis	3	0
Lymphocytosis	4	0
Monocytosis	2	0
Neutrophilia	10	0
Leukopenias NEC		
Leukopenia	7	0
Lymphopenia	8	0
Lymphatic system disorders NEC		
Lymph node fibrosis	1	0
Lymph node pain	440	0
Lymphadenitis	21	0
Lymphadenopathy	3829	

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Reaction Name	<u>Total</u>	<u>Fatal</u>
Blood disorders Blood disorders cont'd		
Lymphatic disorder	1	0
Pseudolymphoma	3	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	1	0
Myelosuppression	2	0
Pancytopenia	13	0
Neutropenias		
Agranulocytosis	4	0
Autoimmune neutropenia	2	0
Febrile neutropenia	1	0
Neutropenia	66	0
Platelet disorders NEC		
Platelet anisocytosis	3	0
Platelet disorder	4	0
Polycythaemia (excl rubra vera)		
Stress polycythaemia	2	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	4	0
Red blood cell abnormal findings NEC		
Anisocytosis	1	0
Poikilocytosis	1	0
Polychromasia	2	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	4	0
Spleen disorders		
Spleen disorder	1	0
Splenic artery thrombosis	2	0
Splenic infarction	9	0
Splenic varices	1	0
Splenic vein thrombosis	7	0
Splenomegaly	5	0
Thrombocytopenias		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	9	0
Immune thrombocytopenia	159	
Thrombocytopenia	583	5
Thrombocytopenic purpura	7	0
Thrombotic thrombocytopenic purpura	1	0
Thrombocytoses		
Thrombocytosis	8	0
White blood cell abnormal findings NEC		
White blood cell disorder	3	0
Blood disorders SOC TOTAL	5518	8

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Cardiac disorders			
Aortic valvular disorders			
Aortic valve incompetence		1	0
Aortic valve stenosis		1	0
Cardiac conduction disorders			
Atrioventricular block		13	0
Atrioventricular block complete		3	0
Atrioventricular block second degree		2	0
Brugada syndrome		1	0
Bundle branch block		1	0
Bundle branch block left		5	0
Bundle branch block right		1	0
Long QT syndrome		1	0
Trifascicular block		1	0
Cardiac disorders NEC			
Acute cardiac event		3	1
Atrial thrombosis		2	0
Cardiac disorder		40	0
Cardiac dysfunction		1	0
Cardiac ventricular thrombosis		5	2
Cardiovascular disorder		4	2
Cardiovascular insufficiency		9	0
Intracardiac thrombus		3	0
Cardiac hypertensive complications			
Hypertensive heart disease		1	0
Cardiac infections and inflammations NEC			
Carditis		1	0
Cardiac signs and symptoms NEC			
Cardiac discomfort		11	0
Palpitations		3954	0
Cardiac valve disorders NEC			
Cardiac valve disease		1	1
Heart valve incompetence		1	0
Cardiomyopathies			
Cardiomyopathy		8	0
Congestive cardiomyopathy		7	0
Stress cardiomyopathy		2	0
Coronary artery disorders NEC			
Arteriosclerosis coronary artery		1	0
Coronary artery disease		4	0
Coronary artery dissection		1	0
Coronary artery embolism		1	0
Coronary artery occlusion		1	0
Coronary artery thrombosis		10	2
Heart failures NEC			
Cardiac failure		42	5
Cardiac failure acute		5	5 0
Cardiac failure congestive			1
Cardiogenic shock		2 5	2
Cardiopulmonary failure		1	1
Ischaemic coronary artery disorders			
Acute coronary syndrome		3	0
Acute myocardial infarction		41	0 7
Angina pectoris		138	

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	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Cardiac disorders Cardiac disorders cont'd			
Angina unstable		12	0
Arteriospasm coronary		2	0
Microvascular coronary artery disease		2 2	0
Myocardial infarction		228	33
Myocardial ischaemia		19	8
Prinzmetal angina		1	0
Left ventricular failures			
Acute left ventricular failure		1	0
Left ventricular failure		2	1
Mitral valvular disorders			
Mitral valve incompetence		4	0
Mitral valve prolapse		1	0
Myocardial disorders NEC			
Cardiomegaly		7	0
Left atrial dilatation		1	0
Left ventricular dilatation		1	0
Left ventricular dysfunction		11	0
Myocardial rupture		1	0
Right ventricular dysfunction		2	0
Ventricular hypertrophy		2	1
Noninfectious myocarditis			
Myocarditis		23	1
Noninfectious pericarditis			
Pericarditis		43	0
Pericardial disorders NEC			
Cardiac tamponade		1	1
Pericardial effusion		14	0
Pericardial haemorrhage		4	
Pericardial rub		1	2
Rate and rhythm disorders NEC			
Arrhythmia		83	0
Bradycardia		54	0
Cardiac fibrillation		2	0
Cardiac flutter		146	0
Extrasystoles		85	0
Heart alternation			0
Paroxysmal arrhythmia		2 2	0
Postural orthostatic tachycardia syndrome		9	0
Tachyarrhythmia		10	0
Tachycardia		1071	0
Right ventricular failures			
Cor pulmonale		1	0
Right ventricular failure		2	1
Supraventricular arrhythmias			
Arrhythmia supraventricular		13	0
Atrial fibrillation		209	0
Atrial flutter		25	0
Atrial tachycardia		1	0
Sinus arrest		1	0
Sinus arrhythmia		2	0
Sinus bradycardia		2 2	0
Sinus node dysfunction		1	0
Sinus tachycardia		55	1

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	23	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	3	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	123	28
Cardio-respiratory arrest	2	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	3	0
Ventricular fibrillation	5	0
Ventricular tachycardia	12	0
Cardiac disorders SOC TOTAL	6673	100

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDI	RA 24.0	
Reaction Name	<u> Total</u>	<u>Fatal</u>
Congenital disorders		
Cardiac disorders congenital NEC		
Heart disease congenital	8	0
Cardiac septal defects congenital		
Hypertrophic cardiomyopathy	5	0
Ventricular septal defect	1	0
Cardiovascular disorders congenital NEC		
Congenital cardiovascular anomaly	1	0
Central nervous system disorders congenital NEC		
Encephalocele	3	0
Neural tube defect	1	1
Syringomyelia	2	0
Cerebellar disorders congenital		
Arnold-Chiari malformation	3	0
Cerebral disorders congenital		
Anencephaly	1	0
Cerebral palsy	5	0
Coagulation disorders congenital		_
Haemophilia	2	
Protein C deficiency	3	
Protein S deficiency	1	0
Congenital disorders NEC		
Foetal malformation	3	
Young's syndrome	2	0
Connective tissue disorders congenital		
Ehlers-Danlos syndrome	6	0
Gastric disorders congenital	4	_
Pyloric stenosis	1	0
Great vessel disorders congenital		
Transposition of the great vessels	3	0
Haematological disorders congenital NEC	1	_
Neonatal alloimmune thrombocytopenia	'	0
Haemoglobinopathies congenital Sickle cell trait	1	0
Immune system abnormalities congenital	· ·	"
Combined immunodeficiency	1	0
Inborn errors of porphyrin metabolism		
Porphyria	1	0
Porphyria acute	1	0
Lymphatic system disorders congenital		
Cystic lymphangioma	1	0
Lysosomal storage disorders		
Mucolipidosis	1	0
Male reproductive tract disorders congenital		Ĭ
Hydrocele	1	0
Micropenis	2	
Musculoskeletal and connective tissue disorders of limbs congeni	_	
Congenital hand malformation	1	0
Limb reduction defect	1	0
Polydactyly	1	0
Musculoskeletal disorders congenital NEC		
Congenital multiplex arthrogryposis	1	0
Dysmorphism	2	
Otopalatodigital spectrum disorder	1	0

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Reaction Name	Total	Fatal
Congenital disordersCongenital disorders cont'd		
Neurological disorders congenital NEC		
Epilepsy with myoclonic-atonic seizures	1	0
Familial hemiplegic migraine	1	0
Familial periodic paralysis	1	0
Spinal muscular atrophy	1	0
Tourette's disorder	1	0
Non-site specific muscle disorders congenital		
Muscular dystrophy	2	0
Ocular disorders congenital NEC		
Colour blindness	1	0
Pancreatic disorders congenital		
Hereditary pancreatitis	1	0
Peripheral nervous system disorders congenital NEC		
Paroxysmal extreme pain disorder	11	0
Pulmonary and bronchial disorders congenital		
Cystic fibrosis	4	0
Renal disorders congenital		
Congenital cystic kidney disease	1	0
Sex chromosomal abnormalities		
Klinefelter's syndrome	1	0
Vascular anomalies congenital NEC		
Arteriovenous malformation	1	0
Klippel-Trenaunay syndrome	2	0
Congenital disorders SOC TOTAL	97	1

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	MedDRA Version: MedDRA 24.0		
Reaction Name		Total_	<u>Fatal</u>
Ear disorders			
Ear disorders NEC			
Ear congestion		19	0
Ear discomfort		71	0
Ear disorder		9	0
Ear haemorrhage		9	0
Ear pain		1585	0
Ear pruritus		3	0
Ear swelling		52	0
Otorrhoea		5	0
Eustachian tube disorders		Ĭ	ŭ
Eustachian tube disorder		3	0
Eustachian tube dysfunction		1	0
Eustachian tube obstruction		3	0
External ear disorders NEC		J	
Excessive cerumen production		20	0
External ear pain		11	0
· ·		5	0
Red ear syndrome  External ear infections and inflammations		၁	U
		2	^
External ear inflammation		2	0
Hearing disorders NEC		ا	0
Auditory disorder		4	0
Hearing losses			_
Deafness		216	0
Deafness bilateral		7	0
Deafness neurosensory		13	0
Deafness transitory		3	0
Deafness unilateral		30	0
Hypoacusis		132	0
Sudden hearing loss		41	0
Hyperacusia			
Hyperacusis		88	0
Inner ear disorders NEC			
Inner ear disorder		5	0
Meniere's disease		18	0
Vestibular disorder		5	0
Inner ear infections and inflammations			
Autoimmune inner ear disease		1	0
Inner ear inflammation		4	0
Inner ear signs and symptoms			
Motion sickness		89	0
Phobic postural vertigo		1	0
Tinnitus		2422	0
Vertigo		1371	0
Vertigo labyrinthine		8	0
Vertigo positional		83	0
Middle ear disorders NEC			
Middle ear disorder		1	0
Middle ear effusion		3	0
Tympanic membrane disorders (excl infection	96)		0
Tympanic membrane perforation	10)	1	0
		6347	0
Ear disorders SOC TOTAL		034/	(

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA Ver		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	3	0
Thyroiditis	6	
Thyroiditis acute	3	0
Thyroiditis chronic	1	0
Thyroiditis subacute	1	0
Adrenal cortical hyperfunctions		
Cushing's syndrome	1	0
Cushingoid	5	0
Adrenal cortical hypofunctions		
Addison's disease	2	0
Adrenal insufficiency	14	
Adrenocortical insufficiency acute	28	1
Glucocorticoid deficiency	1	0
Secondary adrenocortical insufficiency	1	О (
Adrenal gland disorders NEC		
Adrenal disorder	1	0
Adrenal haemorrhage	7	0
Adrenal mass	1	0
Adrenal thrombosis	1	0
Adrenomegaly	1	0
Haemorrhagic adrenal infarction	2	
Anterior pituitary hypofunction		
Hypopituitarism	2	0
Endocrine abnormalities of puberty		
Premature menarche	2	0
Female gonadal function disorders		
Anovulatory cycle	6	0
Ovulation delayed	4	0
Hyperparathyroid disorders		
Hyperparathyroidism	1	0
Hypoparathyroid disorders		
Hypoparathyroidism	2	0
Hypothalamic and pituitary disorders NEC		
Pituitary apoplexy	1	0
Posterior pituitary disorders		
Diabetes insipidus	5	0
Inappropriate antidiuretic hormone secretion	1	0
Thyroid disorders NEC		
Goitre	10	0
Thyroid disorder	4	
Thyroid mass	2	0
Thyroid pain	10	0
Thyroid hyperfunction disorders		
Basedow's disease	3	
Hyperthyroidism	21	0
Thyrotoxic crisis	2	0
Thyroid hypofunction disorders		
Hypothyroidism	33	0
Endocrine disorders SOC TOTAL	188	

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Eye disorders		
Amblyopic vision impairment		
Amblyopia	3	0
Cataract conditions		
Cataract	9	0
Cataract cortical	3	0
Cataract subcapsular	2	0
Choroid and vitreous haemorrhages and vascular disorders		
Vitreous haemorrhage	3	0
Choroid and vitreous structural change, deposit and degeneration		
Chorioretinopathy	3	0
Vitreous detachment	34	0
Vitreous floaters	109	0
Vitreous opacities	1	0
Colour blindness (incl acquired)		
Dyschromatopsia	15	0
Conjunctival and corneal bleeding and vascular disorders		
Conjunctival haemorrhage	89	0
Conjunctival infections, irritations and inflammations		
Conjunctival hyperaemia	1	0
Corneal infections, oedemas and inflammations		
Keratitis	2	0
Ulcerative keratitis	2	0
Corneal structural change, deposit and degeneration		
Corneal perforation	1	0
Eyelid movement disorders		
Blepharospasm	84	0
Excessive eye blinking	6	0
Eyelid ptosis	31	0
Glaucomas (excl congenital)		
Angle closure glaucoma	2	0
Glaucoma	5	0
Ocular hypertension	1	0
Iris and ciliary body structural change, deposit and degeneration		
Eye colour change	6	0
Iris and uveal tract infections, irritations and inflammations		
Autoimmune uveitis	1	0
Iridocyclitis	15	0
Iritis	8	0
Uveitis	24	0
Lacrimation disorders		
Dry eye	221	0
Lacrimation increased	193	0
Lens structural change, deposit and degeneration (excl cataracts)		
Anterior capsule contraction	1	0
Lid bleeding and vascular disorders		
Eyelid bleeding	2	0
Eyelid haematoma	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Blepharitis	12	0
Chalazion	1	0
Eczema eyelids	1	0
Erythema of eyelid	5	0
Eyelid cyst	10	

Reaction NameTotalFaEye disordersEye disorders cont'dEyelid irritation3Eyelid margin crusting1Eyelid oedema10Eyelid rash6Swelling of eyelid87Lid, lash and lacrimal structural disorders1Eyelid exfoliation1Eyelid skin dryness1Eyelid thickening3Growth of eyelashes5Lagophthalmos1Ocular bleeding and vascular disorders NEC5Eye haematoma3Eye haemorrhage68Ocular vascular disorder1Ophthalmic vein thrombosis3Ocular cysts and polyps1Vitreous cyst1Ocular disorders NEC1Dark circles under eyes6	tal C
Eyelid irritation       3         Eyelid margin crusting       1         Eyelid oedema       10         Eyelid rash       6         Swelling of eyelid       87         Lid, lash and lacrimal structural disorders       1         Eyelid exfoliation       1         Eyelid skin dryness       1         Eyelid thickening       3         Growth of eyelashes       5         Lagophthalmos       1         Ocular bleeding and vascular disorders NEC         Eye haematoma       3         Eye haemorrhage       68         Ocular vascular disorder       1         Ophthalmic vein thrombosis       3         Ocular cysts and polyps       Vitreous cyst         Vitreous cyst       1         Ocular disorders NEC       1	C
Eyelid margin crusting Eyelid oedema Eyelid rash Swelling of eyelid  Lid, lash and lacrimal structural disorders Eyelid exfoliation Eyelid skin dryness Eyelid thickening Growth of eyelashes Lagophthalmos  Ocular bleeding and vascular disorders NEC Eye haematoma Eye haemorrhage Ocular vascular disorder Ophthalmic vein thrombosis Ocular cysts and polyps Vitreous cyst Ocular disorders NEC	C
Eyelid oedema Eyelid rash Swelling of eyelid  Lid, lash and lacrimal structural disorders  Eyelid exfoliation Eyelid skin dryness Eyelid thickening Growth of eyelashes Lagophthalmos  Ocular bleeding and vascular disorders NEC Eye haematoma Eye haemorrhage Ocular vascular disorder Ophthalmic vein thrombosis  Ocular cysts and polyps Vitreous cyst Ocular disorders NEC	
Eyelid rash Swelling of eyelid  Lid, lash and lacrimal structural disorders Eyelid exfoliation Eyelid skin dryness Eyelid thickening Growth of eyelashes Lagophthalmos  Ocular bleeding and vascular disorders NEC Eye haematoma Eye haemorrhage Ocular vascular disorder Ophthalmic vein thrombosis  Ocular cysts and polyps Vitreous cyst  Ocular disorders NEC	C
Swelling of eyelid  Lid, lash and lacrimal structural disorders  Eyelid exfoliation  Eyelid skin dryness  Eyelid thickening  Growth of eyelashes  Lagophthalmos  1  Ocular bleeding and vascular disorders NEC  Eye haematoma  Eye haemorrhage  Ocular vascular disorder  Ophthalmic vein thrombosis  Ocular cysts and polyps  Vitreous cyst  Ocular disorders NEC	C
Lid, lash and lacrimal structural disordersEyelid exfoliation1Eyelid skin dryness1Eyelid thickening3Growth of eyelashes5Lagophthalmos1Ocular bleeding and vascular disorders NECEye haematoma3Eye haemorrhage68Ocular vascular disorder1Ophthalmic vein thrombosis3Ocular cysts and polyps1Vitreous cyst1Ocular disorders NEC1	C
Eyelid exfoliation Eyelid skin dryness Eyelid thickening Growth of eyelashes Lagophthalmos  Coular bleeding and vascular disorders NEC Eye haematoma Eye haemorrhage Ocular vascular disorder Ophthalmic vein thrombosis  Coular cysts and polyps Vitreous cyst Ocular disorders NEC	C
Eyelid skin dryness Eyelid thickening Growth of eyelashes Lagophthalmos  Coular bleeding and vascular disorders NEC Eye haematoma Eye haemorrhage Ocular vascular disorder Ophthalmic vein thrombosis  Coular cysts and polyps Vitreous cyst Coular disorders NEC	
Eyelid thickening Growth of eyelashes Lagophthalmos  Coular bleeding and vascular disorders NEC Eye haematoma Eye haemorrhage Ocular vascular disorder Ophthalmic vein thrombosis  Coular cysts and polyps Vitreous cyst  Coular disorders NEC	C
Eyelid thickening Growth of eyelashes Lagophthalmos  Coular bleeding and vascular disorders NEC Eye haematoma Eye haemorrhage Ocular vascular disorder Ophthalmic vein thrombosis  Coular cysts and polyps Vitreous cyst  Coular disorders NEC	C
Lagophthalmos  Ocular bleeding and vascular disorders NEC  Eye haematoma  Eye haemorrhage  Ocular vascular disorder  Ophthalmic vein thrombosis  Ocular cysts and polyps  Vitreous cyst  Ocular disorders NEC	C
Ocular bleeding and vascular disorders NECEye haematoma3Eye haemorrhage68Ocular vascular disorder1Ophthalmic vein thrombosis3Ocular cysts and polyps3Vitreous cyst1Ocular disorders NEC1	C
Eye haematoma Seye haemorrhage Ocular vascular disorder Ophthalmic vein thrombosis Socular cysts and polyps Vitreous cyst Ocular disorders NEC	C
Eye haematoma Seye haemorrhage Ocular vascular disorder Ophthalmic vein thrombosis Socular cysts and polyps Vitreous cyst Ocular disorders NEC	
Eye haemorrhage 68 Ocular vascular disorder 1 Ophthalmic vein thrombosis 3 Ocular cysts and polyps Vitreous cyst 1 Ocular disorders NEC	C
Ocular vascular disorder Ophthalmic vein thrombosis  Ocular cysts and polyps Vitreous cyst Ocular disorders NEC	C
Ocular cysts and polyps Vitreous cyst 1 Ocular disorders NEC	C
Ocular cysts and polyps Vitreous cyst 1 Ocular disorders NEC	C
Vitreous cyst 1 Ocular disorders NEC	
	C
Dark circles under eyes 6	
	C
Eye disorder 15	C
Eye oedema 14	C
Eye pain 2775	C
Eye swelling 460	C
Eye symptom 6	C
Eye ulcer 9	C
Eyelid disorder 4	C
Eyelid pain 16	C
Eyelids pruritus 5	C
Ocular discomfort 50	C
Periorbital oedema 14	C
Periorbital pain 3	C
Periorbital swelling 76	C
Retinal disorder 1	C
Ocular infections, inflammations and associated manifestations	
Autoimmune eye disorder 1	С
Eye allergy 19	C
Eye discharge 19	C
Eye inflammation 25	C
Eye irritation 169	C
Eye pruritus 233	C
Limbal swelling 4	C
Ocular hyperaemia 313	C
Ocular rosacea 1	C
Ocular nerve and muscle disorders	
Extraocular muscle paresis 7	C
Eye movement disorder 34	C
Gaze palsy 3	C
Ocular myasthenia	C
Ophthalmoplegia 1	C
Strabismus 3	C
Ocular sensation disorders	
Abnormal sensation in eye 21	C

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Asthenopia	280	0
Eye paraesthesia	1	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	30	0
Hypoaesthesia eye	21	0
Photophobia	838	0
Optic disc abnormalities NEC		
Optic atrophy	1	0
Optic discs blurred	1	0
Papilloedema	9	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	5	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	3	0
Pupil disorders		
Miosis	9	0
Mydriasis	22	0
Pupil fixed	8	0
Pupils unequal	7	0
Refractive and accommodative disorders		·
Altered visual depth perception	4	0
Hypermetropia	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal aneurysm	1	0
Retinal artery embolism	2	0
Retinal artery occlusion	12	0
Retinal haemorrhage	10	0
Retinal vascular occlusion	1	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	29	0
Retinal vein thrombosis	5	0
Retinal vein varices	1	0
Retinal structural change, deposit and degeneration		
Macular cyst	1	0
Macular degeneration	5	0
Macular detachment	1	0
Macular hole	2	0
Neovascular age-related macular degeneration	8	0
Retinal detachment	14	0
Retinal drusen	1	0
Retinal tear	9	0
Retinal toxicity	2	0
Vitreoretinal traction syndrome	1	0
Retinal, choroid and vitreous infections and inflammations		
Macular oedema	4	0
Retinopathies NEC		
Acute macular outer retinopathy	4	0
Retinal exudates	11	0
Retinopathy	6	0
Scleral infections, irritations and inflammations		
Episcleritis	10	0
Scleritis	5	0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Scleral structural change, deposit and degeneration		
Scleral discolouration	1	0
Structural change, deposit and degeneration of eye NEC		
Deposit eye	1	0
Endocrine ophthalmopathy	2	0
Exophthalmos	3	0
Visual colour distortions		
Chloropsia	1	0
Chromatopsia	1	0
Cyanopsia	1	0
Erythropsia	3	0
Xanthopsia	6	0
Visual disorders NEC		
Charles Bonnet syndrome	1	0
Diplopia	228	0
Dysmetropsia	1	0
Halo vision	10	0
Metamorphopsia	26	0
Photopsia	233	0
Scintillating scotoma	4	0
Vision blurred	1924	0
Visual brightness	6	0
Visual snow syndrome	2	0
Visual field disorders		
Visual field defect	21	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	6	0
Blindness	176	0
Blindness transient	15	0
Blindness unilateral	15	0
Central vision loss	2	0
Night blindness	4	0
Sudden visual loss	3	0
Visual acuity reduced	21	0
Visual acuity reduced transiently	1	0
Visual impairment	474	0
Visual pathway disorders		
Optic nerve disorder	1	0
Optic neuropathy	4	0
Eye disorders SOC TOTAL	9996	0

	edDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Gastrointestinal disorders		
Abdominal findings abnormal		
Abdominal mass	3	0
Gastrointestinal sounds abnormal	16	0
Acute and chronic pancreatitis		
Obstructive pancreatitis	1	1
Pancreatitis	26	1
Pancreatitis acute	9	0
Pancreatitis chronic	1	0
Anal and rectal disorders NEC		
Anal fissure	2	2 0
Anal and rectal pains		
Proctalgia	23	o
Anal and rectal signs and symptoms		
Anal blister	2	2 0
Anal hypoaesthesia	4	
Anal inflammation	1	0
Anal paraesthesia	1	0
Anal pruritus	3	
Anal spasm	1	
Anorectal discomfort	4	
Anorectal swelling	1	0
Rectal discharge	1	0
Benign oral cavity neoplasms		
Mouth cyst	12	2 0
Tongue cyst		
Tongue polyp	3	2 0
Colitis (excl infective)		
Autoimmune colitis	2	2 0
Colitis	32	
Colitis ischaemic	2	
Colitis microscopic	2	
Colitis ulcerative	61	
Crohn's disease	59	
Inflammatory bowel disease	3	
Terminal ileitis	1	0
Dental and periodontal infections and inflamma	tions	Ŭ
Dental caries	2	2 0
Dental disorders NEC		
Diastema	1	0
Loose tooth	1	0
Malpositioned teeth	1	0
Teething	18	0
Tooth disorder	2	
Tooth socket haemorrhage	1	0
Dental pain and sensation disorders		
Dental discomfort	11	0
Dental paraesthesia	15	
Hyperaesthesia teeth	38	
Hypoaesthesia teeth		Ö
Toothache	253	
Dental pulp disorders	200	
Dental pulp disorder  Dental pulp disorder	1	0
Dental surface disorders		
Delital Sullave UISUIUEIS		<u> </u>

