### COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

All UK spontaneous reports received between 04/01/21 and 28/03/21 for COVID-19 vaccine Oxford University/AstraZeneca

Report Run Date: 01-Apr-2021, Page 1

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name	Tota	<u>1</u>	Fatal
Blood disorders			
Anaemia deficiencies			
Anaemia vitamin B12 deficiency		2	0
Iron deficiency anaemia		1	0
Pernicious anaemia		1	0
Anaemias NEC			
Anaemia		15	0
Normocytic anaemia		1	0
Anaemias haemolytic NEC			
Haemolytic anaemia		3	0
Anaemias haemolytic immune			
Autoimmune haemolytic anaemia		1	0
Bleeding tendencies			
Increased tendency to bruise		26	0
Spontaneous haematoma		1	0
Coagulation factor deficiencies			
Hypofibrinogenaemia		1	0
Coagulopathies			
Abnormal clotting factor		2	0
Antiphospholipid syndrome		7	0
Coagulopathy		9	0
Disseminated intravascular coagulation		5	0
Hypercoagulation		6	0
Eosinophilic disorders			_
Eosinophilia		7	0
Haematological disorders			_
Bone marrow disorder		1	0
Bone marrow oedema		1	0
Mast cell activation syndrome		3	0
Mastocytosis		1	0
Methaemoglobinaemia		1	0
Haemolyses NEC			
Haemolysis		2	0
Leukocytoses NEC			
Leukocytosis		1	0
Lymphocytosis		1	0
Neutrophilia		1	0
Leukopenias NEC			
Leukopenia		4	0
Lymphopenia		5	0
Lymphatic system disorders NEC		Ĭ	J
Lymph node fibrosis		1	0
Lymph node pain	2	66	0
Lymphadenitis		13	0
Lymphadenopathy	24	23	0
Lymphatic disorder		1	0
Marrow depression and hypoplastic anaemias			Ŭ
Pancytopenia		5	0
Neutropenias		Ĭ	J
Agranulocytosis		1	0
Autoimmune neutropenia		1	0
Neutropenia		39	0
Platelet disorders NEC		33	J
Platelet disorder		2	0
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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Polycythaemia (excl rubra vera)		
Stress polycythaemia	2	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	1	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	2	0
Spleen disorders		
Spleen disorder	1	0
Splenic artery thrombosis	1	0
Splenic infarction	4	0
Splenic vein thrombosis	4	0
Splenomegaly	3	0
Thrombocytopenias		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	2	0
Immune thrombocytopenia	58	1
Thrombocytopenia	83	1
Thrombocytopenic purpura	5	0
Thrombocytoses		
Thrombocytosis	1	0
White blood cell abnormal findings NEC		
White blood cell disorder	1	0
Blood disorders SOC TOTAL	3030	2

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	Fatal
Cardiac disorders			
Aortic valvular disorders			
Aortic valve stenosis		1	0
Cardiac conduction disorders			
Atrioventricular block		7	0
Atrioventricular block complete		2	0
Bundle branch block left		2	0
Long QT syndrome		1	0
Trifascicular block		1	0
Cardiac disorders NEC			
Acute cardiac event		2	1
Cardiac disorder		18	0
Cardiac ventricular thrombosis		1	1
Cardiovascular disorder		2	0
Cardiovascular insufficiency		2 5	0
Intracardiac thrombus		1	0
Cardiac hypertensive complications			
Hypertensive heart disease		1	0
Cardiac infections and inflammations NEC			
Carditis		1	0
Cardiac signs and symptoms NEC			
Cardiac discomfort		5	0
Palpitations		2658	0
Cardiac valve disorders NEC			
Cardiac valve disease		1	1
Heart valve incompetence		1	0
Cardiomyopathies			
Cardiomyopathy		3	0
Congestive cardiomyopathy		5	0
Coronary artery disorders NEC			
Coronary artery disease		1	0
Coronary artery thrombosis		1	0
Heart failures NEC			
Cardiac failure		15	4
Cardiac failure acute		2	0
Cardiac failure congestive		1	0
Cardiogenic shock		2	1
Cardiopulmonary failure		1	1
Ischaemic coronary artery disorders			
Acute coronary syndrome		2	0
Acute myocardial infarction		2 15	2
Angina pectoris		61	0
Angina unstable		6	0
Arteriospasm coronary			0
Microvascular coronary artery disease		2 2	0
Myocardial infarction		87	23
Myocardial ischaemia		11	4
Prinzmetal angina		1	0
Left ventricular failures			
Left ventricular failure		1	1
Mitral valvular disorders			·
Mitral valve incompetence		1	0
Myocardial disorders NEC		•	Ŭ
Cardiomegaly		3	0

	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	Fatal
Cardiac disorders Cardiac disorders cont'd			
Left ventricular dilatation		1	0
Left ventricular dysfunction		2	0
Myocardial rupture		1	0
Right ventricular dysfunction		1	0
Noninfectious myocarditis			
Myocarditis		10	1
Noninfectious pericarditis			
Pericarditis		20	0
Pericardial disorders NEC			
Pericardial effusion		3	0
Pericardial haemorrhage		2	1
Rate and rhythm disorders NEC			
Arrhythmia		58	0
Bradycardia		36	0
Cardiac flutter		90	0
Extrasystoles		44	0
Heart alternation		2	0
Paroxysmal arrhythmia		1	0
Postural orthostatic tachycardia syndrome		6	0
Tachyarrhythmia		9	0
Tachycardia		816	0
Right ventricular failures			
Cor pulmonale		1	0
Right ventricular failure		1	1
Supraventricular arrhythmias			
Arrhythmia supraventricular		9	0
Atrial fibrillation		117	0
Atrial flutter		15	0
Sinus arrest		1	0
Sinus arrhythmia		1	0
Sinus bradycardia		1	0
Sinus node dysfunction		1	0
Sinus tachycardia		44	1
Supraventricular extrasystoles		1	0
Supraventricular tachycardia		15	0
Ventricular arrhythmias and cardiac arrest			
Cardiac arrest		67	14
Pulseless electrical activity		1	0
Ventricular arrhythmia		1	0
Ventricular extrasystoles		2	0
Ventricular fibrillation		2	0
Ventricular tachycardia		9	0
Cardiac disorders SOC TOTAL		4325	57

Reaction Name	Total	Fatal
	Tolai	гацаі
Congenital disorders		
Cardiac disorders congenital NEC	4	^
Heart disease congenital	4	0
Cardiac septal defects congenital	0	0
Hypertrophic cardiomyopathy	3	0
Central nervous system disorders congenital NEC		0
Syringomyelia	1	0
Cerebellar disorders congenital	_	0
Arnold-Chiari malformation	2	0
Cerebral disorders congenital		
Cerebral palsy	3	0
Coagulation disorders congenital		
Haemophilia	1	0
Protein S deficiency	1	0
Connective tissue disorders congenital	_	_
Ehlers-Danlos syndrome	3	0
Inborn errors of porphyrin metabolism		_
Porphyria acute	1	0
Lymphatic system disorders congenital		_
Cystic lymphangioma	1	0
Male reproductive tract disorders congenital		_
Hydrocele	1	0
Musculoskeletal and connective tissue disorders of limbs congenital		
Polydactyly	1	0
Musculoskeletal disorders congenital NEC		_
Congenital multiplex arthrogryposis	1	0
Dysmorphism	2	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	1	0
Familial periodic paralysis	1	0
Non-site specific muscle disorders congenital		
Muscular dystrophy	1	0
Pancreatic disorders congenital		
Hereditary pancreatitis	1	0
Peripheral nervous system disorders congenital NEC		
Paroxysmal extreme pain disorder	7	0
Pulmonary and bronchial disorders congenital		
Cystic fibrosis	3	0
Vascular anomalies congenital NEC		
Klippel-Trenaunay syndrome	1	0
Congenital disorders SOC TOTAL	40	0

# Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 01-Apr-2021 Data Lock Date: 28-Mar-2021 19:00:03
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1

	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	<u>Fatal</u>
Ear disorders		
Ear disorders NEC		
Ear congestion	8	
Ear discomfort	33	0
Ear disorder	4	0
Ear haemorrhage	2	0
Ear pain	1095	0
Ear pruritus	1	0
Ear swelling	32	0
Otorrhoea	1	0
Eustachian tube disorders		
Eustachian tube dysfunction	1	0
External ear disorders NEC		
Excessive cerumen production	7	0
External ear pain	7	0
Red ear syndrome	5	0
Hearing disorders NEC		
Auditory disorder	1	0
Hearing losses		
Deafness	94	- O
Deafness bilateral	1	0
Deafness neurosensory	1 1	0
Deafness transitory	2	
Deafness unilateral	12	0
Hypoacusis	73	
Sudden hearing loss	15	
Hyperacusia		
Hyperacusis	50	0
Inner ear disorders NEC		
Inner ear disorder	3	0
Meniere's disease	12	0
Vestibular disorder	2	0
Inner ear infections and inflammations		
Inner ear inflammation	2	0
Inner ear signs and symptoms		
Motion sickness	49	0
Phobic postural vertigo	1	0
Tinnitus	1009	0
Vertigo	694	0
Vertigo labyrinthine	5	0
Vertigo positional	37	0
Middle ear disorders NEC		
Middle ear effusion	1	0
Tympanic membrane disorders (excl infection	ns)	
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	3261	

Reaction Name	 otal	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Thyroiditis	4	0
Thyroiditis chronic	1	0
Adrenal cortical hyperfunctions		
Cushingoid	4	0
Adrenal cortical hypofunctions		
Addison's disease	1	0
Adrenal insufficiency	10	0
Adrenocortical insufficiency acute	21	0
Glucocorticoid deficiency	1	0
Adrenal gland disorders NEC		
Adrenal haemorrhage	3	0
Anterior pituitary hypofunction		
Hypopituitarism	1	0
Female gonadal function disorders		
Ovulation delayed	3	0
Posterior pituitary disorders		
Diabetes insipidus	3	0
Thyroid disorders NEC		
Goitre	1	0
Thyroid disorder	2	0
Thyroid mass	1	0
Thyroid pain	3	0
Thyroid hyperfunction disorders		
Hyperthyroidism	3	0
Thyrotoxic crisis	2	0
Thyroid hypofunction disorders		
Hypothyroidism	16	0
Endocrine disorders SOC TOTAL	80	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1		
Reaction Name	Total	Fatal
Eye disorders		
Amblyopic vision impairment		
Amblyopia	2	0
Cataract conditions		
Cataract	6	0
Cataract subcapsular	1	0
Choroid and vitreous haemorrhages and vascular disorders		
Vitreous haemorrhage	1	0
Choroid and vitreous structural change, deposit and degeneration		
Chorioretinopathy	1	0
Vitreous detachment	10	0
Vitreous floaters	44	0
Colour blindness (incl acquired)		
Dyschromatopsia	6	0
Conjunctival and corneal bleeding and vascular disorders		
Conjunctival haemorrhage	29	0
Corneal infections, oedemas and inflammations		
Keratitis	2	0
Eyelid movement disorders		
Blepharospasm	29	0
Eyelid ptosis	13	0
Glaucomas (excl congenital)		
Angle closure glaucoma	1	0
Glaucoma	3	0
Iris and ciliary body structural change, deposit and degeneration		
Eye colour change	5	0
Iris and uveal tract infections, irritations and inflammations		
Autoimmune uveitis	1	0
Iridocyclitis	5	0
Iritis	3	0
Uveitis	11	0
Lacrimation disorders		
Dry eye	135	0
Lacrimation increased	111	0
Lens structural change, deposit and degeneration (excl cataracts)		
Anterior capsule contraction	1	0
Lid bleeding and vascular disorders		
Eyelid bleeding	1	0
Eyelid haematoma	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Blepharitis	3	0
Erythema of eyelid	2 2	0
Eyelid cyst	2	0
Eyelid margin crusting	1	0
Eyelid oedema	7	0
Eyelid rash	3	0
Swelling of eyelid	41	0
Lid, lash and lacrimal structural disorders		
Eyelid skin dryness	1	0
Eyelid thickening	1	0
Growth of eyelashes	4	0
Lagophthalmos	1	0
Ocular bleeding and vascular disorders NEC		
Eye haemorrhage	15	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDR	RA 23.1	
Reaction Name	Total	<u>Fatal</u>
Eye disorders Eye disorders cont'd		
Ocular vascular disorder	1	0
Ocular disorders NEC		
Dark circles under eyes	3	0
Eye disorder	6	0
Eye oedema	4	0
Eye pain	1894	
Eye swelling	265	0
Eye symptom	1	_
Eye ulcer	3	0
Eyelid disorder	1	
Eyelid pain	5	0
Eyelids pruritus	2	0
Ocular discomfort	22	0
Periorbital oedema	7	0
Periorbital pain	3	
Periorbital swelling	43	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	10	0
Eye discharge	12	0
Eye inflammation	14	0
Eye irritation	117	0
Eye pruritus	149	0
Limbal swelling	2	0
Ocular hyperaemia	162	0
Ocular nerve and muscle disorders		
Extraocular muscle paresis	4	0
Eye movement disorder	19	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ocular sensation disorders		
Abnormal sensation in eye	15	0
Asthenopia	159	0
Eyelid sensory disorder	2	0
Foreign body sensation in eyes	17	0
Hypoaesthesia eye	9	0
Photophobia	564	0
Optic disc abnormalities NEC		
Papilloedema	1	0
Optic nerve bleeding and vascular disorders		
Optic ischaemic neuropathy	1	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	1	0
Pupil disorders		
Miosis	4	0
Mydriasis	11	0
Pupil fixed	2	0
Pupils unequal	2 2	0
Refractive and accommodative disorders		
Altered visual depth perception	2	0
Hypermetropia	1	
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal aneurysm	1	0
Retinal artery embolism	1	

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name	Tot	<u>al_</u>	Fatal
Eye disorders Eye disorders cont'd			
Retinal artery occlusion		_1	0
Retinal haemorrhage		2	0
Retinal vascular thrombosis		_1	0
Retinal vein occlusion		6	0
Retinal vein thrombosis		_1	0
Retinal vein varices		1	0
Retinal structural change, deposit and degen	eration		
Macular degeneration		1	0
Macular detachment		1	0
Macular hole		1	0
Neovascular age-related macular degenera	tion	3	0
Retinal detachment		2	0
Retinal drusen		1	0
Retinal tear		1	0
Retinal toxicity		1	0
Vitreoretinal traction syndrome		1	0
Retinal, choroid and vitreous infections and in	nflammations		
Macular oedema		1	0
Retinopathies NEC			
Acute macular outer retinopathy		3	0
Retinal exudates		1	0
Retinopathy		1	0
Scleral infections, irritations and inflammation	ns en		
Episcleritis		5	0
Scleritis		2	0
Structural change, deposit and degeneration	of eye NEC		
Deposit eye	,	1	0
Endocrine ophthalmopathy		2	0
Exophthalmos		1	0
Visual colour distortions			
Chloropsia		1	0
Chromatopsia		1	0
Xanthopsia		4	0
Visual disorders NEC			
Diplopia		117	0
Halo vision		7	0
Metamorphopsia		14	0
Photopsia		130	0
Scintillating scotoma		1	0
Vision blurred		336	0
Visual brightness		4	0
Visual snow syndrome		1	0
Visual impairment and blindness (excl colour	blindness)		
Amaurosis fugax	<i>'</i>	3	0
Blindness		73	0
Blindness transient			0
Blindness unilateral		3 3	0
Night blindness		3	0
Sudden visual loss		3	0
Visual acuity reduced		6	0
Visual impairment		222	0
Visual pathway disorders			
Optic nerve disorder		1	0

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Reaction Name		Total	Fatal
Eve disorders	Eye disorders cont'd		
Eve disorders SOC	TOTAL	5521	0

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Date: 01-Apr-2021

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name	Tota	al .	Fatal
Gastrointestinal disorders			
Abdominal findings abnormal		$\perp$	
Abdominal mass		1	0
Gastrointestinal sounds abnormal		9	0
Acute and chronic pancreatitis			
Obstructive pancreatitis		1	1
Pancreatitis		18	1
Pancreatitis acute		3	0
Pancreatitis chronic		1	0
Anal and rectal disorders NEC		$\perp$	
Anal fissure		1	0
Anal and rectal pains		_	
Proctalgia		11	0
Anal and rectal signs and symptoms		_	
Anal hypoaesthesia		3	0
Anal paraesthesia		1	0
Anal pruritus		2	0
Anorectal discomfort		3	0
Rectal discharge		1	0
Benign oral cavity neoplasms		_	
Mouth cyst		6	0
Tongue cyst		1	0
Tongue polyp		2	0
Colitis (excl infective)		_	
Autoimmune colitis		1	0
Colitis		14	0
Colitis ischaemic		2	1
Colitis microscopic		1	0
Colitis ulcerative		35	0
Crohn's disease		37	0
Neutropenic colitis		1	0
Terminal ileitis		-1	0
Dental and periodontal infections and inflam	mations		_
Dental caries		1	0
Dental disorders NEC			_
Diastema		1	0
Loose tooth		42	0
Teething Tooth disorder		13	0
		1	0
Tooth socket haemorrhage		-' -	0
<b>Dental pain and sensation disorders</b> Dental discomfort			٥
Dental discomort  Dental paraesthesia		10	0
Hyperaesthesia teeth		24	0
Toothache		65	0
Dental pulp disorders		الان	U
Dental pulp disorder  Dental pulp disorder		1	0
Dental pulp disorder  Dental surface disorders		'	U
Tooth discolouration		3	0
Diaphragmatic hernias			U
Hiatus hernia		4	0
Diarrhoea (excl infective)		7	U
Diarrhoea (excrimective)  Diarrhoea	F.1	18	0
Diarrhoea haemorrhagic	31	12	0
Diaminoca nacinomiagio		14	U

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Gastrointestinal disorders con	ıt'd		
Diverticula			
Diverticulum		2	0
Duodenal and small intestinal stenosis and or	ostruction		
Small intestinal obstruction		1	0
Duodenal ulcers and perforation			
Duodenal ulcer		1	0
Dyspeptic signs and symptoms			
Dyspepsia		422	0
Epigastric discomfort		9	0
Eructation		48	0
Faecal abnormalities NEC			
Abnormal faeces		8	0
Faecaloma		2	0
Faeces discoloured		25	0
Faeces hard		3	0
Faeces pale		3	0
Faeces soft		9	0
Mucous stools		5	0
Flatulence, bloating and distension			_
Abdominal distension		197	0
Flatulence		230	0
Gastric and oesophageal haemorrhages			
Gastric haemorrhage		3	0
Gastric ulcers and perforation			_
Gastric ulcer		4	0
Gastric ulcer perforation		1	0
Gastritis (excl infective)			Ŭ
Chronic gastritis		2	0
Gastritis		38	0
Reflux gastritis		7	0
Gastrointestinal and abdominal pains (excl or	al and throat)	•	J
Abdominal migraine	ar arra arroaty	1	0
Abdominal pain		2455	0
Abdominal pain lower		116	0
Abdominal pain upper		2755	0
Abdominal rigidity		22	0
Abdominal tenderness		9	0
Gastrointestinal pain		171	0
Oesophageal pain		4	0
Gastrointestinal atonic and hypomotility disort	ders NFC	•	J
Constipation	30/0 / 120	192	0
Duodenogastric reflux		2	0
Gastric dilatation		5	0
Gastrooesophageal reflux disease		102	0
Impaired gastric emptying		1	0
Infrequent bowel movements		2	0
Gastrointestinal disorders NEC		_	· ·
Food poisoning		3	0
Functional gastrointestinal disorder		7	0
Gastric disorder		<i>'</i> Δ	0
Gastric disorder  Gastrointestinal disorder		11	0
Neurogenic bowel		1	0
Gastrointestinal dyskinetic disorders		'	J
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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Gastrointestinal disorders contestinal disorders co	ont'd		
Bowel movement irregularity		2	0
Change of bowel habit		2 7	0
Dyschezia		5	0
Oesophageal achalasia		2	0
Gastrointestinal inflammatory disorders NEC			
Appendicitis noninfective		1	0
Gastrointestinal tract irritation		2	0
Gastrointestinal mucosal dystrophies and se	ecretion disorders		_
Hyperchlorhydria		1	0
Gastrointestinal necrosis and gangrene (exc	el aanarenous hernia)		Ŭ
Gastrointestinal necrosis	gag. ccacca,	1	0
Gastrointestinal signs and symptoms NEC			J
Abdominal discomfort		876	0
Abdominal symptom		2	0
Acute abdomen		8	0
Anal incontinence		17	0
Breath odour		13	0
Dysphagia		98	1
Intestinal congestion		1	0
Gastrointestinal spastic and hypermotility dia	sorders	'	U
Defaecation urgency	BOIGEIS	7	0
Frequent bowel movements		22	0
Irritable bowel syndrome		42	0
Oesophageal spasm		3	0
Gastrointestinal stenosis and obstruction NE	-C	3	U
Intestinal obstruction		3	0
Gastrointestinal vascular malformations		3	U
Gastric antral vascular ectasia		2	0
Gastric antial vascular ectasia  Gastrointestinal vascular occlusion and infa	rction		U
Intestinal ischaemia	Cuon	2	0
Mesenteric artery thrombosis		1	0
Mesenteric vein thrombosis		2	0
Mesenteric venous occlusion		1	0
Visceral venous thrombosis		1	0
Gingival disorders, signs and symptoms NE	C		U
Gingival blister	<b>U</b>	15	0
Gingival discomfort			0
Gingival discomort		3 8	0
Gingival disorder  Gingival hypertrophy		1	0
Gingival riypertrophy Gingival oedema		2	0
Gingival bedefina Gingival pain		112	0
Gingival parifus		1	0
Gingival pruntus Gingival swelling		23	
Gingival swelling Gingival ulceration		3	0
		12	0
Noninfective gingivitis  Gingival haemorrhages		12	U
Gingival haemormages Gingival bleeding		43	0
	eval assantageal)	43	U
Haemorrhoids and gastrointestinal varices (	exci desupriagear)	4	0
Haemorrhoidal haemorrhage Haemorrhoids		14	0
Haemorrhoids Haemorrhoids thrombosed		3	0
		3	U
Inguinal hernias		0	^
Inguinal hernia		2	0

Earliest Reaction Date: 03-Feb-1921 M	edDRA Version: MedDRA 23.1	
Reaction Name	Total	Fatal
Gastrointestinal disorders cont	d	
Intestinal haemorrhages		
Anal haemorrhage	11	0
Intestinal haemorrhage	1	0
Mesenteric haemorrhage	1	0
Rectal haemorrhage	27	0
Small intestinal haemorrhage	11	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	1	0
Large intestinal stenosis and obstruction		
Large intestinal stenosis	1	0
Malabsorption syndromes		
Coeliac disease	4	0
Steatorrhoea	1	0
Nausea and vomiting symptoms		
Acetonaemic vomiting	1	0
Discoloured vomit	12	0
Faecal vomiting	1	0
Infantile vomiting	1	0
Nausea	21367	' 0
Regurgitation	1	0
Retching	163	0
Vomiting	7124	2
Vomiting projectile	94	. 0
Non-site specific gastrointestinal haemorrhages	5	
Gastrointestinal haemorrhage	7	' o
Haematemesis	31	0
Haematochezia	33	0
Melaena	2	2 0
Oesophageal stenosis and obstruction		
Oesophageal obstruction	1	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	2	2 0
Oesophagitis	5	0
Oral dryness and saliva altered		
Aptyalism	3	0
Dry mouth	711	0
Lip dry	34	0
Saliva altered	3	
Saliva discolouration	1	0
Salivary hypersecretion	35	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	1	0
Chapped lips	6	
Cheilitis	18	0
Chronic cheek biting	1	0
Enlarged uvula	4	0
Leukoplakia oral	1	0
Lip blister	19	
Lip disorder	1	0
Oral disorder	7	0
Oral lichen planus	3	0
Uvulitis		· 0
Oral soft tissue haemorrhages		

