#### **COVID-19 Moderna Vaccine Analysis Print**

All UK spontaneous reports received up to and including 27/07/22 for Moderna vaccine.

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

Report Run Date: 27-Jul-2022

Reaction Name	Total	Fatal
Blood disorders		
Anaemia deficiencies		
Iron deficiency anaemia	2	0
Anaemias NEC		
Anaemia	18	0
Autoimmune anaemia	1	0
Microcytic anaemia	1	0
Anaemias haemolytic NEC		
Haemolytic anaemia	3	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	1	0
Bleeding tendencies		
Increased tendency to bruise	7	0
Spontaneous haematoma	1	0
Coagulopathies		
Abnormal clotting factor	2	0
Antiphospholipid syndrome	3	0
Coagulopathy	3	0
Hypercoagulation	2	0
Eosinophilic disorders		
Eosinophilia	2	0
Haematological disorders		
Blood disorder	1	0
Mast cell activation syndrome	3	0
Mastocytosis	1	0
Lymphatic system disorders NEC		
Lymph node pain	354	0
Lymph node ulcer	1	0
Lymphadenitis	27	0
Lymphadenopathy	2097	0
Lymphatic disorder	1	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	1	0
Neutropenias		
Autoimmune neutropenia	1	0
Neutropenia	3	0
Platelet disorders NEC		
Platelet disorder	1	0
Polycythaemia (excl rubra vera)		
Stress polycythaemia	1	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	1	0
Spleen disorders		
Splenic infarction	1	0
Splenic vein thrombosis	1	0
Thrombocytopenias		
Immune thrombocytopenia	11	0
Thrombocytopenia	33	0
Thrombocytopenic purpura	2	0
Blood disorders SOC TOTAL	2587	0

## Case Series Drug Analysis Print ne: COVID-19 Moderna vaccine analysis pri

Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 25.0

<u> </u>	MedDRA Version: MedDRA 25.0	
Reaction Name	Total	<u> Fatal</u>
Cardiac disorders		
Cardiac conduction disorders		
Atrioventricular block		4 0
Atrioventricular block complete		1 0
Bundle branch block left		1 0
Bundle branch block right		2 0
Sinoatrial block		1 0
Cardiac disorders NEC		
Cardiac disorder	2	o o
Cardiac dysfunction		3 0
Cardiac ventricular thrombosis		1 0
Cardiac infections and inflammations NEC		
Carditis		3 o
Cardiac signs and symptoms NEC		
Cardiac discomfort		6l ol
Palpitations	179	1 0
Cardiomyopathies		
Cardiomyopathy		2 0
Congestive cardiomyopathy		1 0
Stress cardiomyopathy		1 0
Toxic cardiomyopathy		1 0
Coronary artery disorders NEC		.  "
Arteriosclerosis coronary artery		1 1
Coronary artery disease		1 0
Coronary artery occlusion		1 0
Coronary artery stenosis		1 0
Coronary artery thrombosis		1 0
Heart failures NEC		1 9
Cardiac failure		8 0
Cardiac failure acute		1 0
Cardiac failure congestive		1 0
Cardiogenic shock		1 0
Cardiopulmonary failure		1 1
Ischaemic coronary artery disorders		'
Acute coronary syndrome		2 0
Acute myocardial infarction		
Angina pectoris	6	9 0
Angina pectors  Angina unstable	0	3 0
Myocardial infarction	4	
Myocardial infaction  Myocardial ischaemia	4	1 0
Left ventricular failures		1 9
Left ventricular failures		1 0
Mitral valvular disorders		1 9
		1 0
Mitral valve incompetence		1 0 1 0
Mitral valve prolapse		1 0
Myocardial disorders NEC		
Cardiomegaly		9 0
Left ventricular dilatation		1 0
Left ventricular dysfunction		5 0
Left ventricular enlargement		
Left ventricular hypertrophy		2 0
Myocardial fibrosis		2 0
Myocardial injury		1 0
Myocardial oedema		2 0

Report Run Date: 27-Jul-2022

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Noninfectious myocarditis		
Hypersensitivity myocarditis	1	0 ا
Myocarditis	199	o
Myopericarditis	28	3 0
Noninfectious pericarditis		
Pericarditis	135	5 O
Pleuropericarditis	1	0 ا
Pericardial disorders NEC		
Pericardial effusion	3	3 O
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	32	0
Bradycardia	18	3 0
Cardiac fibrillation	1	0 ا
Cardiac flutter	142	0
Extrasystoles	57	7 0
Heart alternation	1	0 ا
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	3	3 0
Tachyarrhythmia	3	3 0
Tachycardia	790	1
Tachycardia foetal	1	0
Supraventricular arrhythmias		
Atrial fibrillation	49	0
Atrial flutter	13	0
Atrial tachycardia	3	
Sinus arrhythmia	3	3 0
Sinus tachycardia	11	
Supraventricular extrasystoles	2	
Supraventricular tachycardia	3	3 0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	19	6
Ventricular arrhythmia	1	0
Ventricular extrasystoles		0
Ventricular fibrillation		2 0
Ventricular tachycardia	(	0
Cardiac disorders SOC TOTAL	3540	12

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Reaction Name	Total	Fatal
Congenital disorders		
Cardiac disorders congenital NEC		
Heart disease congenital	3	0
Cerebellar disorders congenital		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
Connective tissue disorders congenital		
Ehlers-Danlos syndrome	2	0
Gene mutations and other alterations NEC		
Hereditary angioedema	1	0
Haematological disorders congenital NEC		
Neonatal alloimmune thrombocytopenia	1	0
Male reproductive tract disorders congenital		
Micropenis	1	0
Musculoskeletal disorders congenital NEC		
Dysmorphism	1	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	1	0
Ocular disorders congenital NEC		
Colour blindness	1	0
Peripheral nervous system disorders congenital NEC		
Paroxysmal extreme pain disorder	1	0
Congenital disorders SOC TOTAL	14	0

## Case Series Drug Analysis Print ne: COVID-19 Moderna vaccine analysis prir

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear canal erythema	1	0
Ear congestion	8	8 0
Ear discomfort	10	0
Ear disorder	6	0
Ear inflammation	1	0
Ear pain	308	s 0
Ear swelling	6	
Eustachian tube disorders		
Eustachian tube obstruction	2	2 0
External ear disorders NEC		
Excessive cerumen production	3	s 0
Red ear syndrome	1	l 0
External ear infections and inflammations		
External ear inflammation	1	0
Hearing losses		
Deafness	54	.l o
Deafness neurosensory	2	
Deafness transitory	1	0
Deafness unilateral	g	0
Hypoacusis	43	
Sudden hearing loss	13	
Hyperacusia		
Hyperacusis	10	0
Inner ear disorders NEC		
Meniere's disease	1	0
Vestibular disorder	1	0
Inner ear infections and inflammations		
Inner ear inflammation	4	l o
Inner ear signs and symptoms		
Motion sickness	20	o l
Tinnitus	468	
Vertigo	322	
Vertigo labyrinthine	2	o o
Vertigo positional	16	0
Middle ear infections and inflammations		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	1314	

## Case Series Drug Analysis Print ne: COVID-19 Moderna vaccine analysis pri

Reaction Name	Total	Fatal
Endocrine disorders	Total	
Acute and chronic thyroiditis		
Autoimmune thyroiditis	1 1	0
Thyroiditis	2	0
Thyroiditis subacute	2	0
Adrenal cortical hypofunctions		
Adrenal insufficiency	1	0
Adrenocortical insufficiency acute	6	0
Anterior pituitary hypofunction		
Hypopituitarism	1	0
Endocrine abnormalities of puberty		
Delayed menarche	2	0
Premature menarche	3	0
Female gonadal function disorders		
Anovulatory cycle	7	' 0
Ovulation delayed	11	0
Hyperparathyroid disorders		
Hyperparathyroidism		0
Hypoparathyroid disorders		
Hypoparathyroidism	1	0
Hypothalamic and pituitary disorders NEC		
Pituitary haemorrhage	1	0
Polyglandular endocrine disorders		
Polyglandular disorder	1	0
Thyroid disorders NEC		
Goitre	6	0
Thyroid disorder	2	0
Thyroid pain	2	0
Thyroid hyperfunction disorders		
Basedow's disease	2	0
Hyperthyroidism	5	0
Thyroid hypofunction disorders		
Hypothyroidism	5	0
Endocrine disorders SOC TOTAL	62	el o

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Reaction Name MedDRA Version: MedDRA 25.0	Total	Fatal
Eye disorders		
Amblyopic vision impairment		
Amblyopia	5	0
Cataract conditions		
Cataract	1	0
Choroid and vitreous structural change, deposit and degeneration		
Vitreous detachment	2	0
Vitreous floaters	20	0
Colour blindness (incl acquired)		
Dyschromatopsia	2	0
Conjunctival and corneal bleeding and vascular disorders		
Conjunctival haemorrhage	9	0
Corneal infections, oedemas and inflammations		
Ulcerative keratitis	1	0
Eyelid movement disorders		
Blepharospasm	35	0
Eyelid ptosis	5	0
Iris and uveal tract infections, irritations and inflammations		
Iridocyclitis	2	0
Iritis	2	0
Uveitis	11	0
Lacrimation disorders		J
Dry eye	38	0
Lacrimation increased	18	0
Lid, lash and lacrimal infections, irritations and inflammations	10	
Blepharitis	2	0
Erythema of eyelid	2 2	0
Eyelid cyst	1	0
Eyelid cyst  Eyelid irritation		0
Eyelid initiation Eyelid oedema	2	0
Eyelid dedema Eyelid rash	2 2 2	0
Swelling of eyelid	33	0
Lid, lash and lacrimal structural disorders	33	U
Lagophthalmos	1	0
Ocular bleeding and vascular disorders NEC	'	U
<u> </u>	1	0
Eye haematoma	4	0
Eye haemorrhage  Ocular disorders NEC	4	U
	1	^
Eye disorder	4	0
Eye oedema	363	0
Eye pain		
Eye swelling	135	0
Eyelid disorder	4	0
Eyelids pruritus	3 17	0
Ocular discomfort		0
Periorbital oedema	3	0
Periorbital swelling	22	0
Ocular infections, inflammations and associated manifestations	_	_
Eye allergy	5	C
Eye discharge	3	C
Eye inflammation	8	C
Eye irritation	21	C
Eye pruritus	41	C
Limbal swelling	1	0

## Case Series Drug Analysis Print e: COVID-19 Moderna vaccine analysis pr

MedDRA Version: MedDRA 25.0		
Reaction Name	Total	<u>Fatal</u>
Eye disorders Eye disorders cont'd		
Ocular hyperaemia	48	C
Ocular nerve and muscle disorders		
Eye movement disorder	9	(
Gaze palsy	1	(
Ophthalmoplegia	1	(
Ocular sensation disorders		
Abnormal sensation in eye	2	(
Asthenopia	30	(
Foreign body sensation in eyes	8	(
Hypoaesthesia eye	6	(
Photophobia	135	(
Optic disc abnormalities NEC		
Optic discs blurred	1	(
Papilloedema	1	(
Optic nerve bleeding and vascular disorders		
Optic ischaemic neuropathy	1	C
Orbital infections, inflammations and irritations		
Orbital myositis	2	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	2	0
Pupil disorders		
Mydriasis	5	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Astigmatism	3	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal ischaemia	1	0
Retinal vein occlusion	11	0
Retinal structural change, deposit and degeneration		
Macular degeneration	1	0
Macular hole	1	0
Retinal detachment	1	0
Retinal, choroid and vitreous infections and inflammations		
Retinal oedema	1	0
Retinopathies NEC		
Acute macular neuroretinopathy	1	C
Central serous chorioretinopathy	4	C
Serous retinopathy	1	C
Scleral infections, irritations and inflammations		
Episcleritis	5	C
Scleritis	1	C
Scleral structural change, deposit and degeneration		
Scleral disorder	1	(
Structural change, deposit and degeneration of eye NEC		
Exophthalmos	2	C
Visual colour distortions		
Cyanopsia	1	(
Xanthopsia	2	(
Visual disorders NEC		
Diplopia	40	(
Halo vision	4	C