Earliest Reaction Date: 03-Feb-1921 Me	edDRA Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Gastrointestinal disorders cont'o	1	
Tooth discolouration	12	0
Diaphragmatic hernias		
Hiatus hernia	10	0
Diarrhoea (excl infective)		
Diarrhoea	7196	6 0
Diarrhoea haemorrhagic	25	0
Diverticula		
Diverticulum		6 0
Duodenal and small intestinal stenosis and obs	truction	
Small intestinal obstruction	1	1 0
Superior mesenteric artery syndrome	1	0
Duodenal ulcers and perforation		
Duodenal ulcer	1	0
Duodenal ulcer haemorrhage	1	1
Dyspeptic signs and symptoms		
Dyspepsia	669	
Epigastric discomfort	16	
Eructation 5-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1	72	0
Faecal abnormalities NEC	4.0	
Abnormal faeces	13	
Faecaloma	2	
Faeces discoloured	39	
Faeces hard	4	
Faeces pale Faeces soft	16	
	11	
Mucous stools		l U
Flatulence, bloating and distension  Abdominal distension	357	7 0
Flatulence	337	
Gastric and oesophageal haemorrhages	320	1
Gastric haemorrhage		6 0
Gastric vicers and perforation		1
Gastric ulcer		0
Gastric ulcer haemorrhage		1
Gastric ulcer perforation		i ő
Gastritis (excl infective)		
Chronic gastritis	3	3 0
Gastritis	61	
Reflux gastritis	12	
Gastrointestinal and abdominal pains (excl oral	and throat)	
Abdominal migraine	, j	3 0
Abdominal pain	3578	3 0
Abdominal pain lower	178	3 0
Abdominal pain upper	4086	
Abdominal rigidity	42	2 0
Abdominal tenderness	17	
Gastrointestinal pain	257	
Oesophageal pain	6	0
Gastrointestinal atonic and hypomotility disorde		
Constipation	333	
Duodenogastric reflux	2	
Gastric dilatation	13	
Gastrooesophageal reflux disease	161	<u>  0</u>

Earliest Reaction Date: 03-Feb-1921 MedI	DRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Impaired gastric emptying	3	
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Gastrointestinal disorders NEC		
Appendix disorder	1	0
Food poisoning	10	o
Functional gastrointestinal disorder	8	0
Gastric disorder	8	0
Gastrointestinal disorder	20	0
Gastrointestinal oedema	3	0
Gastroptosis	1	0
Neurogenic bowel	1	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	4	0
Change of bowel habit	10	0
Defaecation disorder	1 1	1
Dyschezia	12	
Gastrointestinal motility disorder	2	
Oesophageal achalasia	2	
Gastrointestinal inflammatory disorders NEC		
Appendicitis noninfective	1	0
Enteritis	1	0
Gastrointestinal inflammation	1	0
Gastrointestinal tract irritation		
Intestinal angioedema	1	0
Ischaemic enteritis	1	0
Gastrointestinal mucosal dystrophies and secretic	on disorders	
Achlorhydria	1	0
Hyperchlorhydria	2	
Gastrointestinal necrosis and gangrene (excl gang		
Gastrointestinal necrosis	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	1276	0
Abdominal symptom	5	
Acute abdomen	12	
Anal incontinence	30	
Breath odour	18	
Dysphagia	172	
Intestinal congestion	1	1
Odynophagia	25	
Gastrointestinal spastic and hypermotility disorder		
Cardiospasm	2	1
Defaecation urgency	12	
Frequent bowel movements	34	
Irritable bowel syndrome	90	
	6	
Intestinal obstruction	4	0
	1	0
Volvulus	1	1
	ecified	
	1	0
Oesophageal spasm  Gastrointestinal stenosis and obstruction NEC Intestinal obstruction Intussusception	2 4 1 1 1	. (

	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Gastrointestinal disorders con	ıt'd	
Gastric antral vascular ectasia	6	0
Gastrointestinal vascular occlusion and infarc	tion	
Intestinal infarction	3	1
Intestinal ischaemia	19	1
Mesenteric artery embolism	1	0
Mesenteric artery thrombosis	2	
Mesenteric vein thrombosis	11	0
Mesenteric venous occlusion	1	0
Thrombosis mesenteric vessel	3	1
Visceral venous thrombosis	8	1
Gingival disorders, signs and symptoms NEC		
Epulis	1	0
Gingival blister	18	0
Gingival discomfort	5	
Gingival disorder	12	2 0
Gingival hypertrophy	2	2 0
Gingival oedema	2	2 0
Gingival pain	179	0
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	36	0
Gingival ulceration	5	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	18	0
Gingival haemorrhages		
Gingival bleeding	99	0
Haemorrhoids and gastrointestinal varices (ex	kcl oesophageal)	
Haemorrhoidal haemorrhage		0
Haemorrhoids	38	0
Haemorrhoids thrombosed	7	0
Inguinal hernias		
Inguinal hernia	3	0
Intestinal haemorrhages		
Anal haemorrhage	24	0
Intestinal haemorrhage	1	0
Mesenteric haemorrhage	1	0
Rectal haemorrhage	69	0
Small intestinal haemorrhage	26	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	2	2 0
Large intestine perforation	1	0
Large intestinal stenosis and obstruction		
Large intestinal obstruction	1	0
Large intestinal stenosis	1	0
Malabsorption syndromes		
Bile acid malabsorption		0
Coeliac disease	13	0
Steatorrhoea	1	0
Nausea and vomiting symptoms		
Acetonaemic vomiting		0
Discoloured vomit	17	0
Faecal vomiting	2	0
Infantile vomiting	2	el o

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Gastrointestinal disorders contestinal disorder contestinal disorders contestinal disorders contestinal disord	ont'd	
Nausea	28814	4 0
Regurgitation		2 0
Retching	204	1 0
Vomiting	964	
Vomiting projectile	134	
Non-site specific gastrointestinal haemorrha		'l 'l
Gastrointestinal haemorrhage	20	
Haematemesis	63	
Haematochezia	62	
Melaena		6 0
Upper gastrointestinal haemorrhage	4	2 0
Oesophageal disorders NEC		
Oesophageal disorder		2 0
Oesophageal stenosis and obstruction		
Oesophageal obstruction	· ·	1 0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	3	
Oesophagitis	10	이
Oral dryness and saliva altered		
Aptyalism		4 O
Dry mouth	976	3 0
Lip dry	70	0
Saliva altered	Ę	5 0
Saliva discolouration	•	1 0
Salivary hypersecretion	6′	ı  o
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica		ı  o
Chapped lips	16	sl ol
Cheilitis	3′	
Chronic cheek biting		1 o
Enlarged uvula	(	
Leukoplakia oral		2 0
Lip blister	24	
Lip disorder		
Oral disorder	1.	. 1
Oral lichen planus	'8	
Oral papule		
Palatal disorder		2 0
Uvulitis		5 0
Oral soft tissue haemorrhages	· ·	1 1
	,	
Lip haemorrhage	30	
Mouth haemorrhage	28	
Oral blood blister	40	
Oral purpura	2	2 0
Oral soft tissue infections		
Angular cheilitis	3	3 0
Oral soft tissue signs and symptoms		
Anaesthesia oral	7	7 0
Burning mouth syndrome		
Coating in mouth		3 0
Hypoaesthesia oral	48′	1 0
Lip discolouration		1 0
Lip erythema		4l ol

	MedDRA Version: MedDRA 24.0		
Reaction Name		<u> Total</u>	Fatal
Gastrointestinal disorders con	t'd		
Lip exfoliation		9	0
Lip pain		49	0
Lip pruritus		15	0
Oral discharge		1	0
Oral discomfort		69	0
Oral mucosal blistering		24	0
Oral mucosal eruption		18	0
Oral mucosal erythema		4	0
Oral mucosal exfoliation		8	0
Oral mucosal roughening		3	0
Oral pain		284	0
Oral pruritus		18	0
Paraesthesia oral		674	0
Oral soft tissue swelling and oedema			
Lip oedema		7	0
Lip swelling		746	0
Mouth swelling		98	0
Oedema mouth		1	0
Palatal oedema		1	0
Palatal swelling		12	0
Pancreatic disorders NEC			
Pancreatic disorder		1	0
Pancreatic mass		1	0
Peptic ulcers and perforation			
Peptic ulcer		1	0
Peritoneal and retroperitoneal disorders			
Ascites		5	0
Peritoneal and retroperitoneal haemorrhages			
Haemoperitoneum		1	0
Retroperitoneal haemorrhage		1	0
Rectal inflammations NEC			
Proctitis		2	0
Salivary gland disorders NEC			
Salivary gland calculus		3	0
Salivary gland pain		11	0
Salivary gland enlargements			
Parotid gland enlargement		9	0
Salivary gland enlargement		4	0
Salivary gland infections and inflammations			
Noninfective sialoadenitis		2	0
Stomatitis and ulceration			
Aphthous ulcer		52	0
Lip ulceration		14	0
Mouth ulceration		585	0
Stomatitis		78	0
Tongue disorders			
Glossitis		14	0
Plicated tongue		4	0
Tongue disorder		26	0
Tongue geographic			0
Tongue haemorrhage		2 2	0
Tongue ulceration		24	0
Trichoglossia		4	0

# Name: COVID-19 vaccine AstraZeneca analysis print Report Run Date: 13-May-2021 Data Lock Date: 12-May-2021 18:30:08

MedDRA Version: MedDRA 24.0 Earliest Reaction Date: 03-Feb-1921 Reaction Name Fatal <u>Total</u> Gastrointestinal disorders cont'd Tongue signs and symptoms Glossodynia 209 0 Scalloped tongue 0 3 ol Stiff tongue 3 0 Strawberry tongue 0 Swollen tongue 469 0 Tongue blistering 22 30 0 Tongue coated Tongue discolouration 24 0 Tongue discomfort 38 0 ol Tongue dry 18 0 Tongue eruption 6 0 Tongue erythema 4 0 Tongue exfoliation 0 Tongue movement disturbance 6 0 Tongue oedema 13 0 Tongue pruritus 3 o 2 Tongue rough 3 Tongue spasm 0 Tooth missing 0 Tooth loss

Gastrointestinal disorders SOC TOTAL

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
General disorders			
Administration site reactions NEC			
Administration site bruise		12	0
Administration site coldness		1	0
Administration site erythema		6	0
Administration site extravasation		2	0
Administration site induration		1	0
Administration site mass		1	0
Administration site pain		36	0
Administration site rash		2	0
Administration site reaction		2 5	0
Administration site swelling		3	0
Administration site urticaria		3	0
Puncture site bruise		48	0
Puncture site haemorrhage		1	0
Puncture site pain		20	0
Puncture site reaction		3	0
Puncture site swelling		1	0
Adverse effect absent			
No adverse event		19	0
Application and instillation site reactions			
Application site acne		1	0
Application site bruise		22	0
Application site burn		3	0
Application site coldness		1	0
Application site discharge		1	0
Application site discolouration		1	0
Application site erythema		25	0
Application site exfoliation		1	0
Application site haemorrhage		1	0
Application site hypersensitivity		1	0
Application site inflammation		1	0
Application site joint pain		1	0
Application site pain		37	0
Application site pruritus		16	0
Application site rash		1	0
Application site scar		1	0
Application site swelling		4	0
Application site vesicles		7	0
Application site warmth		1	0
Application site wound		1	0
Instillation site bruise		1	0
Instillation site discomfort		1	0
Instillation site pain		4	0
Instillation site pruritus		1	0
Instillation site warmth		12	0
Asthenic conditions			
Asthenia		3817	3
Chronic fatigue syndrome		88	3 0
Decreased activity		5	0
Fatigue		40931	0
Malaise		10289	
Sluggishness		20	3 0
Body temperature altered			

Reaction NameGeneral disordersGeneral disordersGeneral disordersHyperthermia9Hypothermia47Temperature regulation disorder22Complications associated with device NECComplication of device removal1Injury associated with device3Medical device site joint pain1Phantom shocks3Death and sudden death4Brain death4Death238Drowning1Sudden death28Febrile disorders1Hyperpyrexia39Masked fever1PFAPA syndrome1Pyrexia48778
Hyperthermia 9 Hypothermia 47 Temperature regulation disorder 22  Complications associated with device NEC  Complication of device removal 1 Injury associated with device 3 Medical device site joint pain 1 Phantom shocks 3  Death and sudden death Brain death 4 Death Death 238 Drowning 1 Sudden death 28  Febrile disorders Hyperpyrexia 39 Masked fever 1 PFAPA syndrome 1 Pyrexia 48778
Hypothermia       47         Temperature regulation disorder       22         Complications associated with device NEC       1         Complication of device removal       1         Injury associated with device       3         Medical device site joint pain       1         Phantom shocks       3         Death and sudden death       4         Brain death       4         Death       238         Drowning       1         Sudden death       28         Febrile disorders       39         Hyperpyrexia       39         Masked fever       1         PFAPA syndrome       1         Pyrexia       48778
Temperature regulation disorder         22           Complications associated with device NEC         1           Complication of device removal         1           Injury associated with device         3           Medical device site joint pain         1           Phantom shocks         3           Death and sudden death         4           Brain death         4           Death         238           Drowning         1           Sudden death         28           Febrile disorders         39           Hyperpyrexia         39           Masked fever         1           PFAPA syndrome         1           Pyrexia         48778
Complications associated with device NEC           Complication of device removal         1           Injury associated with device         3           Medical device site joint pain         1           Phantom shocks         3           Death and sudden death         3           Brain death         4           Death         238           Drowning         1           Sudden death         28           Febrile disorders         39           Masked fever         1           PFAPA syndrome         1           Pyrexia         48778
Complication of device removal       1         Injury associated with device       3         Medical device site joint pain       1         Phantom shocks       3         Death and sudden death       4         Brain death       4         Death       238         Drowning       1         Sudden death       28         Febrile disorders       39         Masked fever       1         PFAPA syndrome       1         Pyrexia       48778
Complication of device removal       1         Injury associated with device       3         Medical device site joint pain       1         Phantom shocks       3         Death and sudden death       4         Brain death       4         Death       238         Drowning       1         Sudden death       28         Febrile disorders       39         Masked fever       1         PFAPA syndrome       1         Pyrexia       48778
Injury associated with device       3         Medical device site joint pain       1         Phantom shocks       3         Death and sudden death       4         Brain death       4         Death       238         Drowning       1         Sudden death       28         Febrile disorders       39         Masked fever       1         PFAPA syndrome       1         Pyrexia       48778
Medical device site joint pain       1         Phantom shocks       3         Death and sudden death       4         Brain death       4         Death       238         Drowning       1         Sudden death       28         Febrile disorders       39         Hyperpyrexia       39         Masked fever       1         PFAPA syndrome       1         Pyrexia       48778
Phantom shocks       3         Death and sudden death       4         Brain death       4         Death       238         Drowning       1         Sudden death       28         Febrile disorders       39         Hyperpyrexia       39         Masked fever       1         PFAPA syndrome       1         Pyrexia       48778
Death and sudden death         4           Brain death         4           Death         238           Drowning         1           Sudden death         28           Febrile disorders         8           Hyperpyrexia         39           Masked fever         1           PFAPA syndrome         1           Pyrexia         48778
Brain death       4         Death       238         Drowning       1         Sudden death       28         Febrile disorders       39         Hyperpyrexia       39         Masked fever       1         PFAPA syndrome       1         Pyrexia       48778
Drowning       1         Sudden death       28         Febrile disorders       39         Hyperpyrexia       39         Masked fever       1         PFAPA syndrome       1         Pyrexia       48778
Drowning       1         Sudden death       28         Febrile disorders       39         Hyperpyrexia       39         Masked fever       1         PFAPA syndrome       1         Pyrexia       48778
Sudden death  Febrile disorders  Hyperpyrexia  Masked fever  PFAPA syndrome  Pyrexia  28  39  48778
Febrile disorders         39           Hyperpyrexia         1           Masked fever         1           PFAPA syndrome         1           Pyrexia         48778
Hyperpyrexia       39         Masked fever       1         PFAPA syndrome       1         Pyrexia       48778
Masked fever 1 PFAPA syndrome 1 Pyrexia 48778
PFAPA syndrome 1 Pyrexia 48778
Pyrexia 48778
Feelings and sensations NEC
Chills 38873
Early satiety 1
Feeling abnormal 2349
Feeling cold 4598
Feeling drunk 102
Feeling hot 1994
Feeling jittery 37
Feeling of body temperature change 835
Feeling of relaxation 1
Hangover 150
Hunger 62
Sensation of blood flow
Sensation of foreign body 34
Temperature intolerance 57
Thirst 1097
Thirst decreased 9
Fibrosis NEC
Fibrosis 2
Gait disturbances
Decreased gait velocity 2
Gait disturbance 283
Gait inability 146
Loss of control of legs 37
General signs and symptoms NEC
Apparent death 1
Chronic disease
Condition aggravated 171
Crepitations 5
Crying 215
Developmental delay 4
Discharge 5
Disease progression 1
Disease progression  Disease recurrence
Effusion 1

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
General disorders General disorders cont'd			
Energy increased		18	0
Exercise tolerance decreased		22	0
Foaming at mouth		4	0
General physical health deterioration		18	1
General symptom		10	0
Glassy eyes		5	0
High-pitched crying		4	0
III-defined disorder		3	0
Illness		4184	0
Induration		18	0
Influenza like illness		8269	1
Irritability postvaccinal		2	0
Local reaction		144	0
Moaning		8	0
Multiple organ dysfunction syndrome		13	4
Nonspecific reaction		3	0
Organ failure		1	0
Perforation		1	0
Peripheral swelling		4592	0
Pre-existing condition improved		11	0
Premature ageing		1	0
Prolapse		1	0
Screaming		19	0
Secretion discharge		20	0
Sensitivity to weather change		1	0
Stenosis		1	0
Swelling		2112	0
Swelling face		790	0
Symptom recurrence		4	0
Tissue discolouration		1	0
Tissue infiltration		1	0
Unevaluable event		2	0
Healing abnormal NEC			
Impaired healing		2	0
Hernias NEC			
Hernia		2	0
Implant and catheter site reactions			
Catheter site urticaria		1	0
Implant site coldness		1	0
Implant site discharge		1	0
Implant site discolouration		3 2	0
Implant site hypoaesthesia			0
Implant site pain		4	0
Implant site rash		1	0
Implant site swelling		2 7	0
Implant site warmth		7	0
Inflammations			_
Granuloma		1	0
Inflammation		513	0
Systemic inflammatory response syndrome		2	0
Infusion site reactions			
Infusion site bruising		1	0
Infusion site erythema		2	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
General disorders General disorders cont'd			
Infusion site mass		2	0
Infusion site nodule		2	0
Infusion site pain		9	0
Infusion site urticaria		1	0
Infusion site warmth		6	0
Injection site reactions			_
Injected limb mobility decreased		30	0
Injection site atrophy		8	0
Injection site bruising		97	0
Injection site coldness		5	0
Injection site cyst		2	0
Injection site discolouration		4	0
Injection site discomfort		15	0
Injection site discomore		13	0
Injection site dryfless Injection site erythema		510	0
Injection site erytherna Injection site exfoliation		1	0
Injection site extravasation		2	0
1		2	-
Injection site haematoma		10	0
Injection site haemorrhage			0
Injection site hypersensitivity		4	0
Injection site hypoaesthesia		12	0
Injection site indentation		11	0
Injection site induration		7	0
Injection site inflammation		53	0
Injection site injury		3	0
Injection site irritation		2	0
Injection site joint discomfort		1	0
Injection site joint erythema		8	0
Injection site joint pain		33	0
Injection site mass		1227	0
Injection site movement impairment		3	0
Injection site muscle weakness		1	0
Injection site necrosis		1	0
Injection site nodule		4	0
Injection site oedema		24	0
Injection site pain		3934	0
Injection site papule		2	0
Injection site paraesthesia		20	0
Injection site pruritus		255	0
Injection site rash		253	0
Injection site reaction		109	0
Injection site scab		4	0
Injection site scar		5	0
Injection site swelling		202	0
Injection site ulcer		1	0
Injection site urticaria		34	0
Injection site vesicles		9	0
Injection site warmth		314	0
Interactions			
Drug interaction		23	0
Inhibitory drug interaction		8	0
Mass conditions NEC		0	
Cyst		15	0
·			U

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	<u>Total</u>	Fatal
General disorders General disorders cont'd		
Mass	59	0
Nodule	12	2 0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal disorder		0
Mucosal dryness	1	0
Mucosal haemorrhage	4	. o
Mucosal inflammation	8	0
Mucosal pain	2	2 0
Mucosal ulceration	1	
Oedema mucosal		
Polyp	1	0
Necrosis NEC		
Fat necrosis	2	2 0
Necrosis	7	' ol
Oedema NEC		
Face oedema	28	s o
Localised oedema	10	
Oedema	46	
Oedema peripheral	90	
Pain and discomfort NEC		
Axillary pain	586	
Chest discomfort	1601	
Chest pain	3775	
Discomfort	404	
Facial discomfort	13	
Facial pain	207	
Hernia pain	2	_
Inflammatory pain	18	
Non-cardiac chest pain	32	
Pain	13353	
Suprapubic pain	1	0
Tenderness	1654	o
Visceral pain	2	1
Therapeutic and nontherapeutic responses		
Adverse drug reaction	396	0
Adverse event	12	
Adverse reaction	35	
Diet failure	1	0
Drug ineffective	105	
Drug intolerance	3	
Immediate post-injection reaction	4	
Inadequate analgesia	16	
No reaction on previous exposure to drug	45	
Remission not achieved	1	0
Similar reaction on previous exposure to d	rug 1	0
Therapeutic product effect decreased	1	0
Therapeutic product effect incomplete	1	O
Therapeutic product ineffective	1	
Therapeutic reaction time decreased	1	O
Therapeutic response decreased	1	l o
Therapeutic response shortened	1	o o
Therapeutic response unexpected	81	_