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Gastrointestinal disorders contestinal disorders co	ont'd		
Lip haemorrhage		2	0
Mouth haemorrhage		12	0
Oral blood blister		19	0
Oral soft tissue infections			
Angular cheilitis		2	0
Oral soft tissue signs and symptoms			
Anaesthesia oral		4	0
Burning mouth syndrome		5	0
Coating in mouth		2	0
Hypoaesthesia oral		323	0
Lip discolouration		1	0
Lip erythema		3	0
Lip exfoliation		7	0
Lip pain		37	0
Lip pruritus		9	0
Odynophagia		16	0
Oral discomfort		42	0
Oral mucosal blistering		17	0
Oral mucosal eruption		12	0
Oral mucosal erythema		1	0
Oral mucosal exfoliation		5	0
Oral mucosal roughening		2	0
Oral pain		192	0
Oral pruritus		12	0
Paraesthesia oral		469	0
Oral soft tissue swelling and oedema		100	Ŭ
Lip oedema		5	0
Lip swelling		502	0
Mouth swelling		66	0
Oedema mouth		1	0
Palatal swelling		8	0
Rectal inflammations NEC		Ŭ	Ŭ
Proctitis		1	0
Salivary gland disorders NEC			Ţ.
Salivary gland calculus		1	0
Salivary gland pain		4	0
Salivary gland enlargements		·	•
Parotid gland enlargement		7	0
Salivary gland enlargement		4	0
Salivary gland infections and inflammations			
Noninfective sialoadenitis		1	0
Stomatitis and ulceration			
Aphthous ulcer		39	0
Lip ulceration		11	0
Mouth ulceration		358	0
Stomatitis		48	0
Tongue disorders			•
Glossitis		10	0
Plicated tongue		3	n
Tongue disorder		16	0
Tongue geographic		2	0
Tongue ulceration		18	0
Trichoglossia		2	0

Reaction Name	Total	Fatal
Gastrointestinal disordersointestinal disorders cont'd		
Tongue signs and symptoms		
Glossodynia	146	0
Scalloped tongue	3	0
Stiff tongue	2	0
Swollen tongue	309	0
Tongue blistering	16	0
Tongue coated	21	0
Tongue discolouration	11	0
Tongue discomfort	25	0
Tongue dry	10	0
Tongue eruption	2	0
Tongue exfoliation	1	0
Tongue movement disturbance	5	0
Tongue oedema	10	0
Tongue pruritus	1	0
Tongue rough	1	0
Tongue spasm	3	0
Tooth missing		
Tooth loss	2	0
Gastrointestinal disorders SOC TOTAL	46391	6

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
General disorders			
Administration site reactions NEC			
Administration site bruise		9	0
Administration site coldness		1	0
Administration site erythema		2	0
Administration site induration		1	0
Administration site mass		1	0
Administration site pain		30	0
Administration site rash		2	0
Administration site reaction		3	0
Administration site urticaria		1	0
Puncture site bruise		33	0
Puncture site haemorrhage		1	0
Puncture site pain		11	0
Puncture site reaction		3	0
Puncture site swelling		1	0
Adverse effect absent			
No adverse event		10	0
Application and instillation site reactions			
Application site bruise		13	0
Application site burn		2	0
Application site erythema		16	0
Application site haemorrhage		1	0
Application site hypersensitivity		1	0
Application site inflammation		1	0
Application site irritation		1	0
Application site joint pain		1	0
Application site pain		22	0
Application site pruritus		8	0
Application site reaction		1	0
Application site swelling		4	0
Application site vesicles		1	0
Application site warmth		1	0
Application site wound		1	0
Instillation site discomfort		1	0
Instillation site pain		2	0
Instillation site pruritus		1	0
Instillation site warmth		9	0
Asthenic conditions			
Asthenia		2638	3
Chronic fatigue syndrome		45	3 0
Decreased activity		2	0
Fatigue		29037	0
Malaise		7474	
Sluggishness		10	3 0
Body temperature altered			
Hyperthermia		6	0
Hypothermia		34	0
Temperature regulation disorder		10	0
Complications associated with device NEC			
Injury associated with device		2	0
Medical device site joint pain		1	0
Phantom shocks		3	0
Death and sudden death			

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	Fatal
General disorders General disorders cont'd			
Brain death		3	3
Death		175	175
Drowning		1	0
Sudden death		17	17
Febrile disorders			
Hyperpyrexia		32	0
Masked fever		1	0
Pyrexia		36823	0
Feelings and sensations NEC			
Chills		29625	0
Early satiety		1	0
Feeling abnormal		1406	0
Feeling cold		3446	0
Feeling drunk		70	0
Feeling hot		1367	0
Feeling jittery		18	0
Feeling of body temperature change		628	0
Hangover		85	0
Hunger		33	0
Sensation of blood flow		5	0
Sensation of foreign body		23	0
Temperature intolerance		34	0
Thirst		817	0
Thirst decreased		7	0
Fibrosis NEC			
Fibrosis		2	0
Gait disturbances			
Decreased gait velocity		2	0
Gait disturbance		167	0
Gait inability		95	0
Loss of control of legs		21	0
General signs and symptoms NEC			
Apparent death		1	0
Chronic disease		1	0
Condition aggravated		102	0
Crepitations		2	0
Crying		134	0
Developmental delay		1	0
Discharge		3	0
Energy increased		10	0
Exercise tolerance decreased		8	0
Foaming at mouth		3	0
General physical health deterioration		10	1
General symptom		7	0
Glassy eyes		2 2 2	0
High-pitched crying		2	0
III-defined disorder			0
Illness		3114	0
Induration		10	0
Influenza like illness		6204	1
Irritability postvaccinal		2	0
Local reaction		121	0
Moaning		6	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
General disorders General disorders cont'd			
Multiple organ dysfunction syndrome		5	0
Nonspecific reaction		3	0
Organ failure		1	0
Peripheral swelling		2941	0
Pre-existing condition improved		1	0
Screaming		8	0
Secretion discharge		13	0
Stenosis		1	0
Swelling		1345	0
Swelling face		493	0
Symptom recurrence		1	0
Tissue discolouration		1	0
Tissue infiltration		1	0
Unevaluable event		1	0
Hernias NEC		'	U
Hernia		1	0
		ı	U
Implant and catheter site reactions  Catheter site urticaria		1	0
Implant site coldness			
		1	0
Implant site discharge		1	_
Implant site discolouration		2 1	0
Implant site hypoaesthesia		- 1	0
Implant site pain		3	0
Implant site rash		1	0
Implant site swelling		2	0
Implant site warmth		4	0
Inflammations		205	•
Inflammation		305	0
Systemic inflammatory response syndrom	е	1	0
Infusion site reactions			_
Infusion site bruising		1	0
Infusion site nodule		1	0
Infusion site pain		6	0
Infusion site urticaria		1	0
Infusion site warmth		4	0
Injection site reactions			
Injected limb mobility decreased		22	0
Injection site atrophy		3	0
Injection site bruising		69	0
Injection site coldness		3	0
Injection site cyst		1	0
Injection site discolouration		3	0
Injection site discomfort		8	0
Injection site erythema		374	0
Injection site exfoliation		1	0
Injection site haematoma		2	0
Injection site haemorrhage		1	0
Injection site hypersensitivity		4	0
Injection site hypoaesthesia		8	0
Injection site indentation		6	0
Injection site induration		1	0
Injection site inflammation		39	0
Injection site injury		1	0

# Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 01-Apr-2021 Data Lock Date: 28-Mar-2021 19:00:03
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	<u>Fatal</u>
General disorders General disorders cont'd			
Injection site irritation		2	0
Injection site joint erythema		6	0
Injection site joint pain		26	0
Injection site mass		865	0
Injection site movement impairment		1	0
Injection site muscle weakness		1	0
Injection site nodule		3	0
Injection site oedema		21	0
Injection site pain		2810	0
Injection site papule		2	0
Injection site paraesthesia		10	0
Injection site pruritus		196	0
Injection site rash		172	0
Injection site reaction		72	0
Injection site scab		4	0
Injection site scar		4	0
Injection site swelling		144	0
Injection site urticaria		24	0
Injection site vesicles		5	0
Injection site warmth		240	0
Interactions			
Drug interaction		11	0
Inhibitory drug interaction		2	0
Mass conditions NEC			
Cyst		6	0
Mass		35	0
Nodule		5	0
Mucosal findings abnormal			
Mucosal disorder		1	0
Mucosal dryness		1	0
Mucosal haemorrhage		2	0
Mucosal inflammation		2 2 1	0
Mucosal pain		1	0
Mucosal ulceration		1	0
Oedema mucosal		2	0
Oedema NEC			
Face oedema		17	0
Localised oedema		5	0
Oedema		18	
Oedema peripheral		37	0
Pain and discomfort NEC			
Axillary pain		360	0
Chest discomfort		1067	0
Chest pain		2174	0
Discomfort		187	0
Facial discomfort		6	0
Facial pain		133	0
Hernia pain		1	0
Inflammatory pain		12	0
Non-cardiac chest pain		17	0
Pain		8917	0
Tenderness		1220	0
Visceral pain		1	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1	Tatal	Catal
Reaction Name General disorders General disorders cont'd		<u>Total</u>	Fatal
Corioral dicordoro			
Therapeutic and nontherapeutic responses		204	2
Adverse drug reaction		394	2
Adverse event		4	0
Adverse reaction		13	0
Diet failure		20	0
Drug ineffective		30	0
Drug intolerance		2	0
Immediate post-injection reaction		1	0
Inadequate analgesia		8	0
No reaction on previous exposure to drug		29	0
Therapeutic product effect decreased		1	0
Therapeutic reaction time decreased		1	0
Therapeutic response shortened		20	0
Therapeutic response unexpected		30	0
Therapy non-responder		1	0
Treatment failure		3	0
Vaccine positive rechallenge		1	0
Trophic disorders			0
Atrophy		1	0
Calcinosis		1	0
Ulcers NEC		4.5	•
Ulcer		15	0
Ulcer haemorrhage		1	0
Vaccination site reactions		4.0	0
Extensive swelling of vaccinated limb		12	0
Shoulder injury related to vaccine administ	ration	5	0
Vaccination site bruising		73	0
Vaccination site coldness		1	0
Vaccination site cyst		1	0
Vaccination site discharge		1	0
Vaccination site discolouration		5	0
Vaccination site discomfort		20	0
Vaccination site erythema		373	0
Vaccination site extravasation		1	0
Vaccination site granuloma		5	0
Vaccination site haemorrhage		3	0
Vaccination site hyperaesthesia		1	0
Vaccination site hypersensitivity		3	0
Vaccination site hypoaesthesia		11	0
Vaccination site induration		37	0
Vaccination site inflammation		34	0
Vaccination site injury		2	0
Vaccination site irritation		8	0
Vaccination site joint erythema		1	0
Vaccination site joint movement impairmer	t	5	0
Vaccination site joint pain		30	0
Vaccination site joint swelling		3	0
Vaccination site joint warmth		1	0
Vaccination site lymphadenopathy		2	0
Vaccination site mass		299	0
Vaccination site movement impairment		24	0
Vaccination site oedema		2	0
Vaccination site pain		1094	0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site papule	2	. 0
Vaccination site paraesthesia	7	0
Vaccination site pruritus	61	0
Vaccination site rash	78	0
Vaccination site reaction	16	0
Vaccination site scar	2	. 0
Vaccination site swelling	269	0
Vaccination site urticaria	7	0
Vaccination site vesicles	4	. 0
Vaccination site warmth	211	0
Vascular complications associated with device		
Vascular stent occlusion		0
Withdrawal and rebound effects		
Drug withdrawal syndrome	4	. 0
Withdrawal syndrome	30	0
General disorders SOC TOTAL	151940	205

Reaction Name	Total	Fatal
Hepatic disorders		
Bile duct infections and inflammations		
Biliary colic	g	0
Cholangitis		0
Cholecystitis and cholelithiasis		
Cholecystitis	5	0
Cholelithiasis	4	0
Cholestasis and jaundice		
Jaundice	18	0
Jaundice cholestatic	3	
Ocular icterus	1	0
Hepatic and hepatobiliary disorders NEC		
Liver disorder	2	2 0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	1	0
Hepatic failure and associated disorders		
Hepatic failure	1	0
Subacute hepatic failure	1	0
Hepatic fibrosis and cirrhosis		
Hepatic cirrhosis	2	2 0
Hepatic vascular disorders		
Hepatic vein thrombosis	3	
Portal vein thrombosis	7	' 0
Hepatobiliary signs and symptoms		
Hepatic pain	35	
Liver tenderness	3	0
Hepatocellular damage and hepatitis NEC		
Hepatitis	8	0
Hepatitis acute	1	0
Liver injury	4	0
Hepatic disorders SOC TOTAL	109	0

# Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 01-Apr-2021 Data Lock Date: 28-Mar-2021 19:00:03
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1