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Metamorphopsia	5	0
Photopsia	32	0
Scintillating scotoma	1	0
Vision blurred	329	0
Visual field disorders		
Visual field defect	5	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	2	0
Blindness	42	0
Blindness transient	8	0
Blindness unilateral	2	0
Night blindness	1	0
Visual acuity reduced	3	0
Visual impairment	69	0
Eve disorders SOC TOTAL	1667	0

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Reaction Name		<u> Total</u>	<u>Fatal</u>
Gastrointestinal disorders			
Abdominal findings abnormal			
Gastrointestinal sounds abnor	rmal	1	(
Acute and chronic pancreatitis			
Pancreatitis		4	(
Pancreatitis acute		1	(
Anal and rectal disorders NEC			
Anal sphincter atony		1	(
Anal and rectal pains			
Proctalgia		9	(
Anal and rectal signs and symp	toms		
Anal pruritus		1	(
Anal rash		1	(
Anorectal discomfort		1	(
Colitis (excl infective)			
Colitis		6	(
Colitis ischaemic		1	(
Colitis ulcerative		10	(
Crohn's disease		8	(
Inflammatory bowel disease		7	(
Dental and periodontal infection	ns and inflammations		
Dental caries		1	C
Dental disorders NEC			
Loose tooth		1	C
Teething		2	C
Tooth disorder		1	C
Dental pain and sensation disor	rders		
Dental discomfort		1	C
Dental paraesthesia		5	C
Hyperaesthesia teeth		7	C
Toothache		38	(
Dental pulp disorders			
Dental pulp disorder		1	(
Diaphragmatic hernias			
Hiatus hernia		2	C
Diarrhoea (excl infective)			
Diarrhoea		1288	(
Diarrhoea haemorrhagic		7	Č
Diverticula			
Diverticulum		1	(
Duodenal ulcers and perforation	1	·	
Duodenal ulcer		1	(
Dyspeptic signs and symptoms		·	
Dyspepsia Dyspepsia		162	(
Epigastric discomfort		4	Ò
Eructation		19	(
Faecal abnormalities NEC		10	·
Faeces discoloured		10	(
Faeces hard		10	
Faeces naid		1	
Mucous stools		2	
Flatulence, bloating and distens	eion		
Abdominal distension	DIUI I	84	(
Flatulence		42	

## Case Series Drug Analysis Print ne: COVID-19 Moderna vaccine analysis prir

-	A Version: MedDRA 25.0	
Reaction Name	Total	<u>Fatal</u>
Gastrointestinal disorders ointestinal disorders cont'd		
Gastric ulcers and perforation		
Gastric ulcer	2	2 (
Gastritis erosive	1	(
Gastritis (excl infective)		
Gastritis	12	2 (
Gastrointestinal and abdominal pains (excl oral and	throat)	
Abdominal pain	367	·  (
Abdominal pain lower	27	1
Abdominal pain upper	946	
Abdominal rigidity	3	1
Abdominal tenderness	5	
Gastrointestinal pain	44	
Oesophageal pain	1	
Gastrointestinal atonic and hypomotility disorders Ni	FC	
Constipation	45	
Gastric dilatation	3	1
Gastrooesophageal reflux disease	40	
Gastrointestinal disorders NEC	1	
Food poisoning	3	3
Functional gastrointestinal disorder	3	
Gastric disorder	2	
Gastrointestinal disorder	4	1
	4	
Lymphoid hyperplasia of intestine Stomach mass		
Gastrointestinal dyskinetic disorders	4	
Bowel movement irregularity	1	
Change of bowel habit	3	
Gastrointestinal motility disorder	2	
Oesophageal achalasia	1	
Gastrointestinal inflammatory disorders NEC		
Gastrointestinal inflammation		2
Gastrointestinal mucosal dystrophies and secretion		
Hyperchlorhydria	2	2
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	185	
Acute abdomen	1 1	3
Anal incontinence	3	1
Breath odour	8	
Dysphagia	39	
Odynophagia	9	
Gastrointestinal spastic and hypermotility disorders		
Defaecation urgency	1	
Frequent bowel movements	10	1
Irritable bowel syndrome	21	
Gastrointestinal stenosis and obstruction NEC		
Intestinal obstruction	1	
Gastrointestinal vascular malformations		
Gastric antral vascular ectasia	2	2
Gastrointestinal vascular occlusion and infarction		
Intestinal ischaemia	2	2
Mesenteric vein thrombosis	1	
Gingival disorders, signs and symptoms NEC		
Gingival discomfort	2	

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Reaction Name	<u>Total</u>	<u>Fatal</u>
Gastrointestinal disordersointestinal disorders cont'd		
Gingival disorder	3	0
Gingival pain	25	0
Gingival swelling	9	0
Noninfective gingivitis	2	0
Gingival haemorrhages		
Gingival bleeding	14	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		-
Haemorrhoids	7	0
Intestinal haemorrhages		-
Anal haemorrhage	1	0
Rectal haemorrhage	20	0
Malabsorption syndromes		
Coeliac disease	2	0
Nausea and vomiting symptoms		
Discoloured vomit	1	0
Nausea	5015	0
	3013	0
Regurgitation	26	0
Retching	36	0
Vomiting	1970	0
Vomiting projectile	28	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	3	0
Haematemesis	8	0
Haematochezia	17	0
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
Oesophageal disorders NEC		
Oesophageal disorder	1	0
Oesophagitis (excl infective)		
Oesophagitis	1	0
Oral dryness and saliva altered		
Aptyalism	2	0
Dry mouth	115	0
Lip dry	11	0
Saliva altered	2	0
Salivary hypersecretion	13	0
Oral soft tissue disorders NEC		
Chapped lips	3	C
Cheilitis	5	C
Enlarged uvula	1	C
Lip blister	4	C
Lip disorder	1	C
Oral disorder	1	Č
Uvulitis	1	
Oral soft tissue haemorrhages	'	
Mouth haemorrhage	5	C
Oral blood blister	4	C
	4	
Oral soft tissue signs and symptoms		,
Coating in mouth	2	
Hypoaesthesia oral	94	(
Lip discolouration	1	(
Lip exfoliation	1	(
Lip pain	12	C

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MedDRA Version: MedDRA 25.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Gastrointestinal disorders ointestinal disorders cont'd		
Lip pruritus	3	0
Oral discomfort	13	0
Oral mucosal blistering	2	0
Oral mucosal eruption	3	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	38	0
Oral pruritus	2	C
Paraesthesia oral	134	C
Oral soft tissue swelling and oedema		
Lip oedema	1	C
Lip swelling	231	C
Mouth swelling	24	C
Peptic ulcers and perforation		
Peptic ulcer	1	C
Peptic ulcer haemorrhage	3	C
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Retroperitoneal fibrosis	1	C
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland mass	1	C
Salivary gland pain	3	C
Salivary gland enlargements		
Parotid gland enlargement	3	C
Submaxillary gland enlargement	3	C
Stomatitis and ulceration		
Aphthous ulcer	7	C
Lip ulceration	4	C
Mouth ulceration	105	C
Oral mucosa erosion	1	C
Stomatitis	6	C
Tongue disorders		
Glossitis	8	C
Tongue disorder	11	C
Tongue haemorrhage	1	C
Tongue ulceration	5	C
Tongue signs and symptoms		
Glossodynia	33	C
Stiff tongue	1	C
Swollen tongue	96	C
Tongue blistering	3	C
Tongue coated	5	(
Tongue discolouration	3	Č
Tongue discomfort	7	ſ
Tongue dry	3	C
Tongue eruption	1	(
Tongue exfoliation	1	
Tongue movement disturbance	1	Č
Tongue oedema	3	(

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Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Tongue pruritus	1	0
Tongue rough	1	0
Tongue spasm	1	0
Tooth missing		
Tooth loss	2	0
Gastrointestinal disorders SOC TOTAL	11767	l o

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MedDRA Version: MedDRA 25.0		
Reaction Name	<u> Total</u>	<u> Fatal</u>
General disorders		
Administration site reactions NEC		
Administration site bruise	3	0
Administration site erythema	1	0
Administration site extravasation	1	0
Administration site lymphadenopathy	1	
Administration site pain	2	l 0
Administration site reaction	2	
Administration site warmth	1	l 0
Puncture site bruise	6	0
Puncture site pain	4	
Vessel puncture site bruise	2	
Adverse effect absent		
No adverse event	1	
Application and instillation site reactions		·
Application site bruise	1	
Application site burn	1	
Application site erythema	11	
Application site inflammation	1	
Application site joint erythema	1	o
Application site pain	4	
Application site pruritus	10	_
Application site rash	1	Ö
Application site reaction	1	Ö
Application site swelling	3	
Application site vesicles	5	
Application site warmth	2	
Instillation site erythema	1	_
Instillation site warmth	5	
Asthenic conditions		
Asthenia	691	
Chronic fatigue syndrome	9	
Decreased activity	1	
Fatigue	7052	_
Malaise	1255	
Sluggishness		۱ ,
Body temperature altered	2	
Hyperthermia	2	l
Hypothermia	5	
Temperature regulation disorder	3	
Complications associated with device NEC	3	· ·
Complication associated with device  Complication associated with device	1	
Injury associated with device	1	
Death and sudden death	'	
Cardiac death	,	2
Death	25	
Sudden cardiac death	25	20
		'
Sudden death	1	1
Febrile disorders	7400	_
Pyrexia	7193	
Feelings and sensations NEC	4404	,
Chills	4401	
Feeling abnormal	498	
Feeling cold	470	

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Reaction Name  MedDRA Version: MedDRA 25.0	Total	Fatal
General disorders General disorders cont'd	1 0 101	
Feeling drunk	17	0
Feeling hot	396	0
Feeling jittery	13	
Feeling of body temperature change	135	0
Hangover	22	0
Hunger	18	0
Sensation of blood flow	1	0
Sensation of foreign body	8	0
Temperature intolerance	22	0
Thirst	131	0
Thirst decreased	1	0
Fibrosis NEC		0
Fibrosis	1	0
Gait disturbances	'	U
Gait disturbance	47	0
Gait inability	28	0
Loss of control of legs	4	0
	4	U
General signs and symptoms NEC	47	_
Condition aggravated	47	0
Crepitations	20	0
Crying	38	0
Discharge	4	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	19	0
Foaming at mouth	2	0
General physical health deterioration	4	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	767	0
Induration	11	0
Influenza like illness	860	0
Irritability postvaccinal	1	0
Local reaction	30	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	2287	0
Pre-existing disease	1	0
Screaming	8	0
Secretion discharge	2	0
Swelling	1291	0
Swelling face	221	0
Healing abnormal NEC		_
Impaired healing	1	0
Implant and catheter site reactions		
Catheter site related reaction	1	0
Implant site warmth	3	0
Inflammations		
Granuloma	1	0
Inflammation	215	0
Scar inflammation	1	0
Soft tissue inflammation	1	0

### Case Series Drug Analysis Print e: COVID-19 Moderna vaccine analysis pri

MedDRA Version: MedDRA 25.0		
Reaction Name	Total_	<u>Fatal</u>
General disorders General disorders cont'd		
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site erythema	2	0
Infusion site mass	1	0
Infusion site pain	5	0
Infusion site pruritus	2	C
Infusion site urticaria	5	C
Infusion site warmth	1	C
Injection site reactions		
Injected limb mobility decreased	10	C
Injection site bruising	15	C
Injection site cyst	1	0
Injection site dermatitis	1	0
Injection site discolouration	1	C
Injection site erythema	227	0
Injection site haemorrhage	4	C
Injection site hypersensitivity	6	C
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site inflammation	20	0
Injection site irritation	3	0
Injection site joint erythema	5	0
Injection site joint pain	2	0
Injection site mass	220	0
Injection site movement impairment	1	0
Injection site nodule	1	0
Injection site oedema	6	0
Injection site pain	931	0
Injection site paraesthesia	2	0
Injection site plaque	1	C
Injection site pruritus	143	C
Injection site rash	213	0
Injection site reaction	25	0
Injection site swelling	122	0
Injection site urticaria	58	0
Injection site vesicles	3	C
Injection site warmth	105	
Interactions		
Alcohol interaction	2	0
Drug interaction	4	C
Drug-device interaction	2	C
Mass conditions NEC		
Cyst	9	0
Mass	32	C
Nodule	6	l c
Mucosal findings abnormal		
Enanthema	1	C
Mucosal discolouration	2	C
Mucosal inflammation	2	
Mucosal pain	1	C
Oedema mucosal	1	
Polyp	2	
Necrosis NEC		