Name: COVID-19 vaccine AstraZeneca analysis print

Date: 13-May-2021
Date: 13-May-2021
Date: 03-Feb-1921
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Earliest Reaction Date: 03-Feb-1921

	dDRA Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
General disorders General disorders cont'd		
Therapy non-responder	2	2 0
Treatment failure	4	. 0
Vaccination failure	22	. 0
Vaccine positive rechallenge	1	0
Trophic disorders		
Atrophy	3	0
Calcinosis	1	0
Dysplasia	2	0
Ulcers NEC		,
Ulcer	31	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	16	0
Shoulder injury related to vaccine administrati		
Vaccination site bruising	106	1
Vaccination site oldness	100	) o
Vaccination site columess  Vaccination site cyst		
1	2	
Vaccination site discharge Vaccination site discolouration		0
	37	-
Vaccination site discomfort	37	
Vaccination site dryness	500	0
Vaccination site erythema	589	
Vaccination site extravasation	1	0
Vaccination site granuloma	8	
Vaccination site haemorrhage	4	1 .
Vaccination site hyperaesthesia	1	0
Vaccination site hypersensitivity	3	
Vaccination site hypoaesthesia	19	
Vaccination site induration	57	1
Vaccination site inflammation	45	
Vaccination site injury	3	
Vaccination site irritation	12	0
Vaccination site joint erythema	4	- 0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	8	1
Vaccination site joint pain	41	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth		0
Vaccination site lymphadenopathy	2	. 0
Vaccination site mass	451	0
Vaccination site movement impairment	54	. 0
Vaccination site nodule		0
Vaccination site oedema	3	0
Vaccination site pain	1689	0
Vaccination site papule	3	0
Vaccination site paraesthesia	12	0
Vaccination site pruritus	92	0
Vaccination site rash	154	. 0
Vaccination site reaction	19	
Vaccination site scab	1	0
Vaccination site scar	4	
Vaccination site swelling	419	_
Vaccination site urticaria	10	

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site vesicles	6	0
Vaccination site warmth	324	0
Vascular complications associated with device		
Vascular stent occlusion	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	6	0
Withdrawal syndrome	69	0
General disorders SOC TOTAL	210853	277

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Hepatic disorders		
Bile duct infections and inflammations		
Biliary colic	22	0
Cholangitis	3	0
Cholecystitis and cholelithiasis		
Cholecystitis	9	0
Cholelithiasis	10	l 0
Cholestasis and jaundice		
Cholestasis	4	0
Jaundice	36	
Jaundice cholestatic	7	Ö
Ocular icterus	1	0
Gallbladder disorders NEC		
Gallbladder disorder	1	0
Gallbladder oedema	1	ő
Hepatic and hepatobiliary disorders NEC		
Liver disorder	10	0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	6	0
Hepatic failure and associated disorders		
Acute hepatic failure	1	0
Hepatic failure	4	_
Subacute hepatic failure	1	Ö
Hepatic fibrosis and cirrhosis	'	
Hepatic cirrhosis	6	0
Hepatic vascular disorders		
Budd-Chiari syndrome	1	1
Hepatic artery thrombosis	1	,
Hepatic haemorrhage	1	0
Hepatic infarction	2	1
Hepatic vascular thrombosis	2	Ö
Hepatic vein thrombosis	9	_
Portal hypertension	1	o o
Portal vein occlusion	1	o o
Portal vein declasion  Portal vein phlebitis	1	o o
Portal vein prilebilis Portal vein thrombosis	43	
Portosplenomesenteric venous thrombosis	1	0
Hepatobiliary signs and symptoms	'	l
Hepatic pain	50	0
Hepatomegaly	30	
Liver tenderness	4	
Hepatocellular damage and hepatitis NEC	4	l
Autoimmune hepatitis	2	0
Drug-induced liver injury	1	0
Hepatic necrosis	1	0
Hepatic steatosis	3	
Hepatitis	19	
Hepatitis acute	5	
Immune-mediated hepatitis	1	0
Ischaemic hepatitis	17	0
Liver injury Reye's syndrome	17	
	1	0
Obstructive bile duct disorders (excl neoplasms)	2	^
Sphincter of Oddi dysfunction	2	0

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<b>Reaction Name</b>		Total	Fatal
Hepatic disorders	Hepatic disorders cont'd		
Hepatic disorders S	OC TOTAL	294	7

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Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 13-May-2021 Data Lock Date: 12-May-2021 18:30:08
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders ne system disorders cont'd		
Immunodeficiency disorders NEC		
Immunodeficiency	2	0
Immunosuppression	4	0
Transplant rejections		
Corneal graft rejection	2	0
Transplant rejection	6	0
Vasculitides		
Eosinophilic granulomatosis with polyangiitis	1	0
Immune system disorders SOC TOTAL	2136	1

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Infections			
Abdominal and gastrointestinal infections			
Abdominal infection		1	0
Abdominal wall infection		1	0
Anal abscess		1	0
Appendicitis		22	0
Appendicitis perforated		2	0
Diarrhoea infectious		1	0
Diverticulitis		17	0
Dysentery		4	0
Gastroenteritis		27	0
Gastrointestinal infection		5	0
Large intestine infection		1	0
Peritonitis		1	0
Aspergillus infections			
Aspergillus infection		1	0
Bacterial infections NEC			
Administration site cellulitis		1	0
Arthritis bacterial		3	0
Bacterial infection		21	1
Bacterial vaginosis		1	0
Cellulitis		420	1
Ear infection bacterial		1	0
Endocarditis bacterial		2	0
Folliculitis		6	0
Injection site cellulitis		6	0
Perichondritis		1	0
Periorbital cellulitis		2	0
Pneumonia bacterial		4	1
Post procedural cellulitis		1	0
Skin bacterial infection		4	0
Urinary tract infection bacterial		4	0
Vaccination site cellulitis		20	0
Bone and joint infections			
Arthritis infective		2	0
Intervertebral discitis		2	0
Osteomyelitis		1	0
Bordetella infections			
Pertussis		2	0
Borrelial infections			
Erythema migrans		2	0
Lyme disease		6	0
Relapsing fever		1	0
Breast infections			
Mastitis		16	0
Brucella infections			
Brucellosis		1	0
Caliciviral infections			
Gastroenteritis norovirus		1	0
Campylobacter infections			
Campylobacter colitis		1	0
Candida infections			
Anal candidiasis		1	0
Balanitis candida		1	0

Name: COVID-19 vaccine AstraZeneca analysis print

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Earliest Reaction Date: 03-Feb-1921

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.		
Reaction Name	Total_	<u>Fatal</u>
Infections Infections cont'd		
Candida infection	40	0
Oral candidiasis	32	0
Skin candida	2	
Vulvovaginal candidiasis	33	0
Cardiac infections		
Endocarditis	1	0
Central nervous system and spinal infections		
Cavernous sinus thrombosis	5	0
Central nervous system infection	1	0
Encephalitis	24	
Encephalomyelitis	2	0
Extradural abscess	1	0
Meningitis	20	
Myelitis	10	0
Chlamydial infections		
Chlamydial infection	1	0
Clostridia infections		
Clostridium difficile colitis	2	0
Clostridium difficile infection		0
Tetanus	2	0
Coronavirus infections		
Asymptomatic COVID-19	3	
COVID-19	385	
COVID-19 pneumonia	23	
Coronavirus infection	4	0
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	31	0
Corynebacteria infections		_
Diphtheria	1	0
Coxiella infections	100	_
Q fever	102	0
Dental and oral soft tissue infections		
Abscess oral	3	
Gingival abscess	5	0
Gingivitis	20	
Lip infection	1	0
Oral infection	1	0
Oral pustule	2	0
Parotitis	10	
Pericoronitis Periodontitis	2	
Sialoadenitis		0
	1	
Tongue abscess Tooth abscess	3 12	0
Tooth infection	12	
Ear infections	/	0
Ear infection	71	0
	104	0
Labyrinthitis Mastoiditis		
Otitis externa	3	0
Otitis externa Otitis media	3	
	9	0
Otosalpingitis	1	

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Infections Infections cont'd			
Ectoparasitic infestations			
Acarodermatitis		1	0
Infestation		1	0
Trombidiasis		2	0
Epstein-Barr viral infections			
Epstein-Barr virus infection		1	0
Infectious mononucleosis		37	0
Escherichia infections			
Escherichia infection		2	0
Escherichia sepsis		2 2	0
Eye and eyelid infections			
Conjunctivitis		60	0
Eye infection		18	0
Eyelid boil		2	0
Eyelid infection		3	0
Hordeolum		22	0
Keratouveitis		1	0
Retinitis		2	0
Female reproductive tract infections			
Endometritis		1	0
Pelvic inflammatory disease		1	0
Pyometra		1	1
Vaginal abscess		1	0
Vaginal infection		4	0
Flaviviral infections			
Yellow fever		1	0
Yellow fever vaccine-associated neurotrop	oic disease	1	0
Fungal infections NEC			
Ear infection fungal		1	0
Fungal infection		13	0
Fungal skin infection		4	0
Oral fungal infection		1	0
Severe asthma with fungal sensitisation		4	0
Tonsillitis fungal		1	0
Vulvovaginal mycotic infection		3	0
Hepatitis virus infections			
Hepatitis E		1	0
Hepatobiliary and spleen infections			
Biliary sepsis		5	1
Herpes viral infections			
Eczema herpeticum		3	0
Genital herpes		41	0
Genital herpes simplex		1	0
Haemorrhagic varicella syndrome		1	0
Herpes dermatitis		2 13	0
Herpes ophthalmic			0
Herpes simplex		31	0
Herpes simplex reactivation		2	0
Herpes virus infection		11	0
Herpes zoster		902	0
Herpes zoster oticus		9	0
Herpes zoster reactivation		2	0
Meningoencephalitis herpetic		1	0

	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Infections Infections cont'd			
Nasal herpes		12	0
Ophthalmic herpes simplex		1	0
Ophthalmic herpes zoster		7	0
Oral herpes		558	0
Varicella		22	0
Varicella zoster virus infection		1	0
Infections NEC			
Abscess		23	0
Abscess limb		15	0
Abscess soft tissue		1	0
Catheter site infection		1	0
Coinfection		1	0
Device related infection		1	0
Genital abscess		1	0
Infected bite		2	0
Infected cyst		1	0
Infection		359	3
Infection in an immunocompromised host		3	0
Infectious thyroiditis		1	0
Injection site abscess		2	0
Injection site abscess		15	0
Localised infection		86	
		3	0
Lymph gland infection			
Omphalitis		1	0
Pathogen resistance		2	
Respiratory tract infection		5	0
Toxic shock syndrome		1	0
Vaccination site abscess		3 20	0
Vaccination site infection			
Vestibulitis		3	0
Infectious disorders carrier		4	0
SARS-CoV-2 carrier		1	0
Infectious transmissions		_	0
Secondary transmission		6	0
Vaccine virus shedding		1	0
Influenza viral infections		0	0
H2N2 influenza		5707	0
Influenza		5797	0
Klebsiella infections		4	0
Pneumonia klebsiella		1	0
Lower respiratory tract and lung infections			_
Atypical pneumonia		2	0
Bronchitis		18	0
Infectious pleural effusion		3	0
Infective exacerbation of bronchiectasis		1	0
Lower respiratory tract infection		180	3 17
Pneumonia		157	
Sputum purulent		1	0
Male reproductive tract infections			_
Epididymitis		5	0
Orchitis		1	0
Mumps viral infections			
Mumps		5	0

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Infections Infections cont'd		
Muscle and soft tissue infections		
Muscle abscess	1	0
Soft tissue infection	5	0
Orthopox viral infections		
Cow pox	1	0
Paravaccinia infections		
Paravaccinia	1	0
Plasmodia infections		
Malaria	5	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	1	0
Polyomavirus infections		
Progressive multifocal leukoencephalopathy	1	0
Prion-associated disorders		
Creutzfeldt-Jakob disease	2	0
Retroviral infections		
Acquired immunodeficiency syndrome	2	0
HIV-associated neurocognitive disorder	1	0
Rubeola viral infections		
Measles	3	0
Salmonella infections		
Typhoid fever	2	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Abdominal sepsis	1	0
Bacteraemia	1	0
Neutropenic sepsis	7	0
Sepsis	67	6
Sepsis syndrome	1	0
Septic rash	6	0
Septic shock	4	1
Urosepsis	5	1
Viraemia	3	0
Skin structures and soft tissue infections		
Carbuncle	1	0
Dermatitis infected	9	0
Eczema infected	1	0
Impetigo	5	0
Infected dermal cyst	3	0
Pilonidal cyst	1	
Pustule	14	0
Rash pustular	14	0
Skin infection	57	0
Subcutaneous abscess	7	0
Vaccination site pustule	3	0
Staphylococcal infections		
Furuncle	29	0
Staphylococcal bacteraemia	1	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	3	1
Toxic shock syndrome staphylococcal	1	0
Streptococcal infections		<b>J</b>
Cellulitis streptococcal	1	0
Erysipelas	1	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name	<del>,</del>	<u>Total</u>	<u>Fatal</u>
Infections Infections cont'd			
Pharyngitis streptococcal		6	0
Scarlet fever		1	0
Tonsillitis streptococcal		1	0
Tinea infections			
Body tinea		3	0
Tinea cruris		1	0
Tinea infection		1	0
Tinea pedis		2 1	0
Tinea versicolour		1	0
Treponema infections			
Syphilis		3	0
Trypanosomal infections			
African trypanosomiasis		6	0
Tuberculous infections			
Disseminated Bacillus Calmette-Guerin in	fection	1	0
Lymph node tuberculosis		3	0
Meningitis tuberculous		1	0
Pulmonary tuberculosis		2	0
Tuberculosis		4	0
Upper respiratory tract infections			
Acute sinusitis		3	0
Chronic sinusitis		10	0
Epiglottitis		1	0
Laryngitis		19	0
Nasal vestibulitis		1	0
Nasopharyngitis		1425	0
Pharyngitis		19	0
Rhinitis		36	0
Sinobronchitis		1	0
Sinusitis		249	0
Tonsillitis		59	0
Tracheitis		1	0
Upper respiratory tract infection		4	0
Urinary tract infections			
Cystitis		65	0
Genitourinary tract infection		1	0
Kidney infection		35	0
Pyelonephritis		3	0
Urinary tract infection		157	0
Vascular infections			
Haematoma infection		2	0
Infected lymphocele		1	0
Infected varicose vein		1	0
Lymphangitis		6	0
Viral infections NEC			
Arthritis viral		1	0
Bronchitis viral		1	0
Encephalitis viral		4	0
Gastroenteritis viral		57	0
Gastrointestinal viral infection		1	0
Hepatitis viral		2	0
Meningitis viral		13	0
Pneumonia viral		5	1

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Post viral fatigue syndrome	81	0
Sweating fever	668	0
Vestibular neuronitis	18	0
Viral diarrhoea	4	0
Viral infection	49	0
Viral labyrinthitis	4	0
Viral myocarditis	2	0
Viral pericarditis	1	0
Viral pharyngitis	22	0
Viral rash	60	0
Viral sepsis	1	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	13561	67

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Injuries		
Abdominal and gastrointestinal injuries NEC		
Abdomen crushing	3	0
Colon injury	1	0
Lip injury	2	0
Mouth injury	1	0
Oral contusion	11	0
Palate injury	1	0
Splenic rupture	3	0
Tongue injury	2	0
Tooth injury	1	0
Accidental exposures to product		
Accidental exposure to product	15	0
Anaesthetic and allied procedural complications		
Anaesthetic complication	3	0
Anaesthetic complication neurological	1	0
Delayed recovery from anaesthesia	4	0
Sedation complication	2	0
Atmospheric pressure injuries		
Barotrauma	1	0
Decompression sickness	1	0
Hypobarism	2	0
Bone and joint injuries NEC		
Bursa injury	2 1	0
Cartilage injury	1	0
Joint injury	6	0
Synovial rupture	2	0
Cardiac and vascular procedural complications		
Vascular access site bruising	1	0
Vascular graft thrombosis	1	0
Vasoplegia syndrome	1	0
Cardiovascular injuries		
Heart injury	3	0
Vascular injury	2	0
Cerebral injuries NEC		
Brain contusion	10	0
Brain herniation	4	0
Concussion	4	0
Craniocerebral injury	1	0
Extradural haematoma	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	1
Subdural haemorrhage	1	0
Chemical injuries		
Chemical burn	1	0
Chemical burn of oral cavity	1	0
Chemical burn of skin	4	0
Chemical phlebitis	2	0
Chest and respiratory tract injuries NEC		
Chest crushing	11	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	53	0

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Injuries cont'd			
Cranial nerve injuries			
Cranial nerve injury		1	0
Optic nerve injury		2	0
Exposures associated with pregnancy, deli	very and lactation		
Exposure during pregnancy		5	0
Exposure via breast milk		41	0
Foetal exposure during pregnancy		34	0
Maternal exposure during breast feeding		880	0
Maternal exposure during pregnancy		187	0
Maternal exposure timing unspecified		1	0
Paternal exposure before pregnancy		4	0
Paternal exposure during pregnancy		14	0
Exposures to agents or circumstances NEC	2		
Exposure to SARS-CoV-2		3	0
Exposure to toxic agent		1	0
Eye injuries NEC			
Cataract traumatic		1	0
Eye contusion		42	0
Eye injury		18	0
Eyelid contusion		1	0
Foreign body in eye		1	0
Hyphaema		1	0
Injury corneal		1	0
Periorbital haematoma		1	0
Periorbital haemorrhage		1	0
Retinal injury		3	0
Superficial injury of eye		1	0
Fractures and dislocations NEC			
Fracture		1	0
Joint dislocation		7	0
Multiple fractures		1	0
Stress fracture		4	0
Gastrointestinal and hepatobiliary procedur	al complications		
Peripancreatic fluid collection	-	1	0
Procedural nausea		24	0
Procedural vomiting		7	0
Heat injuries (excl thermal burns)			
Heat exhaustion		4	0
Heat illness		4	0
Heat oedema		13	0
Heat stroke		7	0
Intentional product misuses			
Intentional product misuse		1	0
Intentional product use issues			
Intentional product use issue		1	0
Limb fractures and dislocations			
Ankle fracture		3	0
Clavicle fracture		11	0
Femoral neck fracture		2	0
Femur fracture		2 1	0
Foot fracture		1	0
Humerus fracture		1	0
Lower limb fracture		2	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Injuries Injuries cont'd		
Patella fracture	1	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	3	0
Device use issue	1	0
Drug titration error	1	0
Inadequate aseptic technique in use of product	1	0
Intercepted medication error	2	0
Medication error	27	0
Product use issue	3	0
Vaccination error	4	0
Wrong drug	3	0
Wrong technique in product usage process	6	0
Muscle, tendon and ligament injuries		
Epicondylitis	10	0
Ligament injury	2	0
Ligament rupture	1	0
Ligament sprain	13	0
Muscle injury	25	0
Muscle rupture	10	0
Muscle strain	34	0
Post-traumatic neck syndrome	3	0
Repetitive strain injury	2 2	0
Tendon injury	2	0
Tendon rupture	10	0
Nerve injuries NEC		
Nerve injury	66	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	7	0
Procedural dizziness	28	0
Non-occupational environmental exposures		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	4	0
Exposure to noise	2	0
Non-site specific injuries NEC		
Animal bite	1	0
Arthropod bite	4	0
Arthropod sting	10	0
Bite	1	0
Electric shock	22	0
Fall	185	1
Inflammation of wound	3	0
Injury	10	0
Internal injury	1	0
Nervous system injury	2 2	0
Post concussion syndrome		0
Road traffic accident	1	0
Soft tissue injury	1	0
Tissue injury	1	0
Traumatic haematoma	3	0
Traumatic shock	1	0

Name: COVID-19 vaccine AstraZeneca analysis print

Date: 13-May-2021
Date: 13-May-2021
Date: 03-Feb-1921
Data Lock Date: 12-May-2021 18:30:08
MedDRA Version: MedDRA 24.0 Report Run Date: 13-May-2021
Earliest Reaction Date: 03-Feb-1921

	edDRA Version: MedDRA 24.0		
Reaction Name	Tot	<u>:al_</u>	<u>Fatal</u>
Injuries cont'd			
Wound		5	0
Wound complication		10	0
Wound haemorrhage		8	0
Wound secretion		2	0
Non-site specific procedural complications			
Incision site erythema		1	0
Incision site haemorrhage		1	0
Incision site oedema		1	0
Incision site pain		9	0
Infusion related reaction		19	0
Injection related reaction		571	0
Needle fatigue		1	0
Post procedural complication		33	0
Post procedural contusion		2	0
Post procedural haematoma		1	0
Procedural hypertension		1	0
Procedural pain		5	0
Procedural site reaction		1	0
Suture related complication		1	0
Occupational exposures			
Occupational exposure to product		1	0
Off label uses			
Off label use		6	0
Overdoses NEC			
Intentional overdose		3	0
Overdose		15	0
Pathways and sources of exposure			
Exposure via body fluid		1	0
Exposure via unknown route		1	0
Peripheral nerve injuries			
Brachial plexus injury		1	0
Median nerve injury		2	0
Sciatic nerve injury		2 1	0
Ulnar nerve injury		1	0
Poisoning and toxicity			
Alcohol poisoning		3	0
Chemical poisoning		1	0
Metal poisoning		1	0
Poisoning		5	0
Systemic toxicity		1	0
Toxicity to various agents		9	0
Product administration errors and issues			
Accidental overdose		2	0
Accidental underdose		1	0
Contraindicated product administered		4	0
Duplicate therapy error		2	0
Expired product administered		23	0
Extra dose administered			0
Inappropriate schedule of product administra	tion	5 7	0
Incorrect dose administered		3	0
Incorrect product formulation administered		1	0
Incorrect route of product administration		19	0
Intercepted product administration error		2	0