Immune system disorders	Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Acute and chronic sarcoidosis         9           Allergic conditions NEC         14           Allergy to edema         14           Allergy to metals         1           Allergy to sting         1           Allergy to venom         1           Dust allergy         1           Hypersensitivity         635           Infusion related hypersensitivity reaction         3           Multiple allergies         8           Serum sickness-like reaction         14           Type IV immune complex mediated reaction         4           Type IV hypersensitivity reaction         2           Allergies to foods, food additives, drugs and other chemicals           Allergy to chemicals         3           Allergy to chemicals         3           Allergy to vaccine         29           Contrast media reaction         1           Drug hypersensitivity         40           Food allergy         4           Reaction to excipient         5           Reaction to preservatives         7           Anaphylactic and anaphylactoid responses           Anaphylactic shock         63           Anaphylactic shock         63           Anaphylactid shock         3 </th <th>Reaction Name</th> <th></th> <th><u>Total</u></th> <th><u>Fatal</u></th>	Reaction Name		<u>Total</u>	<u>Fatal</u>
Sarcoidosis         9           Allergic conditions NEC           Allergic cedema         14           Allergy to arthropod sting         2           Allergy to metals         1           Allergy to sting         1           Allergy to venom         1           Dust allergy         1           Hypersensitivity         635           Infusion related hypersensitivity reaction         3           Multiple allergies         8           Serum sickness         14           Serum sickness-like reaction         11           Type IV hypersensitivity reaction         4           Type IV hypersensitivity reaction         2           Allergies to foods, food additives, drugs and other chemicals         4           Allergies to foods, food additives, drugs and other chemicals         3           Allergy to chemicals         3           Allergy to vaccine         29           Contrast media reaction         1           Drug hypersensitivity         40           Food allergy         4           Reaction to excipient         5           Reaction to preservatives         7           Anaphylactic and anaphylactoid responses         63           Anaphylactic				
Allergic conditions NEC           Allergy to arthropod sting         14           Allergy to metals         1           Allergy to sting         1           Allergy to venom         1           Dust allergy         1           Hypersensitivity         635           Infusion related hypersensitivity reaction         3           Multiple allergies         8           Serum sickness-like reaction         11           Serum sickness-like reaction         11           Type IVI hypersensitivity reaction         2           Allergies to foods, food additives, drugs and other chemicals         4           Allergic reaction to excipient         1           Allergy to chemicals         3           Allergy to vaccine         29           Contrast media reaction         1           Drug hypersensitivity         40           Food allergy         4           Reaction to excipient         5           Reaction to preservatives         7           Anaphylactic and anaphylactoid responses         7           Anaphylactic shock         63           Anaphylactic shock         63           Anaphylactid shock         3           Antoimmune disorders				
Allergic oedema       14         Allergy to arthropod sting       2         Allergy to metals       1         Allergy to sting       1         Allergy to venom       1         Dust allergy       1         Hypersensitivity       635         Infusion related hypersensitivity reaction       3         Multiple allergies       8         Serum sickness       14         Serum sickness-like reaction       11         Type III immune complex mediated reaction       4         Type IV hypersensitivity reaction       2         Allergies to foods, food additives, drugs and other chemicals         Allergies to foods, food additives, drugs and other chemicals         Allergies to foods, food additives, drugs and other chemicals         Allergie reaction to excipient       1         Allergy to chemicals       3         Allergy to vaccine       29         Contrast media reaction       1         Drug hypersensitivity       40         Food allergy       4         Reaction to excipient       5         Reaction to preservatives       7         Anaphylactic reaction       378         Anaphylactic shock       63         Anaphylactic deact			9	0
Allergy to arthropod sting       2         Allergy to metals       1         Allergy to sting       1         Allergy to venom       1         Dust allergy       1         Hypersensitivity       635         Infusion related hypersensitivity reaction       3         Multiple allergies       8         Serum sickness       14         Serum sickness-like reaction       11         Type III immune complex mediated reaction       2         Type IV hypersensitivity reaction       4         Allergies to foods, food additives, drugs and other chemicals         Allergic reaction to excipient       1         Allergy to vaccine       29         Contrast media reaction       1         Drug hypersensitivity       40         Food allergy       4         Reaction to excipient       5         Reaction to preservatives       7         Anaphylactic and anaphylactoid responses       3         Anaphylactic eraction       378         Anaphylactic shock       3         Anaphylactic shock       3         Anaphylactic desorders       9         Seasonal allergy       19         Autoimmune disorder       6				
Allergy to sting 1 Allergy to sting 1 Allergy to sting 1 Allergy to venom 1 Dust allergy 1 Hypersensitivity 635 Infusion related hypersensitivity reaction 3 Multiple allergies 8 Serum sickness 14 Serum sickness-like reaction 11 Type III immune complex mediated reaction 4 Type IV hypersensitivity reaction 2 Allergies to foods, food additives, drugs and other chemicals Allergic reaction to excipient 1 Allergy to chemicals 3 Allergy to vaccine 29 Contrast media reaction 1 Drug hypersensitivity 40 Food allergy 4 Reaction to excipient 5 Reaction to excipient 5 Reaction to excipient 5 Reaction to preservatives 7 Anaphylactic and anaphylactoid responses Anaphylactic reaction 378 Anaphylactic shock 63 Anaphylactici shock 63 Anaphylactoid reaction 11 Anaphylactoid reaction 11 Anaphylactoid shock 3 Atopic disorders Seasonal allergy 19 Autoimmune disorder 6 Immune and associated conditions NEC Bacille Calmette-Guerin scar reactivation 9 Haemophagocytic lymphohistiocytosis 2 Immune system disorder 8	Allergic oedema		14	0
Allergy to venom 1 Dust allergy (1 Hypersensitivity 635 Infusion related hypersensitivity reaction 3 Multiple allergies 8 Serum sickness 8 Serum sickness-like reaction 11 Type III immune complex mediated reaction 2 Allergies to foods, food additives, drugs and other chemicals Allergic reaction to excipient 1 Allergy to chemicals 3 Allergy to vaccine 29 Contrast media reaction 1 Drug hypersensitivity 40 Food allergy Reaction to excipient 5 Reaction to excipient 5 Reaction to excipient 5 Reaction to preservatives 7 Anaphylactic and anaphylactoid responses 7 Anaphylactic reaction 378 Anaphylactic dreaction 378 Anaphylactic shock 63 Anaphylactic reaction 378 Anaphylactic dreaction 378 Atopic disorders Seasonal allergy 19 Autoimmune disorder 66 Immune and associated conditions NEC Bacille Calmette-Guerin scar reactivation 9 Haemophagocytic lymphohistiocytosis 2 Immune system disorder 8	Allergy to arthropod sting		2	0
Allergy to venom	Allergy to metals		1	0
Dust allergy	Allergy to sting		1	0
Hypersensitivity Infusion related hypersensitivity reaction Multiple allergies Serum sickness Serum sickness-like reaction Type III immune complex mediated reaction Type IV hypersensitivity reaction Allergic sto foods, food additives, drugs and other chemicals Allergic reaction to excipient Allergy to chemicals Allergy to vaccine Contrast media reaction Drug hypersensitivity Food allergy Reaction to excipient Reaction to excipient Reaction to preservatives Anaphylactic and anaphylactoid responses Anaphylactic reaction Anaphylactic reaction Anaphylactoid reaction Anaphylactoid reaction Anaphylactoid reaction Anaphylactoid shock Atopic disorders Seasonal allergy Autoimmune disorder Immune and associated conditions NEC Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Inmune system disorder	Allergy to venom		1	0
Infusion related hypersensitivity reaction  Multiple allergies Serum sickness 14 Serum sickness-like reaction 11 Type III immune complex mediated reaction 4 Type IV hypersensitivity reaction 2 Allergies to foods, food additives, drugs and other chemicals Allergic reaction to excipient 1 Allergy to chemicals 3 Allergy to vaccine 29 Contrast media reaction 10 Drug hypersensitivity 40 Food allergy 4 Reaction to excipient 5 Reaction to preservatives 7 Anaphylactic and anaphylactoid responses Anaphylactic reaction 378 Anaphylactic reaction 378 Anaphylactoid reaction 378 Anaphylactoid reaction 378 Anaphylactoid shock 33 Atopic disorders Seasonal allergy Autoimmune disorder Bacille Calmette-Guerin scar reactivation 9 Haemophagocytic lymphohistiocytosis 12 Immune system disorder	Dust allergy		1	0
Multiple allergies Serum sickness Serum sickness-like reaction Type III immune complex mediated reaction Type IV hypersensitivity reaction Allergies to foods, food additives, drugs and other chemicals Allergic reaction to excipient Allergy to chemicals Allergy to vaccine Contrast media reaction Drug hypersensitivity Food allergy Reaction to excipient Reaction to excipient Seaction to preservatives Anaphylactic and anaphylactoid responses Anaphylactic reaction 378 Anaphylactic shock Anaphylactoid reaction 11 Anaphylactoid reaction 11 Anaphylactoid reaction 11 Anaphylactoid reaction 11 Anaphylactoid shock Atopic disorders Seasonal allergy 19 Autoimmune disorder NEC Autoimmune disorder Bacille Calmette-Guerin scar reactivation 9 Haemophagocytic lymphohistiocytosis 12 Immune system disorder	Hypersensitivity		635	0
Serum sickness         14           Serum sickness-like reaction         11           Type III immune complex mediated reaction         4           Type IV hypersensitivity reaction         2           Allergies to foods, food additives, drugs and other chemicals         1           Allergic reaction to excipient         1           Allergy to chemicals         3           Allergy to vaccine         29           Contrast media reaction         1           Drug hypersensitivity         40           Food allergy         4           Reaction to excipient         5           Reaction to preservatives         7           Anaphylactic and anaphylactoid responses         378           Anaphylactic reaction         378           Anaphylactic shock         63           Anaphylactoid reaction         11           Anaphylactoid shock         3           Atopic disorders         3           Seasonal allergy         19           Autoimmune disorder         6           Immune and associated conditions NEC           Bacille Calmette-Guerin scar reactivation         9           Haemophagocytic lymphohistiocytosis         2           Immune system disorder	Infusion related hypersensitivity	reaction	3	0
Serum sickness-like reaction Type III immune complex mediated reaction 4 Type IV hypersensitivity reaction  Allergies to foods, food additives, drugs and other chemicals Allergic reaction to excipient Allergy to chemicals Allergy to vaccine 29 Contrast media reaction Drug hypersensitivity Food allergy 40 Reaction to excipient Reaction to preservatives 7 Anaphylactic and anaphylactoid responses Anaphylactic reaction 378 Anaphylactic reaction 378 Anaphylactoid reaction 378 Anaphylactoid reaction 378 Anaphylactoid shock 33 Atopic disorders Seasonal allergy  Autoimmune disorder Immune and associated conditions NEC Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Inmune system disorder  8	Multiple allergies		8	0
Type III immune complex mediated reaction Type IV hypersensitivity reaction  Allergies to foods, food additives, drugs and other chemicals Allergic reaction to excipient Allergy to chemicals Allergy to vaccine 29 Contrast media reaction 11 Drug hypersensitivity 40 Food allergy 44 Reaction to excipient 55 Reaction to preservatives 77 Anaphylactic and anaphylactoid responses Anaphylactic reaction 378 Anaphylactic reaction 378 Anaphylactoid reaction 378 Anaphylactoid reaction 311 Anaphylactoid shock 33 Atopic disorders Seasonal allergy Autoimmune disorder NEC Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Immune system disorder			14	0
Type IV hypersensitivity reaction  Allergies to foods, food additives, drugs and other chemicals  Allergic reaction to excipient  Allergy to chemicals  Allergy to vaccine  Contrast media reaction  Drug hypersensitivity  Food allergy  Reaction to excipient  Reaction to excipient  Reaction to preservatives  Anaphylactic and anaphylactoid responses  Anaphylactic reaction  Anaphylactic reaction  Anaphylactoid reaction  Anaphylactoid reaction  Anaphylactoid reaction  Anaphylactoid shock  Atopic disorders  Seasonal allergy  Autoimmune disorder  Immune and associated conditions NEC  Bacille Calmette-Guerin scar reactivation  Haemophagocytic lymphohistiocytosis  Immune system disorder  8	Serum sickness-like reaction		11	0
Allergies to foods, food additives, drugs and other chemicals  Allergic reaction to excipient  Allergy to chemicals  Allergy to vaccine  Contrast media reaction  Drug hypersensitivity  Food allergy  Reaction to excipient  Reaction to preservatives  Anaphylactic and anaphylactoid responses  Anaphylactic reaction  Anaphylactic shock  Anaphylactoid reaction  Anaphylactoid reaction  Anaphylactoid shock  Atopic disorders  Seasonal allergy  Autoimmune disorder  Immune and associated conditions NEC  Bacille Calmette-Guerin scar reactivation  Haemophagocytic lymphohistiocytosis  Inmune system disorder  Bacille Calmetter Guerin scar reactivation  Haemophagocytic lymphohistiocytosis  Inmune system disorder	Type III immune complex media	ed reaction	4	0
Allergic reaction to excipient Allergy to chemicals Allergy to vaccine Contrast media reaction Drug hypersensitivity Food allergy Reaction to excipient Reaction to preservatives 7 Anaphylactic and anaphylactoid responses Anaphylactic reaction Anaphylactic shock Anaphylactoid reaction Anaphylactoid reaction Anaphylactoid reaction Anaphylactoid shock Anaphylactoid shock Atopic disorders Seasonal allergy Autoimmune disorder NEC Autoimmune disorder Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Immune system disorder  8	Type IV hypersensitivity reaction		2	0
Allergy to chemicals       3         Allergy to vaccine       29         Contrast media reaction       1         Drug hypersensitivity       40         Food allergy       4         Reaction to excipient       5         Reaction to preservatives       7         Anaphylactic and anaphylactoid responses       7         Anaphylactic reaction       378         Anaphylactic shock       63         Anaphylactoid reaction       11         Anaphylactoid shock       3         Atopic disorders       3         Seasonal allergy       19         Autoimmune disorder       6         Immune and associated conditions NEC       6         Bacille Calmette-Guerin scar reactivation       9         Haemophagocytic lymphohistiocytosis       2         Immune system disorder       8	Allergies to foods, food additives,	drugs and other chemicals		
Allergy to vaccine       29         Contrast media reaction       1         Drug hypersensitivity       40         Food allergy       4         Reaction to excipient       5         Reaction to preservatives       7         Anaphylactic and anaphylactoid responses       378         Anaphylactic reaction       378         Anaphylactic shock       63         Anaphylactoid reaction       11         Anaphylactoid shock       3         Atopic disorders       3         Seasonal allergy       19         Autoimmune disorders NEC       6         Autoimmune and associated conditions NEC       6         Bacille Calmette-Guerin scar reactivation       9         Haemophagocytic lymphohistiocytosis       2         Immune system disorder       8		-	1	0
Allergy to vaccine       29         Contrast media reaction       1         Drug hypersensitivity       40         Food allergy       4         Reaction to excipient       5         Reaction to preservatives       7         Anaphylactic and anaphylactoid responses       378         Anaphylactic reaction       378         Anaphylactic shock       63         Anaphylactoid reaction       11         Anaphylactoid shock       3         Atopic disorders       3         Seasonal allergy       19         Autoimmune disorders NEC       6         Autoimmune and associated conditions NEC       6         Bacille Calmette-Guerin scar reactivation       9         Haemophagocytic lymphohistiocytosis       2         Immune system disorder       8	Allergy to chemicals		3	0
Drug hypersensitivity         40           Food allergy         4           Reaction to excipient         5           Reaction to preservatives         7           Anaphylactic and anaphylactoid responses         378           Anaphylactic reaction         378           Anaphylactoid reaction         11           Anaphylactoid shock         3           Atopic disorders         3           Seasonal allergy         19           Autoimmune disorder NEC         6           Autoimmune and associated conditions NEC         6           Bacille Calmette-Guerin scar reactivation         9           Haemophagocytic lymphohistiocytosis         2           Immune system disorder         8			29	0
Food allergy Reaction to excipient Reaction to preservatives Reaction to preservatives  Anaphylactic and anaphylactoid responses Anaphylactic reaction Anaphylactic shock Anaphylactoid reaction Anaphylactoid shock Atopic disorders Seasonal allergy Autoimmune disorder NEC Autoimmune disorder Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Immune system disorder  8	Contrast media reaction		1	0
Reaction to excipient Reaction to preservatives  Anaphylactic and anaphylactoid responses Anaphylactic reaction Anaphylactic shock Anaphylactoid reaction Anaphylactoid shock Anaphylactoid shock Atopic disorders Seasonal allergy Autoimmune disorder NEC Autoimmune disorder Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Immune system disorder  8	Drug hypersensitivity		40	0
Reaction to preservatives  Anaphylactic and anaphylactoid responses  Anaphylactic reaction  Anaphylactic shock  Anaphylactoid reaction  Anaphylactoid shock  Atopic disorders  Seasonal allergy  Autoimmune disorder NEC  Autoimmune disorder  Bacille Calmette-Guerin scar reactivation  Haemophagocytic lymphohistiocytosis  Immune system disorder  Immune system disorder	Food allergy		4	0
Reaction to preservatives  Anaphylactic and anaphylactoid responses  Anaphylactic reaction  Anaphylactic shock  Anaphylactoid reaction  Anaphylactoid shock  Atopic disorders  Seasonal allergy  Autoimmune disorder NEC  Autoimmune disorder  Bacille Calmette-Guerin scar reactivation  Haemophagocytic lymphohistiocytosis  Immune system disorder  Immune system disorder			5	0
Anaphylactic reaction Anaphylactic shock Anaphylactoid reaction Anaphylactoid shock Atopic disorders Seasonal allergy Autoimmune disorder NEC Autoimmune disorder Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Immune system disorder    378	Reaction to preservatives		7	0
Anaphylactic reaction Anaphylactic shock Anaphylactoid reaction Anaphylactoid shock Atopic disorders Seasonal allergy Autoimmune disorder NEC Autoimmune disorder Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Immune system disorder    378	Anaphylactic and anaphylactoid re	sponses		
Anaphylactoid reaction Anaphylactoid shock  Atopic disorders Seasonal allergy  Autoimmune disorders NEC Autoimmune disorder  Immune and associated conditions NEC  Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Immune system disorder  8		•	378	1
Anaphylactoid shock  Atopic disorders Seasonal allergy Autoimmune disorders NEC Autoimmune disorder Immune and associated conditions NEC Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Immune system disorder  8			63	0
Atopic disorders Seasonal allergy Autoimmune disorders NEC Autoimmune disorder Autoimmune disorder Immune and associated conditions NEC Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Immune system disorder  9 Immune system disorder	Anaphylactoid reaction		11	0
Atopic disorders19Seasonal allergy19Autoimmune disorders NEC6Autoimmune and associated conditions NEC6Bacille Calmette-Guerin scar reactivation9Haemophagocytic lymphohistiocytosis2Immune system disorder8			3	0
Seasonal allergy  Autoimmune disorders NEC  Autoimmune disorder  Autoimmune disorder  Immune and associated conditions NEC  Bacille Calmette-Guerin scar reactivation  Haemophagocytic lymphohistiocytosis  Immune system disorder  19  6  8				
Autoimmune disorders NEC Autoimmune disorder  Immune and associated conditions NEC  Bacille Calmette-Guerin scar reactivation Haemophagocytic lymphohistiocytosis Immune system disorder  6  9  Haemophagocytic lymphohistiocytosis			19	0
Immune and associated conditions NECBacille Calmette-Guerin scar reactivation9Haemophagocytic lymphohistiocytosis2Immune system disorder8				
Bacille Calmette-Guerin scar reactivation 9 Haemophagocytic lymphohistiocytosis 2 Immune system disorder 8	Autoimmune disorder		6	0
Haemophagocytic lymphohistiocytosis 2 Immune system disorder 8	Immune and associated conditions	S NEC		
Immune system disorder 8	Bacille Calmette-Guerin scar rea	ctivation	9	0
Immune system disorder 8	Haemophagocytic lymphohistiod	ytosis	2	0
			8	0
Immunisation reaction 1	Immunisation reaction		1	0
Pre-engraftment immune reaction 1	Pre-engraftment immune reaction	n	1	0
Sensitisation 14			14	0
Immunodeficiency disorders NEC	Immunodeficiency disorders NEC			
Immunodeficiency 1			1	0
Transplant rejections	_		·	J
Corneal graft rejection			1	0
Transplant rejection 1	,		1	Ő
Immune system disorders SOC TOTAL 1314		AL	1314	1

# Name: COVID-19 vaccine AstraZeneca analysis print Date: 01-Apr-2021 Data Lock Date: 28-Mar-2021 19:00:03

Report Run Date: 01-Apr-2021

Earliest Reaction Date: 03-Feb-1921 MedDRA Version	on: MedDRA 23.1	
Reaction Name	Total	Fatal
Infections		
Abdominal and gastrointestinal infections		
Anal abscess	1	0
Appendicitis	8	0
Diverticulitis	3	0
Dysentery	3	0
Gastroenteritis	19	0
Gastrointestinal infection	3	0
Bacterial infections NEC		
Administration site cellulitis	1	0
Arthritis bacterial	2	0
Bacterial infection	11	1
Cellulitis	272	1
Injection site cellulitis	6	0
Perichondritis	1	0
Pneumonia bacterial		0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	13	0
Bone and joint infections		
Arthritis infective	2	0
Intervertebral discitis	1	0
Bordetella infections		
Pertussis	1	0
Borrelial infections		
Erythema migrans	1	0
Lyme disease	3	0
Breast infections		
Mastitis	7	0
Candida infections		
Anal candidiasis	1	0
Balanitis candida	1	0
Candida infection	23	
Oral candidiasis	14	0
Skin candida	1	0
Vulvovaginal candidiasis	15	0
Central nervous system and spinal infections		0
Cavernous sinus thrombosis	2	0
Encephalitis	8	0
Meningitis	8	
Myelitis	4	0
Chlamydial infections		0
Chlamydial infection	1	0
Clostridia infections		_
Clostridium difficile colitis	1	0
Coronavirus infections		0
Asymptomatic COVID-19	3	0
COVID-19	253	
COVID-19 pneumonia Coronavirus infection	14	6
	2	0
Severe acute respiratory syndrome	4	0 0
Suspected COVID-19	20	U
Corynebacteria infections		0
Diphtheria	1	0
Coxiella infections		

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Infections Infections cont'd		
Q fever	77	0
Dental and oral soft tissue infections		
Abscess oral	1	0
Gingival abscess	2	0
Gingivitis	11	0
Lip infection	1	0
Oral pustule	2	0
Parotitis	8	
Pericoronitis	1	l 0
Tongue abscess	3	0
Tooth abscess	3 2	. 0
Tooth infection	4	
Ear infections		
Ear infection	21	0
Labyrinthitis	53	
Mastoiditis	1	1
Otitis externa	1	0
Otitis media	3	_
Ectoparasitic infestations	_	_
Acarodermatitis	1	0
Trombidiasis	1	0
Epstein-Barr viral infections		Ĭ
Epstein-Barr virus infection	1	0
Infectious mononucleosis	25	
Escherichia infections		Ŭ
Escherichia sepsis	1	0
Eye and eyelid infections		Ŭ
Conjunctivitis	36	0
Eye infection	5	
Eyelid boil	1	
Eyelid infection	2	
Hordeolum	12	
Keratouveitis	1	0
Female reproductive tract infections		
Vaginal abscess	1	0
Vaginal infection	1	0
Flaviviral infections		
Yellow fever	1	0
Yellow fever vaccine-associated neurotropic disease	1 1	0
Fungal infections NEC		
Fungal infection	4	l 0
Fungal skin infection	3	
Severe asthma with fungal sensitisation		
Tonsillitis fungal	1	0
Vulvovaginal mycotic infection	2	
Hepatitis viral infections		
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	2	1
Herpes viral infections		
Eczema herpeticum	1	0
Genital herpes	19	1
Genital herpes simplex	1	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Infections Infections cont'd			
Herpes ophthalmic		8	0
Herpes simplex		15	0
Herpes simplex reactivation		2	0
Herpes virus infection		7	0
Herpes zoster		349	0
Herpes zoster oticus		2	0
Nasal herpes		6	0
Ophthalmic herpes zoster		1	0
Oral herpes		347	0
Varicella		9	0
Infections NEC		ŭ	·
Abscess		13	0
Abscess limb		5	0
Catheter site infection		1	0
Coinfection		1	0
Genital abscess		1	0
			_
Infected cyst Infection		106	0 3
		186	
Infection in an immunocompromised host		2	0
Injection site abscess		7	
Injection site infection		7	0
Localised infection		56	0
Lymph gland infection		1	0
Omphalitis		1	0
Pathogen resistance		1	0
Respiratory tract infection		4	0
Toxic shock syndrome		1	0
Vaccination site abscess		2	0
Vaccination site infection		13	0
Vestibulitis		1	0
Infectious transmissions			
Secondary transmission		2	0
Influenza viral infections			
H2N2 influenza		1	0
Influenza		4302	0
Lower respiratory tract and lung infections			
Bronchitis		8	0
Infectious pleural effusion		1	0
Infective exacerbation of bronchiectasis		1	0
Lower respiratory tract infection		83	3
Pneumonia		74	14
Male reproductive tract infections			
Epididymitis		1	0
Orchitis		1	0
Mumps viral infections			
Mumps		2	0
Muscle and soft tissue infections			
Muscle abscess		1	0
Soft tissue infection		3	0
Phleboviral infections			
Severe fever with thrombocytopenia syndro	ome	5	0
Plasmodia infections		, in the second second	
Malaria		1	0

# Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 01-Apr-2021 Data Lock Date: 28-Mar-2021 19:00:03
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Infections Infections cont'd			
Pneumocystis infections			
Pneumocystis jirovecii pneumonia		1	0
Retroviral infections			
Acquired immunodeficiency syndrome		1	0
HIV-associated neurocognitive disorder		1	0
Rubeola viral infections			
Measles		1	0
Salmonella infections			
Typhoid fever		1	0
Sepsis, bacteraemia, viraemia and fungaem	ia NEC		
Neutropenic sepsis		4	0
Sepsis		36	4
Sepsis syndrome		1	0
Septic rash		3	0
Septic shock		1	0
Urosepsis		3	1
Viraemia		3	0
Skin structures and soft tissue infections			
Dermatitis infected		4	0
Folliculitis		3	0
Infected dermal cyst		2	0
Pustule		4	0
Rash pustular		8	0
Skin infection		38	0
Subcutaneous abscess		7	0
Vaccination site pustule		2	0
Staphylococcal infections			
Furuncle		17	0
Staphylococcal scalded skin syndrome		1	0
Staphylococcal sepsis		1	1
Toxic shock syndrome staphylococcal		1	0
Streptococcal infections			
Cellulitis streptococcal		1	0
Erysipelas		1	0
Pharyngitis streptococcal		3	0
Scarlet fever		1	0
Tonsillitis streptococcal		1	0
Tinea infections			
Body tinea		2	0
Tinea cruris		1	0
Tinea infection		1	0
Treponema infections			
Syphilis		1	0
Trypanosomal infections			
African trypanosomiasis		5	0
Tuberculous infections			
Lymph node tuberculosis		3	0
Tuberculosis		3	0
Upper respiratory tract infections			
Acute sinusitis		2	0
Chronic sinusitis		4	0
Epiglottitis		1	0
Laryngitis		12	0

Reaction Name	<u>Total</u>	Fatal
Infections Infections cont'd		
Nasopharyngitis	943	0
Pharyngitis	12	0
Rhinitis	23	
Sinobronchitis	1	0
Sinusitis	116	0
Tonsillitis	33	0
Tracheitis	1	0
Upper respiratory tract infection	2	0
Urinary tract infections		
Cystitis	39	
Kidney infection	19	
Urinary tract infection	85	0
Vascular infections		
Infected lymphocele	1	0
Lymphangitis	3	0
Viral infections NEC		
Arthritis viral	1	0
Encephalitis viral	1	0
Gastroenteritis viral	39	0
Meningitis viral	6	0
Pneumonia viral	4	1
Post viral fatigue syndrome	43	0
Sweating fever	488	0
Vestibular neuronitis	7	0
Viral diarrhoea	3	
Viral infection	17	0
Viral labyrinthitis	2	0
Viral myocarditis	1	0
Viral pharyngitis	14	l 0
Viral rash	31	0
Viral sepsis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	8705	52

# Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 01-Apr-2021 Data Lock Date: 28-Mar-2021 19:00:03
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1		
Reaction Name	<u>Total</u>	Fatal
Injuries		
Abdominal and gastrointestinal injuries NEC		
Abdomen crushing	1	0
Lip injury	1	0
Oral contusion	2	0
Palate injury	1	0
Splenic rupture	1	0
Accidental exposures to product		
Accidental exposure to product	7	0
Anaesthetic and allied procedural complications		
Anaesthetic complication	1	0
Anaesthetic complication neurological	1	0
Delayed recovery from anaesthesia	4	0
Sedation complication	1	0
Atmospheric pressure injuries		Ŭ
Barotrauma	1	0
Hypobarism	2	0
Bone and joint injuries NEC		0
Bursa injury	1	0
Joint injury	3	0
Cardiovascular injuries	J	J
Heart injury	1	0
Vascular injury	2	0
Cerebral injuries NEC		U
Brain contusion	3	0
	3	0
Brain herniation	1	0
Concussion	1	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	2	0
Subdural haemorrhage	ı	0
Chemical injuries Chemical burn of skin	2	0
	2	0
Chemical phlebitis	ı	0
Chest and respiratory tract injuries NEC	2	0
Chest crushing	3	0
Traumatic lung injury	ı	U
Conditions caused by cold Chillblains	27	0
	27	0
Cranial nerve injuries	4	0
Optic nerve injury	I.	0
Exposures associated with pregnancy, delivery and lactation	2	0
Exposure during pregnancy	2	0
Exposure via breast milk	11	0
Foetal exposure during pregnancy	21	0
Maternal exposure during breast feeding	463	0
Maternal exposure during pregnancy	104	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	1	0
Paternal exposure during pregnancy	4	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	0
Eye injuries NEC		
Eye contusion	18	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.	.1	
Reaction Name	<u>Total</u>	<u>Fatal</u>
Injuries Injuries cont'd		
Eye injury	6	0
Foreign body in eye	1	0
Periorbital haematoma	1	0
Periorbital haemorrhage	1	0
Retinal injury	1	0
Superficial injury of eye	1	0
Fractures and dislocations NEC		
Joint dislocation	2	0
Stress fracture	2	0
Gastrointestinal and hepatobiliary procedural complications		
Procedural nausea	21	0
Procedural vomiting	5	0
Heat injuries (excl thermal burns)		
Heat exhaustion	3	0
Heat illness	1	0
Heat oedema	9	0
Heat stroke	4	0
Limb fractures and dislocations		
Ankle fracture	2	0
Clavicle fracture	7	0
Lower limb fracture	1	0
Patella fracture	1	0
Upper limb fracture	1	0
Medication errors, product use errors and issues NEC		
Device use issue	1	0
Intercepted medication error	1	0
Medication error	7	0
Product use issue	1	0
Vaccination error	1	0
Wrong drug	2	0
Wrong technique in product usage process	3	0
Muscle, tendon and ligament injuries		
Epicondylitis	5	0
Ligament rupture	1	0
Ligament sprain	7	0
Muscle injury	8	0
Muscle rupture	6	0
Muscle strain	11	0
Post-traumatic neck syndrome	1	0
Repetitive strain injury	1	0
Tendon injury	1	0
Tendon rupture	4	0
Nerve injuries NEC		
Nerve injury	27	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	6	0
Procedural dizziness	20	0
Non-occupational environmental exposures		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	5	0
Exposure to noise	5 2	0
Non-site specific injuries NEC		
Animal bite	1	0