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	MedDRA Version: MedDRA 25.0		
Reaction Name		<u> Total</u>	<u>Fatal</u>
Contoral allocitation	disorders cont'd		
Necrosis		1	C
Oedema NEC			
Face oedema		11	C
Localised oedema		7	C
Oedema		19	0
Oedema peripheral		17	0
Pain and discomfort NEC			
Axillary pain		928	0
Chest discomfort		487	0
Chest pain		1887	0
Discomfort		147	0
Facial discomfort		1	0
Facial pain		48	0
Hernia pain		1	0
Inflammatory pain		6	0
Non-cardiac chest pain		3	0
Pain		2878	0
Tenderness		213	0
Visceral pain		1	0
Therapeutic and nontherap	eutic responses		
Adverse drug reaction		159	0
Adverse reaction		4	0
Drug ineffective		28	0
Drug intolerance		1	0
Immediate post-injection	reaction	1	0
Inadequate analgesia		3	0
No reaction on previous e	exposure to drug	1	0
Therapeutic product effect	t decreased	1	0
Therapeutic response cha	anged	1	0
Therapeutic response un	expected	3	0
Treatment failure		1	0
Vaccination failure		16	0
Ulcers NEC			
Ulcer		6	0
Vaccination site reactions			
Extensive swelling of vac	cinated limb	1	0
Shoulder injury related to	vaccine administration	19	0
Vaccination site bruising		28	0
Vaccination site discolour	ation	2	0
Vaccination site discomfo	rt	9	0
Vaccination site eczema		1	0
Vaccination site erythema	1	314	0
Vaccination site haemorrh	nage	6	0
Vaccination site hypoaest	hesia	5	0
Vaccination site induration		23	0
Vaccination site inflamma	tion	23	C
Vaccination site irritation		3	C
Vaccination site joint erytl	nema	3 2	C
Vaccination site joint mov		2	C
Vaccination site joint pain	·	4	C
Vaccination site joint war		1	C
Vaccination site lymphade		3	C
Vaccination site macule		1	C

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site mass	86	0
Vaccination site movement impairment	25	0
Vaccination site oedema	1	0
Vaccination site pain	435	0
Vaccination site papule	2	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	75	0
Vaccination site rash	153	0
Vaccination site reaction	9	0
Vaccination site scar	1	0
Vaccination site swelling	215	0
Vaccination site urticaria	14	0
Vaccination site vesicles	3	0
Vaccination site warmth	147	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Rebound effect	1	0
Withdrawal syndrome	7	0
General disorders SOC TOTAL	39073	31

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Reaction Name	Total	Fatal
Hepatic disorders		
Bile duct infections and inflammations		
Biliary colic	6	0
Cholecystitis and cholelithiasis		
Cholelithiasis	2	0
Cholestasis and jaundice		
Cholestasis	1	0
Jaundice	6	0
Jaundice cholestatic	2	0
Hepatic and hepatobiliary disorders NEC		
Hepatic cyst	1	0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	2	0
Hypertransaminasaemia	1	0
Hepatic failure and associated disorders		
Acute hepatic failure	1	0
Acute on chronic liver failure	1	0
Hepatic vascular disorders		
Portal vein thrombosis	2	0
Hepatobiliary signs and symptoms		
Hepatic pain	13	0
Liver tenderness	2	0
Hepatocellular damage and hepatitis NEC		
Autoimmune hepatitis	3	0
Drug-induced liver injury	1	0
Hepatic steatosis	1	0
Hepatitis	3	0
Immune-mediated hepatitis	1	0
Liver injury	5	0
Hepatic disorders SOC TOTAL	54	0

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MedDRA Version: MedDRA 25.0	Total	Ectal
Reaction Name	Total	<u>Fatal</u>
Immune system disorders		
Acute and chronic sarcoidosis	2	_
Sarcoidosis	2	0
Allergic conditions NEC	4	_
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	074	0
Hypersensitivity	374	0
Infusion related hypersensitivity reaction	14	I
Multiple allergies	4	0
Serum sickness	3	0
Serum sickness-like reaction	1	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	1	0
Type IV hypersensitivity reaction	13	0
Allergies to foods, food additives, drugs and other chemicals	0	_
Allergy to chemicals	2	0
Allergy to vaccine	15	
Drug hypersensitivity	16	I
Food allergy	4	0
Milk allergy	1	0
Perfume sensitivity	1	0
Reaction to excipient	2	0
Anaphylactic and anaphylactoid responses	7.5	_
Anaphylactic reaction	75	
Anaphylactic shock	8	0
Anaphylactoid reaction	11	0
Atopic disorders	47	_
Seasonal allergy	17	0
Autoimmune disorders NEC	_	_
Autoimmune disorder	5	0
Immune and associated conditions NEC	F.2	_
Bacille Calmette-Guerin scar reactivation	53	
Immune system disorder	5	0
Immune-mediated adverse reaction	1 00	0
Immunisation reaction	26	Ĭ.
Sensitisation	4	0
Systemic immune activation	1	0
Immunodeficiency disorders NEC		_
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	1	0
Immune system disorders SOC TOTAL	669	0

#### Case Series Drug Analysis Print me: COVID-19 Moderna vaccine analysis prir

MedDRA Version: MedDRA		
Reaction Name	Total	<u>Fatal</u>
nfections		
Abdominal and gastrointestinal infections		
Appendicitis	10	(
Appendicitis perforated	1	(
Diverticulitis	6	(
Dysentery	1	(
Gastroenteritis	7	(
Peritonitis	1	(
Bacterial infections NEC		
Administration site cellulitis	1	(
Application site cellulitis	1	(
Arthritis bacterial	1	
Bacterial infection	3	
Bacterial vaginosis	1	
Cellulitis	84	
Folliculitis	1	
Injection site cellulitis	2	
Meningitis bacterial	1	
Paronychia	1	
Skin bacterial infection	1	
Vaccination site cellulitis	4	
Bone and joint infections		
Arthritis infective	1	
Osteomyelitis	1	
Borrelial infections		
Lyme disease	1	
Relapsing fever	1	
Breast infections		
Breast abscess	2	
Mastitis	11	
Candida infections		
Anal candidiasis	1	
Candida infection	11	
Oral candidiasis	7	
Vulvovaginal candidiasis	12	
Cardiac infections		
Endocarditis	1	
Central nervous system and spinal infections		
Central nervous system infection	1	
Encephalitis	4	
Meningitis	6	
Meningitis aseptic	1	
Myelitis	1	
Chlamydial infections		
Eye infection chlamydial	1	
Coronavirus infections		
Asymptomatic COVID-19	1	
COVID-19	442	
COVID-19 pneumonia	6	
Coronavirus infection	1	
Post-acute COVID-19 syndrome	6	
Suspected COVID-19	5	
Coxiella infections		
Q fever	9	

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Reaction Name	Total	<u> Fatal</u>
Infections Infections cont'd		
Cytomegaloviral infections		
Cytomegalovirus infection	2	(
Cytomegalovirus infection reactivation	2	(
Pneumonia cytomegaloviral	1	(
Dental and oral soft tissue infections		
Abscess oral	1	(
Gingivitis	2	(
Oral infection	1	(
Sialoadenitis	2	(
Tooth abscess	2	(
Tooth infection	2	(
Ear infections		
Ear infection	11	(
Labyrinthitis	16	(
Otitis externa	1	(
Ectoparasitic infestations		
Acarodermatitis	1	(
Lice infestation	1	(
Enteroviral infections NEC		
Hand-foot-and-mouth disease	1	(
Epstein-Barr viral infections		
Epstein-Barr virus infection	1	(
Infectious mononucleosis	2	
Eye and eyelid infections		
Chorioretinitis	1	(
Conjunctivitis	13	
Eye infection	5	
Eyelid boil	1	(
Eyelid infection	1	
Hordeolum	5	
Female reproductive tract infections	Ĭ	
Vaginal infection	1	(
Flaviviral infections		·
Dengue fever	2	
Encephalitis Japanese B	1	Ò
Fungal infections NEC		Ì
Fungal infection	4	
Fungal skin infection	3	
Overgrowth fungal	1	
Pneumonia fungal		1
Fusobacterium infections	,	,
Necrotising ulcerative gingivostomatitis	1	(
Helicobacter infections	· ·	
Helicobacter infection	1	(
Hepatitis virus infections	'	`
Hepatitis A	1	(
Herpes viral infections	· ·	,
Eczema herpeticum	1	
Genital herpes	15	
Herpes ophthalmic	10	
Herpes simplex	8	
	0	I .
Herpes simplex reactivation Herpes virus infection		

## Case Series Drug Analysis Print ne: COVID-19 Moderna vaccine analysis pri

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Reaction Name	Total	<u> Fatal</u>
Infections Infections cont'd		
Herpes zoster	140	) 0
Herpes zoster oticus		3 0
Nasal herpes		1 0
Ophthalmic herpes simplex		1 C
Ophthalmic herpes zoster		1 C
Oral herpes	99	el d
Varicella ·		3 0
Varicella zoster virus infection		1 c
Infections NEC		
Abscess		2 (
Abscess limb		2 (
Abscess rupture		1 0
Empyema		1
Groin infection		1 0
Infection	96	
Injection site infection		1 0
Localised infection	19	
Lymph gland infection		2 0
Lymph node abscess		3 C 2 C
Respiratory tract infection	4	1
Vaccination site abscess	4	2 0
Vaccination site infection		
Vaccine breakthrough infection		1 0
Vestibulitis	,	1 0
Wound infection		1  C
Infectious disorders carrier		
SARS-CoV-2 carrier	2	2 0
Infectious transmissions		
Secondary transmission	2	2 (
Influenza viral infections		
Influenza	636	6 0
Lower respiratory tract and lung infections		
Atypical pneumonia	•	1  C
Bronchitis	7	7 (
Lower respiratory tract infection	88	3 1
Pleural infection		1 (
Pneumonia	24	
Pneumonia aspiration		1 (
Male reproductive tract infections		
Epididymitis		1 (
Orchitis		4 <b> </b> (
Mumps viral infections		
Mumps		1 c
Nematode infections		
Enterobiasis		1 (
Orthopox viral infections		
Vaccinia virus infection		1 0
Parvoviral infections		
Erythema infectiosum	,	1 (
Rabies viral infections		`
Rabies VII al II liections Rabies		1 -
Rables Rotaviral infections		1 1
		,
Gastroenteritis rotavirus		1  (

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Reaction Name	Total_	<u>Fatal</u>
Infections Infections cont'd		
Rubella viral infections	_	_
Rubella	2	C
Sepsis, bacteraemia, viraemia and fungaemia NEC		_
Intestinal sepsis	1	
Sepsis	8	
Septic shock	1	
Urosepsis	1	(
Skin structures and soft tissue infections		
Acne pustular	1	(
Blister infected	1	
Dermatitis infected	1	(
Eczema infected	1	( C
Impetigo	6	_
Infected skin ulcer	_   1	C
Nail infection	1	(
Pustule	11	
Pyoderma	1	(
Rash pustular	3	
Skin infection	15	c
Vaccination site pustule	1	( C
Staphylococcal infections		
Furuncle	12	(
Streptococcal infections		
Meningitis pneumococcal	1	
Pharyngitis streptococcal	1	( C
Tinea infections		
Body tinea	3	( C
Tinea capitis	1	
Tinea infection	1	c
Tuberculous infections		
Lymph node tuberculosis	1	0
Upper respiratory tract infections		
Acute sinusitis	2	(
Chronic sinusitis	1	
Laryngitis	7	l c
Nasopharyngitis	332	1 0
Peritonsillar abscess	1	l c
Pharyngitis	6	
Rhinitis	8	
Sinusitis	39	
Tonsillitis	15	
Upper respiratory tract infection	3	
Urinary tract infections		
Cystitis	12	C
Kidney infection	6	
Urinary tract infection	44	
Vascular infections		
Lymphangitis	3	
Viral infections NEC		
Arthritis viral	1	
Conjunctivitis viral	2	
Gastroenteritis viral	4	ı
Meningitis viral	2	