### Name: COVID-19 vaccine AstraZeneca analysis print

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	<u>Fatal</u>
Injuries Injuries cont'd		
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	7	0
Product administered to patient of inappropriate age	12	0
Product administration error	12	0
Product dose omission issue	2	0
Wrong patient received product	1	0
Wrong product administered	12	0
Product confusion errors and issues		
Product label confusion	1	0
Product name confusion	1	0
Product dispensing errors and issues		
Product dispensing error	11	0
Product monitoring errors and issues		
Documented hypersensitivity to administered product	1	0
Product monitoring error	1	0
Product prescribing errors and issues	'	J
Contraindicated product prescribed	7	0
Product prescribing error	2	0
Product selection errors and issues		U
Product selection error	1	0
Product storage errors and issues in the product use system	'	U
Product storage error	2	0
Radiation injuries		U
Sunburn	34	0
Renal and urinary tract injuries NEC	34	U
Bladder injury	1	0
Kidney rupture	1	
		0
Reproductive system and breast injuries  Penile contusion	2	0
Reproductive tract and breast procedural complications		0
Postmastectomy lymphoedema syndrome	1	0
Respiratory tract and thoracic cavity procedural complications		0
	4	0
Pulmonary oil microembolism	I	0
Site specific injuries NEC	_	0
Back injury	6	0
Central nervous system injury	1	
Face crushing	1	0
Face injury	20	
Head injury	30	0
Limb crushing injury	450	
Limb injury	156	0
Neck crushing	1	
Neck injury	2	0
Site specific procedural complications NEC	0	0
Axillary web syndrome	3	0
Skin injuries NEC	0450	0
Contusion	2150	0
Nail injury	1	0
Scar	18	0
Scratch	2	0
Skin abrasion	5	0
Skin injury	10	0
Skin laceration	1	0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Skin pressure mark	1	0
Skin wound	6	0
Subcutaneous haematoma	1	0
Skin procedural complications		
Recall phenomenon	1	0
Spinal cord injuries NEC		
Prevertebral soft tissue swelling of cervical space	1	0
Spinal cord injury	1	0
Spinal cord injury sacral	1	0
Spinal fractures and dislocations		
Spinal compression fracture	3	0
Spinal fracture	4	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma obstruction	1	0
Stoma site haemorrhage	1	0
Stoma site pain	1	0
Stoma site rash	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	4	0
Burn oral cavity	6	
Burns second degree	7	0
Cold burn	3	0
Thermal burn	40	0
Thermal burns of eye	38	0
Transplantation complications		
Transplant failure	1	0
Underdoses NEC		
Intentional underdose	1	0
Underdose	2	0
Vaccination related complications		
Adverse event following immunisation	3	0
Post vaccination syndrome	1	0
Reaction to previous exposure to any vaccine	1	0
Vaccination complication	84	0
Injuries SOC TOTAL	5559	2

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Investigations		
Adrenal cortex tests		
Blood cortisol	1	0
Cortisol decreased	1	0
Cortisol increased	1	0
Adrenal medulla tests		
Epinephrine increased	1	0
Norepinephrine increased	2	0
Auditory and vestibular diagnostic procedures		
Acoustic stimulation tests	5	0
Audiogram	1	0
Autoimmunity analyses		
Antimitochondrial antibody positive	1	0
Antinuclear antibody positive	1	0
Antiphospholipid antibodies	1	0
Antiphospholipid antibodies positive	1	0
Cold agglutinins positive	1	0
DNA antibody positive	1	0
Rheumatoid factor	2	0
Rheumatoid factor increased	1	0
Bacteria identification and serology (excl mycobacteria)		
Bacterial test	1	0
Blood counts NEC		
Blood count	6	0
Blood count abnormal	2	0
Full blood count	6	0
Full blood count abnormal	1	0
Full blood count decreased	2	0
Full blood count increased	1	0
Blood gas and acid base analyses		
Blood gases	1	0
Blood lactic acid	2	0
Blood lactic acid increased	3	0
Blood pH	13	
Blood pH increased	11	0
Carbon dioxide increased	1	0
Oxygen consumption	1	0
Oxygen saturation	21	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	154	1
Blood grouping and cross-matching analyses		
Blood group O	1	0
Bone marrow and immune tissue imaging procedures		
Scan lymph nodes	2	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	19	0
Blood glucose abnormal	13	0
Blood glucose decreased	34	
Blood glucose fluctuation	26	0
Blood glucose increased	158	
Glycosylated haemoglobin increased	2	0
Cardiac auscultatory investigations		
Cardiac murmur	20	0
Heart sounds	14	

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name	<u> </u>	otal	Fatal
Investigations Investigations cont'd			
Heart sounds abnormal		5	0
Cardiac function diagnostic procedures			
Cardiac monitoring		1	0
Central venous pressure		1	0
Echocardiogram		1	0
Ejection fraction decreased		1	0
Myocardial strain		12	0
Venous pressure jugular increased		1	0
Cardiac imaging procedures			
Magnetic resonance imaging heart		1	0
Cell marker analyses			
Carcinoembryonic antigen increased		1	0
Prostatic specific antigen increased		2	0
Central nervous system histopathology proc	edures		
Biopsy brain		1	0
Central nervous system imaging procedures	:		
Computerised tomogram head		14	0
Magnetic resonance imaging head		37	0
Cerebrospinal fluid tests (excl microbiology)			
CSF pressure		3	0
Chemistry analyses NEC			
Histamine abnormal		1	0
Histamine level increased		1	0
Inflammatory marker decreased		1	0
Inflammatory marker increased		4	0
Cholesterol analyses			
Blood cholesterol increased		5	0
Low density lipoprotein		1	0
Low density lipoprotein increased		1	0
Very low density lipoprotein decreased		1	0
Coagulation and bleeding analyses			
Activated partial thromboplastin time		1	0
Activated partial thromboplastin time prolo	nged	92	0
Bleeding time		3	0
Bleeding time abnormal		2	0
Bleeding time prolonged		2	0
Blood fibrinogen decreased		6	0
Blood fibrinogen increased		1	0
Blood thromboplastin		1	0
Blood thromboplastin abnormal		2	0
Coagulation factor		1	0
Coagulation time		6	0
Coagulation time prolonged		8	0
Coagulation time shortened		2	0
Fibrin D dimer		1	0
Fibrin D dimer increased		25	0
International normalised ratio		2	0
International normalised ratio abnormal		9	0
International normalised ratio decreased		37	0
International normalised ratio fluctuation		3	0
International normalised ratio increased		70	0
Prothrombin level increased		1	0
Prothrombin time prolonged		1	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u>  Total                                    </u>	<u>Fatal</u>
Investigations Investigations cont'd		
Thrombin time	1	0
Digestive enzymes		
Amylase increased	1	0
Pancreatic enzymes increased	1	0
ECG investigations		
Cardiac telemetry	1	0
Electrocardiogram	3	0
Electrocardiogram ST segment elevation	3 2 7	0
Electrocardiogram ST-T segment abnormal		0
Electrocardiogram T wave inversion	3	0
Electrocardiogram abnormal	11	0
Electrocardiogram change	1	0
Electrocardiogram normal	1	0
Exercise electrocardiogram	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	11	0
Faecal analyses NEC		
Faecal calprotectin increased	6	0
Stool analysis abnormal	1	0
Fertility analyses		
Semen volume decreased	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	4	0
Gastrointestinal function diagnostic procedures		
Gastric pH	1	0
Gastric pH decreased	1	0
Gastrointestinal stoma output increased	1	0
Swallow study	2	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood gastrin	1	0
Blood gastrin normal	1	0
Blood insulin	4	0
Blood insulin decreased	3	0
Blood insulin increased	3	0
Haematological analyses NEC	4	
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	1	0
Haematology test abnormal	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	4	0
Heart rate and pulse investigations	4	0
Brachial pulse decreased	1	0
Heart rate	887	0
Heart rate abnormal	40	
Heart rate decreased	86	
Heart rate increased	1713	
Heart rate irregular	131	0
Heart rate variability decreased	1	0
Heart rate variability increased	1	0
Maximum heart rate	6	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Investigations Investigations cont'd			
Maximum heart rate decreased		1	0
Orthostatic heart rate response increased		1	0
Pulse abnormal		18	0
Pulse absent		4	0
Pulse pressure abnormal		1	0
Pulse pressure increased		3	0
Pulse waveform abnormal		1	0
Sinus rhythm		5	0
Imaging procedures NEC			
Computerised tomogram		4	0
Magnetic resonance imaging		1	0
Scan		1	0
X-ray		1	0
Immune response protein analyses NEC			
C1 esterase inhibitor test		1	0
Immunoglobulin analyses			
Blood immunoglobulin E		1	0
Blood immunoglobulin E increased		2	0
Blood immunoglobulin M		2 1	0
Blood immunoglobulin M increased		1	0
Immunology analyses NEC			_
Antibody test		1	0
Antibody test abnormal		1	0
Antibody test negative		3	0
Immunology test		6	0
Immunology test normal		1	0
Mast cell degranulation present		1	0
Immunology skin tests NEC			
Allergy alert test		2	0
Skin test positive		4	0
Investigations NEC			_
Blood test		33	0
Blood test abnormal		32	0
Laboratory test		1	0
Polymerase chain reaction positive		2	0
Liver function analyses			
Alanine aminotransferase increased		15	0
Aspartate aminotransferase increased			0
Bile output		3 3	0
Blood bilirubin		1	0
Blood bilirubin increased		2	0
Gamma-glutamyltransferase increased		3	0
Hepatic enzyme abnormal		1	0
Hepatic enzyme increased		8	0
Liver function test		3	0
Liver function test abnormal		21	0
Liver function test increased		3	0
Transaminases increased		8	0
Metabolism tests NEC		j	
Blood ketone body		9	0
Ubiquinone		3	0
Microbiology and serology tests NEC			
Blood culture		2	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Investigations Investigations cont'd		
Blood culture negative	1	0
Septic screen	1	0
Mineral and electrolyte analyses		
Blood calcium	1	0
Blood iron	8	0
Blood iron decreased	5	0
Blood iron increased	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	4	0
Blood phosphorus increased	2	0
Blood potassium decreased	5 7	0
Blood potassium increased	7	0
Blood sodium	2	0
Blood sodium decreased	2	0
Serum ferritin	1	0
Serum ferritin decreased	2	0
Serum ferritin increased	1	0
Sweat test	1	0
Urine copper	1	0
Musculoskeletal and soft tissue imaging procedures		
Bone densitometry	1	0
Skull X-ray	5	0
X-ray of pelvis and hip	1	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count	2	0
Swollen joint count increased	2	0
Tender joint count	3	0
Mycobacteria identification and serology		
Interferon gamma release assay positive	1	0
Neurologic diagnostic procedures		J
Coma scale abnormal	13	0
Electromyogram abnormal	1	0
Lumbar puncture	9	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	2	0
Intraocular pressure increased	2	0
Intraocular pressure test	6	0
Visual tracking test	1	0
Physical examination procedures and organ system status		
Body height decreased	1	0
Body surface area	2	0
Body temperature	918	
Body temperature abnormal	70	
Body temperature decreased	120	
Body temperature fluctuation	150	
Body temperature increased	1006	
Body temperature normal	1	0
Breath sounds	1	0
Breath sounds abnormal	1	0
Dermatologic examination abnormal	1	0
General physical condition abnormal	1	0
Grip strength	6	0
Grip strength Grip strength decreased	27	0

Name: COVID-19 vaccine AstraZeneca analysis print

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>otal</u>	<u>Fatal</u>
Investigations Investigations cont'd			
Head lag		16	0
Lymph node palpable		4	0
Male genital examination abnormal		1	0
Menstruation normal		1	0
Muscle strength abnormal		2	0
Neurological examination		1	0
Neurological examination normal		1	0
Palpatory finding abnormal		1	0
Psoriasis area severity index decreased		1	0
Respiratory rate		9	0
Respiratory rate decreased		22	0
Respiratory rate increased		67	0
Skin temperature		164	0
Temperature difference of extremities		4	0
Urological examination		1	0
Vital signs measurement		1	0
Weight decreased		117	0
Weight increased		22	0
Pituitary analyses anterior			
Blood corticotrophin		1	0
Blood prolactin increased		1	0
Blood thyroid stimulating hormone		1	0
Blood thyroid stimulating hormone decrea	sed	2	0
Blood thyroid stimulating hormone increas		4	0
Platelet analyses			
Platelet count		2	0
Platelet count abnormal		1	0
Platelet count decreased		191	0
Platelet count increased		5	0
Platelet count normal		1	0
Protein analyses NEC			
C-reactive protein abnormal		2	0
C-reactive protein increased		12	0
Red blood cell analyses			
Haematocrit		8	0
Haematocrit increased		1	0
Haemoglobin		4	0
Haemoglobin decreased		9	0
Mean cell haemoglobin concentration		1	0
Mean cell volume abnormal		2	0
Red blood cell count		1	0
Red blood cell count decreased		1	0
Renal function analyses			
Blood creatine increased		1	0
Blood creatinine abnormal		1	0
Blood creatinine decreased		2	0
Blood creatinine increased		1	0
Blood urea		5	0
Blood urea increased		1	0
Glomerular filtration rate decreased		1	0
Reproductive hormone analyses			
Blood oestrogen increased		1	0
Dihydrotestosterone decreased		1	0

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Investigations Investigations cont'd		
False negative pregnancy test	•	1 0
Human chorionic gonadotropin decreased	d /	1 0
Pregnancy test		3 0
Pregnancy test false positive	•	1 0
Pregnancy test negative	•	1 0
Reproductive organ and breast imaging pro	ocedures	
Ultrasound scan vagina normal	•	1 0
Respiratory and pulmonary function diagno	stic procedures	
Forced expiratory volume	2	2 0
Forced expiratory volume decreased	·	1 0
Forced expiratory volume increased	11	1 0
Forced expiratory volume normal	•	1 0
Forced vital capacity decreased	•	1 0
Maximal voluntary ventilation	•	1 0
Peak expiratory flow rate		1 0
Peak expiratory flow rate decreased	4	4 0
Pulmonary function test	2	2 0
Pulmonary function test decreased	2	2 0
Slow vital capacity		1 0
Total lung capacity decreased	3	3 0
Respiratory tract and thoracic histopathology	gy procedures	
Sputum abnormal	2	2 0
Respiratory tract and thoracic imaging proc	edures	
Chest X-ray	11	1 0
Computerised tomogram thorax	4	4 0
Laryngoscopy	•	1 0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	Ę	5 0
Myocardial necrosis marker		1 0
Myocardial necrosis marker increased	•	1 0
Troponin		2 0
Troponin I increased	•	1 0
Troponin T		1 0
Troponin T increased	•	1 0
Therapeutic drug monitoring analyses		
Analgesic drug level	17	7 0
Analgesic drug level increased		1 0
Analgesic drug level therapeutic	•	1 0
Anticoagulation drug level above therape	utic 3	3 0
Anticoagulation drug level below therape		2 0
Anticoagulation drug level increased		1 0
Antidepressant drug level decreased		1 0
Thyroid analyses		
Thyroid function test abnormal		1 0
Thyroxine		ıl ol
Thyroxine abnormal		1 0
Tri-iodothyronine decreased		6 0
Tissue enzyme analyses NEC		
Blood lactate dehydrogenase		ı  o
Blood lactate dehydrogenase increased		
Lactate dehydrogenase urine increased		
Toxicology laboratory analyses		
Blood aluminium		ıl ol

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Investigations Investigations cont'd			
Blood cannabinoids		1	0
Blood carbon monoxide increased		1	0
Blood heavy metal test		1	0
Blood lead		1	0
Drug screen positive		2	0
Urinalysis NEC			
Blood urine		24	0
Blood urine present		55	0
Cells in urine		1	0
Crystal urine		3	0
Medication crystals in urine present		1	0
Protein urine present		1	0
Red blood cells urine		1	0
Urea urine increased		1	0
Urine analysis		1	0
Urine analysis abnormal		11	0
Urine analysis normal		3	0
pH urine		8	0
pH urine decreased		1	0
pH urine increased		2	0
Urinary tract function analyses NEC			
Urine output		40	0
Urine output decreased		17	0
Urine output increased		7	0
Urinary tract imaging procedures			
Cystoscopy		1	0
Vascular auscultatory investigations			
Abdominal bruit		1	0
Carotid bruit		1	0
Vascular imaging procedures NEC			
Venogram		1	0
Vascular tests NEC (incl blood pressure)			
Blood pressure abnormal		3	0
Blood pressure decreased		67	0
Blood pressure diastolic decreased		1	0
Blood pressure diastolic increased		3	0
Blood pressure increased		228	0
Blood pressure measurement		75	0
Blood pressure normal		2	0
Blood pressure systolic		1	0
Blood pressure systolic increased		5	0
Capillary nail refill test		1	0
Virus identification and serology			
Coronavirus test		36	0
Cytomegalovirus test		1	0
HIV antibody negative		2	0
Hepatitis B core 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 antibody test		4	0
SARS-CoV-2 antibody test negative		12	0
SARS-CoV-2 antibody test positive		3	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
SARS-CoV-2 test	17	' O
SARS-CoV-2 test false negative	3	3 0
SARS-CoV-2 test false positive		2 0
SARS-CoV-2 test negative	12	0
SARS-CoV-2 test positive	70	
Viral test	3	0
Vitamin analyses		
Blood folate	2	
Blood folate decreased		0
Vitamin B12 decreased	1	0
Vitamin D decreased	1	0
Water and electrolyte analyses NEC		
Blood osmolarity	1	0
Volume blood		1 0
White blood cell analyses		
CD4 lymphocytes decreased	1	0
Eosinophil count increased	3	3 0
Lymphocyte count	1	0
Lymphocyte count decreased	3	
Lymphocyte count increased	3	0
Mononuclear cell count abnormal	1	0
Neutrophil count	2	0
Neutrophil count decreased	12	2 0
Neutrophil count increased	1	0
Neutrophil toxic granulation present	1	. 0
White blood cell count	12	2 0
White blood cell count decreased	19	0
White blood cell count increased		0
Investigations SOC TOTAL	8110	) 1

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Metabolic disorders		
Appetite disorders		
Appetite disorder	35	0
Decreased appetite	5699	1
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	20	0
Food refusal	34	0
Hyperphagia	6	0
Hypophagia	24	0
Increased appetite	48	0
Salt craving	4	0
Calcium metabolism disorders		
Hypocalcaemia	5	0
Tetany	1	0
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	62	0
Diabetes mellitus inadequate control	26	0
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Type 1 diabetes mellitus	15	0
Type 2 diabetes mellitus	1	0
Diabetic complications NEC		
Diabetic ketoacidosis	28	2
Diabetic ketosis	5	0
Euglycaemic diabetic ketoacidosis	1	0
Diabetic complications neurological		
Hyperglycaemic hyperosmolar nonketotic syndrome	1	0
Disorders of purine metabolism		
Gout	96	0
Electrolyte imbalance NEC		
Electrolyte imbalance	1	0
Fluid imbalance	1	0
Hyperosmolar state	1	1
Fat soluble vitamin deficiencies and disorders		
Vitamin D deficiency	5	0
Fluid intake decreased		
Fluid intake reduced	8	0
Fluid intake increased		
Polydipsia	12	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Alcohol intolerance	5	0
Food intolerance	9	0
Gluten sensitivity	3	0
Histamine intolerance	3	0
General nutritional disorders NEC		
Abnormal loss of weight	36	0
Abnormal weight gain	16	0
Cachexia	1	0
Feeding disorder	159	0
Food aversion	49	0
Neonatal insufficient breast milk syndrome	2	0
Obesity	1	0
Overweight	2	0

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Earliest Reaction Date: 03-Feb-1921 Med	DRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Poor feeding infant	9	0
Starvation	1	0
Underweight	1	0
Weight loss poor	2	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	119	0
Insulin resistance	8	0
Metabolic syndrome	1	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	83	0
Hypoglycaemia unawareness	2	
Postprandial hypoglycaemia	2	0
Iron deficiencies		
Iron deficiency	5	0
Iron excess		
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Lipoedema	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	1	0
Ketosis	4	
Lactic acidosis	2	
Metabolic acidosis	9	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	3	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Potassium imbalance		
Hyperkalaemia	6	1
Hypokalaemia	4	0
Protein metabolism disorders NEC		
Hypoalbuminaemia	1	0
Sodium imbalance		
Hypernatraemia	2	0
Hyponatraemia	17	0
Hyponatraemic syndrome	2	I
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	5	0
Total fluid volume decreased		
Dehydration	574	0
Hypovolaemia	1	l ő
Total fluid volume increased		
Fluid overload	6	0
Fluid retention	49	
Vitamin deficiencies NEC		·
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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hypovitaminosis	1	0
Water soluble vitamin deficiencies		
Folate deficiency	3	0
Vitamin B12 deficiency	2	0
Metabolic disorders SOC TOTAL	7363	7

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Reaction Name		Total	Fatal
Muscle & tissue disorders			
Arthropathies NEC			
Arthritis		284	0
Arthritis enteropathic		1	0
Arthropathy		21	0
Autoimmune arthritis		5	0
Haemarthrosis		6	0
Palindromic rheumatism		3	0
Polyarthritis		12	0
Rheumatic fever		4	0
Sacroiliitis		3	0
		ગ	U
Bone disorders NEC			0
Bone disorder		2	0
Bone erosion		1	0
Bone loss		1	0
Jaw disorder		4	0
Medial tibial stress syndrome		7	0
Osteitis		6	0
Osteonecrosis of jaw		3	0
Spinal disorder		1	0
Bone related signs and symptoms			
Bone pain		869	0
Coccydynia		3	0
Pain in jaw		470	0
Pubic pain		1	0
Spinal pain		195	0
Bursal disorders			
Bursitis		79	0
Cartilage disorders			
Chondritis		1	0
Chondropathy		1	0
Costochondritis		36	0
Connective tissue disorders NEC			Ū
Connective tissue disorder		2	0
Mixed connective tissue disease		2 1	0
Morphoea		1	0
Polymyalgia rheumatica		50	0
Reynold's syndrome		5	0
Scleroderma		2	0
Crystal arthropathic disorders		-	U
Gouty tophus		1	0
Epiphyseal disorders			U
		1	0
Epiphyses premature fusion		l l	0
Extremity deformities		_	0
Finger deformity		3	0
Foot deformity		1	0
Hand deformity		1	0
Limb deformity		4	0
Wrist deformity		1	0
Fractures NEC			
Osteoporotic fracture		1	0
Intervertebral disc disorders NEC			
Intervertebral disc protrusion		1	0
Joint related disorders NEC			

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Reaction Name	Tot	<u>al</u>	Fatal
Muscle & tissue disorders e & tissue disorders con	nt'd		
Femoroacetabular impingement		2	0
Joint ankylosis		1	0
Joint instability		2	0
Joint laxity		4	0
Joint lock		34	0
Patellofemoral pain syndrome		3	0
Periarthritis		189	0
Rotator cuff syndrome		42	0
Temporomandibular joint syndrome		14	0
Joint related signs and symptoms		• •	·
Arthralgia	18	794	0
Jaw clicking	10	/ J-	0
Joint effusion		3	0
Joint endson  Joint noise		29	0
Joint noise  Joint range of motion decreased		3	0
Joint stiffness		331	0
		580	0
Joint swelling Joint vibration			
		2	0
Joint warmth		25	
Loose body in joint		1	0
Ligament disorders		_	_
Ligament pain		7	0
Lupus erythematosus (incl subtypes)			
Lupus-like syndrome		1	0
Systemic lupus erythematosus		25	0
Metabolic bone disorders			_
Osteopenia		1	0
Osteoporosis		8	0
Muscle infections and inflammations			
Myositis		23	0
Polymyositis		1	0
Muscle pains			
Fibromyalgia		200	0
Myalgia	23	349	0
Myalgia intercostal		2	0
Myofascial pain syndrome		18	0
Muscle related signs and symptoms NEC			
Haematoma muscle		2	0
Muscle atrophy		13	0
Muscle discomfort		8	0
Muscle disorder		4	0
Muscle fatigue		785	0
Muscle haemorrhage		1	0
Muscle mass		5	0
Muscle oedema		2	0
Muscle spasms	2	230	0
Muscle swelling		20	0
Muscle tightness		137	0
Muscle twitching		353	0
Muscle tone abnormalities			
Muscle rigidity		42	0
Nuchal rigidity		14	0
Torticollis		8	0