	IDRA Version: MedDRA 23.1	
Reaction Name	Total	Fatal
Injuries cont'd		
Arthropod bite		3 0
Arthropod sting	8	3 0
Bite	•	1 0
Electric shock	11	1 0
Fall	106	3 1
Inflammation of wound	;	3 0
Injury	•	1 0
Nervous system injury	•	1 0
Post concussion syndrome	•	1 0
Road traffic accident	•	1 0
Tissue injury	•	1 0
Traumatic haematoma	•	1 0
Traumatic shock	•	1 0
Wound	•	1 0
Wound complication	7	7 0
Wound haemorrhage	4	4 0
Non-site specific procedural complications		
Incision site pain	7	7 0
Infusion related reaction	16	0
Injection related reaction	495	5 0
Post procedural complication	26	6 0
Procedural hypertension	•	1 0
Procedural pain		2 0
Procedural site reaction	•	1 0
Suture related complication		1 0
Occupational exposures		
Occupational exposure to product		1 0
Overdoses NEC		
Intentional overdose		1 0
Overdose	10	0 (
Peripheral nerve injuries		
Ulnar nerve injury	•	1 0
Poisoning and toxicity		
Alcohol poisoning		2 0
Chemical poisoning		1 0
Poisoning	2	2 0
Systemic toxicity		1 0
Toxicity to various agents	4	1 0
Product administration errors and issues		
Accidental overdose		2 0
Contraindicated product administered		0
Duplicate therapy error	•	1 0
Expired product administered	9	0 0
Extra dose administered		
Inappropriate schedule of product administration	on 2	0
Incorrect dose administered	•	1 0
Incorrect route of product administration		5 0
Lack of vaccination site rotation		1 0
Product administered at inappropriate site		1 0
Product administered to patient of inappropriate	e age	3 0
Product administration error	_	4 O
Wrong patient received product		1 0
Wrong product administered		4 0

Name: COVID-19 vaccine AstraZeneca analysis print

Date: 01-Apr-2021
Date: 03-Feb-1921
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Date: 03-Feb-1921 Report Run Date: 01-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1		
Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Product confusion errors and issues		
Product label confusion	1	0
Product dispensing errors and issues		
Product dispensing error	5	0
Product monitoring errors and issues		
Product monitoring error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	3	0
Product prescribing error	1	0
Product storage errors and issues in the product use system		
Product storage error	2	0
Radiation injuries		
Sunburn	12	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Reproductive system and breast injuries		
Penile contusion	1	0
Reproductive tract and breast procedural complications		
Postmastectomy lymphoedema syndrome	1	0
Respiratory tract and thoracic cavity procedural complications		
Pulmonary oil microembolism	1	0
Site specific injuries NEC		_
Back injury	5	0
Central nervous system injury	1	0
Face injury	1	0
Head injury	8	0
Limb crushing injury	4	0
Limb injury	54	0
Neck crushing	1	0
Neck injury	2	0
Skin injuries NEC		
Contusion	838	0
Scar	5	0
Skin abrasion	2	0
Skin injury	3	0
Skin laceration	1	0
Skin wound	3	0
Subcutaneous haematoma	1	0
Spinal cord injuries NEC		
Prevertebral soft tissue swelling of cervical space	1	0
Spinal cord injury sacral	1	0
Spinal fractures and dislocations		
Spinal compression fracture	1	0
Spinal fracture	1	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Thermal burns		
Airway burns	1	0
Burn of internal organs	3	0
Burn oral cavity		0
	2	0
	2	0
	27	0
Burns second degree Cold burn Thermal burn	3 2 2 27	

Reaction Name	Total	Fatal
Injuries cont'd		
Thermal burns of eye	29	0
Underdoses NEC		
Intentional underdose	1	0
Underdose	2	0
Vaccination related complications		
Adverse event following immunisation	1	0
Vaccination complication	60	0
Vaccination failure	6	0
Injuries SOC TOTAL	2758	1

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	<u> Fatal</u>
Investigations		
Adrenal cortex tests		
Blood cortisol		1 0
Cortisol decreased		1 0
Cortisol increased		1 0
Adrenal medulla tests		
Norepinephrine increased		2 0
Auditory function diagnostic procedures		
Acoustic stimulation tests		1 0
Autoimmunity analyses		
Antiphospholipid antibodies positive		1 0
Cold agglutinins positive		1 0
DNA antibody positive		1 0
Blood counts NEC		
Blood count		2 0
Full blood count		2 0
Full blood count decreased		1 0
Blood gas and acid base analyses		
Blood gases		1 0
Blood lactic acid		1 0
Blood pH		9 0
Blood pH increased		5 0
Oxygen consumption		1 0
Oxygen saturation	1	6 0
Oxygen saturation decreased	11	3 0
Blood grouping and cross-matching analyse	s	
Blood group O		1 0
Bone marrow and immune tissue imaging pr	ocedures	
Scan lymph nodes		1 0
Carbohydrate tolerance analyses (incl diabe	tes)	
Blood glucose	1	6 0
Blood glucose abnormal		9 0
Blood glucose decreased	2	7 0
Blood glucose fluctuation	1	
Blood glucose increased	12	7 0
Glycosylated haemoglobin increased		2 0
Cardiac auscultatory investigations		
Cardiac murmur		8 0
Heart sounds	1	1 0
Heart sounds abnormal		3 0
Cardiac function diagnostic procedures		
Cardiac monitoring		1 0
Echocardiogram		1 0
Myocardial strain		1 0
Cardiac imaging procedures		
Magnetic resonance imaging heart		1 0
Central nervous system imaging procedures		
Computerised tomogram head		2 0
Magnetic resonance imaging brain	3	5 0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure		1 0
Chemistry analyses NEC		
Histamine abnormal		1 0
Histamine level increased		1 0

Name: COVID-19 vaccine AstraZeneca analysis print

Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03 Report Run Date: 01-Apr-2021

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name	Tota	<u>al</u>	Fatal
Investigations Investigations cont'd			
Inflammatory marker decreased		1	0
Inflammatory marker increased		2	0
Cholesterol analyses			
Blood cholesterol increased		1	0
Very low density lipoprotein decreased		1	0
Coagulation and bleeding analyses			
Bleeding time abnormal		1	0
Blood fibrinogen		1	0
Blood fibrinogen decreased		1	0
Coagulation time		3	0
Coagulation time prolonged			0
Coagulation time shortened		2	0
Fibrin D dimer increased		5	0
International normalised ratio		1	0
International normalised ratio abnormal		2	0
International normalised ratio decreased		22	0
International normalised ratio increased		35	0
Prothrombin time prolonged		1	0
ECG investigations			
Electrocardiogram T wave inversion		1	0
Electrocardiogram abnormal		5	0
Electrocardiogram change		1	0
Endocrine analyses and imaging NEC			
Hormone level abnormal		3	0
Faecal analyses NEC			
Faecal calprotectin increased		4	0
Fertility analyses			
Semen volume decreased		1	0
Foetal and neonatal diagnostic procedures			
Foetal heart rate		1	0
Gastrointestinal and abdominal imaging proc	edures		
Computerised tomogram abdomen		2	0
Gastrointestinal function diagnostic procedure	es		
Gastrointestinal stoma output increased		1	0
Swallow study		1	0
Gastrointestinal, pancreatic and APUD horme	one analyses		
Blood gastrin		1	0
Blood gastrin normal		1	0
Blood insulin		4	0
Blood insulin decreased		2	0
Blood insulin increased		2	0
Haematological analyses NEC			
Blood viscosity increased		1	0
Red blood cell sedimentation rate increased	d	1	0
Heart rate and pulse investigations			
Brachial pulse decreased		1	0
Heart rate		13	0
Heart rate abnormal		24	0
Heart rate decreased		47	0
Heart rate increased		81	0
Heart rate irregular		86	0
Maximum heart rate		4	0
Maximum heart rate decreased		1	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Investigations Investigations cont'd			
Orthostatic heart rate response increased		1	0
Pulse abnormal		14	0
Pulse absent		3	0
Pulse waveform abnormal		1	0
Sinus rhythm		3	0
Imaging procedures NEC			
Computerised tomogram		2	0
Scan		1	0
Immunoglobulin analyses			
Blood immunoglobulin E increased		2	0
Immunology analyses NEC			
Antibody test negative		1	0
Immunology test		2	0
Immunology test normal		1	0
Mast cell degranulation present		1	0
Immunology skin tests NEC			
Allergy alert test		1	0
Skin test positive		1	0
Investigations NEC			
Blood test		14	0
Blood test abnormal		8	0
Investigation		1	0
Polymerase chain reaction positive		1	0
Liver function analyses			
Alanine aminotransferase increased		4	0
Aspartate aminotransferase increased		2	0
Bile output		3	0
Blood bilirubin		1	0
Blood bilirubin increased		1	0
Gamma-glutamyltransferase increased		2	0
Hepatic enzyme increased		1	0
Liver function test		2	0
Liver function test abnormal		11	0
Transaminases increased		3	0
Metabolism tests NEC			
Blood ketone body		9	0
Ubiquinone		2	0
Microbiology and serology tests NEC			
Blood culture		1	0
Mineral and electrolyte analyses			
Blood iron		1	0
Blood iron decreased		2	0
Blood phosphorus decreased		1	0
Blood phosphorus increased		1	0
Blood potassium decreased		3	0
Blood potassium increased		3 2	0
Blood sodium		2 2	0
Blood sodium decreased		2	0
Sweat test		1	0
Urine copper		1	0
Musculoskeletal and soft tissue imaging prod	cedures		
Skull X-ray		1	0
Musculoskeletal and soft tissue tests NEC			

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		<u> Total</u>	<u>Fatal</u>
Investigations Investigations cont'd			
Swollen joint count		1	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			
Coma scale abnormal		1	0
Lumbar puncture		6	0
Ophthalmic function diagnostic procedures			
Corneal reflex decreased		1	0
Intraocular pressure increased		1	0
Intraocular pressure test		3	0
Visual tracking test		1	0
Physical examination procedures and organ	system status		
Body surface area		1	0
Body temperature		693	0
Body temperature abnormal		47	0
Body temperature decreased		77	0
Body temperature fluctuation		109	0
Body temperature increased		777	0
Breath sounds abnormal		3	0
Dermatologic examination abnormal		1	0
Grip strength		2	0
Grip strength decreased		17	0
Head lag		6	0
Lymph node palpable		2	0
Male genital examination abnormal		1	0
Menstruation normal		1	0
Muscle strength abnormal		1	0
Neurological examination		1	0
Psoriasis area severity index decreased		1	0
Respiratory rate		7	0
Respiratory rate decreased		12	0
Respiratory rate increased		43	0
Skin temperature		124	0
Temperature difference of extremities		3	0
Urological examination		1	0
Weight decreased		65	0
Weight increased		7	0
Pituitary analyses anterior			
Blood corticotrophin		1	0
Blood thyroid stimulating hormone decreas	sed	1	0
Blood thyroid stimulating hormone increase		4	0
Platelet analyses			
Platelet count		1	0
Platelet count decreased		42	0
Platelet count increased		2	0
Protein analyses NEC			
C-reactive protein abnormal		2	0
C-reactive protein increased		3	0
Red blood cell analyses			
Haematocrit		2	0
Haemoglobin		2 3	0

Investigations   Investigations cont'd   Haemoglobin decreased   2	Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Haemoglobin decreased   2   0   Mean cell volume abnormal   1   0   0   0   0   0   0   0   0   0	Reaction Name	To	<u>otal</u>	<u>Fatal</u>
Mean cell volume abnormal   1	Investigations Investigations cont'd			
Real blood cell count   Renal function analyses   Blood creatine increased   1   0   0   0   0   0   0   0   0   0			2	0
Renal function analyses   Blood creatinine increased   1   0   0   0   0   0   0   0   0   0			1	0
Blood creatinine increased   1	Red blood cell count		1	0
Blood creatinine abnormal   1				
Blood creatinine decreased   1			1	0
Blood creatinine increased   1	Blood creatinine abnormal		1	0
Blood urea increased   Reproductive hormone analyses   Pregnancy test   Pregnancy test	Blood creatinine decreased		1	0
Reproductive hormone analyses   Pregnancy test   2 0 0   Pregnancy test negative   1 0 0   Respiratory and pulmonary function diagnostic procedures   Forced expiratory volume   2 0 0   Forced expiratory volume horceased   1 0 0   Forced expiratory volume increased   7 0 0   Forced expiratory volume normal   1 0 0   Maximal voluntary ventilation   1 0 0   Peak expiratory flow rate   1 0 0   Peak expiratory flow rate   1 0 0   Peak expiratory flow rate decreased   4 0 0   Pulmonary function test decreased   1 0 0   Respiratory tract and thoracic histopathology procedures   1 0 0   Sputum abnormal   1 0 0   Respiratory tract and thoracic imaging procedures   2 0 0   Chest X-ray   4 0 0   Computerised tomogram thorax   2 0 0   Laryngoscopy   1 0 0   Skeletal and cardiac muscle analyses   1 0 0   Blood creatine phosphokinase increased   1 0 0   Myocardial necrosis marker   1 0 0   Myocardial necrosis marker   1 0 0   Myocardial necrosis marker   1 0 0   Analgesic drug level increased   1 0 0   Analgesic drug level therapeutic   1 0 0   Thyroxine   1 0 0   Thyroxine   1 0 0   Thyroxine abnormal   1 0 0   Tri-iodothyronine decreased   2 0 0   Thyroxine abnormal   1 0 0   Tri-iodothyronine decreased   1 0 0   Thyroxine abnormal   1 0 0   Tri-iodothyronine decreased   1 0 0   Tokaciology laboratory analyses   1 0 0   Blood leavy metal test   0 0 0   Blood heavy metal test   1 0 0 0   Blood heavy metal test   1 0 0 0			1	0
Pregnancy test negative   Respiratory and pulmonary function diagnostic procedures   Forced expiratory volume   Forced expiratory volume decreased   1	Blood urea increased		1	0
Pregnancy test negative  Respiratory and pulmonary function diagnostic procedures  Forced expiratory volume Forced expiratory volume decreased Forced expiratory volume increased Forced expiratory volume increased Forced expiratory volume normal Maximal voluntary ventilation Peak expiratory flow rate Peak expiratory flow rate Peak expiratory flow rate Peak expiratory flow rate Pulmonary function test 1 0 Respiratory tract and thoracic instepathology procedures Sputum abnormal Respiratory tract and thoracic imaging procedures Chest X-ray Computerised tomogram thorax Laryngoscopy Skeletal and cardiac muscle analyses Blood creatine phosphokinase increased Myocardial necrosis marker 1 0 Analgesic drug level therapeutic Anticoagulation drug level above therapeutic 3 0 Analgesic drug level therapeutic Anticoagulation drug level above therapeutic Thyroxine 1 0 Thyroxine 1 0 Thyroxine 1 0 Thyroxine abnormal Tri-iodothyronine decreased Trisue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test 1 0 Blood heavy metal test 1 0 Blood heavy metal test	Reproductive hormone analyses			
Respiratory and pulmonary function diagnostic procedures	Pregnancy test		2	0
Forced expiratory volume	Pregnancy test negative		1	0
Forced expiratory volume decreased   1   0	Respiratory and pulmonary function diagno	stic procedures		
Forced expiratory volume increased   7   0	Forced expiratory volume		2	0
Forced expiratory volume normal   1	Forced expiratory volume decreased		1	0
Maximal voluntary ventilation         1         0           Peak expiratory flow rate         1         0           Peak expiratory flow rate decreased         4         0           Pulmonary function test         1         0           Pulmonary function test decreased         1         0           Slow vital capacity         1         0           Total lung capacity decreased         1         0           Respiratory tract and thoracic histopathology procedures         1         0           Sputum abnormal         1         0           Respiratory tract and thoracic imaging procedures         1         0           Chest X-ray         4         0           Computerised tomogram thorax         2         0           Laryngoscopy         1         0           Skeletal and cardiac muscle analyses         2         0           Blood creatine phosphokinase increased         1         0           Myocardial necrosis marker         1         0           Myocardial necrosis marker increased         1         0           Troponin T         1         0           Therapeutic drug monitoring analyses         1         0           Analgesic drug level         1	Forced expiratory volume increased		7	0
Peak expiratory flow rate   1	Forced expiratory volume normal		1	0
Peak expiratory flow rate decreased Pulmonary function test Pulmonary function test Pulmonary function test decreased Slow vital capacity Total lung capacity decreased Respiratory tract and thoracic histopathology procedures Sputum abnormal Respiratory tract and thoracic imaging procedures Chest X-ray Computerised tomogram thorax Laryngoscopy Skeletal and cardiac muscle analyses Blood creatine phosphokinase increased Myocardial necrosis marker Myocardial necrosis marker Myocardial necrosis marker increased Troponin T Therapeutic drug monitoring analyses Analgesic drug level Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic Anticoagulation drug level above therapeutic Thyroid analyses Thyroxine Thyroxine Tri-iodothyronine decreased Trisue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased 1 0 Blood heavy metal test 1 0 Blood heavy metal test	Maximal voluntary ventilation		1	0
Pulmonary function test Pulmonary function test decreased Slow vital capacity Total lung capacity decreased Respiratory tract and thoracic histopathology procedures Sputum abnormal Respiratory tract and thoracic imaging procedures Chest X-ray Computerised tomogram thorax Laryngoscopy Skeletal and cardiac muscle analyses Blood creatine phosphokinase increased Myocardial necrosis marker Myocardial necrosis marker increased Troponin T Therapeutic drug monitoring analyses Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic Anticoagulation drug level above therapeutic Thyroxine Thyroxine Thyroxine Thyroxine abnormal Tri-iodothyronine decreased Troxicology laboratory analyses Blood carbon monoxide increased Toxicology laboratory analyses Blood carbon monoxide increased Toxicology laboratory analyses Blood carbon monoxide increased Toxicology laboratory analyses Blood carbon monoxide increased 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0	Peak expiratory flow rate		1	0
Pulmonary function test decreased Slow vital capacity Total lung capacity decreased Respiratory tract and thoracic histopathology procedures Sputum abnormal Respiratory tract and thoracic imaging procedures Chest X-ray Computerised tomogram thorax Laryngoscopy Skeletal and cardiac muscle analyses Blood creatine phosphokinase increased Myocardial necrosis marker Myocardial necrosis marker increased Troponin T Therapeutic drug monitoring analyses Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic Anticoagulation drug level below therapeutic Thyroxine Thyroxine Thyroxine abnormal Tri-iodothyronine decreased Trisue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Toxicology laboratory analyses Blood carbon monoxide increased Toxicology laboratory analyses Blood carbon monoxide increased Toxicology metal test	Peak expiratory flow rate decreased		4	0
Slow vital capacity Total lung capacity decreased  Respiratory tract and thoracic histopathology procedures  Sputum abnormal  Respiratory tract and thoracic imaging procedures  Chest X-ray Computerised tomogram thorax Laryngoscopy  Skeletal and cardiac muscle analyses  Blood creatine phosphokinase increased Myocardial necrosis marker Myocardial necrosis marker 1 0 Myocardial necrosis marker 1 0 Therapeutic drug monitoring analyses  Analgesic drug level Analgesic drug level therapeutic Anticoagulation drug level above therapeutic Anticoagulation drug level below therapeutic Anticoagulation drug level below therapeutic Thyroxine Thyroxine Thyroxine Tri-iodothyronine decreased Trisue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase 1 0 Toxicology laboratory analyses Blood carbon monoxide increased 1 0 Blood heavy metal test 1 0	Pulmonary function test		1	0
Total lung capacity decreased  Respiratory tract and thoracic histopathology procedures  Sputum abnormal  Respiratory tract and thoracic imaging procedures  Chest X-ray  Computerised tomogram thorax  Laryngoscopy  Skeletal and cardiac muscle analyses  Blood creatine phosphokinase increased  Myocardial necrosis marker  Myocardial necrosis marker increased  Troponin T  Therapeutic drug monitoring analyses  Analgesic drug level  Analgesic drug level increased  Analgesic drug level therapeutic  Anticoagulation drug level above therapeutic  Anticoagulation drug level below therapeutic  Anticoagulation drug level below therapeutic  Thyroid analyses  Thyroxine  Thyroxine abnormal  Tri-iodothyronine decreased  Tissue enzyme analyses NEC  Blood lactate dehydrogenase urine increased  Toxicology laboratory analyses  Blood carbon monoxide increased  1 00  Toxicology laboratory analyses  Blood carbon monoxide increased  1 00  Blood heavy metal test	Pulmonary function test decreased		1	0
Respiratory tract and thoracic histopathology procedures Sputum abnormal Respiratory tract and thoracic imaging procedures Chest X-ray Computerised tomogram thorax Laryngoscopy 1 0 Skeletal and cardiac muscle analyses Blood creatine phosphokinase increased Myocardial necrosis marker Myocardial necrosis marker Myocardial necrosis marker increased Troponin T Therapeutic drug monitoring analyses Analgesic drug level Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic Anticoagulation drug level below therapeutic Thyroid analyses Thyroxine Thyroxine Thyroxine Thyroxine abnormal Tri-iodothyronine decreased Tissue enzyme analyses NEC Blood lactate dehydrogenase Blood carbon monoxide increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test	Slow vital capacity		1	0
Sputum abnormal  Respiratory tract and thoracic imaging procedures Chest X-ray Computerised tomogram thorax Laryngoscopy Skeletal and cardiac muscle analyses Blood creatine phosphokinase increased Myocardial necrosis marker Myocardial necrosis marker Myocardial necrosis marker increased Troponin T Therapeutic drug monitoring analyses Analgesic drug level Analgesic drug level increased Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic 3 0 Anticoagulation drug level below therapeutic 2 0 Thyroid analyses Thyroxine Thyroxine Thyroxine abnormal Tri-iodothyronine decreased Tissue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test			1	0
Sputum abnormal  Respiratory tract and thoracic imaging procedures Chest X-ray Computerised tomogram thorax Laryngoscopy Skeletal and cardiac muscle analyses Blood creatine phosphokinase increased Myocardial necrosis marker Myocardial necrosis marker Myocardial necrosis marker increased Troponin T Therapeutic drug monitoring analyses Analgesic drug level Analgesic drug level increased Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic 3 0 Anticoagulation drug level below therapeutic 2 0 Thyroid analyses Thyroxine Thyroxine Thyroxine abnormal Tri-iodothyronine decreased Tissue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test	Respiratory tract and thoracic histopatholog	y procedures		
Chest X-ray Computerised tomogram thorax Laryngoscopy Skeletal and cardiac muscle analyses Blood creatine phosphokinase increased Myocardial necrosis marker Myocardial necrosis marker Myocardial necrosis marker increased Troponin T Therapeutic drug monitoring analyses Analgesic drug level Analgesic drug level increased Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic 3 00 Anticoagulation drug level below therapeutic Anticoagulation drug level below therapeutic 2 00 Thyroid analyses Thyroxine Thyroxine 1 0 Tri-iodothyronine decreased Trissue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Troxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test 1 00			1	0
Chest X-ray Computerised tomogram thorax Laryngoscopy Skeletal and cardiac muscle analyses Blood creatine phosphokinase increased Myocardial necrosis marker Myocardial necrosis marker Myocardial necrosis marker increased Troponin T Therapeutic drug monitoring analyses Analgesic drug level Analgesic drug level increased Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic 3 00 Anticoagulation drug level below therapeutic Anticoagulation drug level below therapeutic 2 00 Thyroid analyses Thyroxine Thyroxine 1 0 Tri-iodothyronine decreased Trissue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Troxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test 1 00	Respiratory tract and thoracic imaging proc	edures		
Laryngoscopy  Skeletal and cardiac muscle analyses  Blood creatine phosphokinase increased  Myocardial necrosis marker  Myocardial necrosis marker increased  Troponin T  Therapeutic drug monitoring analyses  Analgesic drug level  Analgesic drug level increased  Analgesic drug level therapeutic  Anticoagulation drug level above therapeutic  Anticoagulation drug level below therapeutic  Anticoagulation drug level below therapeutic  Thyroid analyses  Thyroxine  Thyroxine  Thyroxine abnormal  Tri-iodothyronine decreased  Trisue enzyme analyses NEC  Blood lactate dehydrogenase  Lactate dehydrogenase urine increased  Toxicology laboratory analyses  Blood carbon monoxide increased  Blood heavy metal test			4	0
Laryngoscopy  Skeletal and cardiac muscle analyses  Blood creatine phosphokinase increased  Myocardial necrosis marker  Myocardial necrosis marker increased  Troponin T  Therapeutic drug monitoring analyses  Analgesic drug level  Analgesic drug level increased  Analgesic drug level therapeutic  Anticoagulation drug level above therapeutic  Anticoagulation drug level below therapeutic  Anticoagulation drug level below therapeutic  Thyroid analyses  Thyroxine  Thyroxine  Thyroxine abnormal  Tri-iodothyronine decreased  Trisue enzyme analyses NEC  Blood lactate dehydrogenase  Lactate dehydrogenase urine increased  Toxicology laboratory analyses  Blood carbon monoxide increased  Blood heavy metal test			2	0
Blood creatine phosphokinase increased Myocardial necrosis marker Myocardial necrosis marker Myocardial necrosis marker increased Troponin T  Therapeutic drug monitoring analyses Analgesic drug level Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic Anticoagulation drug level below therapeutic Anticoagulation drug level below therapeutic Thyroid analyses Thyroxine Thyroxine Thyroxine abnormal Tri-iodothyronine decreased Trisue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test			1	0
Myocardial necrosis marker  Myocardial necrosis marker increased  Troponin T  Therapeutic drug monitoring analyses  Analgesic drug level  Analgesic drug level increased  Analgesic drug level therapeutic  Anticoagulation drug level above therapeutic  Anticoagulation drug level below therapeutic  2  Thyroid analyses  Thyroxine  Thyroxine abnormal  Tri-iodothyronine decreased  Tissue enzyme analyses NEC  Blood lactate dehydrogenase  Lactate dehydrogenase urine increased  Toxicology laboratory analyses  Blood carbon monoxide increased  Blood heavy metal test	Skeletal and cardiac muscle analyses			
Myocardial necrosis marker  Myocardial necrosis marker increased  Troponin T  Therapeutic drug monitoring analyses  Analgesic drug level  Analgesic drug level increased  Analgesic drug level therapeutic  Anticoagulation drug level above therapeutic  Anticoagulation drug level below therapeutic  2  Thyroid analyses  Thyroxine  Thyroxine abnormal  Tri-iodothyronine decreased  Tissue enzyme analyses NEC  Blood lactate dehydrogenase  Lactate dehydrogenase urine increased  Toxicology laboratory analyses  Blood carbon monoxide increased  Blood heavy metal test			1	0
Myocardial necrosis marker increased Troponin T  Therapeutic drug monitoring analyses  Analgesic drug level Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic Anticoagulation drug level below therapeutic Anticoagulation drug level below therapeutic  Thyroid analyses Thyroxine Thyroxine Thyroxine abnormal Tri-iodothyronine decreased Tissue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test  1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1			1	0
Therapeutic drug monitoring analyses  Analgesic drug level Analgesic drug level increased Analgesic drug level therapeutic Analgesic drug level therapeutic Anticoagulation drug level above therapeutic Anticoagulation drug level below therapeutic Thyroid analyses Thyroxine Thyroxine Thyroxine abnormal Tri-iodothyronine decreased Trisue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test  1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Myocardial necrosis marker increased		1	0
Analgesic drug level 12 0 Analgesic drug level increased 1 0 Analgesic drug level therapeutic 1 0 Anticoagulation drug level above therapeutic 3 0 Anticoagulation drug level below therapeutic 2 0 Thyroid analyses Thyroxine 1 0 Thyroxine abnormal 1 0 Tri-iodothyronine decreased 2 0 Tissue enzyme analyses NEC Blood lactate dehydrogenase 1 0 Lactate dehydrogenase urine increased 1 0 Toxicology laboratory analyses Blood carbon monoxide increased 1 0 Blood heavy metal test 1 0	Troponin T		1	0
Analgesic drug level 12 0 Analgesic drug level increased 1 0 Analgesic drug level therapeutic 1 0 Anticoagulation drug level above therapeutic 3 0 Anticoagulation drug level below therapeutic 2 0 Thyroid analyses Thyroxine 1 0 Thyroxine abnormal 1 0 Tri-iodothyronine decreased 2 0 Tissue enzyme analyses NEC Blood lactate dehydrogenase 1 0 Lactate dehydrogenase urine increased 1 0 Toxicology laboratory analyses Blood carbon monoxide increased 1 0 Blood heavy metal test 1 0				
Analgesic drug level increased Analgesic drug level therapeutic Anticoagulation drug level above therapeutic Anticoagulation drug level below therapeutic  Thyroid analyses Thyroxine Thyroxine abnormal Tri-iodothyronine decreased Tissue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test  1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1			12	0
Anticoagulation drug level above therapeutic Anticoagulation drug level below therapeutic  Thyroid analyses Thyroxine Thyroxine abnormal Tri-iodothyronine decreased Tissue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test  3 0 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0	Analgesic drug level increased		1	0
Anticoagulation drug level below therapeutic  Thyroid analyses Thyroxine Thyroxine abnormal Tri-iodothyronine decreased  Tissue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased  Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test  2 0  1 0  0  1 0  1 0  1 0  1 0  1 0	Analgesic drug level therapeutic		1	0
Thyroid analyses Thyroxine Thyroxine abnormal Thyroxine abnormal Tri-iodothyronine decreased 2 0 Tissue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test  1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1	Anticoagulation drug level above therape	utic	3	0
Thyroid analyses Thyroxine Thyroxine abnormal Thyroxine abnormal Tri-iodothyronine decreased 2 0 Tissue enzyme analyses NEC Blood lactate dehydrogenase Lactate dehydrogenase urine increased Toxicology laboratory analyses Blood carbon monoxide increased Blood heavy metal test  1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1	Anticoagulation drug level below therapeu	ıtic	2	0
Thyroxine 1 0 Thyroxine abnormal 1 0 Tri-iodothyronine decreased 2 0  Tissue enzyme analyses NEC Blood lactate dehydrogenase 1 0 Lactate dehydrogenase urine increased 1 0  Toxicology laboratory analyses Blood carbon monoxide increased 1 0 Blood heavy metal test 1 0				
Tri-iodothyronine decreased  Tissue enzyme analyses NEC  Blood lactate dehydrogenase Lactate dehydrogenase urine increased  Toxicology laboratory analyses  Blood carbon monoxide increased  Blood heavy metal test  2 0 7 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0			1	0
Tissue enzyme analyses NEC  Blood lactate dehydrogenase Lactate dehydrogenase urine increased  Toxicology laboratory analyses  Blood carbon monoxide increased  Blood heavy metal test  1 0	Thyroxine abnormal		1	0
Tissue enzyme analyses NEC  Blood lactate dehydrogenase Lactate dehydrogenase urine increased  Toxicology laboratory analyses  Blood carbon monoxide increased  Blood heavy metal test  1 0			2	0
Blood lactate dehydrogenase 1 0 Lactate dehydrogenase urine increased 1 0  Toxicology laboratory analyses Blood carbon monoxide increased 1 0 Blood heavy metal test 1 0				
Lactate dehydrogenase urine increased 1 0  Toxicology laboratory analyses  Blood carbon monoxide increased 1 0  Blood heavy metal test 1 0			1	0
Toxicology laboratory analysesBlood carbon monoxide increased10Blood heavy metal test10			1	0
Blood carbon monoxide increased 1 0 Blood heavy metal test 1 0				
Blood heavy metal test 1 0			1	0
			1	_
			1	0
Urinalysis NEC			'	