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Pneumonia viral	2	0
Post viral fatigue syndrome	9	0
Sweating fever	65	0
Vestibular neuronitis	4	0
Viral infection	10	0
Viral labyrinthitis	2	0
Viral myocarditis	1	0
Viral pharyngitis	6	0
Viral rash	7	0
Infections SOC TOTAL	2611	8

#### Case Series Drug Analysis Print me: COVID-19 Moderna vaccine analysis pri

MedDRA Version: MedDRA 25.0		
Reaction Name	<u> Total</u>	<u> Fatal</u>
njuries		
Abdominal and gastrointestinal injuries NEC		
Oral contusion	1	
Palate injury	1	
Accidental exposures to product		
Accidental exposure to product	2	
Anaesthetic and allied procedural complications		
Anaesthetic complication	1	
Atmospheric pressure injuries		
Barotrauma	1	
Bone and joint injuries NEC		
Joint injury	3	
Cardiovascular injuries		
Vascular injury	1	
Cerebral injuries NEC		
Brain herniation	1	
Concussion	8	
Subdural haematoma	1	
Chest and respiratory tract injuries NEC		
Chest crushing	3	
Conditions caused by cold		
Chillblains	18	
Cranial nerve injuries		
Cranial nerve injury	1	
Optic nerve injury	1	
Exposures associated with pregnancy, delivery and lactation		
Exposure via breast milk	25	
Foetal exposure during pregnancy	11	
Maternal exposure before pregnancy	2	
Maternal exposure during breast feeding	599	
Maternal exposure during pregnancy	277	
Maternal exposure timing unspecified	1	
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	
Eye injuries NEC		
Blindness traumatic	1	
Eye contusion	2	
Eye injury	7	
Fractures and dislocations NEC		
Compression fracture	1	
Joint dislocation	1	
Gastrointestinal and hepatobiliary procedural complications		
Procedural vomiting	1	
Heat injuries (excl thermal burns)		
Heat exhaustion	1	
Heat illness	1	
Heat oedema	9	
Heat stroke	9	
Limb fractures and dislocations		
Clavicle fracture	8	
Upper limb fracture	1	
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	6	
Medication error	56	

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Reaction Name Injuries cont'd	Total	<u>Fatal</u>
mjanoe .	4	
Wrong schedule	1	(
Wrong technique in device usage process	2	(
Wrong technique in product usage process	1	(
Muscle, tendon and ligament injuries	2	,
Epicondylitis	3	(
Ligament sprain	7	(
Muscle injury	/	(
Muscle rupture Muscle strain		(
	5 2	(
Tendon injury	2	
Tendon rupture		(
Nerve injuries NEC	25	,
Nerve injury	25	(
Nerve root injury lumbar	1	(
Neurological and psychiatric procedural complications  Procedural dizziness	-	,
	5	C
Non-occupational environmental exposures	4	_
Exposure to extreme temperature	1	C
Non-site specific injuries NEC		_
Arthropod bite	5	
Bite		C
Electric shock	7	
Fall	64	C
Inflammation of wound	2	C
Injury	5	C
Multiple injuries	1	C
Nervous system injury	1	C
Stab wound	1	C
Struck by lightning	1	(
Wound to a program of the	8	
Wound haemorrhage	2	C
Non-site specific procedural complications		_
Incision site pain	1	C
Infusion related reaction	1	C
Injection related reaction	40	
Post procedural complication	1	
Post procedural erythema	1	
Procedural pain	1	(
Occupational exposures		_
Occupational exposure to toxic agent	1	C
Off label uses	0.0	
Off label use	33	C
Overdoses NEC		,
Overdose	6	(
Peripheral nerve injuries		_
Sciatic nerve injury	1	(
Ulnar nerve injury	1	(
Poisoning and toxicity		
Systemic toxicity	1	
Toxicity to various agents	1	(
Product administration errors and issues		
Accidental overdose	73	
Accidental underdose	l 3	

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MedDRA Version: MedDRA 25.0		
Reaction Name	<u>  Total                                    </u>	<u>Fatal</u>
Injuries Injuries cont'd		
Expired product administered	88	0
Extra dose administered	93	0
Inappropriate schedule of product administration	104	0
Inappropriate schedule of product discontinuation	1	0
Incorrect dose administered	14	0
Incorrect product administration duration	1	0
Incorrect route of product administration	3	0
Poor quality product administered	2	0
Product administered at inappropriate site	6	0
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	3	0
Product confusion errors and issues		
Product label confusion	12	0
Product dispensing errors and issues		
Product dispensing error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	1	0
Product selection errors and issues		
Product selection error	7	0
Product storage errors and issues in the product use system		
Product storage error	11	0
Product transcribing errors and communication issues		
Product communication issue	1	0
Radiation injuries		
Sunburn	16	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Respiratory tract and thoracic cavity procedural complications		
Post procedural pulmonary embolism	1	0
Site specific injuries NEC		
Back injury	2	0
Head injury	10	0
Limb injury	56	0
Nasal injury	1	0
Skin injuries NEC		
Contusion	358	0
Scar	12	0
Scratch	2	0
Skin abrasion	1	0
Skin injury	1	0
Skin laceration	1	0
Skin wound	3	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Dermal filler reaction	1	0
Skull fractures, facial bone fractures and dislocations		
Jaw fracture	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Stoma complications		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Stoma site discomfort	1	0
Stoma site oedema	1	0
Thermal burns		
Burn oesophageal	1	0
Cold burn	1	0
Thermal burn	14	0
Thermal burns of eye	6	0
Thoracic cage fractures and dislocations		
Sternal fracture	1	0
Vaccination related complications		
Vaccination complication	3	0
Injuries SOC TOTAL	2239	0

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Reaction Name	_Total_	<u>Fatal</u>
Investigations		
Adrenal medulla tests	_	_
Norepinephrine increased	2	0
Auditory and vestibular diagnostic procedures		_
Audiogram abnormal	1	0
Autoimmunity analyses		
Rheumatoid factor increased	1	0
Bacteria identification and serology (excl mycobacteria)		
Campylobacter test positive	1	0
Blood counts NEC		
Full blood count abnormal	1	0
Blood gas and acid base analyses		_
Blood lactic acid	1	0
Oxygen consumption decreased	1	0
Oxygen saturation	3	0
Oxygen saturation decreased	20	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	1	0
Blood glucose abnormal	2	0
Blood glucose decreased	3	0
Blood glucose increased	7	0
Cardiac auscultatory investigations		
Cardiac murmur	4	0
Heart sounds	5	0
Heart sounds abnormal	1	0
Cardiac function diagnostic procedures		
Ejection fraction decreased	1	0
Central nervous system imaging procedures		
Computerised tomogram head	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Cholesterol analyses		
Blood cholesterol increased	2	0
Low density lipoprotein increased	1	0
Coagulation and bleeding analyses		
Bleeding time	1	0
Bleeding time abnormal	1	0
Blood fibrinogen	1	0
Blood thrombin	1	0
Coagulation time shortened	1	0
Fibrin D dimer increased	5	0
Fibrin degradation products increased	1	0
International normalised ratio decreased	1	0
International normalised ratio increased	2	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	1	C
Electrocardiogram P wave abnormal	1	C
Electrocardiogram QT prolonged	1	C
Electrocardiogram ST segment elevation	2	C
Electrocardiogram ST-T segment abnormal	3	C
Electrocardiogram T wave inversion	2	C
Electrocardiogram abnormal	l 3	0

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Reaction Name	<u> Total</u>	<u>Fatal</u>
nvestigations Investigations cont'd		
Electrocardiogram change	1	(
Endocrine analyses and imaging NEC		
Hormone level abnormal	16	(
Faecal analyses NEC		
Faecal volume	1	(
Fertility analyses		
Semen analysis abnormal	1	(
Foetal and neonatal diagnostic procedures		
Foetal heart rate decreased	1	(
Foetal heart rate increased	1	(
Fungus identification and serology		
Fungal test	1	(
Gastrointestinal and abdominal imaging procedures		
X-ray with contrast upper gastrointestinal tract	1	(
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	1	(
Haematological analyses NEC		
Blood viscosity increased	1	(
Red blood cell sedimentation rate increased	1	(
Heart rate and pulse investigations		
Heart rate	278	(
Heart rate abnormal	22	(
Heart rate decreased	19	(
Heart rate increased	427	(
Heart rate irregular	95	(
Heart rate variability decreased	1	(
Maximum heart rate	1	(
Maximum heart rate increased	1	(
Pulse abnormal	3	(
Pulse absent	1	(
Sinus rhythm	3	(
Hepatobiliary function diagnostic procedures	Ĭ	
Alanine aminotransferase increased	6	(
Aspartate aminotransferase	2	Ò
Bile output	3	,
Blood bilirubin increased	1	
Liver function test abnormal	8	Ò
Liver function test increased	1	
Imaging procedures NEC	'	•
X-ray	1	(
Immunology analyses NEC		
Immunology test	1	(
Immunology skin tests NEC	'	•
Allergy alert test	1	(
Allergy alert test positive	1	
Investigations NEC	'	
Blood test	1	(
Blood test Blood test abnormal	5	
Blood test normal	5 2	
	2	
Polymerase chain reaction positive	4	
Mineral and electrolyte analyses  Blood calcium increased		
	2	
Blood iron	1	

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Investigations Investigations cont'd		
Blood iron decreased	3	C
Blood magnesium decreased	1	C
Blood potassium decreased	3	C
Blood sodium decreased	1	C
Serum ferritin increased	2	C
Urine copper	1	C
Musculoskeletal and soft tissue imaging procedures		
Bone scan	1	C
Face and mouth X-ray abnormal	1	C
X-ray limb normal	1	C
Musculoskeletal and soft tissue tests NEC		
Tender joint count	1	C
Neurologic diagnostic procedures		
Coma scale abnormal	2	C
Electromyogram abnormal	1	C
Sensory level	1	C
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	C
Intraocular pressure increased	2	Č
Visual tracking test	1	C
Visual tracking test Visual tracking test abnormal	1	
Physical examination procedures and organ system status	<b>'</b>	
Body temperature	110	_
	110	
Body temperature abnormal		
Body temperature decreased	18	
Body temperature fluctuation	28	0
Body temperature increased	144	C
Breath sounds	1	0
Breath sounds abnormal	2	0
Grip strength	1	C
Grip strength decreased	4	C
Head lag	4	0
Lymph node palpable	5	0
Muscle strength abnormal	3	0
Ophthalmological examination	1	0
Palpatory finding abnormal	1	C
Product residue present	1	0
Respiratory rate	6	C
Respiratory rate decreased	6	C
Respiratory rate increased	10	C
Skin temperature	24	0
Temperature difference of extremities	6	0
Weight decreased	31	0
Weight increased	11	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone decreased	1	C
Blood thyroid stimulating hormone increased	2	C
Platelet analyses		
Platelet count decreased	10	C
Platelet count normal	1	C
Protein analyses NEC		
C-reactive protein increased	10	C
Red blood cell analyses		