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Reaction Name	<u>Total</u>	<u>Fatal</u>
Muscle & tissue disorders & tissue disorders cont'd		
Trismus	49	0
Muscle weakness conditions		
Muscular weakness	1525	0
Musculoskeletal and connective tissue conditions NEC		
Extremity contracture	1	0
Infantile back arching	1	0
Limb mass	9	0
Mandibular mass	1	0
Mastication disorder	2	0
Mobility decreased	88	
Muscle contracture	2	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	1749	0
Posture abnormal	1	0
Somatic dysfunction	1	0
Weight bearing difficulty	5	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	2	0
Head deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Dactylitis	2	0
Fasciitis	1	0
Plantar fasciitis	6	0
Musculoskeletal and connective tissue pain and discomfort		
Amplified musculoskeletal pain syndrome	1	0
Back pain	4705	0
Flank pain	61	0
Growing pains	8	0
Limb discomfort	1789	
Musculoskeletal chest pain	333	0
Musculoskeletal discomfort	101	0
Musculoskeletal pain	55	0
Neck pain	2402	
Pain in extremity	17010	
Rheumatic disorder	14	0
Myopathies		
Compartment syndrome	3	0
Muscle necrosis	1	0
Myopathy	3	0
Rhabdomyolysis	7	1
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	33	
Spinal osteoarthritis	3	0
Psoriatic arthropathies	0.4	0
Psoriatic arthropathy	24	0
Rheumatoid arthropathies		_
Felty's syndrome	1	0
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	108	
Still's disease	3	0

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Reaction Name	Total	<u>Fatal</u>
Muscle & tissue disorders & tissue disorders cont'd		
Soft tissue disorders NEC		
Axillary mass	38	0
Clubbing	1	0
Fistula	1	0
Groin pain	157	0
Neck mass	15	0
Soft tissue disorder	2	0
Soft tissue mass	2	0
Soft tissue swelling	5	0
Spine and neck deformities		
Kyphosis	3	0
Scoliosis	2	0
Spinal stenosis	2	0
Spondyloarthropathies		
Ankylosing spondylitis	21	0
Arthritis reactive	19	0
Axial spondyloarthritis	1	0
Spondylitis	2	0
Synovial disorders		
Synovial cyst	5	0
Synovitis	11	0
Tendon disorders		
Enthesopathy	1	0
Tendon discomfort	2	0
Tendon disorder	4	0
Tendon pain	28	0
Tendonitis	47	0
Tenosynovitis	1	0
Tenosynovitis stenosans	1	0
Trigger finger	15	0
Muscle & tissue disorders SOC TOTAL	79918	1

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Reaction Name	Total	<u>Fatal</u>
Neoplasms		
B-cell lymphomas NEC		
Follicular lymphoma	1	0
Bladder neoplasms malignant		
Bladder cancer	1	0
Bone neoplasms malignant (excl sarcomas)		
Bone cancer	1	0
Breast and nipple neoplasms benign		
Benign breast neoplasm	1	0
Breast and nipple neoplasms malignant		
Breast cancer	33	0
Breast cancer male	2	0
Breast cancer metastatic	1	0
Breast cancer stage III	1	0
Cardiovascular neoplasms benign		
Haemangioma	2	0
Central nervous system neoplasms malignant NEC		
Brain cancer metastatic	2	0
Brain neoplasm malignant	1	0
Cervix neoplasms malignant		
Cervix carcinoma	1	0
Colorectal neoplasms malignant		
Colon cancer	1	0
Colorectal cancer	1	0
Endocrine neoplasms benign NEC		
Pituitary tumour benign	1	0
Endometrial neoplasms malignant		
Endometrial cancer	2	0
Gastrointestinal neoplasms benign NEC		
Gastrointestinal tract adenoma	1	0
Gastrointestinal neoplasms malignant NEC		
Gastrointestinal carcinoma	2	0
Haematologic neoplasms NEC		
Systemic mastocytosis	1	0
Hepatic neoplasms malignant		
Hepatocellular carcinoma	3	0
Hepatoblastomas		
Hepatoblastoma	1	0
Hodgkin's disease NEC		
Hodgkin's disease	1	0
Leukaemias NEC		
Leukaemia	1	0
Leukaemia recurrent	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	5	0
Leukaemias chronic myeloid		
Chronic myeloid leukaemia	1	0
Lip and oral cavity neoplasms benign		
Papillary cystadenoma lymphomatosum	1	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer	1	0
Squamous cell carcinoma of the oral cavity	1	0
Lymphomas unspecified NEC		
Lymphoma	10	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		
Lymphoproliferative disorder in remission	1	0
Mediastinal neoplasms malignancy unspecified NEC		
Good syndrome	1	0
Metastases to specified sites		
Metastases to bone	1	0
Metastases to central nervous system	1	1
Metastases to lung	1	1
Metastases to unknown and unspecified sites		
Metastasis	3	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	2	0
Neoplasms benign site unspecified NEC		
Fibroma	1	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma	2	0
Metastatic neoplasm	3	0
Neoplasm malignant	5	1
Squamous cell carcinoma	1	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm recurrence	6	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	2	0
Meningioma	2	0
Neuromas		
Acoustic neuroma	2	0
Ocular neoplasms benign		
Eye naevus	2	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	4	0
Oesophageal carcinoma	4	0
Oesophageal squamous cell carcinoma	1	0
Oncologic complications and emergencies		
Cancer fatigue	4	0
Cancer pain	1	0
Intracranial tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and		
unspecified	_	
Tonsil cancer	2	0
Ovarian neoplasms malignant (excl germ cell)	_	
Ovarian cancer	5	0
Ovarian cancer stage IV	2	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)	_	
Pancreatic carcinoma	3	0
Plasma cell myelomas		_
Plasma cell myeloma	1	0
Prostatic neoplasms malignant		
Prostate cancer	7	0
Renal neoplasms malignant		
Clear cell renal cell carcinoma	3	0
Metastatic renal cell carcinoma	1	0
Renal cancer	1	0
Respiratory tract and pleural neoplasms malignancy unspecified NEC		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Maxillofacial sinus neoplasm	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified		
NEC		
Bronchial carcinoma	4	0
Lung cancer metastatic	1	0
Lung neoplasm malignant	8	0
Throat cancer	1	0
Salivary gland neoplasms malignant		
Salivary gland cancer stage 0	1	0
Salivary gland cancer stage III	1	0
Skin melanomas (excl ocular)		
Acral lentiginous melanoma stage III	1	0
Malignant melanoma	2	0
Malignant melanoma in situ	1	0
Skin neoplasms benign		
Acrochordon	1	0
Haemangioma of skin	7	0
Melanocytic naevus	2	0
Skin papilloma	13	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Basal cell carcinoma	1	0
Bowen's disease	1	0
Neoplasm skin	1	0
Skin cancer	2	0
Squamous cell carcinoma of skin	1	0
Soft tissue neoplasms benign NEC		
Knuckle pads	1	0
Lipoma	4	0
Uterine neoplasms benign		
Uterine leiomyoma	3	0
Neoplasms SOC TOTAL	216	3

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Reaction Name	<u>Total</u>	<u>Fatal</u>
Nervous system disorders		
Abnormal reflexes		
Areflexia	13	0
Extensor plantar response	1	0
Hyperreflexia	1	0
Hyporeflexia	10	0
Poor sucking reflex	1	0
Reflexes abnormal	1	0
Abnormal sleep-related events		
Sleep paralysis	20	0
Absence seizures		
Petit mal epilepsy	26	0
Acute polyneuropathies		
Acute motor axonal neuropathy	3	0
Acute polyneuropathy	2	0
Guillain-Barre syndrome	223	4
Miller Fisher syndrome	13	0
Subacute inflammatory demyelinating polyneuropathy	1	0
Auditory nerve disorders		
Acoustic neuritis	1	0
Autonomic nervous system disorders		
Autonomic nervous system imbalance	9	0
Horner's syndrome	1	0
Orthostatic intolerance	2	0
Central nervous system aneurysms and dissections		
Carotid artery dissection	1	0
Intracranial aneurysm	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Basal ganglia haemorrhage	2	0
Basal ganglia stroke	1	0
Basilar artery thrombosis	1	0
Brain stem haemorrhage	2	0
Brain stem infarction	2	2
Brain stem stroke	3	2
Carotid artery occlusion	1	0
Carotid artery thrombosis	8	0
Cerebellar haemorrhage	8	0
Cerebellar infarction	4	0
Cerebellar stroke	8	0
Cerebral artery embolism	7	0
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	7	0
Cerebral haematoma	11	1
Cerebral haemorrhage	122	31
Cerebral infarction	57	3
Cerebral ischaemia	3	0
Cerebral thrombosis	26	1
Cerebral vascular occlusion	2	0
Cerebrovascular accident	701	32
Embolic stroke	16	
Haemorrhage intracranial	40	6
Haemorrhagic cerebral infarction	2	1
Haemorrhagic stroke	25	4
Haemorrhagic transformation stroke	5	

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Reaction Name		Total	<u>Fatal</u>
Nervous system disorders us system disorders	cont'd		
Intracranial haematoma		5	1
Intraventricular haemorrhage		6	0
Ischaemic cerebral infarction		2	0
Ischaemic stroke		84	3
Lacunar infarction		4	3
Lacunar stroke		17	0
Spinal cord haematoma		1	0
Subarachnoid haemorrhage		74	4
Thalamus haemorrhage		6	0
Thrombotic stroke		8	0
Vertebral artery occlusion		1	0
Central nervous system inflammatory disor	ders NEC		
Arachnoiditis		2	0
Central nervous system inflammation		9	0
Neurosarcoidosis		2	0
Central nervous system vascular disorders	NEC		
Brain hypoxia		1	1
Carotid artery stenosis		2	0
Central nervous system vasculitis		2	0
Cerebral amyloid angiopathy		2	0
Cerebral congestion		2 2	0
Cerebral microhaemorrhage		1	0
Cerebral small vessel ischaemic disease		2	0
Cerebral vasoconstriction		1	0
Cerebrovascular disorder		3	0
Internal carotid artery deformity		1	0
Reversible cerebral vasoconstriction sync	rome	1	0
Cerebrovascular venous and sinus thrombo			
Cerebral venous sinus thrombosis		159	18
Cerebral venous thrombosis		33	
Superior sagittal sinus thrombosis		22	3
Transverse sinus thrombosis		5	0
Cervical spinal cord and nerve root disorde	rs		
Cervical radiculopathy		3	0
Cervicobrachial syndrome		5	0
Choreiform movements			
Chorea		3	0
Choreoathetosis		1	0
Sydenham's chorea		1	0
Chronic polyneuropathies			
Demyelinating polyneuropathy		2	0
Diabetic neuropathy		2	0
Coma states			
Coma		11	0
Diabetic coma		3	0
Coordination and balance disturbances			
Ataxia		24	0
Balance disorder		622	0
Cerebellar ataxia		1	0
Coordination abnormal		91	0
Dysdiadochokinesis		1	0
Dysstasia		76	0
Hand-eye coordination impaired		1	0

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Reaction Name		Total	Fatal
Nervous system disorders us system disorders co	ont'd		
Nystagmus		12	0
Cortical dysfunction NEC			
Alexia		3	0
Aphasia		95	0
Apraxia		1	0
Dysgraphia		4	0
Dyslexia		2	0
Dyspraxia		2 3	0
Neurologic neglect syndrome		3 2	0
Visuospatial deficit		2	0
Cranial nerve disorders NEC			
Cranial nerve disorder		2	0
Cranial nerve paralysis		1	0
Neurovascular conflict		1	0
Paresis cranial nerve		1	0
Dementia (excl Alzheimer's type)			
Dementia		16	0
Dementia with Lewy bodies		1	0
Frontotemporal dementia		1	0
Senile dementia		1	0
Vascular dementia		4	0
Demyelinating disorders NEC			
Acute disseminated encephalomyelitis		5	0
Demyelination		11	0
Neuromyelitis optica spectrum disorder		1	0
Disturbances in consciousness NEC			
Altered state of consciousness		10	0
Consciousness fluctuating		4	0
Depressed level of consciousness		69	0
Lethargy		3965	0
Loss of consciousness		808	0
Postictal state		1	0
Sedation		11	0
Somnolence		1496	1
Stupor		8	0
Syncope		1996	0
Disturbances in sleep phase rhythm			
Advanced sleep phase		1	0
Circadian rhythm sleep disorder		2	
Irregular sleep phase		2 1	0
Irregular sleep wake rhythm disorder		1	0
Dyskinesias and movement disorders NEC			
Akathisia		10	0
Ballismus		1	0
Bradykinesia		23	0
Clumsiness		36	0
Dyskinesia		91	0
Extrapyramidal disorder		18	0
Fine motor delay		1	0
Fine motor skill dysfunction		9	0
Hyperkinesia		25	0
Hypokinesia		39	0
Motor dysfunction		10	0

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Reaction Name		<u>Total</u>	<u>Fatal</u>
Nervous system disordersus system disorders	cont'd		
Movement disorder		59	0
Psychomotor hyperactivity		30	0
Dystonias			
Dystonia		15	0
Dystonic tremor		3	0
Opisthotonus		4	0
Encephalitis NEC			
Noninfective encephalitis		4	0
Encephalopathies NEC			
Autoimmune encephalopathy		3	0
Encephalopathy		4	0
Hypoxic-ischaemic encephalopathy		1	0
Posterior reversible encephalopathy syn	drome	2	0
Encephalopathies toxic and metabolic			
Hepatic encephalopathy		2	0
Eye movement disorders			
IIIrd nerve disorder		1	0
IIIrd nerve paralysis		5	0
Microvascular cranial nerve palsy		1	0
VIth nerve paralysis		7	0
Facial cranial nerve disorders			
Bell's palsy		314	0
Facial nerve disorder		3	0
Facial paralysis		186	0
Facial paresis		102	0
Facial spasm		23	0
Oculofacial paralysis		1	0
Generalised tonic-clonic seizures			
Generalised tonic-clonic seizure		59	0
Headaches NEC			
Cervicogenic headache		4	0
Cluster headache		553	0
Cold-stimulus headache		62	0
Drug withdrawal headache		14	0
Exertional headache		10	0
External compression headache		3	0
Headache		68106	4
Medication overuse headache		14	0
New daily persistent headache		14	0
Occipital neuralgia		14	0
Ophthalmoplegic migraine		1	0
Post-traumatic headache		2 2	0
Primary cough headache		2	0
Primary headache associated with sexua	al activity	10	0
Sinus headache		788	0
Tension headache		1148	0
Thunderclap headache		37	0
Vascular headache		64	0
Hydrocephalic conditions			
Hydrocephalus		8	0
Hypoglossal nerve disorders			
Tongue paralysis		5	0
Increased intracranial pressure disorders			

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Reaction Name		Total	Fatal
Nervous system disorders co	ont'd		
Brain compression		2	0
Brain oedema		21	1
Cerebrospinal fluid circulation disorder		3	0
Idiopathic intracranial hypertension		5	0
Intracranial pressure increased		17	0
Intellectual disabilities			
Intellectual disability		9	0
Lumbar spinal cord and nerve root disorders			
Lumbar radiculopathy		1	0
Sciatica		131	0
Memory loss (excl dementia)			
Amnesia		205	0
Memory impairment		199	0
Transient global amnesia		15	0
Meningitis NEC			
Meningitis noninfective		1	0
Mental impairment (excl dementia and mem	ory loss)		
Cognitive disorder	•	115	1
Disturbance in attention		477	0
Judgement impaired		3	0
Mental impairment		93	0
Migraine headaches			
Basilar migraine		3	0
Hemiplegic migraine		23	0
Migraine		5786	0
Migraine with aura		257	0
Migraine without aura		35	0
Ophthalmic migraine		8	0
Retinal migraine		50	0
Status migrainosus		1	0
Typical aura without headache		8	0
Vestibular migraine		16	0
Mixed cranial nerve disorders			
Bulbar palsy		1	0
Mononeuropathies			
Carpal tunnel syndrome		18	0
Diabetic mononeuropathy		1	0
Meralgia paraesthetica		2	0
Mononeuritis		2 2 2	0
Mononeuropathy		2	0
Nerve compression		31	0
Peroneal nerve palsy		8	0
Piriformis syndrome		1	0
Radial nerve palsy		2	0
Sciatic nerve neuropathy		2 3 1	
Ulnar nerve palsy		1	0
Ulnar neuritis		3	0
Ulnar tunnel syndrome		1	0
Motor neurone diseases			
Motor neurone disease		1	0
Multiple sclerosis acute and progressive			
Band sensation		4	0
Multiple sclerosis		45	0

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Reaction Name		Total	Fatal
Nervous system disorders con system disorders con the system disorders contain the system disorder con the system disorders contain the system disorders contai	ont'd		
Multiple sclerosis relapse		33	0
Relapsing multiple sclerosis		1	0
Uhthoff's phenomenon		4	0
Muscle tone abnormal			
Hypertonia		1	0
Hypotonia		27	0
Serotonin syndrome		1	0
Stiff leg syndrome		7	0
Myelitis (incl infective)			
Myelitis transverse		57	0
Narcolepsy and hypersomnia			
Cataplexy		1	0
Hypersomnia		155	0
Narcolepsy		13	0
Nervous system cysts and polyps			
Pineal gland cyst		1	0
Nervous system disorders NEC			
Brain stem syndrome		2	0
Cerebral disorder		1	0
Nervous system disorder		27	0
Neurotoxicity		1	0
Psychomotor skills impaired		4	0
Neurologic visual problems NEC			_
Hemianopia		6	0
Hemianopia homonymous		1	0
Tunnel vision		14	0
Neurological signs and symptoms NEC			_
Agitation neonatal		1	0
Dizziness		17821	0
Dizziness exertional		76	0
Dizziness postural		1779	1
Drooling		13	0
Exaggerated startle response		3	0
Fontanelle bulging		3	0
Head discomfort		472	0
Hyporesponsive to stimuli			0
Infant irritability		5	0
Intracranial hypotension		2 5 2 2	0
Meningism		2	0
Myoclonus		22	0
Neurological decompensation		4	0
Neurological symptom		73	0
Patient elopement		1	0
Persistent postural-perceptual dizziness		26	0
Pleocytosis		2	0
Presyncope		495	
Sensory overload		8	0
Slow response to stimuli		5	0
Tongue biting		8	0
Unresponsive to stimuli		76	0
Neuromuscular disorders NEC		, ,	
Muscle contractions involuntary		24	0
Muscle spasticity		17	0

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Reaction Name		<u>Total</u>	Fatal
Nervous system disorders co	ont'd		
Neuromuscular pain		5	0
Neuromyopathy		3	0
Neuromyotonia		1	0
Neuromuscular junction dysfunction			
Myasthenia gravis		7	0
Myasthenia gravis crisis		1	0
Olfactory nerve disorders			
Anosmia		217	0
Hyposmia		10	0
Parosmia		300	0
Optic nerve disorders NEC			
Optic neuritis		30	0
Paraesthesias and dysaesthesias			
Anaesthesia		2	0
Burning feet syndrome		18	0
Burning sensation		616	0
Burning sensation mucosal		3	0
Dysaesthesia		6	0
Formication		49	0
Hand-arm vibration syndrome		1	0
Hemianaesthesia		3	0
Hemiparaesthesia		2	0
Hyperaesthesia		218	0
Hypoaesthesia		3934	0
Lhermitte's sign		1	0
Paraesthesia		6688	0
Paralysis and paresis (excl cranial nerve)			· ·
Diplegia		23	0
Hemiparesis		71	0
Hemiplegia		21	0
Monoparesis		66	0
Monoplegia		92	0
Paralysis		226	0
Paraparesis		6	0
Paraplegia		_	0
Paresis		5	0
Peripheral nerve palsy		1	
Postictal paralysis		1	0
Quadriplegia		3	0
Parkinson's disease and parkinsonism			Ū
Freezing phenomenon		139	0
Parkinson's disease		15	0
Parkinsonism		10	
Reduced facial expression		4	0
Vascular parkinsonism		1	0
Partial complex seizures			J
Dreamy state		17	0
Focal dyscognitive seizures		5	0
Temporal lobe epilepsy		3	0
Partial simple seizures NEC		J	- J
Autonomic seizure		1	0
Simple partial seizures		4	0
Peripheral neuropathies NEC		7	J
renpheral neuropathies NEC			

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Reaction Name		Total	Fatal
Nervous system disorders us system disorders co	nt'd		
Autoimmune neuropathy		2	0
Neuralgic amyotrophy		1	0
Neuritis		7	0
Neuropathy peripheral		134	0
Peripheral motor neuropathy		1	0
Peripheral sensorimotor neuropathy		1	0
Peripheral sensory neuropathy		12	0
Polyneuropathy		7	0
Small fibre neuropathy		2	0
Thoracic outlet syndrome		1	0
Seizures and seizure disorders NEC			
Alcoholic seizure		1	0
Atonic seizures		9	0
Change in seizure presentation		3	0
Clonic convulsion		8	0
Drug withdrawal convulsions		2	0
Epilepsy		196	0
Epileptic aura		2	0
Febrile convulsion		75	0
Migraine-triggered seizure		1	0
Myoclonic epilepsy		4	0
Partial seizures		44	0
Psychogenic seizure		5	0
Seizure		904	2
Seizure anoxic		3	2 0
Seizure cluster		4	0
Seizure like phenomena		2	0
Status epilepticus		96	3
Tonic clonic movements		2	3 0
Tonic convulsion		28	0
Sensory abnormalities NEC			
Ageusia		834	0
Allodynia		49	0
Aura		17	0
Central pain syndrome		2	0
Complex regional pain syndrome		8	0
Dysgeusia		1650	0
Electric shock sensation		64	0
Hypogeusia		4	0
Intercostal neuralgia		1	0
Loss of proprioception		2	0
Neuralgia		912	0
Persistent genital arousal disorder		1	0
Phantom limb syndrome		17	0
Post herpetic neuralgia		8	0
Restless arm syndrome		10	0
Restless legs syndrome		291	0
Sensory disturbance		74	0
Sensory loss		144	0
Taste disorder		405	0
Vibratory sense increased		1	0
Visual perseveration		1	0
Sleep disturbances NEC			

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Reaction Name	Total	<u> Fatal</u>
Nervous system disorders us system disorders cont'd		
Microsleep	2	
Sleep deficit	39	0
Speech and language abnormalities		
Dysarthria	264	l 0
Incoherent	13	
Language disorder	2	0
Muscle tension dysphonia	1	0
Slow speech	20	0
Speech disorder	53	0
Spinal cord and nerve root disorders NEC		
Cauda equina syndrome	3	
Myelopathy	2	0
Radicular pain	1	
Radiculitis brachial	10	0
Radiculopathy	1	0
Spinal cord disorder	3	3 O
Structural brain disorders NEC		
Brain injury	17	1
Cerebral mass effect	4	· o
Intracranial mass	3	3 O
White matter lesion		0
Transient cerebrovascular events		
Transient ischaemic attack	303	3 o
Tremor (excl congenital)		
Action tremor	2	2 0
Asterixis	1	0
Essential tremor	4	· o
Head titubation	13	3 o
Intention tremor		0
Postural tremor	1	0
Resting tremor	5	
Tremor	8571	3
Trigeminal disorders		
Facial neuralgia	25	5 O
Numb chin syndrome	2	2 0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	57	
Trigeminal neuritis	1	0
Trigeminal palsy	1	0
Vagus nerve disorders		
Vagus nerve paralysis	1	0
Nervous system disorders SOC TOTAL	140409	139