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		<u> Total</u>	<u>Fatal</u>
Investigations Investigations cont'd			
Blood urine		12	0
Blood urine present		22	0
Cells in urine		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		8	0
Urine analysis normal		1	0
pH urine		8	0
pH urine decreased		1	0
pH urine increased		2	0
Urinary tract function analyses NEC			
Urine output		30	0
Urine output decreased		9	0
Urine output increased		6	0
Vascular auscultatory investigations			
Abdominal bruit		1	0
Vascular tests NEC (incl blood pressure)			
Blood pressure abnormal		1	0
Blood pressure decreased		39	0
Blood pressure diastolic increased		2	0
Blood pressure increased		143	0
Blood pressure measurement		40	0
Blood pressure normal		1	0
Blood pressure systolic increased		2	0
Capillary nail refill test		1	0
Virus identification and serology			
Coronavirus test		23	0
HIV antibody negative		1	0
Herpes virus test		1	0
SARS-CoV-2 antibody test		2	0
SARS-CoV-2 antibody test negative		2 8	0
SARS-CoV-2 antibody test positive		1	0
SARS-CoV-2 test		16	0
SARS-CoV-2 test false negative		1	0
SARS-CoV-2 test false positive		1	0
SARS-CoV-2 test negative		10	0
SARS-CoV-2 test positive		45	0
Viral test		2	0
Vitamin analyses			
Blood folate		1	0
Vitamin B12 decreased		1	0
Water and electrolyte analyses NEC			
Blood osmolarity		1	0
Volume blood		2	0
White blood cell analyses			
Eosinophil count increased		1	0
Lymphocyte count		1	0
Lymphocyte count decreased		1	0
Neutrophil count			0
Neutrophil count decreased		2 5 8	0
White blood cell count		8	0

Name: COVID-19 vaccine AstraZeneca analysis print

Date: 01-Apr-2021 Data Lock Date: 28-Mar-2021 19:00:03
action Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1 Report Run Date: 01-Apr-2021 Earliest Reaction Date: 03-Feb-1921

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
White blood cell count decreased	8	0
White blood cell count increased	3	0
Investigations SOC TOTAL	5251	0

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Earliest Reaction Date: 03-Feb-1921 Med	DRA Version: MedDRA 23.1	
Reaction Name	<u>Total</u>	Fatal
Metabolic disorders		
Appetite disorders		
Appetite disorder	24	1 0
Decreased appetite	4292	<u>2</u> 0
Diet refusal		2 0
Food craving	10	
Food refusal	26	
Hyperphagia	Ę	
Hypophagia	17	
Increased appetite	27	
Salt craving		
Calcium metabolism disorders	_	
Hypocalcaemia	3	3 0
Tetany		íl ő
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	36	6 0
Diabetes mellitus inadequate control	2	
Increased insulin requirement		
Type 1 diabetes mellitus	1.	
Type 2 diabetes mellitus		0
Diabetic complications NEC	44	
Diabetic ketoacidosis	15	
Diabetic ketosis	4	
Euglycaemic diabetic ketoacidosis		0
Disorders of purine metabolism		
Gout	4	0
Electrolyte imbalance NEC		
Electrolyte imbalance	· ·	0
Hyperosmolar state	ŕ	1
Fluid intake decreased		
Fluid intake reduced	7	0
Fluid intake increased		
Polydipsia	10	0
Food malabsorption and intolerance syndromes		
Alcohol intolerance	2	2 0
Food intolerance		
Gluten sensitivity	•	0
Histamine intolerance	2	2 0
General nutritional disorders NEC		
Abnormal loss of weight	19	
Abnormal weight gain	6	6 0
Cachexia	•	1 0
Feeding disorder	94	1 0
Food aversion	36	
Neonatal insufficient breast milk syndrome	2	2 0
Poor feeding infant		6 0
Starvation		ı  o
Underweight		ı  o
Hyperglycaemic conditions NEC		
Glucose tolerance impaired		ıl o
Hyperglycaemia	94	
Insulin resistance		
Metabolic syndrome		
Hyperlipidaemias NEC		
- 1.7 politipidadimad ITEO		

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd	lotai	i atai
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC	·	
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	63	0
Hypoglycaemia unawareness	2	0
Postprandial hypoglycaemia	1	0
Iron deficiencies		J
Iron deficiency	1	0
Lipid metabolism and deposit disorders NEC		J
Lipoedema	1	0
Magnesium metabolism disorders		J
Hypomagnesaemia	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	1	0
Ketosis	1	0
Lactic acidosis	1	0
Metabolic acidosis	2	0
Mixed acid-base disorders		
Acidosis	1	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Potassium imbalance		
Hyperkalaemia	2	0
Hypokalaemia	2	0
Protein metabolism disorders NEC		
Hypoalbuminaemia	1	0
Sodium imbalance		
Hypernatraemia	1	0
Hyponatraemia	9	0
Hyponatraemic syndrome	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	2	0
Total fluid volume decreased		
Dehydration	382	0
Hypovolaemia	1	0
Total fluid volume increased		
Fluid overload	3	0
Fluid retention	32	0
Water soluble vitamin deficiencies		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	5353	3

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	<u> Fatal</u>
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	141	0
Arthropathy	8	0
Autoimmune arthritis	1	0
Haemarthrosis	1	0
Palindromic rheumatism	2	2 0
Polyarthritis	5	0
Rheumatic fever	1	0
Sacroiliitis	3	0
Bone disorders NEC		
Bone loss	1	0
Jaw disorder	3	0
Medial tibial stress syndrome	6	0
Osteitis	3	0
Osteonecrosis of jaw	2	2 0
Bone related signs and symptoms		
Bone pain	612	2 0
Coccydynia	2	2 0
Pain in jaw	304	. 0
Spinal pain	123	0
Bursal disorders		
Bursitis	33	0
Cartilage disorders		
Chondritis	1	0
Chondropathy	1	0
Costochondritis	13	0
Connective tissue disorders NEC		
Connective tissue disorder	1	0
Mixed connective tissue disease	1	0
Morphoea	1	0
Polymyalgia rheumatica	23	0
Reynold's syndrome	3	
Scleroderma	1	0
Epiphyseal disorders		
Epiphyses premature fusion	1	0
Extremity deformities		
Finger deformity	1	0
Hand deformity	1	0
Limb deformity	2	2 0
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	1	0
Joint related disorders NEC		
Joint laxity	3	0
Joint lock	21	
Patellofemoral pain syndrome	1	0
Periarthritis	76	0
Rotator cuff syndrome	16	
Temporomandibular joint syndrome		
Joint related signs and symptoms		
Arthralgia	13513	0
Jaw clicking	3	_
Joint effusion		Ö
Joint noise	12	_

Reaction Name	<u>1</u>
Joint stiffness   212     Joint swelling   254     Joint swelling   254     Joint vibration   1     Joint warmth   14     Loose body in joint   1     Ligament disorders     Ligament pain   1     Lupus erythematosus (incl subtypes)     Lupus-like syndrome   1     Systemic lupus erythematosus   12     Metabolic bone disorders   1     Osteopenia   1     Osteopenia   1     Osteopenosis   4     Muscle infections and inflammations     Myositis   7     Polymyositis   1     Muscle pains     Fibromyalgia   133     Myalgia   17544     Myofascial pain syndrome   9     Muscle atrophy   2     Muscle discomfort   6     Muscle discomfort   6     Muscle discomfort   6     Muscle fatigue   539     Muscle haemorrhage   1     Muscle mass   3     Muscle syasms   1291     Muscle syasms   1291     Muscle syaling   14     Muscle tightness   77     Muscle tothe abnormalities     Muscle rigidity   26	
Joint swelling	
Joint vibration	0
Joint warmth	0
Loose body in joint         1           Ligament disorders         1           Ligament pain         1           Lupus erythematosus (incl subtypes)         1           Lupus-like syndrome         1           Systemic lupus erythematosus         12           Metabolic bone disorders         1           Osteopenia         1           Osteoporosis         4           Muscle infections and inflammations         4           Myositis         7           Polymyositis         1           Muscle pains         1           Fibromyalgia         133           Myalgia         17544           Myofascial pain syndrome         9           Muscle related signs and symptoms NEC         9           Muscle atrophy         2           Muscle discomfort         6           Muscle fatigue         539           Muscle haemorrhage         1           Muscle mass         3           Muscle spasms         1291           Muscle spasms         1291           Muscle tightness         77           Muscle tone abnormalities         195           Muscle rigidity         26	0
Ligament disorders         1           Lupus erythematosus (incl subtypes)         1           Lupus-like syndrome         1           Systemic lupus erythematosus         12           Metabolic bone disorders         1           Osteopenia         1           Osteoporosis         4           Muscle infections and inflammations         7           Myositis         7           Polymyositis         1           Muscle pains         1           Fibromyalgia         133           Myalgia         17544           Myofascial pain syndrome         9           Muscle related signs and symptoms NEC         2           Muscle discomfort         6           Muscle discomfort         6           Muscle fatigue         539           Muscle haemorrhage         1           Muscle nass         3           Muscle oedema         2           Muscle syelling         14           Muscle tightness         77           Muscle tone abnormalities         79           Muscle rigidity         26	0
Ligament pain  Lupus erythematosus (incl subtypes)  Lupus-like syndrome  Systemic lupus erythematosus  Metabolic bone disorders  Osteopenia  Osteoporosis  Muscle infections and inflammations  Myositis  Polymyositis  7  Polymyositis  Fibromyalgia  Myalgia  Myalgia  Myofascial pain syndrome  Muscle related signs and symptoms NEC  Muscle discomfort  Muscle disorder  Muscle fatigue  Muscle haemorrhage  Muscle nass  Muscle oedema  2  Muscle synams  Muscle synams  Muscle synams  Muscle synams  Muscle synams  Muscle toletmas  Muscle synams  Muscle toletmas  Muscle toletmas  Muscle toletmas  Muscle synams  Muscle toletmas  Muscle tightness  Muscle tightness  Muscle tone abnormalities  Muscle tore  Muscle tone abnormalities  Muscle rigidity	0
Lupus erythematosus (incl subtypes)         1           Lupus-like syndrome         1           Systemic lupus erythematosus         12           Metabolic bone disorders         0           Osteoporosis         4           Muscle infections and inflammations         1           Myositis         7           Polymyositis         1           Muscle pains         1           Fibromyalgia         133           Myalgia         17544           Myofascial pain syndrome         9           Muscle related signs and symptoms NEC         2           Muscle discomfort         6           Muscle discomfort         6           Muscle discomfort         6           Muscle fatigue         539           Muscle haemorrhage         1           Muscle neass         3           Muscle oedema         2           Muscle syeasms         1291           Muscle syeasms         1291           Muscle tightness         77           Muscle tone abnormalities         195           Muscle rigidity         26	
Lupus-like syndrome       1         Systemic lupus erythematosus       12         Metabolic bone disorders       1         Osteopenia       1         Osteopenosis       4         Muscle infections and inflammations       7         Myositis       7         Polymyositis       1         Muscle pains       1         Fibromyalgia       133         Myalgia       17544         Myofascial pain syndrome       9         Muscle related signs and symptoms NEC       2         Muscle discomfort       6         Muscle discomfort       6         Muscle discomfort       6         Muscle discomfort       2         Muscle fatigue       539         Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle syaems       1291         Muscle syelling       14         Muscle tightness       77         Muscle tone abnormalities       195         Muscle rigidity       26	0
Systemic lupus erythematosus         Metabolic bone disorders         Osteopenia       1         Osteoporosis       4         Muscle infections and inflammations       7         Myositis       7         Polymyositis       1         Muscle pains       1         Fibromyalgia       133         Myalgia       17544         Myofascial pain syndrome       9         Muscle related signs and symptoms NEC       2         Muscle discomfort       6         Muscle disorder       2         Muscle fatigue       539         Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle swelling       14         Muscle tightness       77         Muscle twitching       195         Muscle rigidity       26	
Metabolic bone disorders         1           Osteopenia         1           Osteoporosis         4           Muscle infections and inflammations         7           Myositis         7           Polymyositis         1           Muscle pains         1           Fibromyalgia         133           Myalgia         17544           Myofascial pain syndrome         9           Muscle related signs and symptoms NEC         2           Muscle discomfort         6           Muscle discomfort         6           Muscle fatigue         539           Muscle haemorrhage         1           Muscle mass         3           Muscle oedema         2           Muscle spasms         1291           Muscle swelling         14           Muscle tightness         77           Muscle twitching         195           Muscle rigidity         26	0
Metabolic bone disordersOsteopenia1Osteoporosis4Muscle infections and inflammations7Myositis7Polymyositis1Muscle pains1Fibromyalgia133Myalgia17544Myofascial pain syndrome9Muscle related signs and symptoms NECMuscle discomfort6Muscle disorder2Muscle fatigue539Muscle haemorrhage1Muscle mass3Muscle oedema2Muscle syasms1291Muscle swelling14Muscle tightness77Muscle tightness77Muscle tone abnormalities195Muscle rigidity26	0
Osteoporosis         4           Muscle infections and inflammations         7           Myositis         7           Polymyositis         1           Muscle pains         1           Fibromyalgia         133           Myalgia         17544           Myofascial pain syndrome         9           Muscle related signs and symptoms NEC         2           Muscle atrophy         2           Muscle discomfort         6           Muscle disorder         2           Muscle fatigue         539           Muscle haemorrhage         1           Muscle mass         3           Muscle oedema         2           Muscle syelling         14           Muscle swelling         14           Muscle tightness         77           Muscle twitching         195           Muscle tone abnormalities         Muscle rigidity	
Muscle infections and inflammations         7           Myositis         7           Polymyositis         1           Muscle pains         1           Fibromyalgia         133           Myalgia         17544           Myofascial pain syndrome         9           Muscle related signs and symptoms NEC         2           Muscle atrophy         2           Muscle discomfort         6           Muscle disorder         2           Muscle fatigue         539           Muscle haemorrhage         1           Muscle mass         3           Muscle oedema         2           Muscle spasms         1291           Muscle swelling         14           Muscle tightness         77           Muscle twitching         195           Muscle tone abnormalities         Muscle rigidity	0
Myositis         7           Polymyositis         1           Muscle pains         1           Fibromyalgia         133           Myalgia         17544           Myofascial pain syndrome         9           Muscle related signs and symptoms NEC         2           Muscle atrophy         2           Muscle discomfort         6           Muscle disorder         2           Muscle fatigue         539           Muscle haemorrhage         1           Muscle mass         3           Muscle oedema         2           Muscle spasms         1291           Muscle swelling         14           Muscle tightness         77           Muscle twitching         195           Muscle tone abnormalities         0           Muscle rigidity         26	0
Polymyositis       1         Muscle pains       133         Fibromyalgia       17544         Myofascial pain syndrome       9         Muscle related signs and symptoms NEC       2         Muscle atrophy       2         Muscle discomfort       6         Muscle fatigue       539         Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle swelling       14         Muscle tightness       77         Muscle twitching       195         Muscle tone abnormalities       Muscle rigidity	
Muscle pains133Fibromyalgia17544Myofascial pain syndrome9Muscle related signs and symptoms NEC2Muscle atrophy2Muscle discomfort6Muscle fatigue539Muscle haemorrhage1Muscle mass3Muscle oedema2Muscle spasms1291Muscle swelling14Muscle tightness77Muscle twitching195Muscle tone abnormalities195Muscle rigidity26	0
Fibromyalgia       133         Myalgia       17544         Myofascial pain syndrome       9         Muscle related signs and symptoms NEC       2         Muscle discomfort       6         Muscle disorder       2         Muscle fatigue       539         Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle tightness       77         Muscle twitching       195         Muscle tone abnormalities       Muscle rigidity	0
Fibromyalgia       133         Myalgia       17544         Myofascial pain syndrome       9         Muscle related signs and symptoms NEC       2         Muscle atrophy       2         Muscle discomfort       6         Muscle disorder       2         Muscle fatigue       539         Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle swelling       14         Muscle tightness       77         Muscle twitching       195         Muscle tone abnormalities       Muscle rigidity	
Myalgia       17544         Myofascial pain syndrome       9         Muscle related signs and symptoms NEC       2         Muscle atrophy       2         Muscle discomfort       6         Muscle disorder       2         Muscle fatigue       539         Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle swelling       14         Muscle tightness       77         Muscle twitching       195         Muscle tone abnormalities       0         Muscle rigidity       26	0
Myofascial pain syndrome9Muscle related signs and symptoms NEC2Muscle atrophy2Muscle discomfort6Muscle disorder2Muscle fatigue539Muscle haemorrhage1Muscle mass3Muscle oedema2Muscle spasms1291Muscle swelling14Muscle tightness77Muscle twitching195Muscle tone abnormalities195Muscle rigidity26	0
Muscle related signs and symptoms NEC           Muscle atrophy         2           Muscle discomfort         6           Muscle disorder         2           Muscle fatigue         539           Muscle haemorrhage         1           Muscle mass         3           Muscle oedema         2           Muscle spasms         1291           Muscle swelling         14           Muscle tightness         77           Muscle twitching         195           Muscle tone abnormalities         26	0
Muscle atrophy       2         Muscle discomfort       6         Muscle disorder       2         Muscle fatigue       539         Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle swelling       14         Muscle tightness       77         Muscle twitching       195         Muscle tone abnormalities       26	
Muscle discomfort       6         Muscle disorder       2         Muscle fatigue       539         Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle swelling       14         Muscle tightness       77         Muscle twitching       195         Muscle tone abnormalities       26         Muscle rigidity       26	0
Muscle disorder       2         Muscle fatigue       539         Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle swelling       14         Muscle tightness       77         Muscle twitching       195         Muscle tone abnormalities       26         Muscle rigidity       26	0
Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle swelling       14         Muscle tightness       77         Muscle twitching       195         Muscle tone abnormalities       26         Muscle rigidity       26	0
Muscle haemorrhage       1         Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle swelling       14         Muscle tightness       77         Muscle twitching       195         Muscle tone abnormalities       26         Muscle rigidity       26	0
Muscle mass       3         Muscle oedema       2         Muscle spasms       1291         Muscle swelling       14         Muscle tightness       77         Muscle twitching       195         Muscle tone abnormalities       26         Muscle rigidity       26	0
Muscle oedema2Muscle spasms1291Muscle swelling14Muscle tightness77Muscle twitching195Muscle tone abnormalities26	0
Muscle swelling 14 Muscle tightness 77 Muscle twitching 195  Muscle tone abnormalities Muscle rigidity 26	0
Muscle swelling14Muscle tightness77Muscle twitching195Muscle tone abnormalities26	0
Muscle tightness 77 Muscle twitching 195  Muscle tone abnormalities Muscle rigidity 26	0
Muscle twitching 195  Muscle tone abnormalities  Muscle rigidity 26	0
Muscle tone abnormalities  Muscle rigidity  26	0
	0
Nuchal rigidity 10	0
Torticollis 6	0
Trismus 34	0
Muscle weakness conditions	
Muscular weakness 962	0
Musculoskeletal and connective tissue conditions NEC	
Extremity contracture 1	0
Infantile back arching 1	0
Limb mass 2	0
Mastication disorder 1	0
Mobility decreased 63	0
Muscle contracture 3	0
Musculoskeletal disorder 1	0
Musculoskeletal stiffness 1125	0
Somatic dysfunction 1	0
Weight bearing difficulty 5	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	
Facial asymmetry 1	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Muscle & tissue disorders & tissue disorders cont'd		
Head deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Dactylitis	1	0
Plantar fasciitis	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	3268	0
Flank pain	41	0
Growing pains	5	0
Limb discomfort	1149	0
Musculoskeletal chest pain	225	
Musculoskeletal discomfort	63	
Musculoskeletal pain	35	
Neck pain	1530	
Pain in extremity	10685	
Rheumatic disorder	7	0
Myopathies		
Compartment syndrome	1	0
Myopathy	2	Ō
Rhabdomyolysis	5	
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	16	
Spinal osteoarthritis	2	Ö
Psoriatic arthropathies	_	
Psoriatic arthropathy	14	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	70	
Still's disease	3	0
Soft tissue disorders NEC		
Axillary mass	19	0
Groin pain	90	
Neck mass	8	0
Soft tissue mass	1	0
Soft tissue swelling	4	0
Spine and neck deformities		
Kyphosis	1	0
Scoliosis	1	0
Spinal stenosis	1	0
Spondyloarthropathies		
Ankylosing spondylitis	15	0
Arthritis reactive	14	0
Synovial disorders		
Synovial cyst	3	0
Synovitis	5	0
Tendon disorders		
Tendon discomfort	1	0
Tendon pain	11	0
Tendonitis	18	0
Tenosynovitis stenosans	1	0
Trigger finger	9	0
Muscle & tissue disorders SOC TOTAL	54853	