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Reaction Name	Total	<u>Fatal</u>
Investigations Investigations cont'd		_
Haemoglobin E	1	(
Haemoglobin decreased	2	C
Renal function analyses		_
Blood creatinine increased	1	(
Reproductive hormone analyses		
Blood testosterone decreased	1	(
False negative pregnancy test	2	(
Pregnancy test	1	(
Pregnancy test false positive	1	(
Reproductive organ and breast histopathology procedures Smear cervix	1	(
Reproductive organ and breast imaging procedures		
Hysteroscopy	1	(
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume decreased	1	(
Forced expiratory volume increased	3	(
Pulmonary function test decreased	1	Č
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	(
Myocardial necrosis marker increased	1	Č
Troponin I increased	1	Č
Troponin T increased	1	Č
Troponin increased	5	Ó
Therapeutic drug monitoring analyses		•
Analgesic drug level	5	(
Thyroid analyses		
Tri-iodothyronine decreased	1	(
Tissue enzyme analyses NEC	'	•
Blood alkaline phosphatase increased	1	(
Blood lactate dehydrogenase increased	1	Ò
Urinalysis NEC	1	
Blood urine	5	(
Blood urine present	28	(
Protein urine	1	(
pH urine	1	(
Urinary tract function analyses NEC	'	•
Urine output	12	(
Urine output decreased	1	(
Urinary tract imaging procedures	1	
Bladder scan	1	(
Vascular tests NEC (incl blood pressure)	1	
Blood pressure abnormal	3	(
Blood pressure decreased	11	,
Blood pressure diastolic increased	1	(
Blood pressure increased	44	(
Blood pressure measurement	11	(
Blood pressure normal	1	
Virus identification and serology		
Coronavirus test	5	(
Influenza A virus test	1	
SARS-CoV-2 antibody test	2	(
SARS-CoV-2 antibody test SARS-CoV-2 antibody test negative	1	(
SARS-CoV-2 antibody test negative SARS-CoV-2 antibody test positive	2	(

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Reaction Name	Total	<u>Fatal</u>
Investigations Investigations cont'd		
SARS-CoV-2 test	5	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	8	0
Vitamin analyses		
Blood folate decreased	1	0
White blood cell analyses		
Neutrophil count	1	0
Neutrophil count decreased	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	3	0
Investigations SOC TOTAL	1669	0

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Reaction Name	Total	<u>Fatal</u>
Metabolic disorders		
Appetite disorders		
Appetite disorder	3	(
Decreased appetite	472	(
Eating disorder symptom	1	(
Food craving	2 4	(
Food refusal		(
Hyperphagia	5	(
Hypophagia	3	(
Increased appetite	9	(
Salt craving	1	(
Copper metabolism disorders		
Copper deficiency	1	(
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	6	(
Diabetes mellitus inadequate control	4	(
Type 1 diabetes mellitus	2	(
Type 2 diabetes mellitus	1	(
Diabetic complications NEC		
Diabetic ketoacidosis	2	(
Disorders of purine metabolism		
Gout	24	(
Fat soluble vitamin deficiencies and disorders		
Vitamin D deficiency	1	(
Fluid intake decreased		
Fluid intake reduced	1	(
Fluid intake increased		
Polydipsia	1	(
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Alcohol intolerance	2	(
Food intolerance	3	(
Gluten sensitivity	1	(
Histamine intolerance	1	(
General nutritional disorders NEC		
Abnormal loss of weight	6	(
Abnormal weight gain	9	(
Feeding disorder	58	(
Food aversion	6	(
Neonatal insufficient breast milk syndrome	4	(
Overweight	1	(
Poor feeding infant	1	(
Weight loss poor	1	(
Hyperglycaemic conditions NEC		
Hyperglycaemia	8	(
Hypoglycaemic conditions NEC		
Hypoglycaemia	12	(
Iron excess		
Haemochromatosis	1	(
Potassium imbalance		
Hypokalaemia	2	(
Sodium imbalance		
Hyponatraemia	1	(
Sugar intolerance (excl glucose intolerance)	'	
Lactose intolerance	1	(

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Total fluid volume decreased		
Dehydration	114	0
Total fluid volume increased		
Fluid retention	12	0
Water soluble vitamin deficiencies		
Folate deficiency	2	0
Metabolic disorders SOC TOTAL	789	0

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Reaction Name	Total	<u> Fatal</u>
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	65	(
Arthritis allergic	1	
Arthritis enteropathic	1	(
Arthropathy	g	
Autoimmune arthritis	1	(
Palindromic rheumatism		
Polyarthritis	2	2 (
Rheumatic fever	1	(
Bone disorders NEC		
Bone erosion	1	
Exostosis	2	
Jaw cyst	1	
Jaw disorder	2	
Medial tibial stress syndrome	1	
Osteitis	1	
Bone related signs and symptoms		
Bone pain	123	
Bone swelling	2	
Coccydynia	1	
Pain in jaw	110	
	110	
Pubic pain	21	
Spinal pain	21	
Bursal disorders	0.5	
Bursitis	25	
Cartilage disorders		
Chondritis	1	
Costochondritis	23	
Connective tissue disorders NEC		
Morphoea	1	
Polymyalgia rheumatica	7	
Reynold's syndrome	2	
Systemic scleroderma	2	
Extremity deformities		
Finger deformity		
Foot deformity	2	2
Hand deformity	2	!
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	2	
Joint related disorders NEC		
Greater trochanteric pain syndrome	1	
Hypermobility syndrome	1	
Joint lock	12	2
Periarthritis	58	
Rotator cuff syndrome	7	·
Temporomandibular joint syndrome	3	3
Joint related signs and symptoms		
Arthralgia	2740	
Joint effusion	1	
Joint noise		
Joint range of motion decreased	1	
Joint stiffness	84	
Joint swelling	94	

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Reaction Name	Total	<u>Fatal</u>
Muscle & tissue disorders e & tissue disorders cont'd		
Joint vibration	2	0
Joint warmth	7	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	3	0
Muscle infections and inflammations		
Myositis	10	0
Muscle pains		
Fibromyalgia	27	0
Myalgia	3518	0
Myalgia intercostal	1	0
Muscle related signs and symptoms NEC		
Muscle atrophy	3	0
Muscle discomfort	3	0
Muscle disorder	1	0
Muscle fatigue	119	0
Muscle haemorrhage	1	0
Muscle mass	1	0
Muscle spasms	529	0
Muscle swelling	17	0
Muscle tightness	32	0
Muscle twitching	97	0
Myosclerosis	1	0
Muscle tone abnormalities		Ū
Muscle rigidity	6	0
Nuchal rigidity	5	0
Trismus	11	0
Muscle weakness conditions		J
Muscular weakness	290	0
Musculoskeletal and connective tissue conditions NEC	200	
Growth retardation	1	0
Limb mass	3	0
Mastication disorder	2	0
Mobility decreased	35	0
Muscle contracture	1	0
Musculoskeletal disorder	3	0
Musculoskeletal disorder  Musculoskeletal stiffness	514	0
Weight bearing difficulty	1	0
Musculoskeletal and connective tissue deformities of skull, face and	I	J
buccal cavity		
Facial asymmetry	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis		0
Musculoskeletal and connective tissue pain and discomfort	'	U
Back pain	882	0
Flank pain	19	
Limb discomfort	417	
		0
Musculoskeletal chest pain	70	
Musculoskeletal discomfort	31	0
Musculoskeletal pain	27	0
Neck pain	519	

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Reaction Name	Total	Fatal
Muscle & tissue disorders & tissue disorders cont'd		
Pain in extremity	4200	1
Sacral pain	1	0
Myopathies		
Rhabdomyolysis	1	0
Osteoarthropathies		
Osteoarthritis	6	0
Psoriatic arthropathies		
Psoriatic arthropathy	4	0
Rheumatoid arthropathies		
Rheumatoid arthritis	25	0
Soft tissue disorders NEC		
Axillary mass	59	0
Fluctuance	1	0
Groin pain	28	0
Neck mass	14	0
Soft tissue swelling	2	0
Spine and neck deformities		
Scoliosis	1	0
Spinal stenosis	1	0
Spondyloarthropathies		
Ankylosing spondylitis	5	0
Arthritis reactive	19	0
Axial spondyloarthritis	1	0
Spondylitis	1	0
Synovial disorders		
Synovial cyst	5	0
Synovitis	2	0
Tendon disorders		
Tendon pain	4	0
Tendonitis	8	0
Trigger finger	3	0
Trunk deformities		
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	15029	1

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Reaction Name	Total	Fatal
Neoplasms		
B-cell lymphomas NEC		
B-cell lymphoma stage II	1	0
B-cell lymphoma stage III	1	0
Breast and nipple neoplasms benign		
Benign breast neoplasm	2	0
Fibroadenoma of breast	1	0
Breast and nipple neoplasms malignant		
Breast cancer	4	0
Breast neoplasms unspecified malignancy		
Phyllodes tumour	1	0
Cardiovascular neoplasms benign		
Haemangioma	1	0
Gastrointestinal neoplasms malignant NEC		
Gastrointestinal carcinoma	1	1
Leukaemias NEC		
Leukaemia	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	1	0
Lymphomas unspecified NEC		
Lymphoma	9	0
Mediastinal neoplasms malignancy unspecified NEC		
Good syndrome	1	0
Metastases to specified sites		
Metastases to lymph nodes	1	0
Metastases to unknown and unspecified sites		
Metastasis	1	0
Neoplasms malignant site unspecified NEC		
Neoplasm malignant	1	0
Oesophageal neoplasms malignant		
Oesophageal carcinoma	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and		
unspecified		
Tonsil cancer	2	0
Plasma cell neoplasms NEC		
Hypergammaglobulinaemia benign monoclonal	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified		
NEC ' ' '		
Bronchial carcinoma	1	0
Skin neoplasms benign		
Acrochordon	2	0
Anogenital warts	1	0
Haemangioma of skin	3	0
Melanocytic naevus	1	0
Skin papilloma	4	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Keratoacanthoma	1	0
Small intestinal neoplasms malignant		
Small intestine adenocarcinoma	1	0
Small intestine carcinoma	1	0
Soft tissue neoplasms benign NEC		
Lipoma	2	0
Urinary tract neoplasms unspecified malignancy NEC	_	
Renal neoplasm	1	0

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<b>Reaction Nam</b>	ne		Total	Fatal
Neoplasms	Neoplasms cont'd			
Uterine neopla	sms benign			
Uterine leion	nyoma		3	0
Uterine neopla	isms malignant NEC			
Uterine canc	er		1	0
Neonlasms SOC	TOTAL		53	1

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MedDRA Version: MedDRA 25.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Nervous system disorders		
Abnormal sleep-related events		
Sleep paralysis	5	(
Absence seizures		
Petit mal epilepsy	1	(
Acute polyneuropathies		
Guillain-Barre syndrome	24	(
Autonomic nervous system disorders	_	
Autonomic nervous system imbalance	3	(
Orthostatic intolerance	3	(
Central nervous system haemorrhages and cerebrovascular accidents	4	
Brain stem infarction	1	(
Cerebral artery embolism	1	
Cerebral haemorrhage	5	
Cerebral infarction	1	
Cerebrovascular accident	46	
Haemorrhage intracranial	2	
Haemorrhagic stroke	1	
Intracranial haematoma	1	
Intraventricular haemorrhage	1	(
Ischaemic stroke	6	(
Lacunar infarction	1	(
Ruptured cerebral aneurysm	1	
Subarachnoid haemorrhage	8	
Central nervous system inflammatory disorders NEC		
Central nervous system inflammation	2	(
Central nervous system vascular disorders NEC	_	
Cerebral congestion	2	(
Cerebrovascular venous and sinus thrombosis	_	
Cerebral venous sinus thrombosis	4	,
Cerebral venous thrombosis	1	(
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	1	
Choreiform movements		
Chorea	1	(
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	3	
Demyelinating polyneuropathy	1	
Coordination and balance disturbances		
Ataxia	6	
Balance disorder	113	
Coordination abnormal	8	
Dysstasia	22	
Nystagmus	3	(
Cortical dysfunction NEC		
Aphasia	10	
Dysgraphia	1	
Cranial nerve disorders NEC		
Cranial nerve disorder	1	
Dementia (excl Alzheimer's type)		
Dementia	3	(
Demyelinating disorders NEC	_	
Demyelination	2	(
Disturbances in consciousness NEC		1