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA Ver		Cotal
Reaction Name	Total	<u>Fatal</u>
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	57	1
Foetal complications NEC		
Foetal disorder	1	
_Foetal hypokinesia	2	0
Foetal position and presentation abnormalities		_
Face presentation	1	0
High risk pregnancies		
Pregnancy with young maternal age	1	0
Labour onset and length abnormalities		
Precipitate labour	1	
Premature labour	3	
Premature rupture of membranes	1	
Prolonged labour	1	0
Maternal complications of labour NEC		
Uterine contractions abnormal	1	
Uterine hypertonus	1	0
Maternal complications of pregnancy NEC		
Ectopic pregnancy	2 2	0
Hyperemesis gravidarum	2	0
Morning sickness	30	0
Pelvic girdle pain	1	0
Normal pregnancy, labour and delivery		
Labour pain	1	0
Pregnancy	13	0
Uterine contractions during pregnancy	1	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	4	0
Stillbirth and foetal death		
Stillbirth	2	1
Umbilical cord complications		
Umbilical cord abnormality	1	0
Unintended pregnancies		
Pregnancy after post coital contraception	3	0
Pregnancy on contraceptive		
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	1	
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	4	
Pregnancy conditions SOC TOTAL	139	0

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Reaction Name	Total	Fatal
Device electrical issues		
Device electrical impedance issue	1	0
Device incompatibility issues		
Patient-device incompatibility	1	0
Device issues NEC		
Device issue	2	0
Device leakage	2	0
Device malfunction events NEC		
Oversensing	23	0
Stent malfunction	1	0
Thrombosis in device	30	0
Undersensing	3	0
Device physical property and chemical issues		
Needle issue	4	0
Syringe issue	1	0
Manufacturing facilities and equipment issues		
Manufacturing equipment issue	1	0
Product contamination and sterility issues		
Product contamination	1	0
Product label issues		
Product label issue	1	0
Product physical issues		
Product leakage	1	0
Product physical issue	1	0
Product taste abnormal	6	0
Product quality issues NEC		
Product origin unknown	2	0
Product quality issue	1	0
Suspected product quality issue	2	0
null SOC TOTAL	84	0

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version:	MedDRA 24.0	
Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	12	0
Breath holding	3	0
Staring	8	0
Abnormal food elimination		
Self-induced vomiting	1	0
Adjustment disorders		
Adjustment disorder with depressed mood	5	0
Affect alterations NEC		
Affect lability	6	0
Constricted affect	5	1
Flat affect	9	
Inappropriate affect	14	1
Amnestic symptoms		
Paramnesia	3	0
Anxiety disorders NEC		
Anxiety disorder	2	0
Generalised anxiety disorder	2	0
Neurosis	1	0
Anxiety symptoms		
Agitation	161	0
Anxiety	745	
Immunisation anxiety related reaction	1	
Nervousness	499	
Stress	72	
Tension	48	
Attention deficit and disruptive behaviour disorders		
Attention deficit hyperactivity disorder	12	0
Behaviour and socialisation disturbances		
Aggression	10	0
Asocial behaviour	1	0
Aversion	1	0
Impatience	2	
Indifference	2	0
Paranoia	30	_
Personality change	4	
Social avoidant behaviour	4	
Soliloquy	2	
Violence-related symptom	2	
Bipolar disorders		
Bipolar I disorder	6	0
Bipolar disorder	3	
Cognitive and attention disorders and disturbances NEC		
Change in sustained attention	1	0
Daydreaming	11	
Distractibility	1	Ö
Mental fatigue	355	
Communications disorders	000	
Communication disorder	2	0
Mutism	2 2	Ö
Speech sound disorder	1	Ö
Confusion and disorientation		
	1552	1
Confusional state	1552	<u>1</u>

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0  Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd	I Olai	i alai
Disorientation	585	0
Decreased physical activity levels	303	U
Catatonia	2	0
Deliria Deliria		U
Delirium	414	0
Delirium febrile	3	0
Delusional disorders	J	
Alice in wonderland syndrome	3	0
Delusional symptoms	J	
Delusion	33	0
Delusion of parasitosis	1	0
Mixed delusion	1	0
Thought withdrawal	1	0
Depressive disorders		
Agitated depression	3	0
Depression	405	0
Depression suicidal	12	0
Major depression	18	0
Mixed anxiety and depressive disorder	1	0
Dissociative states		_
Depersonalisation/derealisation disorder	13	0
Dissociation	50	0
Dissociative disorder	1	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	29	0
Insomnia	2502	0
Middle insomnia	63	0
Terminal insomnia	8	0
Dyssomnias		
Dyssomnia	4	0
Poor quality sleep	569	0
Eating disorders NEC		
Eating disorder	6	0
Emotional and mood disturbances NEC		
Anger	57	0
Dysphoria	2	0
Emotional disorder	74	0
Emotional distress	53	0
Emotional poverty	2	0
Euphoric mood	54	0
Frustration tolerance decreased	2	0
Irritability	233	0
Mood altered	52	0
Factitious disorders		_
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		_
Acrophobia	1	0
Agoraphobia	3	0
Claustrophobia	1	0
Fear	23	0
Fear of death	8	0
Fear of disease	2 1	0
Fear of eating	1	0

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Reaction Name		<u> Fotal</u>	Fatal
Psychiatric disordersPsychiatric disorders cont'd			
Fear of falling		2	0
Fear of injection		2	0
Fear of open spaces		1	0
Performance fear		1	0
Phobia		2	0
Phonophobia		3	0
Fluctuating mood symptoms			
Mood swings		45	0
Hallucinations (excl sleep-related)			
Hallucination		791	0
Hallucination, auditory		34	0
Hallucination, olfactory		7	0
Hallucination, tactile		1	0
Hallucination, visual		45	0
Hallucinations, mixed		7	0
Impulse control disorders			
Impulse-control disorder		2	0
Impulsive behaviour		1	0
Intermittent explosive disorder		1	0
Increased physical activity levels			
Restlessness		418	0
Infancy, childhood and adolescence psychiatr	ic disorders NEC		
Emotional disorder of childhood		1	0
Mental disorders NEC			
Mental disorder		7	0
Mental status changes		3	0
Mental disorders due to a general medical col	ndition NEC		
Neuropsychiatric symptoms		1	0
Mood alterations with depressive symptoms			
Anhedonia		3	0
Decreased interest		12	0
Depressed mood		428	0
Depressive symptom		1	0
Feeling guilty		1	0
Feeling of despair		15	0
Negative thoughts		6	0
Sense of a foreshortened future		1	0
Tearfulness		85	0
Mood alterations with manic symptoms			
Hypomania		1	0
Mania		25	0
Mood disorders NEC			
Affective disorder		2	0
Apathy		41	0
Listless		104	0
Mood disorder due to a general medical cor	dition	1	0
Substance-induced mood disorder		1	0
Narcolepsy and associated conditions			
Hypnagogic hallucination		4	0
Sleep attacks		1	0
Obsessive-compulsive disorders and symptor	ms	·	
Compulsive shopping		2	0
Dermatillomania		1	0

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Reaction Name		Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd			
Obsessive thoughts		2	0
Obsessive-compulsive disorder		1	0
Orgasmic disorders and disturbances			
Anorgasmia		2	0
Orgasmic sensation decreased		4	0
Premature ejaculation		1	0
Panic attacks and disorders			
Limited symptom panic attack		1	0
Panic attack		214	0
Panic disorder		2	0
Panic reaction		28	0
Paraphilias and paraphilic disorders			
Fetishism		2	0
Parasomnias			
Abnormal dreams		310	0
Abnormal sleep-related event		1	0
Confusional arousal		2	0
Exploding head syndrome		6	0
Nightmare		385	0
Parasomnia		1	0
Rapid eye movements sleep abnormal		3	0
Sleep inertia		1	0
Sleep talking		15	0
Sleep terror		49	0
Sleep-related eating disorder		2	0
Somnambulism		7	0
Perception disturbances NEC			
Autoscopy		19	0
Deja vu		4	0
Delusional perception		2	0
Derealisation		10	0
Flashback		2	0
Illusion		11	0
Pseudohallucination		1	0
Time perception altered		5	0
Pervasive developmental disorders NEC			
Autism spectrum disorder		2	0
Psychiatric elimination disorders			
Enuresis		42	0
Psychiatric symptoms NEC			
Helplessness		2	0
Hypervigilance		13	0
Psychiatric symptom		3	0
Psychological trauma		3	0
Psychotic disorder NEC			
Acute psychosis		2	0
Psychotic behaviour		1	0
Psychotic disorder		27	0
Psychotic symptom		1	0
Rebound psychosis		1	0
Schizoaffective and schizophreniform disord	ers		
Schizoaffective disorder		1	0
Schizophrenia NEC			

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Reaction Name	<del>,</del>	<u>Total</u>	Fatal
Psychiatric disorders Psychiatric disorders cont'd			
Schizophrenia		1	0
Sexual arousal disorders			
Disturbance in sexual arousal		3	0
Sexual desire disorders			
Hypersexuality		1	0
Libido decreased		10	0
Libido increased		5	0
Loss of libido		30	0
Sexual dysfunction NEC			
Genito-pelvic pain/penetration disorder		1	0
Sleep disorders NEC			
Sleep disorder		303	0
Sleep disorder due to general medical con-	dition, insomnia type	2	0
Somatic symptom disorders			
Conversion disorder		11	0
Habit cough		30	0
Illness anxiety disorder		1	0
Psychogenic tremor		1	0
Somatic symptom disorder		1	0
Speech and language usage disturbances			
Disorganised speech		14	0
Logorrhoea		2	0
Pedantic speech		1	0
Poverty of speech		1	0
Verbigeration		1	0
Speech articulation and rhythm disturbances			
Dysphemia		18	0
Lack of spontaneous speech		2	0
Stereotypies and automatisms			
Bruxism		24	0
Head banging		32	0
Waxy flexibility		2	0
Stress disorders			
Acute stress disorder		2	0
Burnout syndrome		8	0
Hyperarousal		3	0
Post-traumatic stress disorder		11	0
Substance related and addictive disorders			_
Alcohol abuse		1	0
Alcohol use disorder		2	0
Alcoholism		2	0
Dependence		1	0
Drug dependence		1	0
Substance abuse		1	0
Suicidal and self-injurious behaviour		-	_
Completed suicide		3	1
Intentional self-injury		7	0
Self-injurious ideation		2	0
Suicidal behaviour		2	0
Suicidal ideation		78	0
Suicide attempt		10	0
Suicide attempt Suicide threat		10	0
Thinking disturbances			U
rninking disturbances			

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Reaction Name	Total	Fatal
Psychiatric disorders <sup>Psychiatric</sup> disorders cont'd		
Bradyphrenia	71	0
Confabulation	1	0
Impaired reasoning	2	0
Intrusive thoughts	3	0
Morbid thoughts	4	0
Tachyphrenia	19	0
Thinking abnormal	19	0
Thought blocking	3	0
Tic disorders		
Tic	8	0
Psychiatric disorders SOC TOTAL	12969	2

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Reaction Name	Total	<u>Fatal</u>
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder discomfort	Į į	5 0
Bladder irritation	7	7 0
Bladder pain	44	4 0
Bladder spasm		1 0
Dysuria	62	
Incontinence	66	
Micturition disorder		3 0
Micturition frequency decreased		i o
Micturition urgency	87	
Mixed incontinence		i ő
Pollakiuria	228	
Urethral pain		2 0
Urge incontinence		
1		1
Urinary hesitation		1 0 6 0
Urinary incontinence	86	1
Urinary retention	56	
Urine flow decreased		9 0
Bladder disorders NEC		
Bladder dilatation		0
Bladder disorder	12	
Urinary bladder haemorrhage	8	3 1
Bladder infections and inflammations		
Cystitis haemorrhagic		1 0
Cystitis interstitial		5 0
Cystitis noninfective		1 0
Lupus cystitis		1 0
Genital and urinary tract disorders NEC		
Urinary tract disorder		3 0
Glomerulonephritis and nephrotic syndrome		
Anti-glomerular basement membrane disease		1 0
Focal segmental glomerulosclerosis		1 0
Glomerulonephritis membranous		1 0
Glomerulonephritis minimal lesion		3 0
Henoch-Schonlein purpura nephritis		1 0
IgA nephropathy		2 0
Nephrotic syndrome	1.	1
Myoneurogenic bladder disorders		
Automatic bladder		1 0
Bladder dysfunction		
Hypertonic bladder	12	1
Loss of bladder sensation	10	
Neurogenic bladder		2 0
Nephritis NEC	·	٦
Lupus nephritis		ا ا
Nephritis		[] 0 5 0
Tubulointerstitial nephritis	-	1 0
Nephropathies and tubular disorders NEC		
Nephropathy NEO		0
Renal disorders NEC		
Oedematous kidney		0
Renal disorder		7 0
Renal haemorrhage		1 0

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Reaction Name	Total	<u>Fatal</u>
Renal & urinary disorders & urinary disorders cont'd		
Renal failure and impairment		
Acute kidney injury	41	1 1
Anuria	4	4 0
Chronic kidney disease	5	5 0
Oliguria	11	
Renal failure	14	1 2 3 0
Renal impairment	8	3 0
Renal injury	3	3 0
Renal hypertension and related conditions		
Hypertensive nephropathy	1	1 0
Renal lithiasis		
Nephrolithiasis	8	3 0
Renal obstructive disorders		
Hydronephrosis	1	1 0
Renal structural abnormalities and trauma		
Kidney enlargement	1	1 0
Renal atrophy	2	2 0
Renal vascular and ischaemic conditions		
Renal artery occlusion	1	1 0
Renal embolism		1 0
Renal infarct	g	e 0
Renal vein embolism	1	1 0
Renal vein thrombosis	8	3 0
Structural and obstructive urethral disorders (excl co	ngenital)	
Urethral spasm	1	1 0
Ureteric disorders NEC		
Ureteral disorder	2	2 0
Urinary abnormalities		
Chromaturia	81	1 0
Glycosuria	1	1 0
Haematuria	45	5 0
Proteinuria	6	
Urine abnormality	16	
Urine odour abnormal	18	3 0
Urinary tract lithiasis (excl renal)		
Calculus bladder	1	1 0
Urinary tract signs and symptoms NEC		
Haemorrhage urinary tract	35	5 0
Nocturia	14	4 0
Polyuria	24	4 0
Renal colic	2	2 0
Renal pain	766	
Urinary tract discomfort	1	1 0
Urinary tract pain	3	1
Renal & urinary disorders SOC TOTAL	1902	

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Reproductive & breast disorders		
Benign and malignant breast neoplasms		
Breast cyst		4 0
Breast disorders NEC		
Breast disorder		1 0
Breast enlargement		5 0
Breast mass	29	9 0
Gynaecomastia		5 0
Breast infections and inflammations		
Breast inflammation		2 0
Nipple inflammation		1 0
Breast signs and symptoms		
Breast discharge		7 0
Breast discolouration		1 0
Breast discomfort		7 0
Breast engorgement		3 0
Breast haemorrhage		1 0
Breast induration		1 0
Breast oedema		1 0
Breast pain	272	2 0
Breast swelling	3.	7 0
Breast tenderness	30	6 ol
Nipple pain	28	3 <b> </b> 0
Nipple swelling		1 0
Erection and ejaculation conditions and disc	orders	
Ejaculation delayed		1 0
Ejaculation disorder	;	3 0
Ejaculation failure	;	3l ol
Erectile dysfunction	38	3 0
Erection increased		2 0
Organic erectile dysfunction	1	7 0
Painful erection		1 0
Priapism	:	2 0
Retrograde ejaculation		2 0
Spontaneous penile erection	:	2 0 2 0
Fallopian tube and ovary infections and infla	mmations	
Noninfective oophoritis		1 0
Lactation disorders		
Galactorrhoea		1 0
Lactation disorder		2 0
Lactation puerperal increased		2 0
Suppressed lactation	1:	1 0
Menopausal effects NEC		
Artificial menopause		2 0
Menopausal disorder		1 0
Menopausal symptoms	19	el ol
Menopause delayed		2 0
Premature menopause		4l ol
Menopausal effects on the genitourinary tra	ct	
Postmenopausal haemorrhage	60	o o
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	4	2 0
Abnormal withdrawal bleeding		- 1
Dysmenorrhoea	138	.

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 13-May-2021 Data Lock Date: 12-May-2021 18:30:08
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0