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1		
Reaction Name	Total	<u>Fatal</u>
Neoplasms		
Bladder neoplasms malignant		
Bladder cancer	1	0
Bone neoplasms malignant (excl sarcomas)		
Bone cancer	1	0
Breast and nipple neoplasms malignant		
Breast cancer	14	0
Breast cancer male	1	0
Breast cancer stage III	1	0
Cardiovascular neoplasms benign		
Haemangioma	2	0
Central nervous system neoplasms malignant NEC		
Brain cancer metastatic	1	0
Gastrointestinal neoplasms benign NEC		
Gastrointestinal tract adenoma	1	0
Hepatic neoplasms malignant		
Hepatocellular carcinoma	1	0
Hepatoblastomas		
Hepatoblastoma	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	4	0
Lip and oral cavity neoplasms malignant		
Squamous cell carcinoma of the oral cavity	1	0
Lymphomas unspecified NEC		
Lymphoma	4	0
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		
Lymphoproliferative disorder in remission	1	0
Metastases to unknown and unspecified sites		
Metastasis	2	0
Neoplasms malignant site unspecified NEC	_	
Metastatic neoplasm	2	0
Neoplasm malignant	2	1
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm recurrence	2	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	1	0
Neuromas		
Acoustic neuroma	1	0
Ocular neoplasms benign		
Eye naevus	1	0
Oesophageal neoplasms malignant		
Oesophageal carcinoma	1	0
Oesophageal squamous cell carcinoma	1	0
Oncologic complications and emergencies		·
Cancer fatigue	3	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and		
unspecified		
Tonsil cancer	2	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	1	0
Plasma cell myelomas		
Plasma cell myeloma	1	0
Prostatic neoplasms malignant		
Prostate cancer	2	0

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Renal neoplasms malignant		
Clear cell renal cell carcinoma	1	0
Metastatic renal cell carcinoma	1	0
Respiratory tract and pleural neoplasms malignancy unspecified NEC		
Maxillofacial sinus neoplasm	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Bronchial carcinoma	4	0
Lung neoplasm malignant	4	0
Salivary gland neoplasms malignant		
Salivary gland cancer stage III	1	0
Skin melanomas (excl ocular)		
Acral lentiginous melanoma stage III	1	0
Malignant melanoma	1	0
Skin neoplasms benign		
Haemangioma of skin	2	0
Melanocytic naevus	1	0
Skin papilloma	5	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Squamous cell carcinoma of skin	1	0
Soft tissue neoplasms benign NEC		
Knuckle pads	1	0
Lipoma	1	0
Uterine neoplasms benign		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	82	1

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Nervous system disorders		
Abnormal reflexes		
Areflexia	4	0
Hyporeflexia	3	0
Poor sucking reflex	1	0
Reflexes abnormal	1	0
Abnormal sleep-related events		
Sleep paralysis	15	0
Absence seizures		
Petit mal epilepsy	17	0
Acute polyneuropathies		
Acute motor axonal neuropathy	2	0
Guillain-Barre syndrome	73	1
Miller Fisher syndrome	3	0
Subacute inflammatory demyelinating polyneuropathy	1	0
Auditory nerve disorders	·	
Acoustic neuritis	1	0
Autonomic nervous system disorders		
Autonomic nervous system imbalance	5	0
Orthostatic intolerance	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Basal ganglia stroke	1	0
Brain stem infarction	1	1
Brain stem stroke	1	'n
Carotid artery occlusion	1	0
Carotid artery declasion  Carotid artery thrombosis	1	0
Cerebellar haemorrhage	1	0
Cerebellar infarction	1	0
Cerebellar stroke	2	0
Cerebral artery embolism	1	0
Cerebral artery occlusion	2	0
Cerebral haematoma	1	0
Cerebral haemorrhage	45	17
Cerebral infarction	13	1
Cerebral infarction	1	0
Cerebral Isoliaemia Cerebral thrombosis	۵	2
Cerebral thombosis Cerebrovascular accident	259	2 18
Embolic stroke	200	0
Haemorrhage intracranial	14	1
Haemorrhagic cerebral infarction	14	1
Haemorrhagic stroke	14	3
Intracranial haematoma	14	1
Ischaemic stroke	31	
Lacunar infarction	1	
Lacunar stroke	1	0
	4	0
Subarachnoid haemorrhage	13	
Thalamus haemorrhage	3	0
Thrombotic stroke	3	0
Central nervous system inflammatory disorders NEC	4	
Arachnoiditis	1	0
Central nervous system inflammation	4	0
Neurosarcoidosis	1	0
Central nervous system vascular disorders NEC		
Cerebral congestion	1	0

Earliest Reaction Date: 03-Feb-1921 Med	DRA Version: MedDRA 23.1	
Reaction Name	Total	<u>Fatal</u>
Nervous system disorders us system disorders cont'd		
Cerebral small vessel ischaemic disease		1 0
Cerebrovascular disorder		3 0
Internal carotid artery deformity		1 0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	4	6 5
Cerebral venous thrombosis		3 0
Superior sagittal sinus thrombosis		8 1
Cervical spinal cord and nerve root disorders		
Cervicobrachial syndrome		4 0
Choreiform movements		
Chorea		1 0
Sydenham's chorea		1 0
Chronic polyneuropathies		
Diabetic neuropathy		2 0
Coma states		
Coma		7 0
Diabetic coma		2 0
Coordination and balance disturbances		
Ataxia		8 0
Balance disorder	38	6 0
Cerebellar ataxia		1 0
Coordination abnormal	5	4 0
Dysstasia	4	3 0
Nystagmus		8 0
Cortical dysfunction NEC		
Aphasia	3	8 0
Apraxia		1 0
Dysgraphia		1 0
Dyslexia		2 0
Dyspraxia		2 0 3 0 2 0
Neurologic neglect syndrome		
Visuospatial deficit		2 0
Cranial nerve disorders NEC		
Cranial nerve disorder		1 0
Dementia (excl Alzheimer's type)		
Dementia	1	0 0
Frontotemporal dementia		1 0
Senile dementia		1 0
Vascular dementia		3 0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis		1 0
Demyelination		3 0
Disturbances in consciousness NEC		
Altered state of consciousness		8 0
Consciousness fluctuating		3 0
Depressed level of consciousness	4	
Lethargy	281	
Loss of consciousness	48	7 0
Postictal state		1 0
Sedation		5 0
Somnolence	100	5 1
Stupor		4 0
Syncope	127	<u>ol o</u>

## Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 01-Apr-2021 Data Lock Date: 28-Mar-2021 19:00:03
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	Fatal
Nervous system disorders co	ont'd		
Disturbances in sleep phase rhythm			
Advanced sleep phase		1	0
Circadian rhythm sleep disorder		1	0
Irregular sleep phase		1	0
Dyskinesias and movement disorders NEC			
Akathisia		8	0
Bradykinesia		13	0
Clumsiness		13	0
Dyskinesia		54	0
Extrapyramidal disorder		16	0
Fine motor skill dysfunction		5	0
Hyperkinesia		9	0
Hypokinesia		19	0
Motor dysfunction		6	0
Movement disorder		30	0
Psychomotor hyperactivity		23	0
Dystonias			
Dystonia		8	0
Dystonic tremor		2	0
Opisthotonus		4	0
Encephalitis NEC			·
Noninfective encephalitis		2	0
Encephalopathies NEC		_	·
Autoimmune encephalopathy		2	0
Encephalopathy		3	0
Hypoxic-ischaemic encephalopathy		1	0
Posterior reversible encephalopathy syndro	ome	1	0
Encephalopathies toxic and metabolic	51116		Ŭ
Hepatic encephalopathy		2	0
Eye movement disorders		_	Ĭ
IIIrd nerve paralysis		3	0
VIth nerve paralysis		2	0
Facial cranial nerve disorders		_	•
Facial nerve disorder		2	0
Facial paralysis		219	0
Facial paresis		40	0
Facial spasm		14	0
Generalised tonic-clonic seizures			
Generalised tonic-clonic seizure		37	0
Headaches NEC			
Cervicogenic headache		2	0
Cluster headache		349	0
Cold-stimulus headache		25	0
Drug withdrawal headache		11	0
Exertional headache		5	0
External compression headache		2	0
Headache		48504	1
Medication overuse headache		6	0
New daily persistent headache		4	0
Occipital neuralgia		5	0
Ophthalmoplegic migraine		1	0
Post-traumatic headache		1	0
Primary headache associated with sexual	activity	4	0

## Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 01-Apr-2021 Data Lock Date: 28-Mar-2021 19:00:03
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1

	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	Fatal
Nervous system disorders us system disorders con	nt'd		
Sinus headache		485	0
Tension headache		744	0
Thunderclap headache		15	0
Vascular headache		36	0
Hydrocephalic conditions			
Hydrocephalus		2	0
Hypoglossal nerve disorders			
Tongue paralysis		3	0
Increased intracranial pressure disorders			
Brain compression		1	0
Brain oedema		6	0
Idiopathic intracranial hypertension		2	0
Intracranial pressure increased		4	0
Intellectual disabilities			_
Intellectual disability		6	0
Lumbar spinal cord and nerve root disorders			
Sciatica		56	0
Memory loss (excl dementia)			J
Amnesia		106	0
Memory impairment		94	0
Transient global amnesia		6	0
Mental impairment (excl dementia and memor	ny loss)	J	J
Cognitive disorder	y 1033)	56	1
Disturbance in attention		265	Ö
Judgement impaired		203	0
Mental impairment		52	0
Migraine headaches		32	U
Basilar migraine		2	0
Hemiplegic migraine		10	0
Migraine		3771	0
Migraine with aura		146	0
Migraine with aura		26	0
Retinal migraine		27	0
Status migrainosus		1	0
Typical aura without headache		6	0
		7	0
Vestibular migraine <i>Mononeuropathies</i>			U
Carpal tunnel syndrome		9	0
Diabetic mononeuropathy		1	0
Mononeuritis		1	
Nerve compression		2 12	0
		3	
Peroneal nerve palsy		3	0 0
Piriformis syndrome		1	
Sciatic nerve neuropathy		1	0
Ulnar nerve palsy		1	
Ulnar neuritis		ı	0
Multiple sclerosis acute and progressive		2	0
Band sensation		2	0
Multiple sclerosis		32	0
Multiple sclerosis relapse		25	0
Relapsing multiple sclerosis		1	0
Uhthoff's phenomenon		3	0
Muscle tone abnormal			

Slow response to stimuli       3       0         Tongue biting       3       0         Unresponsive to stimuli       49       0         Neuromuscular disorders NEC       0         Muscle contractions involuntary       12       0         Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Neuromuscular junction dysfunction       4       0         Myasthenia gravis       4       0         Myasthenia gravis crisis       1       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0	Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Hypotonia   13	Reaction Name		Total	Fatal
Hypotonia   13	Nervous system disorders us system disorders co	nt'd		
Stiff leg syndrome   3			13	0
Myelitis (incl infective)         20           Myelitis transverse         20           Narcolepsy and hypersomnia         1           Cataplexy         1           Hypersomnia         92           Narcolepsy         9           Nervous system cysts and polyps         9           Pineal gland cyst         1           Nervous system disorder         1           Okerous system disorder         11           Psychomotor skills impaired         3           Neurologic visual problems NEC         1           Tunnel vision         8           Visual field defect         10           Neurological signs and symptoms NEC         12105           Dizziness         12105           Dizziness postural         55           Dizziness postural         305           Dizziness postural         1305           Drooling         7           Exaggerated startle response         3           Fontanelle bulging         2           Head discomfort         204           Hyporesponsive to stimuli         1           Infant irritability         4           Myoclonus         12           Neurological decompensation         <	Serotonin syndrome		1	0
Myelitis transverse	Stiff leg syndrome		3	0
Narcolepsy and hypersomnia	Myelitis (incl infective)			
Cataplexy	Myelitis transverse		20	0
Hypersomnia   92   0   Narcolepsy   9   0   Narcolepsy   9   0   Narcolepsy   9   0   Narcolepsy   9   0   0   Narcolepsy   Pineal gland cyst   1   0   0   0   0   0   0   0   0   0	Narcolepsy and hypersomnia			
Narcolepsy         9         0           Nervous system cysts and polyps         1         0           Pineal gland cyst         1         0           Nervous system disorder         11         0           Nevous system disorder         11         0           Neurologic visual problems NEC         11         0           Tunnel vision         8         0           Visual field defect         10         0           Neurological signs and symptoms NEC         10         0           Dizziness         12105         0           Dizziness exertional         55         0           Dizziness postural         1305         1           Drooling         7         0           Exaggerated startle response         3         0           Fontanelle bulging         2         0           Head discomfort         20         0           Hyporesponsive to stimuli         1         0           Infant irritability         4         0           Mycological decompensation         1         0           Neurological symptom         41         0           Peasitent postural-perceptual dizziness         12         0	Cataplexy		1	0
Nervous system clost and polyps   Pineal gland cyst   1	Hypersomnia		92	0
Pineal gland cyst   1	Narcolepsy		9	0
Pineal gland cyst   1	Nervous system cysts and polyps			
Nervous system disorder         1         0           Nervous system disorder         11         0           Psychomotor skills impaired         3         0           Neurologic visual problems NEC         10         0           Tunnel vision         8         0           Visual field defect         10         0           Neurological signs and symptoms NEC         12105         0           Dizziness         12105         0           Dizziness postural         1305         1           Drooling         7         0           Exaggerated startle response         3         0           Fontanelle bulging         2         0           Head discomfort         204         0           Hyporesponsive to stimuli         1         0           Infant irritability         4         0           Myoclonus         12         0           Neurological decompensation         1         0           Neurological symptom         41         0           Patient elopement         1         0           Persistent postural-perceptual dizziness         12         0           Presyncope         335         0			1	0
Nervous system disorder				
Psychomotor skills impaired	Cerebral disorder		1	0
Neurologic visual problems NEC   Tunnel vision   8	Nervous system disorder		11	0
Neurologic visual problems NEC   Tunnel vision   8	Psychomotor skills impaired		3	0
Tunnel vision Visual field defect  Neurological signs and symptoms NEC  Dizziness Dizziness exertional Dizziness postural Drooling Droolin				
Neurological signs and symptoms NEC         12105         0           Dizziness         12105         0           Dizziness postural         1305         1           Drooling         7         0           Exaggerated startle response         3         0           Fontanelle bulging         2         0           Head discomfort         204         0           Hyporesponsive to stimuli         1         0           Infant irritability         4         0           Myoclonus         12         0           Neurological decompensation         1         0           Neurological symptom         41         0           Neurological symptom         41         0           Patient elopement         1         0           Persistent postural-perceptual dizziness         12         0           Pleocytosis         1         0           Presyncope         335         0           Sensory overload         5         0           Slow response to stimuli         3         0           Tongue biting         3         0           Unresponsive to stimuli         49         0           Neuromyopotonia			8	0
Dizziness   12105   0	Visual field defect		10	0
Dizziness   12105   0	Neurological signs and symptoms NEC			
Dizziness postural			12105	0
Drooling	Dizziness exertional			0
Drooling	Dizziness postural			1
Exaggerated startle response   3	I ·		_	0
Fontanelle bulging			3	
Head discomfort				0
Hyporesponsive to stimuli			204	
Infant irritability	Hyporesponsive to stimuli		1	0
Myoclonus       12       0         Neurological decompensation       1       0         Neurological symptom       41       0         Patient elopement       1       0         Persistent postural-perceptual dizziness       12       0         Pleocytosis       1       0         Presyncope       335       0         Sensory overload       5       0         Slow response to stimuli       3       0         Tongue biting       3       0         Unresponsive to stimuli       49       0         Neuromuscular disorders NEC       0       0         Muscle contractions involuntary       12       0         Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyotonia       1       0         Neuromyotonia       1       0         Neuromuscular junction dysfunction       1       0         Myasthenia gravis       4       0         Myasthenia gravis crisis       1       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0			4	
Neurological decompensation         1         0           Neurological symptom         41         0           Patient elopement         1         0           Persistent postural-perceptual dizziness         12         0           Pleocytosis         1         0           Presyncope         335         0           Sensory overload         5         0           Slow response to stimuli         3         0           Tongue biting         3         0           Unresponsive to stimuli         49         0           Neuromuscular disorders NEC         0         0           Muscle spasticity         12         0           Muscle spasticity         13         0           Neuromuscular pain         2         0           Neuromyopathy         2         0           Neuromyotonia         1         0           Neuromuscular junction dysfunction         1         0           Myasthenia gravis         4         0           Myasthenia gravis crisis         1         0           Olfactory nerve disorders         1         0           Anosmia         135         0           Hyposmia	· · · · · · · · · · · · · · · · · · ·		12	0
Neurological symptom       41       0         Patient elopement       1       0         Persistent postural-perceptual dizziness       12       0         Pleocytosis       1       0         Presyncope       335       0         Sensory overload       5       0         Slow response to stimuli       3       0         Tongue biting       3       0         Unresponsive to stimuli       49       0         Neuromuscular disorders NEC       0       0         Muscle contractions involuntary       12       0         Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Myasthenia gravis       4       0         Myasthenia gravis crisis       1       0         Olfactory nerve disorders       135       0         Anosmia       135       0         Hyposmia       8       0				
Patient elopement         1         0           Persistent postural-perceptual dizziness         12         0           Pleocytosis         1         0           Presyncope         335         0           Sensory overload         5         0           Slow response to stimuli         3         0           Tongue biting         3         0           Unresponsive to stimuli         49         0           Neuromuscular disorders NEC         0         0           Muscle contractions involuntary         12         0           Muscle spasticity         13         0           Neuromuscular pain         2         0           Neuromyopathy         2         0           Neuromyotonia         1         0           Myasthenia gravis         4         0           Myasthenia gravis crisis         1         0           Olfactory nerve disorders         135         0           Anosmia         135         0           Hyposmia         8         0			41	0
Persistent postural-perceptual dizziness         12         0           Pleocytosis         1         0           Presyncope         335         0           Sensory overload         5         0           Slow response to stimuli         3         0           Tongue biting         3         0           Unresponsive to stimuli         49         0           Neuromuscular disorders NEC         0           Muscle contractions involuntary         12         0           Muscle spasticity         13         0           Neuromuscular pain         2         0           Neuromyopathy         2         0           Neuromyotonia         1         0           Neuromuscular junction dysfunction         4         0           Myasthenia gravis         4         0           Myasthenia gravis crisis         1         0           Olfactory nerve disorders         135         0           Anosmia         135         0           Hyposmia         8         0			1	
Pleocytosis       1       0         Presyncope       335       0         Sensory overload       5       0         Slow response to stimuli       3       0         Tongue biting       3       0         Unresponsive to stimuli       49       0         Neuromuscular disorders NEC       0         Muscle contractions involuntary       12       0         Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Neuromuscular junction dysfunction       1       0         Myasthenia gravis       4       0         Myasthenia gravis crisis       1       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0	<u> </u>		12	0
Presyncope       335       0         Sensory overload       5       0         Slow response to stimuli       3       0         Tongue biting       3       0         Unresponsive to stimuli       49       0         Neuromuscular disorders NEC       0         Muscle contractions involuntary       12       0         Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Myasthenia gravis       4       0         Myasthenia gravis crisis       1       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0			1	0
Sensory overload       5       0         Slow response to stimuli       3       0         Tongue biting       3       0         Unresponsive to stimuli       49       0         Neuromuscular disorders NEC       0         Muscle contractions involuntary       12       0         Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Neuromuscular junction dysfunction       1       0         Myasthenia gravis       4       0         Myasthenia gravis crisis       1       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0			335	0
Slow response to stimuli       3       0         Tongue biting       3       0         Unresponsive to stimuli       49       0         Neuromuscular disorders NEC       0         Muscle contractions involuntary       12       0         Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Neuromuscular junction dysfunction       4       0         Myasthenia gravis       4       0         Myasthenia gravis crisis       1       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0				0
Tongue biting       3       0         Unresponsive to stimuli       49       0         Neuromuscular disorders NEC       0         Muscle contractions involuntary       12       0         Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Neuromuscular junction dysfunction       0         Myasthenia gravis       4       0         Myasthenia gravis crisis       1       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0	1		3	0
Unresponsive to stimuli       49       0         Neuromuscular disorders NEC       0         Muscle contractions involuntary       12       0         Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Neuromuscular junction dysfunction       0         Myasthenia gravis       4       0         Myasthenia gravis crisis       1       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0			3	0
Neuromuscular disorders NEC         12         0           Muscle contractions involuntary         12         0           Muscle spasticity         13         0           Neuromuscular pain         2         0           Neuromyopathy         2         0           Neuromyotonia         1         0           Neuromuscular junction dysfunction         0           Myasthenia gravis         4         0           Myasthenia gravis crisis         1         0           Olfactory nerve disorders         1         0           Anosmia         135         0           Hyposmia         8         0			49	0
Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Neuromuscular junction dysfunction       3       4       0         Myasthenia gravis       4       0       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0				
Muscle spasticity       13       0         Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Neuromuscular junction dysfunction       3       4       0         Myasthenia gravis       4       0       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0	Muscle contractions involuntary		12	0
Neuromuscular pain       2       0         Neuromyopathy       2       0         Neuromyotonia       1       0         Neuromuscular junction dysfunction       0         Myasthenia gravis       4       0         Myasthenia gravis crisis       1       0         Olfactory nerve disorders       1       0         Anosmia       135       0         Hyposmia       8       0			13	0
Neuromyotonia 1 0  Neuromuscular junction dysfunction  Myasthenia gravis 4 0  Myasthenia gravis crisis 1 0  Olfactory nerve disorders  Anosmia 135 0  Hyposmia 8 0				0
Neuromyotonia 1 0  Neuromuscular junction dysfunction  Myasthenia gravis 4 0  Myasthenia gravis crisis 1 0  Olfactory nerve disorders  Anosmia 135 0  Hyposmia 8 0			2	
Neuromuscular junction dysfunction40Myasthenia gravis40Myasthenia gravis crisis10Olfactory nerve disorders30Anosmia1350Hyposmia80			1	0
Myasthenia gravis 4 0 Myasthenia gravis crisis 1 0  Olfactory nerve disorders Anosmia 135 0 Hyposmia 8 0				
Myasthenia gravis crisis 1 0  Olfactory nerve disorders  Anosmia 135 0  Hyposmia 8 0			4	0
Olfactory nerve disorders Anosmia 135 0 Hyposmia 8 0			1	
Anosmia         135         0           Hyposmia         8         0				
Hyposmia 8 0			135	0
	Parosmia		193	0
Optic nerve disorders NEC				