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MedDRA Version: M		
Reaction Name	Total_	<u>Fatal</u>
Nervous system disordersus system disorders cont'd		
Consciousness fluctuating	1	(
Depressed level of consciousness	16	(
Lethargy	575	(
Loss of consciousness	302	(
Postictal state	1	(
Somnolence	300	(
Stupor	1	(
Syncope	1179	(
Disturbances in sleep phase rhythm		
Delayed sleep phase	1	(
Dyskinesias and movement disorders NEC		
Akathisia	2	(
Bradykinesia	5	(
Clumsiness	4	(
Dyskinesia	17	(
Extrapyramidal disorder	2	(
Fine motor delay	1	(
Fine motor skill dysfunction	4	(
Foetal movement disorder	1	(
Hyperkinesia	1	(
Hypokinesia	23	(
Motor dysfunction	3	(
Movement disorder	13	(
Psychomotor hyperactivity	5	(
Dystonias		
Dystonia	1	C
Encephalitis NEC		
Encephalitis allergic	1	(
Noninfective encephalitis	1	(
Eye movement disorders		
IVth nerve paresis	1	(
Facial cranial nerve disorders		
Bell's palsy	108	(
Facial nerve disorder	1	(
Facial paralysis	62	(
Facial paresis	13	(
Facial spasm	7	(
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	11	(
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	(
Headaches NEC		
Cluster headache	66	(
Cold-stimulus headache	12	(
Drug withdrawal headache	2	(
Headache	8774	(
Medication overuse headache	1	(
New daily persistent headache	2	
Occipital neuralgia	1	
Primary cough headache	1	
Primary headache associated with sexual activity	1	
Sinus headache	111	
Tension headache	177	(

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Reaction Name		_ Total_	<u>Fatal</u>
Nervous system disordersus	system disorders cont'd		
Thunderclap headache		3	C
Vascular headache		8	C
Hydrocephalic conditions			
Hydrocephalus		1	C
Hypoglossal nerve disorde	rs		
Tongue paralysis		1	C
Increased intracranial pres			
Idiopathic intracranial hyp		2	(
Intracranial pressure incr		3	(
Lumbar spinal cord and ne	erve root disorders		
Sciatica		17	(
Memory loss (excl dement	ia)		
Amnesia		65	(
Memory impairment		46	(
Transient global amnesia		2	(
Mental impairment (excl de	ementia and memory loss)		
Cognitive disorder		28	(
Disturbance in attention		95	(
Mental impairment		18	(
Migraine headaches			
Basilar migraine		1	(
Hemiplegic migraine		7	(
Migraine		872	(
Migraine with aura		52	(
Migraine without aura		3	(
Retinal migraine		5	(
Typical aura without head	dache	1	(
Vestibular migraine		4	(
Mononeuropathies			
Carpal tunnel syndrome		7	(
Cubital tunnel syndrome		1	(
Mononeuritis		2	(
Nerve compression		4	(
Multiple sclerosis acute an	d progressive		
Band sensation		1	(
Multiple sclerosis		6	(
Multiple sclerosis pseudo	relapse	1	(
Multiple sclerosis relapse		6	(
Progressive multiple scle	erosis	1	(
Uhthoff's phenomenon		1	(
Muscle tone abnormal			
Drop attacks		1	(
Hypotonia		10	(
Stiff leg syndrome		3	(
Myelitis (incl infective)			
Myelitis transverse		7	(
Narcolepsy and hypersom	nia		
Hypersomnia		35	(
Narcolepsy		1	(
Nervous system disorders	NEC		
Nervous system disorder		5	(
Psychomotor skills impai		1	(
Neurologic visual problems			

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Reaction Name	Total	<u> Fatal</u>
Nervous system disorders us system disorders cont'd		
Hemianopia	1	
Tunnel vision	13	
Neurological signs and symptoms NEC		
Agitation neonatal	1	
Clonus	2	2
Dizziness	3532	
Dizziness exertional	14	
Dizziness postural	235	
Drooling	2	2
Exaggerated startle response		
Head discomfort	73	
Meningism		
Neurological symptom	13	
Persistent postural-perceptual dizziness	4	
Presyncope	268	
Tongue biting	2	
Unresponsive to stimuli	13	3
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	2
Muscle spasticity	4	
Neuromuscular pain	1	
Neuromuscular junction dysfunction		
Myasthenia gravis	1	
Myasthenic syndrome		
Olfactory nerve disorders		
Anosmia	40	
Hyposmia	3	3
Parosmia	50	
Optic nerve disorders NEC		
Optic neuritis	5	
Paraesthesias and dysaesthesias		
Burning feet syndrome	7	'
Burning sensation	137	'
Dysaesthesia		
Formication	8	3
Hemianaesthesia	1	
Hemihypoaesthesia	1	
Hyperaesthesia	58	
Hypoaesthesia	709	
Paraesthesia	1023	
Paralysis and paresis (excl cranial nerve)		
Diplegia	7	'
Hemiparesis	6	5
Hemiplegia	12	2
Monoparesis	25	
, Monoplegia	31	
Paralysis	39	
Paraparesis	2	1
Paresis		
Quadriplegia	1	
Parkinson's disease and parkinsonism		
Freezing phenomenon	12	
Reduced facial expression	12	

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Reaction Name		<u>Total</u>	<u>Fatal</u>
Nervous system disordersus system	m disorders cont'd		
Partial complex seizures			
Focal dyscognitive seizures		2	C
Peripheral neuropathies NEC			
Autoimmune neuropathy		2	0
Neuralgic amyotrophy		4	0
Neuritis		3	C
Neuropathy peripheral		17	0
Peripheral sensory neuropathy	/	1	0
Polyneuropathy		2	0
Seizures and seizure disorders	NEC		
Atonic seizures		1	0
Epilepsy		26	0
Febrile convulsion		6	0
Myoclonic epilepsy		1	0
Partial seizures		8	0
Psychogenic seizure		1	0
Seizure		220	0
Seizure anoxic		2	0
Seizure cluster		1	0
Status epilepticus		30	0
Tonic clonic movements		3	0
Tonic convulsion		5	0
Sensory abnormalities NEC			
Ageusia		97	0
Allodynia		3	0
Aura		4	0
Complex regional pain syndro	me	1	0
Dysgeusia		240	0
Electric shock sensation		15	0
Hypogeusia		1	0
Loss of proprioception		1	0
Neuralgia		162	0
Post herpetic neuralgia		3	0
Restless legs syndrome		48	0
Sensory disturbance		29	0
Sensory loss		37	0
Taste disorder		55	0
Vibratory sense increased		2	0
Sleep disturbances NEC			-
Sleep deficit		6	0
Speech and language abnormal	lities		
Dysarthria		47	0
Incoherent		12	0
Slow speech		5	0
Speech disorder		22	0
Spinal cord and nerve root disor	rders NEC		
Radicular pain		1	0
Radiculitis brachial		3	Č
Radiculopathy		1	Č
Transient cerebrovascular even	ts		
Transient ischaemic attack		27	0
Tremor (excl congenital)		21	
Essential tremor		2	0

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Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Head titubation	2	0
Tremor	769	0
Trigeminal disorders		
Trigeminal neuralgia	12	0
Trigeminal neuritis	1	0
Nervous system disorders SOC TOTAL	21742	6

Report Run Date: 27-Jul-2022

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	71	0
Foetal complications NEC		
Foetal hypokinesia	4	0
Hydrops foetalis	1	0
Foetal growth complications		
Foetal growth restriction	2	0
Gestational age and weight conditions		
Premature baby	2	0
Haemorrhagic complications of pregnancy		
Premature separation of placenta	1	0
Subchorionic haemorrhage	1	0
Labour onset and length abnormalities		
Premature labour	5	0
Maternal complications of labour NEC		
Uterine atony	1	0
Uterine hypertonus	3	0
Maternal complications of pregnancy NEC		
Decidual cast	1	0
Ectopic pregnancy	3	0
Morning sickness	1	0
Somatic symptom disorder of pregnancy	1	0
Uterine irritability	1	0
Multiple pregnancies		
Twin pregnancy	1	0
Normal pregnancy, labour and delivery		
Live birth	2	0
Pregnancy	4	0
Postpartum complications NEC		
Postpartum haemorrhage	1	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	1	0
Stillbirth and foetal death		
Stillbirth	1	1
Umbilical cord complications	'	·
Umbilical cord thrombosis	1	0
Pregnancy conditions SOC TOTAL	109	1

Report Run Date: 27-Jul-2022

Reaction Name	Total	Fatal
Device issues NEC		
Device expulsion	1	0
Device leakage	1	0
Device malfunction events NEC		
Oversensing	1	0
Thrombosis in device	2	0
Undersensing	2	0
Manufacturing materials issues		
Manufacturing materials issue	1	0
Product contamination and sterility issues		
Product contamination physical	8	0
Suspected product contamination	1	0
Product label issues		
Product label issue	5	0
Product physical issues		
Product after taste	1	0
Product taste abnormal	1	0
Product quality issues NEC		
Product complaint	1	0
Product impurity	1	0
Product quality issue	1	0
Product tampering	1	0
Product supply and availability issues		
Product availability issue	2	0
null SOC TOTAL	30	0

## Case Series Drug Analysis Print e: COVID-19 Moderna vaccine analysis pri

MedDRA Version: MedDRA 25.0		
Reaction Name	<u>  Total                                    </u>	<u>Fatal</u>
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	6	0
Breath holding	4	0
Staring	1	0
Affect alterations NEC		
Affect lability	2	C
Constricted affect	2	C
Flat affect	4	C
Inappropriate affect	3	C
Amnestic symptoms		
Paramnesia	2	
Anxiety disorders NEC		
Anxiety disorder	1	
Separation anxiety disorder	1	
Anxiety symptoms		
Agitation	26	C
Anxiety	269	
Nervousness	53	
Stress	24	
Tension	10	
Attention deficit and disruptive behaviour disorders		
Attention deficit hyperactivity disorder	5	0
Behaviour and socialisation disturbances		
Aggression	2	0
Disinhibition	1	Č
Homicidal ideation	1	
Impatience	1	Č
Paranoia	7	
Personality change	3	Č
Social avoidant behaviour	1	
Soliloquy	1	Č
Violence-related symptom	1	
Bipolar disorders		
Bipolar disorder	1	C
Cognitive and attention disorders and disturbances NEC	'	
Daydreaming	1	C
Distractibility	1	
Mental fatigue	64	
Communications disorders	04	
Mutism	1	C
Confusion and disorientation	'	,
Confusional state	250	
Disorientation	102	
Deliria Deliria	102	,
Delirium	62	C
Delinium  Delinium  Delinium	02	,
Alice in wonderland syndrome	1	
· · · · · · · · · · · · · · · · · · ·		l '
Delusion	2	,
Delusion	3	(
Delusion of parasitosis	1	
Depressive disorders	400	
Depression	102	l
Depression suicidal	l 4	I (

#### Case Series Drug Analysis Print e: COVID-19 Moderna vaccine analysis prin

MedDRA Version: MedDRA 25.0		
Reaction Name	<u>    Total                                    </u>	<u>Fatal</u>
Psychiatric disorders Psychiatric disorders cont'd		
Major depression	3	C
Mixed anxiety and depressive disorder	1	C
Dissociative states		
Depersonalisation/derealisation disorder	3	C
Dissociation	13	(
Disturbances in initiating and maintaining sleep		
Initial insomnia	7	(
Insomnia	531	(
Middle insomnia	14	(
Terminal insomnia	13	(
Dyssomnias		
Poor quality sleep	105	(
Eating disorders NEC		
Binge eating	1	(
Eating disorder	1	(
Emotional and mood disturbances NEC		
Anger	15	(
Emotional disorder	21	(
Emotional distress	12	(
Emotional poverty	1	(
Euphoric mood	12	(
Frustration tolerance decreased	4	(
Irritability	55	(
Mood altered	21	C
Factitious disorders		
Factitious disorder	1	C
Fear symptoms and phobic disorders (incl social phobia)		
Fear	7	(
Fear of death	1	(
Fear of eating	1	(
Fear of injection	6	(
Paruresis	1	(
Phobia	1	(
Phonophobia	1	(
Social fear	1	(
Fluctuating mood symptoms		
Mood swings	19	(
Hallucinations (excl sleep-related)		
Hallucination	139	(
Hallucination, auditory	6	(
Hallucination, olfactory	1	(
Hallucination, tactile	1	(
Hallucination, visual	6	(
Hallucinations, mixed	3	(
Somatic hallucination	1	ĺ
Increased physical activity levels		
Restlessness	62	(
Mental disorders NEC	J 02	
Mental disorder	4	
Mood alterations with depressive symptoms	1	
Decreased interest	2	
Decreased interest  Depressed mood	101	
Feeling of despair	5	(