Reproductive & breast*dissorders & breast disorders cont'd                     Reproductive & breast*dissorders & breast disorders cont'd                     Intermenstrual bleeding         122         0           Menstrual discorder         256         0           Menstruation irregular         292         0           Premenstrual pain         12         0           Premenstrual syndrome         5         0           Withdrawal bleed         4         0           Menstruation with decreased bleeding         4         0           Amenorrhoea         71         0           Menstruation with increased bleeding         432         0           Menstruation with increased bleeding         615         0           Menstruation with increased bleeding         615         0           Menstruation with increased bleeding         615         0           Menometrorrhagia         2         0           Polymenorrhoea         615         0           Ovarian and fallopian tube cysts and neoplasms         0         615         0           Ovarian neoryst         4         0         0         0         0         0         0         0         0         0         0         0 <th>Earliest Reaction Date: 03-Feb-1921</th> <th>ledDRA Version: MedDRA 24.0</th> <th></th> <th></th>	Earliest Reaction Date: 03-Feb-1921	ledDRA Version: MedDRA 24.0		
Intermenstrual bleeding			Total	Fatal
Intermenstrual bleeding	Reproductive & breast disorde	rs cont'd		
Menstrual disorder         256         0           Menstruation irregular         292         0           Premenstrual pain         12         0           Premenstrual byordrome         5         0           Withdrawal bleed         4         4           Menstruation with decreased bleeding			122	0
Menstruation irregular         292         0           Premenstrual pain         12         0           Premenstrual syndrome         5         0           Withdrawal bleed         4         0           Menstruation with decreased bleeding         4         0           Amenorrhoea         99         0           Hypomenorrhoea         71         0           Menstruation delayed         432         0           Oligomenorrhoea         21         0           Menometrorrhagia         2         0           Heavy menstrual bleeding         65         0           Menometrorrhagia         2         0           Polymenorrhoea         69         0           Ovarian strubturel         2         0           Polymenorrhoea         69         0           Ovarian draflopian tube cysts and neoplasms         0           Ovarian cyst rupturel         1         0           Polycystic ovaries         5         0           Ovarian cyst rupturel         1         0           Polycystic ovaries         5         0           Ovarian elargement         1         0           Ovarian recrosis         1	Menstrual discomfort		1	0
Premenstrual pain   12	Menstrual disorder		256	0
Premenstrual pain	Menstruation irregular		292	0
Withdrawal bleed         4         0           Menstruation with decreased bleeding         99         0           Amenorrhoea         99         0           Hypomenorrhoea         21         0           Menstruation with increased bleeding         615         0           Heavy menstrual bleeding         615         0           Menometrorrhagia         2         2           Polymenorrhoea         69         0           Ovarian and fallopian tube cysts and neoplasms         69         0           Ovarian and fallopian tube cysts and neoplasms         69         0           Ovarian ocyst ruptured         1         0         0           Polycystic ovaries         5         0         0           Ovarian dallopian tube disorders NEC         0         0         0           Ovarian and fallopian tube disorders NEC         0 <td< td=""><td>Premenstrual pain</td><td></td><td>12</td><td>0</td></td<>	Premenstrual pain		12	0
Menstruation with decreased bleeding         99         0           Amenorrhoea         71         0           Hypomenorrhoea         71         0           Menstruation delayed         432         0           Oligomenorrhoea         21         0           Menstruation with increased bleeding         615         0           Heavy menstrual bleeding         615         0           Menometrorrhagia         2         0           Polymenorrhoea         69         0           Ovarian and fallopian tube cysts and neoplasms         69         0           Ovarian cyst ruptured         1         0           Ovarian cyst ruptured         1         0           Polycystic ovaries         5         0           Ovarian cyst ruptured         1         0           Polycystic ovaries         5         0           Ovarian and fallopian tube disorders NEC         0         0           Ovarian and fallopian tube disorders NEC         0         0           Ovarian near largement         1         0           Ovarian near largement         2         0           Ovarian haemorrhage         1         0           Pelvic prolapse conditions	Premenstrual syndrome		5	0
Amenorrhoea   99   0   0   Hypomenorrhoea   771   322   0   Menstruation delayed   432   0   0   0   0   0   0   0   0   0	Withdrawal bleed		4	0
Hypomenorrhoea	Menstruation with decreased bleeding			
Menstruation delayed         432         0           Oligomenorrhoea         21         0           Menstruation with increased bleeding         615         0           Heavy menstrual bleeding         615         0           Menometrorrhagia         2         0           Polymenorrhoea         69         0           Ovarian and fallopian tube cysts and neoplasms         69         0           Ovarian cyst         4         0           Ovarian cyst ruptured         1         0           Polycystic ovaries         5         0           Ovarian and fallopian tube disorders NEC         0         0           Ovarian and fallopian tube disorders NEC         0         0           Ovarian neorosis         1         0           Ovarian neorosis         2         0           Ovarian neorosis         1         0           Ovarian neorosis         2         0           Ovarian neorosis         1         0           Ovarian neorosis         1         0           Ovarian neorosis         2         0           Ovulation pain         11         0           Prehire nemarkinge         1         0	Amenorrhoea		99	0
Menstruation delayed	Hypomenorrhoea		71	0
Menstruation with increased bleeding         615           Heavy menstrual bleeding         615           Menometrorthagia         2           Polymenorrhoea         69           Ovarian and fallopian tube cysts and neoplasms           Ovarian cyst ruptured         1           Polycystic ovaries         5           Ovarian of fallopian tube disorders NEC           Ovarian enlargement         1           Ovarian neamorrhage         2           Ovarian necrosis         1           Ovarian vein thrombosis         2           Ovulation pain         11           Permetture ovulation         2           Pelvic prolapse conditions         2           Vaginal prolapse         1           Pelvis and broad ligament disorders NEC           Adnexa uteri pain         1           Pelvic haematoma         1           Pelvic haematoma         1           Pelvic haemorrhage         8           Penile and scrotal infections and inflammations           Balanoposthitis         2           Penile disorders NEC (excl erection and ejaculation)           Penile burning sensation         1           Penile curvature         2           Penile discharge	Menstruation delayed		432	
Heavy menstrual bleeding Menometrorhagia 2 0 Polymenorrhoea 69 0 Ovarian and fallopian tube cysts and neoplasms Ovarian cyst Ovarian cyst Ovarian cyst 4 0 Polycystic ovaries 5 0varian and fallopian tube disorders NEC Ovarian enlargement 1 0 Ovarian necrosis 1 1 0 Ovarian necrosis 1 1 0 Ovarian vein thrombosis 0 0 vulation pain 11 0 Premature ovulation Perivic prolapse conditions Vaginal prolapse Petvis and broad ligament disorders NEC Adnexa uteri pain Pelvic haematoma Pelvic haematoma Pelvic haematoma Penile and scrotal infections and inflammations Balanoposthitis Penile disorders NEC (excl erection and ejaculation) Penile curvature Penile discharge Penile and scrotal ore Penile discharge Penile discharge Penile discharge Penile dedema Penile baming sensation Penile bamorrhage Penile and scrotal ore Penile dedema Penile bamorrhage Penile dedema Penile dedema Penile pain Penile descondition Penile pain Penile dedema Penile pain Penile dedema Penile pain Penile dedema Penile dedema Penile pain Penile disorder Peronie's disease Prostatit and seminal vesicles infections and inflammations Prostatitits Prostatitits Prostatitic hyperplasia	Oligomenorrhoea		21	0
Heavy menstrual bleeding Menometrorhagia 2 0 Polymenorrhoea 69 0 Ovarian and fallopian tube cysts and neoplasms Ovarian cyst Ovarian cyst Ovarian cyst 4 0 Polycystic ovaries 5 0varian and fallopian tube disorders NEC Ovarian enlargement 1 0 Ovarian necrosis 1 1 0 Ovarian necrosis 1 1 0 Ovarian vein thrombosis 0 0 vulation pain 11 0 Premature ovulation Perivic prolapse conditions Vaginal prolapse Petvis and broad ligament disorders NEC Adnexa uteri pain Pelvic haematoma Pelvic haematoma Pelvic haematoma Penile and scrotal infections and inflammations Balanoposthitis Penile disorders NEC (excl erection and ejaculation) Penile curvature Penile discharge Penile and scrotal ore Penile discharge Penile discharge Penile discharge Penile dedema Penile baming sensation Penile bamorrhage Penile and scrotal ore Penile dedema Penile bamorrhage Penile dedema Penile dedema Penile pain Penile descondition Penile pain Penile dedema Penile pain Penile dedema Penile pain Penile dedema Penile dedema Penile pain Penile disorder Peronie's disease Prostatit and seminal vesicles infections and inflammations Prostatitits Prostatitits Prostatitic hyperplasia	Menstruation with increased bleeding			
Menometrorrhagia			615	0
Polymenorrhoea Ovarian and fallopian tube cysts and neoplasms Ovarian cyst Ovarian cyst ruptured Polycystic ovaries Sovarian and fallopian tube disorders NEC Ovarian enlargement Ovarian haemorrhage Ovarian necrosis Ovarian necrosis Ovarian vein thrombosis Ovarian vein thrombosis Ovarian pain Premature ovulation Peric prolapse conditions Vaginal prolapse Pelvic prolapse conditions Vaginal prolapse Pelvic haematoma Pelvic haematoma Pelvic haemorrhage Penile and scrotal infections and inflammations Balanoposthitis Penile disorders NEC (excl erection and ejaculation) Penile burning sensation Penile curvature Penile discharge Penile descharge Penile and scrotal tine of the scrotal prolapse Penile discharge Penile discharge Penile discharge Penile dedema Penile pain Penile baemorrhage Penile pain Penile dedema Penile pain Penile discorder Perionie's disease Prostatit and seminal vesicles infections and inflammations Prostatitis Prostatitis Prostatitic hyperplasia			2	
Ovarian and fallopian tube cysts and neoplasms         4         0           Ovarian cyst         4         0           Ovarian cyst ruptured         1         0           Polycystic ovaries         5         0           Ovarian and fallopian tube disorders NEC         0           Ovarian elargement         1         0           Ovarian haemorrhage         2         0           Ovarian necrosis         1         0           Ovarian vein thrombosis         2         0           Pelvis and broad ligament disorder         1         0           Penile and scrotal ligament disorders NEC         4	I = = = = = = = = = = = = = = = = = = =		69	0
Ovarian cyst         4         0           Ovarian cyst ruptured         1         0           Polycystic ovaries         5         0           Ovarian and fallopian tube disorders NEC         0           Ovarian nelargement         1         0           Ovarian haemorrhage         2         0           Ovarian necrosis         1         0           Ovarian vein thrombosis         2         0           Ovulation pain         11         0           Premature ovulation         2         0           Pelvic prolapse conditions         2         0           Vaginal prolapse         1         0           Pelvic prolapse conditions         2         0           Vaginal prolapse         1         0           Pelvic prolapse         1         0           Pelvic prolapse         1         0           Pelvis and broad ligament disorders NEC         4         0           Penlic haematoma         1         0           Penlic haematoma         1         0           Penlie and scrotal infections and inflammations         2         0           Penile disorders NEC (excl erection and ejaculation)         1         0	· · · · · · · · · · · · · · · · · · ·	ns		
Ovarian cyst ruptured         1         0           Polycystic ovaries         5         0           Ovarian and fallopian tube disorders NEC         0           Ovarian enlargement         1         0           Ovarian haemorrhage         2         0           Ovarian necrosis         1         0           Ovarian vein thrombosis         2         0           Ovalation pain         11         0           Premature ovulation         2         0           Pelvic prolapse conditions         2         0           Vaginal prolapse         1         0           Pelvic prolapse conditions         2         0           Vaginal prolapse         1         0           Pelvic prolapse conditions         2         0           Pelvic prolapse conditions         1         0           Pelvic prolapse conditions         1         0           Pelvic prolapse conditions         1         0           Penlie amount discorders NEC         2         0           Penile discorders NEC (excl erection and ejaculation)         2         0           Penile discorders NEC (excl erection and ejaculation)         1         0           Penile discorders NEC (excl er			4	0
Polycystic ovaries  Ovarian and fallopian tube disorders NEC  Ovarian nelargement  Ovarian haemorrhage  Ovarian necrosis  Ovarian vein thrombosis  Ovulation pain  Permature ovulation  Pelvic prolapse conditions  Vaginal prolapse  Pelvis and broad ligament disorders NEC  Adnexa uteri pain  Pelvic haemorrhage  Pelvic haemorrhage  Pelvic haemorrhage  Penile and scrotal infections and inflammations  Balanoposthitis  Penile disorders NEC (excl erection and ejaculation)  Penile blister  Penile burning sensation  Penile discharge  Penile acyrature  Penile discharge  Penile haemorrhage  Penile haemorrhage  Penile discharge  Penile discharge  Penile haemorrhage  Penile blister  Penile discharge  Penile blister  Penile discharge  Penile discharge  Penile pain  Penile pain  Penile pain  Penile pain  Penile pain  Penile gisorder  Peyronie's disease  Prostate and seminal vesicles infections and inflammations  Prostatitis  Prostatit neoplasms and hypertrophy  Benign prostatic hyperplasia			1	
Ovarian and fallopian tube disorders NEC           Ovarian enlargement         1         0           Ovarian necrosis         1         0           Ovarian vein thrombosis         2         0           Ovulation pain         11         0           Permature ovulation         2         0           Pelvic prolapse conditions         Vaginal prolapse         1         0           Pelvic prolapse conditions         Vaginal prolapse         1         0           Pelvis and broad ligament disorders NEC         4         4         0           Adnexa uteri pain         17         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         1         0         1         0         1         0         1         0         1         0         1         0         0         1			5	0
Ovarian enlargement         1         0           Ovarian haemorrhage         2         0           Ovarian necrosis         1         0           Ovarian vein thrombosis         2         0           Ovulation pain         11         0           Premature ovulation         2         0           Pelvic prolapse conditions         2         0           Vaginal prolapse         1         0           Pelvis and broad ligament disorders NEC				
Ovarian haemorrhage         2         0           Ovarian necrosis         1         0           Ovarian vein thrombosis         2         0           Ovulation pain         11         0           Premature ovulation         2         0           Pelvic prolapse conditions			1	0
Ovarian necrosis Ovarian vein thrombosis Ovalation pain Premature ovulation Pelvic prolapse conditions Vaginal prolapse Pelvis and broad ligament disorders NEC Adnexa uteri pain Pelvic haematoma Pelvic haematoma Pelvic haemorrhage Penile and scrotal infections and inflammations Balanoposthitis Penile blister Penile blister Penile blister Penile burning sensation Penile curvature Penile exfoliation Penile exfoliation Penile haemorrhage Penile haemorrhage Penile pain Penile pain Penile odeema Penile pain Penile odeema Penile pain Penile pain Penile disorder Peyronie's disease Prostate and seminal vesicles infections and inflammations Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia			2	
Ovarian vein thrombosis         2         0           Ovulation pain         11         0           Premature ovulation         2         0           Pelvic prolapse conditions         Vaginal prolapse         1         0           Pelvis and broad ligament disorders NEC			1	
Ovulation pain         11         0           Premature ovulation         2         0           Pelvic prolapse conditions	Ovarian vein thrombosis		2	0
Premature ovulation  Pelvic prolapse conditions  Vaginal prolapse  Pelvis and broad ligament disorders NEC  Adnexa uteri pain Pelvic haematoma Pelvic haemorrhage  Penile and scrotal infections and inflammations Balanoposthitis Penile disorders NEC (excl erection and ejaculation) Penile blister Penile burning sensation Penile curvature Penile discharge Penile exfoliation Penile exfoliation Penile pain Penile pain Penis disorder Peyronie's disease Prostate and seminal vesicles infections and inflammations Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia  1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0				
Pelvic prolapse conditionsVaginal prolapse10Pelvis and broad ligament disorders NEC170Adnexa uteri pain170Pelvic haematoma10Pelvic haemorrhage80Penile and scrotal infections and inflammations20Balanoposthitis20Penile disorders NEC (excl erection and ejaculation)20Penile blister50Penile burning sensation10Penile curvature20Penile discharge10Penile exfoliation10Penile haemorrhage20Penile pain10Penile pain10Penis disorder50Peyronie's disease40Prostate and seminal vesicles infections and inflammations1Prostatic neoplasms and hypertrophy0Benign prostatic hyperplasia20			2	
Vaginal prolapse  Pelvis and broad ligament disorders NEC  Adnexa uteri pain Pelvic haematoma Pelvic haemorrhage  Penile and scrotal infections and inflammations Balanoposthitis Penile disorders NEC (excl erection and ejaculation) Penile blister Penile burning sensation Penile curvature Penile discharge Penile discharge Penile exfoliation Penile haemorrhage Penile haemorrhage Penile oedema Penile pain Penis disorder Peyronie's disease Prostate and seminal vesicles infections and inflammations Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia				
Pelvis and broad ligament disorders NEC         Adnexa uteri pain       17       0         Pelvic haematoma       1       0         Pelvic haemorrhage       8       0         Penile and scrotal infections and inflammations       2       0         Balanoposthitis       2       0         Penile disorders NEC (excl erection and ejaculation)       5       0         Penile blister       5       0         Penile burning sensation       1       0         Penile curvature       2       0         Penile discharge       1       0         Penile discharge       1       0         Penile burning sensation       1       0         Penile curvature       2       0         Penile discharge       1       0         Penile discharge       1       0         Penile discharge       2       0         Penile exfoliation       1       0         Penile exfoliation       1       0         Penile baemorrhage       2       0         Penile pain       1       0         Penile pain       1       0         Penile pain       5       0			1	0
Adnexa uteri pain       17       0         Pelvic haematoma       1       0         Pelvic haemorrhage       8       0         Penile and scrotal infections and inflammations       2       0         Balanoposthitis       2       0         Penile disorders NEC (excl erection and ejaculation)       5       0         Penile blister       5       0         Penile burning sensation       1       0         Penile curvature       2       0         Penile discharge       1       0         Penile exfoliation       1       0         Penile haemorrhage       2       0         Penile oedema       2       0         Penile pain       1       0         Penis disorder       5       0         Peyronie's disease       4       0         Prostate and seminal vesicles infections and inflammations       4       0         Prostatic neoplasms and hypertrophy       0       0         Benign prostatic hyperplasia       2       0				
Pelvic haematoma Pelvic haemorrhage Penile and scrotal infections and inflammations Balanoposthitis Penile disorders NEC (excl erection and ejaculation) Penile blister Penile burning sensation Penile curvature Penile discharge Penile exfoliation Penile haemorrhage Penile haemorrhage Penile oedema Penile pain Penis disorder Peyronie's disease Prostate and seminal vesicles infections and inflammations Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia			17	0
Pelvic haemorrhage  Penile and scrotal infections and inflammations  Balanoposthitis  Penile disorders NEC (excl erection and ejaculation)  Penile blister  Penile burning sensation  Penile curvature  Penile discharge  Penile exfoliation  Penile haemorrhage  Penile haemorrhage  Penile pain  Penis disorder  Peyronie's disease  Prostate and seminal vesicles infections and inflammations  Prostatic neoplasms and hypertrophy  Benign prostatic hyperplasia			1	0
Penile and scrotal infections and inflammationsBalanoposthitis20Penile disorders NEC (excl erection and ejaculation)Penile blister50Penile burning sensation10Penile curvature20Penile discharge10Penile exfoliation10Penile haemorrhage20Penile oedema20Penile pain10Penis disorder50Peyronie's disease40Prostate and seminal vesicles infections and inflammations40Prostatitis40Prostatic neoplasms and hypertrophy0Benign prostatic hyperplasia20	Pelvic haemorrhage		8	
Penile disorders NEC (excl erection and ejaculation)Penile blister50Penile burning sensation10Penile curvature20Penile discharge10Penile exfoliation10Penile haemorrhage20Penile oedema20Penile pain10Penis disorder50Peyronie's disease40Prostate and seminal vesicles infections and inflammations40Prostatic neoplasms and hypertrophy0Benign prostatic hyperplasia20		3		
Penile disorders NEC (excl erection and ejaculation)Penile blister50Penile burning sensation10Penile curvature20Penile discharge10Penile exfoliation10Penile haemorrhage20Penile oedema20Penile pain10Penis disorder50Peyronie's disease40Prostate and seminal vesicles infections and inflammations40Prostatic neoplasms and hypertrophy0Benign prostatic hyperplasia20	Balanoposthitis		2	0
Penile blister Penile burning sensation Penile curvature Penile discharge Penile exfoliation Penile haemorrhage Penile haemorrhage Penile pain Penile pain Penile pain Penis disorder Peyronie's disease Prostate and seminal vesicles infections and inflammations Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia		lation)		
Penile curvature       2       0         Penile discharge       1       0         Penile exfoliation       1       0         Penile haemorrhage       2       0         Penile oedema       2       0         Penile pain       1       0         Penis disorder       5       0         Peyronie's disease       4       0         Prostate and seminal vesicles infections and inflammations       4       0         Prostatic neoplasms and hypertrophy       4       0         Benign prostatic hyperplasia       2       0		,	5	0
Penile curvature       2       0         Penile discharge       1       0         Penile exfoliation       1       0         Penile haemorrhage       2       0         Penile oedema       2       0         Penile pain       1       0         Penis disorder       5       0         Peyronie's disease       4       0         Prostate and seminal vesicles infections and inflammations       4       0         Prostatic neoplasms and hypertrophy       4       0         Benign prostatic hyperplasia       2       0	Penile burning sensation		1	0
Penile exfoliation 1 0 Penile haemorrhage 2 0 Penile oedema 2 0 Penile pain 1 0 Penis disorder 5 0 Peyronie's disease 4 0 Prostate and seminal vesicles infections and inflammations Prostatitis 4 0 Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia 2 0			2	0
Penile exfoliation       1       0         Penile haemorrhage       2       0         Penile oedema       2       0         Penile pain       1       0         Penis disorder       5       0         Peyronie's disease       4       0         Prostate and seminal vesicles infections and inflammations       4       0         Prostatitis       4       0         Prostatic neoplasms and hypertrophy       0       0         Benign prostatic hyperplasia       2       0	Penile discharge		1	0
Penile oedema 2 0 Penile pain 1 0 Penis disorder 5 0 Peyronie's disease 4 0  Prostate and seminal vesicles infections and inflammations Prostatitis 4 0  Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia 2 0	_		1	
Penile oedema 2 0 Penile pain 1 0 Penis disorder 5 0 Peyronie's disease 4 0  Prostate and seminal vesicles infections and inflammations Prostatitis 4 0  Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia 2 0	Penile haemorrhage		2	0
Penis disorder 5 0 Peyronie's disease 4 0  Prostate and seminal vesicles infections and inflammations Prostatitis 4 0  Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia 2 0	· · · · · · · · · · · · · · · · · · ·		2	
Penis disorder 5 0 Peyronie's disease 4 0  Prostate and seminal vesicles infections and inflammations Prostatitis 4 0  Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia 2 0	Penile pain		1	0
Prostate and seminal vesicles infections and inflammations Prostatitis 4 0 Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia 2 0			5	
Prostate and seminal vesicles infections and inflammations Prostatitis 4 0 Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia 2 0	Peyronie's disease			0
Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia 2 0		nflammations		
Prostatic neoplasms and hypertrophy Benign prostatic hyperplasia 2 0			4	0
Benign prostatic hyperplasia 2 0			ĺ	
			2	0
I FIOSIAUC SIUNS, SYMDIOMIS AND DISOIDEIS NEC	Prostatic signs, symptoms and disorders NEC		_	Ĭ
Prostatomegaly 1 0			1	0
Reproductive tract disorders NEC (excl neoplasms)		sms)		

Name: COVID-19 vaccine AstraZeneca analysis print

Date: 13-May-2021
Date: 13-May-2021
Date: 03-Feb-1921
Data Lock Date: 12-May-2021 18:30:08
MedDRA Version: MedDRA 24.0 Report Run Date: 13-May-2021 Earliest Reaction Date: 03-Feb-1921

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	<u>Fatal</u>
Reproductive & breast disordeine & breast diso	rders cont'd		
Female genital tract fistula		1	0
Genital blister		3	0
Genital haemorrhage		4	0
Genital hyperaesthesia		1	0
Genital hypoaesthesia		2	0
Genital paraesthesia		2	0
Genital ulceration		9	0
Perineal disorder		1	0
Reproductive tract infections and inflammat	tions NFC	·	
Genital tract inflammation	.0.10 1.120	2	0
Reproductive tract neoplasms NEC		_	·
Genital cyst		1	0
Reproductive tract signs and symptoms NE	rc		J
Genital burning sensation		6	0
Genital discomfort		3	0
Genital discomort		1	0
Genital pain			0
Genital pain		3	0
Pelvic discomfort		2	0
Pelvic pain		100	0
Perineal pain		100	0
Pruritus genital		6	0
Scrotal disorders NEC		U	U
Scrotal dermatitis		1	0
		1	0
Scrotal pain		10	0
Scrotal pain		l .	
Scrotal swelling Varicocele		5	0
			U
Sexual function and fertility disorders NEC  Dyspareunia		2	0
Female sexual dysfunction		1	0
Infertility male		1	0
Sexual dysfunction		6	0
Spermatogenesis and semen disorders		0	U
Aspermia		1	0
Haematospermia		1 7	0
Semen discolouration		2	0
Testicular and epididymal disorders NEC			U
Testicular disorder  Testicular disorder		3	0
Testicular mass		1	0
Testicular mass Testicular oedema		2	_
Testicular pain		76	0
Testicular pain Testicular retraction		10	0
Testicular retraction Testicular swelling		11	0
		11	U
Testicular and epididymal neoplasms  Epididymal cyst		1	0
		1	
Testicular cyst  Uterine disorders NEC		I	0
			^
Adenomyosis		1	0
Endometriosis		24	0
Metrorrhoea		1	0
Uterine enlargement		1	0
Uterine haemorrhage		17	0

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 13-May-2021 Data Lock Date: 12-May-2021 18:30:08
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders cont'd		
Uterine pain	4	0
Uterine neoplasms		
Uterine polyp	1	0
Uterine tone disorders		
Uterine spasm	8	0
Vaginal and vulval infections and inflammations		
Vulvovaginal inflammation	2	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	1	0
Vaginal cyst	6	0
Vulvovaginal disorders NEC		
Vaginal disorder	1	0
Vaginal haemorrhage	353	0
Vaginal ulceration	6	0
Vulval disorder	2	0
Vulval haemorrhage	8	0
Vulval ulceration	4	0
Vulvovaginal ulceration	2	0
Vulvovaginal signs and symptoms		
Enlarged clitoris	1	0
Labia enlarged	1	0
Vaginal discharge	30	0
Vaginal lesion	4	0
Vulval oedema	1	0
Vulvovaginal burning sensation	7	0
Vulvovaginal discomfort	3	0
Vulvovaginal dryness	3	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	20	0
Vulvovaginal pruritus	7	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	3	0
Reproductive & breast disorders SOC TOTAL	3657	0

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Apnoea	9	0
Apnoeic attack	1	0
Dyspnoea	5115	5
Dyspnoea at rest	12	0
Dyspnoea exertional	32	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	76	0
Hypopnoea	180	0
Hypoventilation	1	0
Irregular breathing	21	0
Mouth breathing	7	0
Orthopnoea	3	0
Respiration abnormal	77	0
Respiratory arrest	17	0
Respiratory distress	8	Ö
Respiratory fatigue	6	0
Sleep apnoea syndrome	18	o
Tachypnoea	32	0
Bronchial conditions NEC	52	U
Bronchiectasis	14	0
Bronchospasm and obstruction		U
Aspirin-exacerbated respiratory disease	1	0
Asthma	428	0
Asthma exercise induced	1	0
Asthma late onset	1	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	1	0
Asthmatic crisis	5	0
Bronchitis chronic	1	0
Bronchospasm	14	0
Chronic obstructive pulmonary disease	27	2
Cough variant asthma	6	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	469	0
Conditions associated with abnormal gas exchange	403	U
Asphyxia	2	0
Hypercapnia	1	0
Нурохіа	54	1
Coughing and associated symptoms	54	
	1	0
Allergic cough	3000	0
Cough		0
Haemoptysis Productive cough	93 144	
	144	0
Sputum discoloured	/	0
Sputum increased	1	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		
Reflux laryngitis	1	0
Vocal cord thickening	1	0
Laryngeal spasm, oedema and obstruction		
Laryngeal oedema	2	0

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Earliest Reaction Date: 03-Feb-1921 MedDRA	A Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Respiratory disorders Respiratory disorders cont'd		
Laryngospasm	2	2 0
Stridor	16	6 0
Lower respiratory tract inflammatory and immunolog	ic conditions	
Alveolitis		2 0
Pneumonia aspiration	21	
Pneumonitis	18	
Pulmonary sarcoidosis	1	i o
Lower respiratory tract signs and symptoms		, and the second
Hiccups	36	0
Lower respiratory tract congestion		
Lung opacity	5	
Pleuritic pain	22	
Pulmonary haemorrhage	2	
Pulmonary pain	161	
Rales	101	il ő
Nasal congestion and inflammations		
Nasal congestion	370	o
Nasal inflammation	576	7 0
Rhinitis allergic	20	
Rhinitis perennial	20	
Nasal disorders NEC		
Epistaxis	1533	3 o
I · · ·	1000	1
Intranasal hypoaesthesia Nasal crusting	6	
		1
Nasal cyst Nasal disorder	2	2 0 1 0
	50	
Nasal dryness Nasal mucosal discolouration	50	0
Nasal odour		
Nasal oedema	10	
	1	
Nasal polyps	7	_
Nasal pruritus	1	1
Nasal septum perforation Nasal ulcer	3	1
Neonatal hypoxic conditions		
Cyanosis neonatal		
Gasping syndrome	(aama)	0
Paranasal sinus disorders (excl infections and neoph		
Paranasal sinus hamorrhage	5	
Paranasal sinus hypersecretion Paranasal sinus inflammation		0
		0
Sinonasal obstruction	3	
Sinus congestion	68	
Sinus disorder	11	0
Parenchymal lung disorders NEC		
Atelectasis		0
Emphysema	2	0
Idiopathic pulmonary fibrosis		·   •
Interstitial lung disease	12	
Lung consolidation	3	
Lung cyst		
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	<u>  0</u>