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Nervous system disorders us system disorders con	nt'd		
Optic neuritis		8	0
Paraesthesias and dysaesthesias			
Anaesthesia		2	0
Burning feet syndrome		9	0
Burning sensation		321	0
Dysaesthesia		4	0
Formication		28	0
Hemianaesthesia		2	0
Hyperaesthesia		151	0
Hypoaesthesia		2185	0
Lhermitte's sign		1	0
Paraesthesia		3833	0
Paralysis and paresis (excl cranial nerve)		0000	Ŭ
Diplegia		12	0
Hemiparesis		30	0
Hemiplegia		12	0
Monoparesis		37	0
Monoplegia		51	0
Paralysis		134	0
Paraparesis		4	0
Paraplegia		1	0
Paresis		4	0
Peripheral nerve palsy		1	0
Postictal paralysis		1	0
Quadriplegia		1	0
Parkinson's disease and parkinsonism		·	Ū
Freezing phenomenon		98	0
Parkinson's disease		10	0
Parkinsonism		7	0
Reduced facial expression		3	0
Partial complex seizures		Ĭ	, ,
Dreamy state		10	0
Focal dyscognitive seizures		3	0
Temporal lobe epilepsy		3	0
Partial simple seizures NEC			
Simple partial seizures		3	0
Peripheral neuropathies NEC			
Autoimmune neuropathy		2	0
Neuritis		2 2	0
Neuropathy peripheral		74	0
Peripheral sensory neuropathy		1	0
Polyneuropathy		4	0
Small fibre neuropathy		1	0
Seizures and seizure disorders NEC			
Alcoholic seizure		1	0
Atonic seizures		5	0
Change in seizure presentation		5 2	0
Clonic convulsion		6	0
Drug withdrawal convulsions		2	0
Epilepsy		115	0
Epileptic aura		1	0
Febrile convulsion		52	0
Migraine-triggered seizure		1	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	Fatal
Nervous system disorders co	ont'd		
Myoclonic epilepsy		2	0
Partial seizures		28	0
Psychogenic seizure		5	0
Seizure		539	2
Seizure anoxic		1	0
Seizure cluster		3	0
Seizure like phenomena		2	0
Status epilepticus		34	1
Tonic clonic movements		1	0
Tonic convulsion		17	0
Sensory abnormalities NEC			•
Ageusia		560	0
Allodynia		36	0
Aura		8	0
Central pain syndrome		2	0
Complex regional pain syndrome		6	0
Dysgeusia		1091	0
Hypogeusia		2	0
Loss of proprioception		2	0
Neuralgia		535	0
		333	
Persistent genital arousal disorder		11	0
Phantom limb syndrome			
Post herpetic neuralgia		2 9	0
Restless arm syndrome			
Restless legs syndrome		192	0
Sensory disturbance		34	0
Sensory loss		74	0
Taste disorder		275	0
Sleep disturbances NEC			•
Microsleep		1 1	0
Poor quality sleep		403	0
Sleep deficit		24	0
Speech and language abnormalities		400	
Dysarthria		129	1
Incoherent		2	0
Language disorder			0
Slow speech		11	0
Speech disorder		23	0
Spinal cord and nerve root disorders NEC			_
Cauda equina syndrome		1	0
Myelopathy		2	0
Radiculitis brachial		3	0
Radiculopathy		1	0
Structural brain disorders NEC			
Brain injury		6	0
Transient cerebrovascular events			
Transient ischaemic attack		138	0
Tremor (excl congenital)			
Action tremor		2	0
Asterixis		1	0
Essential tremor		3	0
Head titubation		3 7	0
Intention tremor		1	0

Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Postural tremor	1	0
Resting tremor	3	0
Tremor	6683	1
Trigeminal disorders		
Facial neuralgia	12	. 0
Numb chin syndrome	1	0
Trigeminal neuralgia	25	0
Trigeminal neuritis	1	0
Trigeminal palsy	1	0
Nervous system disorders SOC TOTAL	95234	63

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	15	0
Foetal position and presentation abnormalities		
Face presentation	1	0
Labour onset and length abnormalities		
Precipitate labour	1	0
Premature labour	2	2 0
Premature rupture of membranes	1	0
Maternal complications of pregnancy NEC		
Hyperemesis gravidarum	3	0
Morning sickness	24	0
Pelvic girdle pain	1	0
Normal pregnancy, labour and delivery		
Delivery	1	0
Pregnancy	5	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	4	0
Stillbirth and foetal death		
Foetal death	1	1
Stillbirth	2	2 0
Unintended pregnancies		
Pregnancy after post coital contraception	1	0
Pregnancy on contraceptive	1	0
Pregnancy with contraceptive device	1	0
Unintended pregnancy	2	2 0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	67	1 1

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	13	0
Stent malfunction	1	0
Thrombosis in device	10	0
Undersensing	1	0
Device physical property and chemical issues		
Needle issue	1	0
Product contamination and sterility issues		
Product contamination	1	0
Product label issues		
Product label issue	1	0
Product physical issues		
Product physical issue	1	0
Product taste abnormal	2	0
Product quality issues NEC		
Product origin unknown	1	0
null SOC TOTAL	38	l o

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Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	6	0
Breath holding	2	0
Staring	2 6	0
Adjustment disorders		
Adjustment disorder with depressed mood	2	0
Affect alterations NEC		
Affect lability	2	0
Constricted affect	4	0
Flat affect	4	0
Inappropriate affect	6	0
Amnestic symptoms		
Paramnesia	3	0
Anxiety disorders NEC		
Anxiety disorder	2	0
Generalised anxiety disorder	1	0
Neurosis	1	0
Anxiety symptoms		
Agitation	107	0
Anxiety	416	
Nervousness	381	0
Stress	21	0
Tension	23	0
Attention deficit and disruptive behaviour disorders		
Attention deficit hyperactivity disorder	7	0
Behaviour and socialisation disturbances		
Aggression	5	0
Asocial behaviour	1	0
Impatience	1	0
Indifference	3	0
Paranoia	14	0
Personality change	1	0
Social avoidant behaviour	1	0
Soliloquy	1	0
Violence-related symptom	2	0
Bipolar disorders		
Bipolar I disorder	3	0
Bipolar disorder	2	0
Cognitive and attention disorders and disturbances NEC		
Change in sustained attention	1	0
Daydreaming	7	0
Mental fatigue	224	0
Communications disorders		
Communication disorder	1	0
Mutism	2	0
Speech sound disorder	1	0
Confusion and disorientation		
Confusional state	987	1
Disorientation	395	0
Decreased physical activity levels		
Catatonia	2	0
Deliria		
Delirium	297	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1		
Reaction Name	To	<u>tal</u>	Fatal
Psychiatric disorders Psychiatric disorders cont'd			
Delusional symptoms			
Delusion		23	0
Thought withdrawal		1	0
Depressive disorders			
Agitated depression		2	0
Depression		216	0
Depression suicidal		5	0
Major depression		12	0
Mixed anxiety and depressive disorder		1	0
Dissociative states			
Depersonalisation/derealisation disorder		9	0
Dissociation		27	0
Dissociative disorder		1	0
Disturbances in initiating and maintaining sle	eep		
Initial insomnia	<i>'</i>	14	0
Insomnia	1	750	
Middle insomnia		36	
Terminal insomnia		4	0
Dyssomnias			
Dyssomnia		2	0
Eating disorders NEC			
Eating disorder		3	0
Emotional and mood disturbances NEC			
Anger		33	0
Dysphoria		1	Ō
Emotional disorder		48	-
Emotional distress		33	
Emotional poverty		2	0
Euphoric mood		38	
Frustration tolerance decreased		2	0
Irritability		142	
Mood altered		28	
Factitious disorders			
Factitious disorder		3	0
Fear symptoms and phobic disorders (incl se	ocial phobia)		
Agoraphobia	, , , , , , , , , , , , , , , , , , , ,	2	0
Fear		2 8	0
Fear of death		6	
Fear of disease		1	0
Fear of eating		1	0
Fear of falling		2	0
Fear of open spaces		1	0
Paruresis		1	0
Phobia		2	0
Phonophobia		2	0
Fluctuating mood symptoms			
Mood swings		24	0
Hallucinations (excl sleep-related)			
Hallucination		568	0
Hallucination, auditory		17	ő
Hallucination, olfactory		4	0
Hallucination, tactile		1	0
Hallucination, visual		31	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1	Tatal	Fatal
Reaction Name	Total	Fatal
Psychiatric disordersPsychiatric disorders cont'd		0
Hallucinations, mixed	6	0
Impulse control disorders	_	0
Impulse-control disorder	2	0
Impulsive behaviour	1	0
Increased physical activity levels	200	0
Restlessness	288	0
Infancy, childhood and adolescence psychiatric disorders NEC	4	0
Emotional disorder of childhood  Mental disorders NEC	1	0
Mental disorder MEC  Mental disorder	4	0
	4	0
Mental status changes  Mental disorders due to a general medical condition NEC		U
Neuropsychiatric symptoms	1	0
Mood alterations with depressive symptoms		U
Anhedonia	3	0
Decreased interest	7	0
Depressed mood	249	0
Feeling of despair	9	0
Negative thoughts	5	0
Sense of a foreshortened future	1	0
Tearfulness	57	0
Mood alterations with manic symptoms	57	J
Mania	14	0
Mood disorders NEC	, ,	Ū
Apathy	21	0
Listless	82	0
Narcolepsy and associated conditions	02	
Hypnagogic hallucination	4	0
Obsessive-compulsive disorders and symptoms		
Compulsive shopping	1	0
Dermatillomania	1	0
Obsessive thoughts	1	0
Obsessive-compulsive disorder	1	0
Orgasmic disorders and disturbances		
Orgasmic sensation decreased	2	0
Premature ejaculation	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	130	0
Panic disorder	2	0
Panic reaction	20	0
Parasomnias		
Abnormal dreams	202	0
Confusional arousal	2	0
Exploding head syndrome	4	0
Nightmare	271	0
Rapid eye movements sleep abnormal	2	0
Sleep inertia	1	0
Sleep talking	10	0
Sleep terror	32	0
Sleep-related eating disorder	2	0
Somnambulism	3	0
Perception disturbances NEC		

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1		
Reaction Name	<u>  Total  </u>	<u>Fatal</u>
Psychiatric disorders <sup>Psychiatric</sup> disorders cont'd		
Autoscopy	13	0
Deja vu	2 9	0
Derealisation		0
Flashback	2 7	0
Illusion		0
Time perception altered	5	0
Pervasive developmental disorders NEC		_
Autism spectrum disorder	1	0
Psychiatric elimination disorders		
Enuresis	24	0
Psychiatric symptoms NEC	_	
Hypervigilance	7	0
Psychiatric symptom	1	0
Psychological trauma	2	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	16	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual and gender identity disorders NEC		_
Gender dysphoria	1	0
Sexual arousal disorders	_	_
Disturbance in sexual arousal	3	0
Sexual desire disorders		
Libido decreased	3	0
Libido increased	4	0
Loss of libido	17	0
Sleep disorders NEC		
Sleep disorder	193	0
Sleep disorder due to general medical condition, insomnia type	1	0
Somatic symptom disorders		
Conversion disorder	4	0
Habit cough	23	0
Illness anxiety disorder	1	0
Somatic symptom disorder	1	0
Speech and language usage disturbances		•
Disorganised speech	4	0
Logorrhoea	2	0
Pedantic speech	1	0
Verbigeration Constitution of the three distances and the three distances are the constitution of the cons	1	0
Speech articulation and rhythm disturbances		•
Dysphemia	9	0
Lack of spontaneous speech	1	0
Stereotypies and automatisms	4.0	•
Bruxism	13	0
Head banging	24	0
Waxy flexibility	1	0
Stress disorders	_	_
Acute stress disorder	5	0
Burnout syndrome		0
Hyperarousal	2	0
Post-traumatic stress disorder	10	0

Reaction Name	Total	Fatal
Psychiatric disordersPsychiatric disorders cont'd		
Substance related and addictive disorders		
Alcohol abuse	1	0
Alcohol use disorder	2	2 0
Alcoholism	1	0
Drug dependence		0
Substance abuse	1	0
Suicidal and self-injurious behaviour		
Completed suicide	0	0
Intentional self-injury	3	8 0
Suicidal behaviour	2	2 0
Suicidal ideation	40	0
Suicide attempt	2	2 0
Suicide threat		0
Thinking disturbances		
Bradyphrenia	41	0
Confabulation	1	0
Intrusive thoughts	2	2 0
Morbid thoughts	2	2 0
Tachyphrenia	15	5 0
Thinking abnormal	12	2 0
Thought blocking		0
Tic disorders		
Tic	3	8 0
Psychiatric disorders SOC TOTAL	8047	rl 1

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	<u>Fatal</u>
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder discomfort	4	1 0
Bladder irritation		3 0
Bladder pain	25	5 0
Bladder spasm		1 0
Dysuria	45	5 0
Incontinence	42	2 0
Micturition disorder		2 0
Micturition frequency decreased		1 0
Micturition urgency	62	2 0
Mixed incontinence		1 0
Pollakiuria	166	6 0
Urethral pain		1 0
Urge incontinence		1 0
Urinary hesitation		3 0
Urinary incontinence	62	2 0
Urinary retention	4	1 0
Urine flow decreased		3 0
Bladder disorders NEC		
Bladder dilatation		1 0
Bladder disorder	7	7 0
Urinary bladder haemorrhage		2 0
Bladder infections and inflammations		
Cystitis interstitial	4	1 0
Cystitis noninfective		1 0
Genital and urinary tract disorders NEC		
Urinary tract disorder		1 0
Glomerulonephritis and nephrotic syndrome		
Anti-glomerular basement membrane disea	ase .	1 0
IgA nephropathy		2 0
Nephrotic syndrome		2 0
Myoneurogenic bladder disorders		
Automatic bladder		1 0
Bladder dysfunction		1 0
Hypertonic bladder	3	3 0
Loss of bladder sensation	3	3 0
Neurogenic bladder		1 0
Nephritis NEC		
Nephritis	4	4 0
Tubulointerstitial nephritis		1 0
Nephropathies and tubular disorders NEC		
Nephropathy		1 0
Renal disorders NEC		
Renal disorder		3 0
Renal failure and impairment		
Acute kidney injury	19	0
Anuria		1 0
Chronic kidney disease		4 0
Oliguria	9	0
Renal failure		7 1
Renal impairment		3 0
Renal injury		0
Renal lithiasis		

Reaction Name	Total	Fatal
Renal & urinary disorders & urinary disorders cont'd		
Nephrolithiasis	2	0
Renal structural abnormalities and trauma		
Kidney enlargement	1	0
Renal atrophy	1	0
Renal vascular and ischaemic conditions		
Renal vein thrombosis	1	0
Structural and obstructive urethral disorders (excl congenital)		
Urethral spasm	1	0
Urinary abnormalities		
Chromaturia	61	0
Glycosuria	1	0
Haematuria	17	0
Proteinuria	2	0
Urine abnormality	9	0
Urine odour abnormal	16	0
Urinary tract signs and symptoms NEC		
Haemorrhage urinary tract	10	0
Nocturia	9	0
Polyuria	20	0
Renal colic	2	0
Renal pain	533	0
Urinary tract discomfort	1	0
Urinary tract pain	4	0
Renal & urinary disorders SOC TOTAL	1248	1

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	<u> Fatal</u>
Reproductive & breast disorders		
Benign and malignant breast neoplasms		
Breast cyst		1 0
Breast disorders NEC		
Breast disorder		1 0
Breast enlargement		3  O
Breast mass	1:	2 0
Gynaecomastia		2 <b> </b> 0
Breast infections and inflammations		
Breast inflammation		1 0
Nipple inflammation		1 ol
Breast signs and symptoms		
Breast discharge		1l ol
Breast discomfort	;	3 0
Breast engorgement		1l ol
Breast oedema		il ol
Breast pain	14	il ol
Breast swelling	2	1 1
Breast tenderness	1	
Nipple pain	1	
Nipple swelling	· ·	il ol
Erection and ejaculation conditions and diso	rders	
Ejaculation delayed		1 0
Ejaculation failure		il ől
Erectile dysfunction	33	ا ا
Erection increased		ا ما
Organic erectile dysfunction	10	
Painful erection		1 0
Retrograde ejaculation		1 0
Spontaneous penile erection		il ol
Fallopian tube and ovary infections and infla	mmations	
Noninfective oophoritis		1 ol
Lactation disorders		
Lactation puerperal increased		1l ol
Suppressed lactation		4l ol
Menopausal effects NEC		
Artificial menopause		1 0
Menopausal symptoms		5l ol
Menopausal effects on the genitourinary trace	et	
Postmenopausal haemorrhage	15	5l ol
Menstruation and uterine bleeding NEC		
Abnormal withdrawal bleeding		1l ol
Dysmenorrhoea	3.9	5l ol
Menstrual disorder	55	
Menstruation irregular	60	
Metrorrhagia	29	
Premenstrual pain		sl ol
Premenstrual syndrome		ıl ol
Withdrawal bleed		
Menstruation with decreased bleeding		
Amenorrhoea	2	1 0
Hypomenorrhoea	29	
Menstruation delayed	74	
Oligomenorrhoea		3 0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	Fatal
Reproductive & breast disord	ers cont'd	
Menstruation with increased bleeding		
Menorrhagia	11	7 0
Polymenorrhoea		4 0
Ovarian and fallopian tube cysts and neoplas		
Ovarian cyst ruptured		1 0
Polycystic ovaries		2 0
Ovarian and fallopian tube disorders NEC		
Ovarian enlargement		1 0
Ovarian necrosis		1 0
Ovarian vein thrombosis		1 0
Ovulation pain		1 0
Premature ovulation		2 0
Pelvic prolapse conditions		
Vaginal prolapse		1 0
Pelvis and broad ligament disorders NEC		'  "
Adnexa uteri pain		7 0
		7 0 1 0
Pelvic haemorrhage		1 0
Penile and scrotal infections and inflammation	nis	1 0
Balanoposthitis	ulation)	1 0
Penile disorders NEC (excl erection and ejac	ulation)	
Penile blister		3 0
Penile burning sensation		1 0
Penile curvature		1 0
Penile oedema		2 0
Penile pain		_
Penis disorder		2 0
Peyronie's disease	In G	2 0
Prostate and seminal vesicles infections and	Intiammations	
Prostatitis		2 0
Prostatic neoplasms and hypertrophy		
Benign prostatic hyperplasia	, ,	1 0
Reproductive tract disorders NEC (excl neop	lasms)	
Female genital tract fistula		1 0
Genital blister		3 0
Genital haemorrhage		3 0
Genital hyperaesthesia		1 0
Genital ulceration		6 0
Reproductive tract infections and inflammation	ns NEC	
Genital tract inflammation		1 0
Reproductive tract signs and symptoms NEC		_
Genital burning sensation		5 0
Genital discomfort		3 0
Genital erythema		1 0
Genital pain		2 0
Pelvic discomfort		
Pelvic pain	5	51 0
Pruritus genital		1 0
Scrotal disorders NEC		
Scrotal oedema		1 0
Scrotal pain		3 0
Scrotal swelling		3 0
Sexual function and fertility disorders NEC		
Dyspareunia		2 0