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Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 25.0		
Reaction Name	Total	Fatal
Psychiatric disorders		
Negative thoughts	2	0
Sense of a foreshortened future	1	0
Tearfulness	7	0
Mood alterations with manic symptoms		
Mania	5	0
Mood disorders NEC		
Affective disorder	2	0
Apathy	13	
Listless	13	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Obsessive-compulsive disorders and symptoms		
Dermatophagia	3	0
Orgasmic disorders and disturbances		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	58	0
Panic disorder	1	0
Panic reaction	14	0
Paraphilias and paraphilic disorders		
Exhibitionism	1	0
Parasomnias		
Abnormal dreams	43	0
Abnormal sleep-related event	1	0
Nightmare	68	0
Sleep inertia	1	0
Sleep talking	3	0
Sleep terror	5	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	3	0
Deja vu	1	0
Derealisation	3	0
Illusion	1	0
Psychiatric elimination disorders		
Enuresis	14	0
Psychiatric symptoms NEC		
Helplessness	1	0
Hypervigilance	2 6	0
Psychiatric symptom	6	0
Psychological trauma	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	3	0
Sexual arousal disorders		
Disturbance in sexual arousal	1	0
Sexual desire disorders		
Libido decreased	6	0
Libido increased	1	0
Loss of libido	6	0
Sexual dysfunction NEC		

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Reaction Name	Total	Fatal
Psychiatric disorders <sup>Psychiatric</sup> disorders cont'd		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	82	0
Somatic symptom disorders		
Conversion disorder	5	0
Habit cough	7	0
Speech and language usage disturbances		
Disorganised speech	2	0
Speech articulation and rhythm disturbances		
Dysphemia	4	0
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	4	0
Head banging	7	0
Stress disorders		
Acute stress disorder	1	0
Post-traumatic stress disorder	1	0
Substance related and addictive disorders		
Alcoholism	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	2	0
Suicidal behaviour	2	0
Suicidal ideation	20	0
Suicide attempt	3	0
Thinking disturbances		
Bradyphrenia	5	0
Intrusive thoughts	1	0
Tachyphrenia	5	0
Thinking abnormal	5	0
Thought blocking	2	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	2685	0

## Case Series Drug Analysis Print ne: COVID-19 Moderna vaccine analysis pri

MedDRA Version: MedDRA 25.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder irritation	2	(
Bladder pain	12	(
Dysuria	11	(
Incontinence	18	(
Micturition urgency	16	(
Pollakiuria	48	(
Stress urinary incontinence	1	(
Urethral pain	2	(
Urinary incontinence	22	(
Urinary retention	10	(
Urinary straining	2	(
Urine flow decreased	2	(
Bladder disorders NEC		
Bladder dilatation	1	(
Bladder disorder	4	(
Urinary bladder haemorrhage	2	(
Bladder infections and inflammations		
Cystitis interstitial	1	(
Genitourinary tract infections and inflammations NEC		
Urinary tract inflammation	1	(
Glomerulonephritis and nephrotic syndrome		
Glomerulonephritis acute	1	(
Glomerulonephritis membranous	1	(
IgA nephropathy	2	(
Myoneurogenic bladder disorders		
Bladder dysfunction	1	(
Hypertonic bladder	4	(
Loss of bladder sensation	2	(
Nephritis NEC		
Nephritis	1	(
Nephropathies and tubular disorders NEC		
Nephropathy	1	(
Renal disorders NEC		
Renal disorder	2	(
Renal failure and impairment		
Acute kidney injury	7	(
Chronic kidney disease	2	(
Oliguria	1	(
Renal failure	2	(
Renal impairment	3	(
Renal injury	1	(
Renal lithiasis		
Nephrolithiasis	1	(
Renal vascular and ischaemic conditions		
Renal vein thrombosis	1	(
Urinary abnormalities		
Chromaturia	23	
Haematuria	11	
Loin pain haematuria syndrome	1	(
Urine abnormality	5	
Urine odour abnormal	4	
Urinary tract signs and symptoms NEC		

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Reaction Name	Total	Fatal
Renal & urinary disorders l & urinary disorders cont'd		
Haemorrhage urinary tract	9	0
Nocturia	1	0
Polyuria	1	0
Renal pain	117	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	361	0

## Case Series Drug Analysis Print : COVID-19 Moderna vaccine analysis pri

MedDRA Version: MedDRA 25.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Reproductive & breast disorders		
Benign and malignant breast neoplasms		
Breast cyst	6	(
Breast disorders NEC		
Breast enlargement	4	(
Breast mass	21	(
Fibrocystic breast disease	1	(
Retracted nipple	1	(
Breast infections and inflammations		
Breast inflammation	4	(
Breast signs and symptoms		
Breast discharge	3	(
Breast discomfort	2	(
Breast haemorrhage	1	(
Breast oedema	1	(
Breast pain	159	(
Breast swelling	23	(
Breast tenderness	16	(
Nipple pain	2	(
Nipple swelling	2	(
Cervix disorders NEC		
Cervix haemorrhage uterine	1	(
Ectropion of cervix	1	(
Erection and ejaculation conditions and disorders		
Ejaculation delayed	1	(
Ejaculation failure	3	(
Erectile dysfunction	15	(
Erection increased	1	(
Nocturnal emission	1	(
Organic erectile dysfunction	9	
Painful ejaculation	1	(
Priapism	1	(
Spontaneous penile erection	1	(
Gender disorders		
Feminisation acquired	1	(
Lactation disorders		
Galactorrhoea	2	(
Lactation disorder	3 2	(
Lactation puerperal increased	2	(
Suppressed lactation	10	(
Menopausal effects NEC		
Menopausal symptoms	10	(
Premature menopause	5	
Menopausal effects on the genitourinary tract		
Postmenopausal haemorrhage	24	(
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	1 1	(
Dysmenorrhoea	487	
Intermenstrual bleeding	257	
Menstrual discomfort	4	
Menstrual disorder	427	
Menstruation irregular	699	
Premenstrual dysphoric disorder	1	
Premenstrual headache	2	

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MedDRA Version: MedDRA 25.0		
Reaction Name	Total	<u>Fatal</u>
Reproductive & breas ବ୍ୟାତ୍ତ de breast disorders cont'd		
Premenstrual pain	23	C
Premenstrual syndrome	19	(
Withdrawal bleed	2	(
Menstruation with decreased bleeding		
Amenorrhoea	105	(
Hypomenorrhoea	117	(
Menstruation delayed	855	(
Oligomenorrhoea	35	
Menstruation with increased bleeding		
Heavy menstrual bleeding	1080	(
Menometrorrhagia	9	(
Polymenorrhoea	182	. (
Ovarian and fallopian tube cysts and neoplasms		
Ovarian cyst	7	
Polycystic ovaries	11	
Ovarian and fallopian tube disorders NEC		
Fallopian tube spasm	1	
Ovulation pain	21	
Premature ovulation	1	
Pelvis and broad ligament disorders NEC		Ì
Adnexa uteri pain	22	
Pelvic haemorrhage	2	
Penile disorders NEC (excl erection and ejaculation)		`
Penile pain	1	(
Penis disorder	4	
Prostate and seminal vesicles infections and inflammations	7	
Prostatitis	2	
Prostatic signs, symptoms and disorders NEC		
Prostatic pain	2	. (
Reproductive tract disorders NEC (excl neoplasms)		
Genital blister	1	
Genital blistel Genital haemorrhage	3	
	1	
Genital paraesthesia Genital ulceration	3	1
	3	
Reproductive tract signs and symptoms NEC Genital odour	1	,
Genital odour	1 4	
•	4	
Genital rash Pelvic discomfort		
	1 1	
Pelvic pain	37	(
Scrotal disorders NEC		,
Scrotal pain	8	(
Scrotal swelling		
Varicocele	2	(
Sexual function and fertility disorders NEC	_	
Infertility	5	
Infertility female	1	
Sexual dysfunction	2	
Spermatogenesis and semen disorders		
Haematospermia	1	(
Testicular and epididymal disorders NEC		
Testicular disorder	2	(
Testicular mass	1	(

## Case Series Drug Analysis Print me: COVID-19 Moderna vaccine analysis prin

Name: COVID-19 Moderna vaccine analysis print

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Reaction Name	Total	Fatal
Reproductive & breast disorders cont'd		
Testicular pain	21	0
Testicular swelling	7	0
Uterine disorders NEC		
Adenomyosis	1	0
Endometrial hyperplasia	1	0
Endometriosis	22	0
Metrorrhoea	1	0
Uterine haemorrhage	13	0
Uterine pain	8	0
Uterine neoplasms		
Uterine polyp	1	0
Uterine tone disorders		
Uterine spasm	18	0
Vulvovaginal cysts and neoplasms		
Vaginal cyst	1	0
Vulva cyst	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	352	0
Vaginal ulceration	4	0
Vulval haemorrhage	10	0
Vulval ulceration	5	0
Vulvovaginal signs and symptoms		
Coital bleeding	1	0
Labia enlarged	1	0
Vaginal discharge	21	0
Vaginal odour	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	6	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	5295	

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MedDRA Version: MedDRA 25.0		
Reaction Name	Total_	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Agonal respiration	1	0
Apnoea	1	0
Dyspnoea	1750	
Dyspnoea at rest	1	0
Dyspnoea exertional	7	0
Hyperventilation	15	
Hypopnoea	36	
Hypoventilation	1	0
Irregular breathing	7	0
Mouth breathing	1	0
Obstructive sleep apnoea syndrome	2	0
Respiration abnormal	23	0
Respiratory arrest	2	
Respiratory distress	5	0
Sleep apnoea syndrome	5	0
Tachypnoea	8	0
Bronchospasm and obstruction		
Asthma	86	0
Asthma exercise induced	2	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	2	0
Childhood asthma	2	0
Chronic obstructive pulmonary disease	1	0
Obstructive airways disorder	1	0
Wheezing	140	0
Conditions associated with abnormal gas exchange		
Нурохіа	5	l o
Coughing and associated symptoms		
Allergic cough	3	0
Cough	677	0
Haemoptysis	5	0
Productive cough	40	
Sputum discoloured	7	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		
Reflux laryngitis	1	0
Laryngeal spasm, oedema and obstruction		
Stridor	2	0
Lower respiratory tract inflammatory and immunologic conditions		
Hypersensitivity pneumonitis	2	l o
Pneumonitis	5	
Pulmonary sarcoidosis	1	0
		_
, , ,	16	0
		l ő
	1	l ő
	32	
	32	l
	75	0
Nasal inflammation	13	0
Lower respiratory tract signs and symptoms  Hiccups Lower respiratory tract congestion Pleuritic pain Pulmonary haemorrhage Pulmonary pain  Nasal congestion and inflammations Nasal congestion	1 16 2 3 1 32	

## Case Series Drug Analysis Print ne: COVID-19 Moderna vaccine analysis prir

MedDRA Version: MedDRA 25.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Respiratory disorders espiratory disorders cont'd		
Rhinitis allergic	1	C
Nasal disorders NEC		
Epistaxis	210	C
Nasal crusting	1	C
Nasal dryness	3	(
Nasal oedema	2	(
Nasal pruritus	4	(
Paranasal sinus disorders (excl infections and neoplasms)		
Sinonasal obstruction	5	(
Sinus congestion	13	(
Sinus disorder	4	(
Parenchymal lung disorders NEC		
Emphysema	1	(
Interstitial lung disease	2	(
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal erythema	3	(
Pharyngeal hypoaesthesia	5	(
Pharyngeal oedema	3	(
Pharyngeal paraesthesia	6	(
Pharyngeal swelling	67	(
Tonsillar erythema	3	(
Tonsillar hypertrophy	18	(
Tonsillar inflammation	1	(
Pleural infections and inflammations		
Pleurisy	11	(
Pneumothorax and pleural effusions NEC		
Pleural effusion	4	(
Pulmonary hypertensions		
Pulmonary hypertension	1	(
Pulmonary oedemas		
Acute pulmonary oedema	1	(
Pulmonary congestion	2	(
Pulmonary oedema	6	(
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	83	3
Pulmonary thrombosis	3	(
Respiratory failures (excl neonatal)		
Respiratory failure	2	(
Respiratory signs and symptoms NEC		
Diaphragmalgia	4	(
Painful respiration	4	(
Respiratory symptom	4	(
Use of accessory respiratory muscles	2	(
Respiratory tract disorders NEC		
Allergic respiratory disease	2	(
Lung disorder	1	(
Pulmonary mass	1	(
Respiratory disorder	3	(
Respiratory tract congestion	1	(
Respiratory tract irritation	1	(
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	1	(
Tracheal disorders (excl infections and neoplasms)		