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Reaction Name T	-101	
<u>  Neaction Name                                   </u>	<u>otal</u>	<u>Fatal</u>
Respiratory disorders Respiratory disorders cont'd		
Pulmonary cavitation	2	0
Pulmonary fibrosis	5	0
Pharyngeal disorders (excl infections and neoplasms)		
Oropharyngeal swelling	2	0
Pharyngeal erythema	2	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	30	0
Pharyngeal inflammation	1	0
Pharyngeal oedema	11	0
Pharyngeal paraesthesia	27	0
Pharyngeal swelling	213	0
Pharyngeal ulceration	14	0
Tonsillar disorder	1	0
Tonsillar erythema	5	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	50	0
Tonsillar inflammation	3	0
Tonsillar ulcer	2	0
Pleural infections and inflammations		
Lupus pleurisy	1	0
Pleurisy	29	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	18	0
Pneumothorax	3	0
Pulmonary hypertensions		
Pulmonary hypertension	2	1
Pulmonary oedemas		
Acute lung injury	1	0
Acute pulmonary oedema	3	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	14	0
Pulmonary oedema	19	1
Pulmonary thrombotic and embolic conditions		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	964	78
Pulmonary infarction	7	1
Pulmonary thrombosis	15	1
Pulmonary venous thrombosis	2	0
Respiratory failures (excl neonatal)		
Acute respiratory failure	1	0
Respiratory failure	16	3
Respiratory signs and symptoms NEC		
Allergic respiratory symptom	6	0
Diaphragmalgia	13	0
Painful respiration	5	0
Respiratory symptom	16	0
Suffocation feeling	4	0
Respiratory tract disorders NEC		
Aspiration	8	2
Chronic respiratory disease	2	1
Lung disorder	2 6	0
Pulmonary mass	3	0
Respiratory disorder	3 5	0

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0	<b>T</b>	
Reaction Name	_Total_	Fatal
Respiratory disorders espiratory disorders cont'd		
Respiratory tract congestion	6	0
Respiratory tract haemorrhage	1	0
Respiratory tract irritation	7	0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	1	0
Tracheal disorders (excl infections and neoplasms)		
Tracheal fistula	1	0
Tracheal pain	3	0
Upper respiratory tract signs and symptoms		
Aphonia	68	0
Catarrh	51	0
Choking	15	0
Choking sensation	8	0
Dry throat	222	0
Dysphonia	102	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	17	0
Laryngeal pain	1	0
Nasal discharge discolouration	2	0
Nasal discomfort	89	0
Oropharyngeal blistering	21	0
Oropharyngeal discomfort	28	0
Oropharyngeal pain	3418	0
Paranasal sinus discomfort	49	0
Rhinalgia	31	0
Rhinorrhoea	1395	0
Sinus pain	495	0
Sneezing	386	0
Snoring	5	0
Throat clearing	5	0
Throat irritation	162	0
Throat lesion	1	0
Throat tightness	163	0
Upper airway obstruction	1	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	22	0
Yawning	60	0
Vascular pulmonary disorders NEC	30	Ĭ
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
Respiratory disorders SOC TOTAL	20707	102

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	edDRA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Skin disorders		
Acnes		
Acne	61	0
Acne cystic		
Dermatitis acneiform	6	6 0
Alopecias		
Alopecia	173	3 0
Alopecia areata	10	
Alopecia totalis	1	0
Alopecia universalis		0
Androgenetic alopecia	1	0
Diffuse alopecia	3	3 0
Madarosis	2	2 0
Angioedemas		
Angioedema	257	7 0
Circumoral oedema		2 0
Idiopathic angioedema	3	3 0
Apocrine and eccrine gland disorders		
Anhidrosis	2	0
Cold sweat	1443	3 0
Hyperhidrosis	7907	7 0
Hypohidrosis	3	3 O
Miliaria	167	7 0
Night sweats	1585	0
Sweat discolouration	1	0
Sweat gland disorder	1	0
Bullous conditions		
Blister	361	0
Blister rupture	5	0
Blood blister	59	e o
Dermatitis bullous	11	0
Dermatitis herpetiformis		2 0
Erythema multiforme	28	3 0
Oedema blister	1	0
Pemphigoid	15	5 O
Pemphigus	1	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	3	3 O
Connective tissue disorders		
Cutaneous lupus erythematosus	1	
Dermatomyositis	2	0
Subacute cutaneous lupus erythematosus	1	0
Dermal and epidermal conditions NEC		
Dry skin	330	0
Macule	7	7 0
Myxoid cyst	1	0
Pain of skin	801	
Papule	70	
Peau d'orange	3	
Scab	19	
Scar pain	10	
Sensitive skin	503	
Skin burning sensation	446	
Skin discolouration	134	

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Skin disorders Skin disorders cont'd			
Skin discomfort		3	0
Skin disorder		19	0
Skin fissures		9	0
Skin fragility		1	0
Skin indentation		9	0
Skin induration		13	0
Skin laxity		1	0
Skin lesion		32	0
Skin necrosis		4	0
Skin odour abnormal		41	0
Skin plaque		3	0
Skin reaction		201	0
Skin sensitisation		79	0
Skin swelling		74	0
Skin texture abnormal		1	0
Skin tightness		25	0
Skin warm		493	0
Skin weeping		4	0
Sticky skin		5	0
Transient acantholytic dermatosis		1	0
Yellow skin		23	0
Dermatitis and eczema			
Autoimmune dermatitis		1	0
Dermatitis		142	0
Dermatitis allergic		239	0
Dermatitis atopic		15	0
Dermatitis contact		12	0
Dermatitis diaper			0
Dyshidrotic eczema		2 6	0
Eczema		172	0
Eczema asteatotic		10	0
Eczema nummular		1	0
Eczema weeping		1	0
Hand dermatitis		4	0
Intertrigo		_	0
Perioral dermatitis		3	0
Prurigo		1	0
Rebound eczema		1	
Seborrhoeic dermatitis		6	0
Skin irritation		106	0
Stasis dermatitis		3	0
Dermatitis ascribed to specific agent			
Drug eruption		29	0
Drug reaction with eosinophilia and system	ic symptoms	12	0
Fixed eruption		5	0
Palmar-plantar erythrodysaesthesia syndro	ome	1	0
Erythemas			
Erythema		2790	0
Erythema ab igne		1	0
Palmar erythema		4	0
Exfoliative conditions			Ŭ
Dermatitis exfoliative		2	0
Dermatitis exfoliative generalised		2 4	0

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Skin disorders Skin disorders	cont'd		
Exfoliative rash		12	0
Skin exfoliation		93	0
Granulomatous and deep cutant	eous inflammatory conditions	1	
Granuloma annulare	, and the second	2	0
Hyperpigmentation disorders			
Melanoderma		2	0
Skin hyperpigmentation		1	0
Solar lentigo		3	0
Hypertrichoses		J	·
Hypertrichosis		1	0
Hypopigmentation disorders		'	U
Skin depigmentation		6	0
		1	
Skin hypopigmentation		8	0
Vitiligo		0	U
Lipodystrophies			0
Lipoatrophy		2	0
Lipohypertrophy	al beforeton a read before (attend)	2	0
Nail and nail bed conditions (exc	ci infections and infestations)		_
Nail bed disorder		2	0
Nail bed tenderness		1	0
Nail discolouration		8	0
Nail disorder		1	0
Nail hypertrophy		1	0
Nail necrosis		1	0
Nail pigmentation		1	0
Nail pitting		1	0
Nail ridging		4	0
Onychalgia		3	0
Onychoclasis		5	0
Onycholysis		1	0
Onychomadesis		1	0
Panniculitides			
Erythema nodosum		17	0
Panniculitis		1	0
Papulosquamous conditions		1	
Erythema annulare		2	0
Lichen planus		15	0
Lichen sclerosus		3	0
Parapsoriasis		1	
Pityriasis rosea		25	0
Pityriasis rubra pilaris		2	0
Photosensitivity and photoderma	atosis conditions	_	Ŭ
Photodermatosis		1	0
Photosensitivity reaction		125	0
Polymorphic light eruption		2	0
Solar dermatitis		1	0
Pigmentation changes NEC			U
		11	0
Pigmentation disorder		11	0
Pilar disorders NEC			^
Hair colour changes		3	0
Hair disorder		1	0
Hair growth abnormal		3	0
Hair texture abnormal		2	0

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Reaction Name		Total	Fatal
Skin disorders Skin disorders cont'd			
Piloerection		82	0
Pseudofolliculitis		1	0
Trichodynia		5	0
Pruritus NEC			
Itching scar		4	0
Pruritus		6292	0
Pruritus allergic		1	0
Senile pruritus		1	0
Psoriatic conditions			
Guttate psoriasis		15	0
Psoriasis		122	0
Pustular psoriasis		1	0
Purpura and related conditions			
Ecchymosis		3	0
Henoch-Schonlein purpura		5	0
Petechiae		204	0
Purpura		82	0
Pustular conditions			
Rash follicular		4	0
Rashes, eruptions and exanthems NEC			
Butterfly rash		6	0
Rash		6642	0
Rash erythematous		1826	0
Rash macular		561	0
Rash maculo-papular		47	0
Rash morbilliform		36	0
Rash papular		412	0
Rash pruritic		1477	0
Rash rubelliform		1	0
Rash scarlatiniform		2	0
Rash vesicular		54	0
Systemic lupus erythematosus rash		6	0
Rosaceas			
Erythematotelangiectatic rosacea		1	0
Rosacea		27	0
Scaly conditions			
Pityriasis		6	0
Sebaceous gland disorders			
Seborrhoea		5	0
Skin and subcutaneous conditions NEC			
Cutaneous symptom		7	0
Skin mass		27	0
Skin and subcutaneous tissue ulcerations			
Diabetic foot		1	0
Mucocutaneous ulceration		2	0
Pyoderma gangrenosum		2	0
Skin erosion		35	0
Skin ulcer		21	0
Skin cysts and polyps			
Dermal cyst		11	0
Skin dystrophies			
Skin wrinkling		2	0
Skin haemorrhages			

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Haemorrhage subcutaneous	13	0
Skin haemorrhage	25	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin hypoplasias and atrophies		
Skin atrophy	5	0
Skin striae	6	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	3	0
Needle track marks	3	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Leukoplakia	1	0
Skin vascular conditions NEC		
Angiodermatitis	1	0
Skin oedema	3	0
Skin vasculitides		
Cutaneous vasculitis	7	0
Hypersensitivity vasculitis	3	0
Vasculitic rash	20	1
Skin vasomotor conditions		
Livedo reticularis	40	0
Telangiectasia and related conditions		
Spider naevus	1	0
Telangiectasia	2	0
Urticarias		
Chronic spontaneous urticaria	2	0
Cold urticaria	3	0
Idiopathic urticaria	7	0
Mechanical urticaria	2	0
Solar urticaria	1	0
Urticaria	1844	0
Urticaria chronic	19	0
Urticaria contact	2	0
Urticaria papular	1	0
Urticaria thermal	5	0
Urticarial vasculitis	5	0
Skin disorders SOC TOTAL	39512	1

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Reaction Name	<u>Total</u>	<u>Fatal</u>
Social circumstances		
Age related issues		
Childhood	1	0
Menarche	2	0
Menopause	10	0
Postmenopause	1	0
Bereavement issues		
Death of relative	1	1
Criminal activity		
Chemical submission	1	0
Dietary and nutritional issues	į.	Ŭ
Inadequate diet	1	0
Disability issues	<b>'</b>	J
Bedridden	61	0
Breast prosthesis user	1	0
Dependence on oxygen therapy	1	0
Disability	3	0
Hearing aid user	3	0
Hearing disability	1	0
Housebound		
	200	0
Immobile	36	
Immobilisation prolonged	2	0
Impaired driving ability	3	l
Impaired work ability	14	
Loss of personal independence in daily activities	3	l
Sight disability	14	
Sitting disability	2	
Walking disability	2	0
Employment issues		
Job dissatisfaction	1	0
Retirement	5	0
Stress at work	1	0
Family and partner issues		
Homosexual parent	1	0
Non-occupational and unspecified environmental problems		
Food contamination	1	U
Water pollution	3	0
Pregnancy related circumstances		
Breast feeding	4	0
Sexuality issues		
Anal sex	1	0
Social issues NEC		
Blood donor	1	0
Contraindication to medical treatment	1	0
Contraindication to vaccination	2	0
Convalescent	1	0
Impaired quality of life	1	0
Tobacco use		
Non-tobacco user	2	0
Tobacco user	2	0
	189	
Social circumstances SOC TOTAL	<u>1 189</u>	

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Anaesthesia and allied procedures		
Local anaesthesia	3	0
Nerve block	4	0
Analgesia supportive care		_
Analgesic therapy	1	0
Antiinfective therapies		ŭ
COVID-19 treatment	6	0
Arterial therapeutic procedures (excl aortic)	Ĭ	Ŭ
Cerebral revascularisation	1	0
Coronary artery bypass	1	0
Autonomic nerve therapeutic procedures		0
Vagotomy	2	0
Blood and blood product treatment	-	U
Photopheresis	1	0
Breast therapeutic procedures NEC	'	U
Axillary lymphadenectomy	1	0
Bronchial and pulmonary therapeutic procedures	- '	U
Airway secretion clearance therapy	1	0
, · · · · · · · · · · · · · · · · · · ·	ı	U
Cardiac device therapeutic procedures	1	0
Pacemaker generated rhythm	1	0
Cardiac therapeutic procedures NEC		0
Pericardial excision	2	0
Contraceptive methods female	_	0
Contraceptive diaphragm	2	0
Corneal and scleral therapeutic procedures	4	•
Corneal transplant	1	0
Dental and gingival therapeutic procedures		
Dental care	1	0
Tooth extraction	1	0
Dietary and nutritional therapies		_
Fluid replacement	1	0
Medical diet	4	0
Nothing by mouth order	2	0
External ear therapeutic procedures		
Cerumen removal	1	0
Eye therapeutic procedures NEC		
Eye irrigation	3	0
Facial therapeutic procedures		
Face lift	2	0
Fallopian tube therapeutic procedures		
Fallopian tube operation	1	0
Fertility and fertilisation interventions female		
Ovulation induction	1	0
Gastrointestinal therapeutic procedures NEC		
Intestinal resection	1	0
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	26	0
Gynaecological therapeutic procedures NEC		
Menstrual cycle management	1	0
Haematological therapeutic procedures NEC		
Anticoagulant therapy	1	0
Haemofiltration	1	0
Head, neck and oral cavity therapeutic procedures NEC		

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Reaction Name		Total	<u>Fatal</u>
Surgical & medical procedures medical procedu	es cont'd		
Neck lift		1	0
Hormonal therapeutic procedures NEC			
Hormone replacement therapy		3	0
Immunisations			
COVID-19 immunisation		163	1
Immunisation		76	0
Tuberculosis immunisation		1	0
Induced abortions			
Abortion induced		1	0
Joint therapeutic procedures			
Hip surgery		1	0
Joint injection		1	0
Joint stabilisation		1	0
Knee operation		1	0
Large intestine therapeutic procedures			
Appendicectomy		5	0
Limb therapeutic procedures			
Leg amputation		2	0
Limb immobilisation		24	0
Limb operation		5	0
Limb reattachment surgery		1	0
Toe amputation		4	0
Mastectomies			
Breast conserving surgery		2	0
Muscle therapeutic procedures			
Muscle relaxant therapy		2	0
Nasal therapeutic procedures			
Nasal irrigation		1	0
Nervous system therapeutic procedures NE	c l		
Central nervous system stimulation		3	0
Orbit and globe therapeutic procedures			
Eye muscle operation		1	0
Patient positioning			
Prone position		1	0
Prophylactic procedures NEC			
Anaphylaxis prophylaxis		3	0
Psychiatric therapies			
Antidepressant therapy		1	0
Renal therapeutic procedures			
Dialysis		1	0
Skin and subcutaneous tissue therapeutic p	rocedures NEC		
Dermal filler injection		1	0
Skin lesion excisions			
Tattoo excision		1	0
Small intestine therapeutic procedures			
lleostomy		2	0
Spine and spinal cord therapeutic procedure	es l		
Spinal operation		1	0
Testicular and scrotal therapeutic procedure	s		
Testes exploration		1	0
Therapeutic procedures NEC		'	U
Anaphylaxis treatment		3	0
		1	0
Antiallergic therapy		· I	U

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Reaction Name	Total	Fatal
Surgical & medical procedures cont'd		
Bed rest	19	0
Catheter management	2	0
Catheter placement	1	0
Fatigue management	1	0
Heat therapy	1	0
Hospitalisation	20	0
Injection	33	0
Localised alternating hot and cold therapy	5	0
Manipulation	1	0
Mass excision	10	0
Medication dilution	1	0
Physical fitness training	1	0
Product used for unknown indication	1	0
Promotion of wound healing	1	0
Self-medication	1	0
Smoking cessation therapy	1	0
Specialist consultation	1	0
Stoma care	1	0
Therapeutic hypothermia	2	0
Therapy change	1	0
Transgender operation	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	1	0
Vascular therapeutic procedures NEC		
Thrombectomy	2	0
Venous therapeutic procedures		
Phlebotomy	1	0
Surgical & medical procedures SOC TOTAL	500	1

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Reaction Name	Total	<u>Fatal</u>
Vascular disorders		
Accelerated and malignant hypertension		
Accelerated hypertension	1	0
Hypertensive crisis	9	0
Hypertensive emergency	2	0
Hypertensive urgency	1	0
Malignant hypertension	2	0
Tyramine reaction	1	0
Aneurysms and dissections non-site specific		
Aneurysm	8	2
Artery dissection	1	2
Aortic aneurysms and dissections		
Acute aortic syndrome	1	0
Aortic aneurysm	5	ő
Aortic dissection	5 2	1
Aortic intramural haematoma	1	Ö
Aortic embolism and thrombosis	· ·	
Aortic embolus	22	1
Aortic thrombosis	10	2
Aortic infections and inflammations	10	
Aortitis	2	0
Aortic necrosis and vascular insufficiency		١
Aortic stenosis	1	0
Arterial infections and inflammations		١
Arteritis	3	0
Giant cell arteritis	39	
Blood pressure disorders NEC	33	l o
Blood pressure fluctuation	14	0
Labile blood pressure	2	ő
Bruising, ecchymosis and purpura		ľ
Achenbach syndrome	5	0
Circulatory collapse and shock		Ĭ
Circulatory collapse	84	1
Distributive shock		Ö
Hypoperfusion	2 2	ő
Neurogenic shock		1
Peripheral circulatory failure	9 3	ő
Shock	41	ő
Shock symptom	5	ő
Haemorrhages NEC		ľ
Bloody discharge	8	0
Haematoma	73	I
Haemorrhage	439	
Internal haemorrhage	20	0
Venous haemorrhage	5	ő
Lymphangiopathies		١
Lymphorrhoea	1	0
Lymphoedemas		Ĭ
Lymphoedema	45	0
Non-site specific embolism and thrombosis	73	
Arterial thrombosis	20	1
Embolism	227	ر
		3
		1
Embolism arterial Embolism venous	3 11	

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Microembolism		2 0
Paradoxical embolism		1 0
Thrombophlebitis migrans		1 0
Thrombosis	982	2 20
Venous thrombosis	26	6 0
Non-site specific necrosis and vascular ins	sufficiency NEC	
Arterial occlusive disease		7 0
Arterial spasm		2 0
Arterial stenosis		1 0
Arteriosclerosis		3 0
Infarction		6 0
Ischaemia	-	7 0
Peripheral venous disease	4	4 0
Vascular compression		1 0
Vasospasm	-	7 0
Non-site specific vascular disorders NEC		
Angiopathy		2 0
Arterial rupture		1 0
Capillary fragility	8	3 O
Haemodynamic instability		1 0
Hyperaemia		1 0
Neovascularisation		1 0
Superficial vein prominence		3 0
Vascular pain	76	-
Vascular rupture		1 0
Vascular wall discolouration		1 0
Vasodilatation	74	4 0
Vein collapse		1 0
Vein discolouration	4	4 0
Vein disorder	10	o l
Vein rupture	12	2 0
Peripheral aneurysms and dissections		
Peripheral artery aneurysm		1 0
Peripheral embolism and thrombosis		
Blue toe syndrome	22	2 0
Deep vein thrombosis	732	2 6
Femoral artery embolism		2 0
Iliac artery embolism		2 0
Jugular vein thrombosis	14	4 0
Pelvic venous thrombosis	10	1
Peripheral artery thrombosis	13	3 0
Peripheral embolism	7	7 0
Peripheral vein thrombus extension	,	1 0
Subclavian artery thrombosis	,	1 0
Thrombophlebitis	79	e o
Thrombophlebitis superficial	37	
Venous thrombosis limb		2 0
Peripheral vascular disorders NEC		
Cyanosis	89	e o
Erythromelalgia		2 0
Flushing	615	5 0
Hot flush	1686	
Peripheral vascular disorder		3 0

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Reaction Name	Total	<u>Fatal</u>
Vascular disorders Vascular disorders cont'd		
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Dry gangrene	1	0
Extremity necrosis	3	0
lliac artery occlusion		0
Intermittent claudication	2	0
Ischaemic limb pain		
Jugular vein occlusion	1	0
Peripheral arterial occlusive disease	3	
Peripheral artery occlusion	6	0
Peripheral coldness	1087	0
Peripheral ischaemia	24	0 0 2 0
Poor peripheral circulation	36	
Raynaud's phenomenon	98	0
Phlebitis NEC		
Phlebitis	37	0
Phlebitis superficial	7	0
Site specific embolism and thrombosis NEC		
Brachiocephalic vein thrombosis	1	0
Site specific vascular disorders NEC		
Pallor	352	0
Plethoric face	1	0
Varicose veins NEC		
Bleeding varicose vein	1	0
Spider vein	7	0
Varicophlebitis	3	0
Varicose vein	78	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	3	0
Hypertension	625	0
Labile hypertension	1	0
Systolic hypertension	3	0
Venous hypertension		0
White coat hypertension	9	0
Vascular hypotensive disorders		
Capillary leak syndrome	6	U
Hypotension	412	
Orthostatic hypotension	37	0
Vascular malformations and acquired anomalies		
Arteriovenous fistula	1	0
Vasculitides NEC		
Diffuse vasculitis	1	1
MAGIC syndrome	3	1
Vasculitis	86	2
Vena caval embolism and thrombosis		
Vena cava thrombosis	3	1
Vascular disorders SOC TOTAL	8639	48
TOTAL REACTIONS FOR DRUG	650681	786
TOTAL REPORTS	175057	
TOTAL FATAL OUTCOME REPORTS		786