Reaction Name	Weddra Version, Weddra 25.1	Total	Fatal
Reproductive & breast disording & breast disording	ers cont'd	- I Oldi	<u>i atai</u>
Female sexual dysfunction		1	0
Sexual dysfunction		1	0
Spermatogenesis and semen disorders			
Haematospermia		2	0
Semen discolouration		1	0
Testicular and epididymal disorders NEC			
Testicular disorder		1	0
Testicular pain		46	0
Testicular retraction		1	0
Testicular swelling		6	0
Uterine disorders NEC			
Endometriosis		8	0
Uterine enlargement		1	0
Uterine haemorrhage		6	0
Uterine pain		1	0
Uterine tone disorders			
Uterine spasm		4	0
Vaginal and vulval infections and inflammation	ns		
Vulvovaginal inflammation		1	0
Vulvovaginal cysts and neoplasms			
Vaginal cyst		1	0
Vulvovaginal disorders NEC			
Vaginal haemorrhage		137	0
Vaginal ulceration		2	0
Vulval haemorrhage		4	0
Vulval ulceration		2	
Vulvovaginal ulceration		1	0
Vulvovaginal signs and symptoms			
Enlarged clitoris		1	0
Vaginal discharge		16	0
Vaginal lesion		3	0
Vulval oedema		1	0
Vulvovaginal burning sensation		6	0
Vulvovaginal discomfort		1	
Vulvovaginal dryness		1	0
Vulvovaginal erythema		1	0
Vulvovaginal pain		9	0
Vulvovaginal rash		2	0
Vulvovaginal swelling		3	0
Reproductive & breast disorders SOC TOTAL		1136	0

	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Apnoea		7 o
Apnoeic attack		1 0
Dyspnoea	303	5 3
Dyspnoea at rest		7 0
Dyspnoea exertional	1	6 0
Dyspnoea paroxysmal nocturnal		1 0
Grunting		1 0
Hyperventilation		4 0
Hypopnoea	11	
	''	
Hypoventilation		
Irregular breathing		
Mouth breathing		7 0
Orthopnoea	_	2 0
Respiration abnormal		7 1
Respiratory arrest	1	0 0
Respiratory distress		4 0
Respiratory fatigue		2 0
Sleep apnoea syndrome		4 0
Tachypnoea	2	6 0
Bronchial conditions NEC		
Bronchiectasis		9 0
Bronchospasm and obstruction		
Aspirin-exacerbated respiratory disease		1 0
Asthma	26	
Asthma late onset		1 0
Asthmatic crisis		3 0
Bronchospasm	1	1 0
Chronic obstructive pulmonary disease	2	1 2 5 0
Cough variant asthma		5 0
Obstructive airways disorder		2 0
Reversible airways obstruction		1 0
Wheezing	31	
Conditions associated with abnormal gas excl		
Asphyxia	90	1 0
Hypercapnia		1 0
Нурохіа	3	4 0
Coughing and associated symptoms		il
Allergic cough		2 0
Cough	203	
Haemoptysis		9 0
Productive cough		0 0
Sputum discoloured		4 0
Sputum increased		1 0
	aval infactions and	1 0
Laryngeal and adjacent sites disorders NEC (neoplasms)	exci iniections and	
Reflux laryngitis		1 0
Laryngeal spasm, oedema and obstruction		ή '
		2 0
Laryngespasm		1
Laryngospasm		1 0 3 0
Stridor		ا ا
Lower respiratory tract inflammatory and imme	มาเงเงษูเซ ซงกินเนิงทิร	4
Alveolitis		1 0

Reaction Name  Respiratory disorders Respiratory disorders cont'd  Pneumonia aspiration Pneumonitis Lower respiratory tract signs and symptoms	3 0
Pneumonia aspiration 10 Pneumonitis 10	
Pneumonia aspiration 10 Pneumonitis 10	
	0
Lower respiratory tract signs and symptoms	U
Hiccups 21	0
Lower respiratory tract congestion 2	0
Lung opacity 3	0
Pleuritic pain 10	0
Pulmonary haemorrhage 1	0
Pulmonary pain 102	0
Nasal congestion and inflammations	Ŭ
Nasal congestion 268	0
Nasal inflammation 4	0
Rhinitis allergic 9	0
Rhinitis perennial	0
Nasal disorders NEC	J
Epistaxis 611	0
Intranasal hypoaesthesia 1	0
Nasal crusting 3	0
Nasal cyst 1	0
Nasal disorder 1	0
Nasal dryness 27	0
Nasal odour 2	0
Nasal oedema 6	0
Nasal pruritus 4	0
Nasal ulcer 2	0
Neonatal hypoxic conditions	U
Gasping syndrome 1	0
Paranasal sinus disorders (excl infections and neoplasms)	J
	0
Paranasal sinus haemorrhage 2 Paranasal sinus inflammation 1	0
Sinonasal obstruction 5	0
Sinus congestion 35	0
Sinus disorder 4	0
Parenchymal lung disorders NEC	J
Emphysema 1	0
Idiopathic pulmonary fibrosis	0
Interstitial lung disease 3	0
Lung consolidation 1	0
Lung infiltration 1	0
Pulmonary cavitation 1	0
Pharyngeal disorders (excl infections and neoplasms)	U
Oropharyngeal swelling 1	0
Pharyngeal erythema 3	0
Pharyngeal haemorrhage 1	0
Pharyngeal hypoaesthesia 17	0
Pharyngeal oedema 10	0
Pharyngeal paraesthesia 18	0
Pharyngeal swelling 132	0
Pharyngeal ulceration 8	0
Tonsillar disorder	0
Tonsillar erythema 4	0
Tonsillar hypertrophy 32	0
Tonsillar inflammation 2	0

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Reaction Name	<u> Total</u>	Fatal
Respiratory disorders espiratory disorders cont'd		
Pleural infections and inflammations		
Lupus pleurisy	1	0
Pleurisy	13	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	3	0
Pneumothorax	2	Ő
Pulmonary hypertensions		Ŭ
Pulmonary hypertension	2	1
Pulmonary oedemas		
Acute pulmonary oedema	2	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	11	0
Pulmonary congestion  Pulmonary oedema	10	0
	10	U
Pulmonary thrombotic and embolic conditions	287	37
Pulmonary embolism Pulmonary infarction	207	31
Pulmonary thrombosis		0
	5	U
Respiratory failures (excl neonatal)	6	2
Respiratory failure	6	2
Respiratory signs and symptoms NEC		0
Allergic respiratory symptom	3	0
Diaphragmalgia	9	0
Painful respiration	2	0
Respiratory symptom	10	0
Suffocation feeling	2	0
Respiratory tract disorders NEC		0
Aspiration	3	2
Chronic respiratory disease	1	0
Lung disorder	4	0
Respiratory disorder	2	0
Respiratory tract congestion	3	0
Respiratory tract haemorrhage	1	0
Respiratory tract irritation	3	0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	1	0
Tracheal disorders (excl infections and neoplasms)		
Tracheal fistula	1	0
Tracheal pain	1	0
Upper respiratory tract signs and symptoms		
Aphonia	36	
Catarrh	35	_
Choking	9	0
Choking sensation	5	0
Dry throat	155	
Dysphonia	70	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	10	0
Laryngeal pain	1	0
Nasal discomfort	57	0
Oropharyngeal blistering	12	0
Oropharyngeal discomfort	14	0
Oropharyngeal pain	2441	0
Paranasal sinus discomfort	24	0

Name: COVID-19 vaccine AstraZeneca analysis print

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Rhinalgia	20	0
Rhinorrhoea	980	0
Sinus pain	296	0
Sneezing	253	0
Snoring	2	0
Throat clearing	2	0
Throat irritation	103	0
Throat lesion	1	0
Throat tightness	98	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	12	0
Yawning	45	0
Respiratory disorders SOC TOTAL	12660	52

Earliest Reaction Date: 03-Feb-1921 Me	edDRA Version: MedDRA 23.1	
Reaction Name	Total	<u>Fatal</u>
Skin disorders		
Acnes		
Acne	2	3 0
Acne cystic		1 0
Dermatitis acneiform		1 0
Alopecias		
Alopecia	4	4 0
Alopecia totalis		1 0
Alopecia universalis		1 0
Diffuse alopecia		1 0
Madarosis		1 0
Angioedemas		
Angioedema	16	5 0
Circumoral oedema		1 0
Idiopathic angioedema		3 0
Apocrine and eccrine gland disorders		
Anhidrosis		1 0
Cold sweat	106	в о
Hyperhidrosis	589	
Hypohidrosis		2 0
Miliaria	100	
Night sweats	109	
Sweat discolouration		1 0
Sweat gland disorder		1 0
Bullous conditions		
Blister	173	3 0
Blood blister	10	
Dermatitis bullous		5 0
Erythema multiforme		9 0
Oedema blister		1 0
Pemphigoid		4 0
Pemphigus		1 0
Stevens-Johnson syndrome		3 0
Connective tissue disorders		
Subacute cutaneous lupus erythematosus		1 0
Dermal and epidermal conditions NEC		
Dry skin	16	o lo
Macule		4 0
Myxoid cyst		1 0
Pain of skin	58	1 0
Papule	2:	
Peau d'orange		1 0
Scab		9 0
Scar pain		5 0
Sensitive skin	36	
Skin burning sensation	300	
Skin discolouration	6	
Skin disorder		9 0
Skin fissures		6 0
Skin fragility		1 0
Skin indentation		1 0
Skin induration		7 0
Skin lesion		7 0
Skin necrosis		1 0

	edDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Skin disorders Skin disorders cont'd			
Skin odour abnormal		26	0
Skin plaque		1	0
Skin reaction		121	0
Skin sensitisation		57	0
Skin swelling		52	0
Skin texture abnormal		1	0
Skin tightness		14	0
Skin warm		333	0
Skin weeping		1	0
Sticky skin		1	0
Yellow skin		16	0
Dermatitis and eczema			
Dermatitis		85	0
Dermatitis allergic		138	0
Dermatitis atopic		9	0
Dermatitis contact		1	0
Dermatitis diaper		1	0
Dyshidrotic eczema		2	0
Eczema		75	0
Eczema asteatotic		3	0
Eczema nummular		1	0
Eczema weeping		1	0
Intertrigo		2	0
Perioral dermatitis		2	0
Prurigo		1	0
Rebound eczema		1	0
Seborrhoeic dermatitis		2	0
Skin irritation		59	0
Stasis dermatitis		1	0
Dermatitis ascribed to specific agent			
Drug eruption		19	0
Drug reaction with eosinophilia and systemic	symptoms	6	0
Fixed eruption		2	0
Palmar-plantar erythrodysaesthesia syndrom	e	1	0
Erythemas			
Erythema		1831	0
Erythema ab igne		1	0
Palmar erythema		4	0
Exfoliative conditions			
Dermatitis exfoliative generalised		2	0
Exfoliative rash		7	0
Skin exfoliation		48	0
Granulomatous and deep cutaneous inflamma	tory conditions		
Granuloma annulare		2	0
Hyperpigmentation disorders			
Solar lentigo		1	0
Hypopigmentation disorders			
Skin depigmentation		1	0
Skin hypopigmentation		1	0
Vitiligo		4	0
Lipodystrophies			
Lipoatrophy		2	0
Lipohypertrophy		2 2	0

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Skin disorders Skin disorders cont'd		
Nail and nail bed conditions (excl infections and infestations)		
Nail bed disorder	1	0
Nail bed tenderness	1	0
Nail discolouration	3	0
Nail disorder	1	0
Nail hypertrophy	1	0
Nail pigmentation	1	0
Nail pitting	1	0
Nail ridging	1	0
Onychalgia	2	0
Onychoclasis	3	0
Onychomadesis	1	0
Panniculitides		
Erythema nodosum	4	0
Papulosquamous conditions		
Erythema annulare	1	0
Lichen planus	5	0
Pityriasis rosea	7	0
Pityriasis rubra pilaris	1	0
Photosensitivity and photodermatosis conditions		Ů
Photosensitivity reaction	84	0
Polymorphic light eruption	1	0
Pigmentation changes NEC		· ·
Pigmentation disorder	4	0
Pilar disorders NEC		
Hair colour changes	1	0
Hair disorder	1	0
Hair growth abnormal	1	0
Hair texture abnormal	1	0
Piloerection	55	0
Trichodynia	3	0
Pruritus NEC		J
Itching scar	1	0
Pruritus	3774	0
Pruritus allergic	1	0
Psoriatic conditions		J
Guttate psoriasis	8	0
Psoriasis	49	
Pustular psoriasis	1	0
Purpura and related conditions		J
Ecchymosis	1	0
Henoch-Schonlein purpura	2	0
Petechiae	50	
Purpura	26	
Rashes, eruptions and exanthems NEC	20	
Butterfly rash	4	0
Rash	3639	
Rash erythematous	1085	
Rash macular	314	
Rash maculo-papular	25	
Rash morbilliform	15	
Rash papular	189	
· ·	854	
Rash pruritic	<u>1 854</u>	ı U

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	edDRA Version: MedDRA 23.1	
Reaction Name	Total	<u> Fatal</u>
Skin disorders Skin disorders cont'd		
Rash rubelliform		1 0
Rash vesicular	3	
Systemic lupus erythematosus rash		3 0
Rosaceas		
Rosacea	1	1 0
Scaly conditions		
Pityriasis		1 0
Sebaceous gland disorders		
Seborrhoea		2 0
Skin and subcutaneous conditions NEC		
Cutaneous symptom		3 0
Skin mass	1.	
Skin and subcutaneous tissue ulcerations		
Diabetic foot		1 0
Skin erosion	2	
Skin ulcer	1	
Skin cysts and polyps	·	
Dermal cyst		4 0
Skin dystrophies		
Skin wrinkling		1 0
Skin haemorrhages		
Haemorrhage subcutaneous		2 0
Skin haemorrhage		2 0 7 0
Skin hyperplasias and hypertrophies		<u> </u>
Skin hypertrophy		1 0
Skin hypoplasias and atrophies		Ϊ ,
Skin atrophy		1 0
Skin striae		1 0
Skin injuries and mechanical dermatoses		<u> </u>
Decubitus ulcer		2 0
Needle track marks		3 0
Skin preneoplastic conditions NEC		
Actinic keratosis		1 0
Leukoplakia		1 0
Skin vascular conditions NEC		<u>'</u>
Skin oedema		2 0
Skin vasculitides		
Cutaneous vasculitis		2 0
Hypersensitivity vasculitis		2 0 2 0
Vasculitic rash	1	
Skin vasomotor conditions	1	
Livedo reticularis	2	1 0
Urticarias		'  "
Chronic spontaneous urticaria		2 0
Cold urticaria		1 0
Idiopathic urticaria		3 0
Urticaria	108	
Urticaria chronic	100	
	1	1 0
Urticaria papular Urticaria thermal		1
		4 0
Urticarial vasculitis	0400	2 0
Skin disorders SOC TOTAL	2460	<u>5 1</u>

Reaction Name	Total	Fatal
Social circumstances		
Age related issues		
Childhood	1	0
Menopause	1	0
Criminal activity		
Chemical submission	1	0
Dietary and nutritional issues		
Inadequate diet	1	0
Disability issues		
Bedridden	44	0
Dependence on oxygen therapy	1	0
Disability	1	0
Immobile	20	0
Immobilisation prolonged	1	0
Impaired driving ability	2	0
Impaired work ability	5	0
Loss of personal independence in daily activities	2	0
Sight disability	8	0
Sitting disability	1	0
Walking disability	2	0
Employment issues		
Retirement	3	0
Non-occupational and unspecified environmental problems		
Food contamination	1	0
Water pollution	1	0
Pregnancy related circumstances		
Breast feeding	2	0
Social issues NEC		
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	1	0
Tobacco user	2	0
Social circumstances SOC TOTAL	106	0

Name: COVID-19 vaccine AstraZeneca analysis print

Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03 Report Run Date: 01-Apr-2021

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1		
Reaction Name	Total	Fatal
Surgical & medical procedures		
Anaesthesia and allied procedures		
Local anaesthesia	1	0
Nerve block	1	0
Analgesia supportive care		
Analgesic therapy	1	0
Antiinfective therapies		
COVID-19 treatment	4	0
Blood and blood product treatment		
Photopheresis	1	0
Breast therapeutic procedures NEC		
Axillary lymphadenectomy	1	0
Bronchial and pulmonary therapeutic procedures		
Airway secretion clearance therapy	1	0
Cardiac device therapeutic procedures	·	
Pacemaker generated rhythm	1	0
Cardiac therapeutic procedures NEC		Ŭ
Pericardial excision	1	0
Contraceptive methods female		Ŭ
Contraceptive diaphragm	1	0
Dietary and nutritional therapies	'	J
Fluid replacement	1	0
Medical diet	1	0
Nothing by mouth order	1	0
External ear therapeutic procedures	'	J
Cerumen removal	1	0
Eye therapeutic procedures NEC	'	J
Eye irrigation	1	0
Facial therapeutic procedures		J
Face lift	2	0
Gastrointestinal therapeutic procedures NEC		J
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis against gastrofficestifial dicer	22	0
Hormonal therapeutic procedures NEC	22	U
Hormone replacement therapy	3	0
Immunisations		U
COVID-19 immunisation	107	1
Immunisation	54	o
Induced abortions	34	Ŭ
Abortion induced	1	0
Joint therapeutic procedures	'	Ŭ
Hip surgery	1	0
Joint injection	1	0
Large intestine therapeutic procedures		U
Appendicectomy	1	0
Limb therapeutic procedures		U
Limb immobilisation	14	0
Limb infinobilisation Limb operation		
•	4	0
Limb reattachment surgery	1	0
Toe amputation  Mastectomies	I I	0
	4	0
Breast conserving surgery	1	0
Muscle therapeutic procedures	4	_
Muscle relaxant therapy	1	0

Reaction Name	Total	Fatal
Surgical & medical procedures cont'd		
Nasal therapeutic procedures		
Nasal irrigation	1	0
Nervous system therapeutic procedures NEC		
Central nervous system stimulation	2	0
Patient positioning		
Prone position	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	2	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	1	0
Small intestine therapeutic procedures		
lleostomy	2	0
Spine and spinal cord therapeutic procedures		
Spinal operation	1	0
Therapeutic procedures NEC		
Anaphylaxis treatment	2	0
Bed rest	16	0
Catheter management	1	0
Catheter placement	1	0
Fatigue management	1	0
Hospitalisation	5	0
Injection	25	0
Localised alternating hot and cold therapy	5	0
Manipulation	1	0
Mass excision	6	0
Product used for unknown indication	1	0
Self-medication	1	0
Smoking cessation therapy	1	0
Specialist consultation	1	0
Surgery	1	0
Therapeutic hypothermia	2	0
Therapy change	1	0
Uterine therapeutic procedures		
Endometrial ablation	1	0
Vascular therapeutic procedures NEC		
Thrombectomy	1	0
Thromboembolectomy	1	0
Surgical & medical procedures SOC TOTAL	317	1

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA	x 23.1	
Reaction Name	<u>Total</u>	Fatal
Vascular disorders		
Accelerated and malignant hypertension		
Hypertensive crisis	5	0
Hypertensive emergency	1	0
Hypertensive urgency	1	0
Malignant hypertension	1	0
Tyramine reaction	1	0
Aneurysms and dissections non-site specific		
Aneurysm	3	1
Artery dissection	1	
Aortic aneurysms and dissections		
Aortic aneurysm	3	0
Aortic embolism and thrombosis		
Aortic embolus	5	0
Aortic thrombosis	2	1
Arterial infections and inflammations		
Arteritis	1	0
Giant cell arteritis	18	-
Blood pressure disorders NEC		
Blood pressure fluctuation	6	0
Labile blood pressure	1	0
Bruising, ecchymosis and purpura		
Achenbach syndrome	1	0
Circulatory collapse and shock		
Circulatory collapse	45	1
Neurogenic shock	7	
Peripheral circulatory failure	2	
Shock	30	
Shock symptom	4	
Haemorrhages NEC		
Bloody discharge	2	. 0
Haematoma	34	
Haemorrhage	105	
Internal haemorrhage	3	
Venous haemorrhage	1 1	
Lymphoedemas		
Lymphoedema	30	0
Non-site specific embolism and thrombosis		
Arterial thrombosis	2	0
Embolism	12	
Embolism venous	4	
Thrombophlebitis migrans	1	0
Thrombosis	303	
Venous thrombosis	8	
Non-site specific necrosis and vascular insufficiency NEC		
Arterial occlusive disease	1	0
Arterial spasm	1	0
Arteriosclerosis	1	0
Infarction	1	0
Ischaemia	1	0
Peripheral venous disease	2	
Vasospasm	2	
Non-site specific vascular disorders NEC		
Capillary fragility	1	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 23.1	Tatal	Catal
Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd	4	
Neovascularisation	1	0
Vascular pain	26	0
Vascular rupture	1	0
Vasodilatation	25	0
Vein disorder	1	0
Vein rupture	3	0
Peripheral embolism and thrombosis	4.0	_
Blue toe syndrome	10	0
Deep vein thrombosis	240	3
Iliac artery embolism	1	0
Jugular vein thrombosis	1	0
Pelvic venous thrombosis	1	0
Peripheral artery thrombosis	1	0
Peripheral embolism	1	0
Thrombophlebitis	23	0
Thrombophlebitis superficial	8	0
Venous thrombosis limb	2	0
Peripheral vascular disorders NEC		_
Cyanosis	57	0
Erythromelalgia	2	0
Flushing	445	
Hot flush	1180	0
Peripheral vascular disorder	2	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Extremity necrosis	1	0
Intermittent claudication	2	0
Ischaemic limb pain	2	0
Peripheral artery occlusion	2	0
Peripheral coldness	726	0
Peripheral ischaemia	1	0
Poor peripheral circulation	16	
Raynaud's phenomenon	54	0
Phlebitis NEC		
Phlebitis	15	0
Site specific vascular disorders NEC		
Pallor	249	0
Plethoric face	1	0
Varicose veins NEC		
Spider vein	2	0
Varicophlebitis	2	0
Varicose vein	21	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	1	0
Hypertension	296	0
Systolic hypertension	2	0
White coat hypertension	3	0
Vascular hypotensive disorders		
Capillary leak syndrome	3	0
Hypotension	271	0
Orthostatic hypotension	23	0
Vasculitides NEC		
Diffuse vasculitis	1	1
MAGIC syndrome	3	1

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vasculitis	18	0
Vena caval embolism and thrombosis		
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	4400	24
TOTAL REACTIONS FOR DRUG	440871	472
TOTAL REPORTS	116162	
TOTAL FATAL OUTCOME REPORTS		472