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Reaction Name	Total	Fatal
Respiratory disorders cont'd		
Tracheal inflammation	1	0
Upper respiratory tract signs and symptoms		
Aphonia	23	0
Catarrh	8	0
Choking	8	0
Dry throat	33	0
Dysphonia	26	0
Increased viscosity of upper respiratory secretion	5	0
Nasal discomfort	9	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	4	0
Oropharyngeal pain	623	0
Paranasal sinus discomfort	8	0
Rhinalgia	6	0
Rhinorrhoea	181	0
Sinus pain	77	0
Sneezing	62	0
Throat irritation	44	0
Throat tightness	56	0
Upper-airway cough syndrome	5	0
Yawning	10	0
Respiratory disorders SOC TOTAL	4656	4

## Case Series Drug Analysis Print me: COVID-19 Moderna vaccine analysis pri

	MedDRA Version: MedDRA 25.0	
Reaction Name	Total	<u> Fatal</u>
Skin disorders		
Acnes		
Acne	3	8
Acne cystic		2
Dermatitis acneiform		1
Alopecias		
Alopecia	7	7
Alopecia areata	1	8
Alopecia totalis		2
Angioedemas		
Angioedema	6	9
Apocrine and eccrine gland disorders		
Cold sweat	30	ol
Hidradenitis		2
Hyperhidrosis	106	2
Miliaria	7	1
Night sweats	33	
Bullous conditions		1
Blister	10	6
Blister rupture	10	2
Blood blister		3
Dermatitis bullous		5
	1	
Erythema multiforme		1
Pemphigoid		2
Pemphigus		1
Stevens-Johnson syndrome		11
Connective tissue disorders		
Cutaneous lupus erythematosus		1
Dermatomyositis		2
Dermal and epidermal conditions NEC		
Acute febrile neutrophilic dermatosis		1
Dry skin	11	
Pain of skin	15	
Papule	2	
Scab		5
Scar pain		7
Sensitive skin	15	5
Skin burning sensation	8	1
Skin discolouration	4	7
Skin discomfort		2
Skin disorder		2
Skin induration		8
Skin lesion	2	6
Skin necrosis		2
Skin odour abnormal		3
Skin plaque		1
Skin reaction	12	6
Skin sensitisation	1	
Skin swelling	3	
Skin texture abnormal		1
Skin tightness		7
Skin warm	24	ó
Skin weeping		
Yellow skin		4  5

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MedDRA Version: MedDRA 25.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Skin disorders Skin disorders cont'd		
Dermatitis and eczema		
Autoimmune dermatitis	1	(
Dermatitis	50	(
Dermatitis allergic	120	(
Dermatitis atopic	19	(
Dermatitis contact	10	(
Dyshidrotic eczema	12	(
Eczema	98	(
Eczema asteatotic	1	(
Eczema nummular	2	(
Eczema weeping	2 2	(
Flagellate dermatitis	1	(
Hand dermatitis	1	(
Neurodermatitis	1	(
Skin irritation	42	(
Dermatitis ascribed to specific agent		
Drug eruption	5	(
Fixed eruption	2	(
Palmar-plantar erythrodysaesthesia syndrome	1	(
Erythemas		
Erythema	1256	(
Vancomycin infusion reaction	1	(
Exfoliative conditions		
Dermatitis exfoliative generalised	2	•
Exfoliative rash	4	(
Skin exfoliation	24	(
Hyperkeratoses		
Hyperkeratosis	1	(
Hyperpigmentation disorders		
Ephelides	2	(
Skin hyperpigmentation	1	(
Solar lentigo	1	(
Hypopigmentation disorders		
Skin hypopigmentation	2	(
Vitiligo	2	(
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	1	(
Nail disorder	1	(
Nail ridging	1	(
Onychalgia	1	(
Onychoclasis	3	(
Onychomadesis	1	(
Panniculitides		
Erythema nodosum	11	(
Papulosquamous conditions		
Lichen planus	5	(
Lichen sclerosus	1	
Parapsoriasis	1	
Pityriasis rosea	22	
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	21	(
Pigmentation changes NEC		
Pigmentation disorder	2	(

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MedDRA Version: MedDRA 25.0		
Reaction Name	Total_	<u> Fatal</u>
Skin disorders Skin disorders cont'd		
Pilar disorders NEC		
Hair growth abnormal	2	2 0
Hair texture abnormal		0
Piloerection	16	6 0
Trichodynia	1	0
Trichorrhexis	1	0
Pruritus NEC		
Itching scar	4	∤ o
Pruritus	2623	8 0
Psoriatic conditions		
Guttate psoriasis	3	3 O
Palmoplantar pustulosis	1	0
Psoriasis	41	0
Rebound psoriasis	1	o
Purpura and related conditions		
Henoch-Schonlein purpura	1	o
Petechiae	26	6 0
Purpura	14	↓ <b> </b> 0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	o
Rash	3014	·l o
Rash erythematous	1153	3 <b> </b> 0
Rash macular	207	<b>'</b> 0
Rash maculo-papular	8	3 <b> </b> 0
Rash morbilliform	g	0
Rash papular	192	
Rash pruritic	649	) o
Rash vesicular	14	↓ <b> </b> 0
Rosaceas		
Rosacea	2	2 0
Scaly conditions		
Pityriasis	6	6 0
Sebaceous gland disorders		
Seborrhoea	2	2 0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	5	s  0
Skin mass	13	3 O
Skin and subcutaneous tissue ulcerations		
Skin erosion	8	3 O
Skin ulcer	6	6 0
Skin cysts and polyps		
Dermal cyst	8	3 <b> </b> 0
Skin dystrophies		
Keloid scar	2	2 0
Skin wrinkling	1	l 0
Skin haemorrhages		
Haemorrhage subcutaneous	1	
Skin haemorrhage	4	
Skin hypoplasias and atrophies		
Skin atrophy	3	s c
Skin injuries and mechanical dermatoses		
Decubitus ulcer	1	c
Needle track marks	2	1

# Case Series Drug Analysis Print me: COVID-19 Moderna vaccine analysis prin

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 27-Jul-2022

Data Lock Date: 27-Jul-2022 18:30:07

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin vasculitides		
Capillaritis	1	0
Cutaneous vasculitis	3	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	3	0
Skin vasomotor conditions		
Livedo reticularis	5	0
Telangiectasia and related conditions		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	5	0
Cold urticaria	1	0
Idiopathic urticaria	5	0
Mechanical urticaria	27	0
Urticaria	733	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	8	0
Urticaria contact	1	0
Urticaria papular	1	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	13745	1

Report Run Date: 27-Jul-2022

Reaction Name	Total	Fatal
Social circumstances		
Age related issues		
Menarche	2	0
Menopause	11	0
Postmenopause	2	0
Disability issues		
Bedridden	12	0
Disability	1	0
Immobile	7	0
Impaired driving ability	2	0
Impaired work ability	4	0
Loss of personal independence in daily activities	15	0
Sight disability	2	0
Walking aid user	1	0
Employment issues		
Retirement	2	0
Non-occupational and unspecified environmental problems		
Water pollution	2	0
Pregnancy related circumstances		
Breast feeding	6	0
Social issues NEC		
Social problem	1	0
Tattoo	1	0
Social circumstances SOC TOTAL	71	l o

## Case Series Drug Analysis Print ne: COVID-19 Moderna vaccine analysis prin

MedDRA Version: MedDRA 25.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Surgical & medical procedures		
Anaesthesia and allied procedures		
Light anaesthesia	1	0
Analgesia supportive care		
Analgesic therapy	1	0
Breast therapeutic procedures NEC		
Axillary lymphadenectomy	2	0
Contraceptive methods female		
Post coital contraception	1	0
Dental and gingival therapeutic procedures  Tooth extraction	1	0
Dietary and nutritional therapies		
Medical diet	1	0
Eye therapeutic procedures NEC		
Eye irrigation	1	0
Gastrointestinal therapeutic procedures NEC		
Prophylaxis of nausea and vomiting	2	0
Gynaecological therapeutic procedures NEC		
Menstrual cycle management	3	0
Hormonal therapeutic procedures NEC		
Hormone replacement therapy	1	0
Immunisations		
COVID-19 immunisation	23	0
Immunisation	22	0
Influenza immunisation	1	0
Vaccine coadministration	1	0
Joint therapeutic procedures		
Joint injection	1	0
Joint stabilisation	1	0
Limb therapeutic procedures		
Limb immobilisation	1	0
Psychiatric therapies		
Electroconvulsive therapy	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	2	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	3	0
Therapeutic procedures NEC		
Bed rest	6	0
Botulinum toxin injection	1	0
Hospitalisation	4	0
Injection	17	0
Interchange of vaccine products	50	
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	149	0

## Case Series Drug Analysis Print ne: COVID-19 Moderna vaccine analysis prir

MedDRA Version: MedDRA 25.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Vascular disorders		
Accelerated and malignant hypertension		
Hypertensive urgency	1	(
Aneurysms and dissections non-site specific		
Aneurysm ruptured	1	(
Aortic necrosis and vascular insufficiency		
Aortic stenosis	1	(
Arterial infections and inflammations		
Giant cell arteritis	5	(
Blood pressure disorders NEC		
Blood pressure fluctuation	3	(
Circulatory collapse and shock		
Circulatory collapse	12	(
Neurogenic shock	1	(
Shock	6	(
Haemorrhages NEC		
Bloody discharge	2	(
Haematoma	10	(
Haemorrhage	243	(
Internal haemorrhage	3	(
Lymphangiopathies		
Lymphocele	1	(
Lymphoedemas		
Lymphoedema	30	(
Non-site specific embolism and thrombosis		
Embolism	3	(
Embolism venous	1	(
Thrombosis	75	(
Venous thrombosis	1	(
Non-site specific necrosis and vascular insufficiency NEC		
Arterial spasm	1	
Arteriosclerosis	1	
Infarction	1	
Ischaemia	1	
Peripheral venous disease	1	(
Vasospasm	1	
Non-site specific vascular disorders NEC		
Vascular pain	8	(
Vasodilatation	3	
Vein discolouration	1	
Vein rupture	2	
Peripheral embolism and thrombosis		
Axillary vein thrombosis	1	(
Blue toe syndrome	8	
Deep vein thrombosis	65	
Pelvic venous thrombosis	3	
Superficial vein thrombosis		
Thrombophlebitis	6	
Peripheral vascular disorders NEC		
Cyanosis	14	
Erythromelalgia	1	
Flushing	59	
Hot flush	323	(
Peripheral vasoconstriction, necrosis and vascular insufficiency		

## Case Series Drug Analysis Print ne: COVID-19 Moderna vaccine analysis prin

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Extremity necrosis	1	0
Peripheral coldness	114	0
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	14	0
Phlebitis NEC		
Phlebitis	2	0
Phlebitis superficial	1	0
Site specific vascular disorders NEC		
Pallor	92	0
Varicose veins NEC		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	8	0
Varicose vein ruptured	1	0
Vascular hypertensive disorders NEC		
Hypertension	132	0
Prehypertension	1	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	2	0
Hypotension	120	0
Orthostatic hypotension	6	0
Vasculitides NEC		
MAGIC syndrome	1	0
Vasculitis	9	0
Vena caval embolism and thrombosis		
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	1412	0
TOTAL REACTIONS FOR DRUG	133392	65
TOTAL REPORTS	40270	
TOTAL FATAL OUTCOME REPORTS		65