

COVID-19 Moderna vaccine analysis print

All UK spontaneous reports received for Moderna vaccine analysis print.

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

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	3	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	142	0
Lymphadenitis	10	0
Lymphadenopathy	828	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	4	0
Thrombocytopenia	17	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	1015	0

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Data Lock Date: 03-Nov-2021 18:30:04

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	2	0
Bundle branch block left	1	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	6	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	426	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	20	0
Myocardial infarction	7	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	2	0
Left ventricular dysfunction	1	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial injury	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	92	0
<i>Noninfectious pericarditis</i>		
Pericarditis	57	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	12	0
Bradycardia	8	0
Cardiac fibrillation	1	0
Cardiac flutter	39	0
Extrasystoles	14	0
Tachycardia	58	0
Tachycardia foetal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	3	0
Atrial flutter	2	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	2	0
Supraventricular tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	0
Ventricular extrasystoles	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	774	0

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Data Lock Date: 03-Nov-2021 18:30:04

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	1	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Male reproductive tract disorders congenital</i>		
Micropenis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	6	0

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Data Lock Date: 03-Nov-2021 18:30:04

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	6	0
Ear discomfort	3	0
Ear disorder	2	0
Ear pain	120	0
Ear swelling	2	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i>Hearing losses</i>		
Deafness	18	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	18	0
Sudden hearing loss	7	0
<i>Hyperacusia</i>		
Hyperacusis	5	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	12	0
Tinnitus	180	0
Vertigo	136	0
Vertigo positional	3	0
Ear disorders SOC TOTAL	523	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	5	0
Ovulation delayed	8	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	3	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	26	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	1	0
Vitreous floaters	7	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	3	0
<i>Eyelid movement disorders</i>		
Blepharospasm	19	0
Eyelid ptosis	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	4	0
<i>Lacrimation disorders</i>		
Dry eye	14	0
Lacrimation increased	6	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
Swelling of eyelid	7	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	2	0
Eye pain	132	0
Eye swelling	39	0
Eyelids pruritus	1	0
Ocular discomfort	4	0
Periorbital oedema	2	0
Periorbital swelling	9	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye inflammation	1	0
Eye irritation	10	0
Eye pruritus	17	0
Ocular hyperaemia	17	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	5	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	9	0
Foreign body sensation in eyes	2	0
Hypoaesthesia eye	1	0
Photophobia	55	0
<i>Optic disc abnormalities NEC</i>		
Optic discs blurred	1	0
Papilloedema	1	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	1	0
<i>Orbital infections, inflammations and irritations</i>		
Orbital myositis	1	0
<i>Pupil disorders</i>		
Mydriasis	3	0

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Eye disorders Eye disorders cont'd		
<i>Refractive and accommodative disorders</i>		
Accommodation disorder	1	0
Astigmatism	2	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	3	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	1	0
Serous retinopathy	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	4	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual colour distortions</i>		
Cyanopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	15	0
Halo vision	1	0
Metamorphopsia	1	0
Photopsia	8	0
Vision blurred	161	0
<i>Visual field disorders</i>		
Visual field defect	2	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	18	0
Blindness transient	3	0
Blindness unilateral	1	0
Visual acuity reduced	2	0
Visual impairment	25	0
Eye disorders SOC TOTAL	634	0

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Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal pains</i>		
Proctalgia	4	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Colitis ulcerative	5	0
Crohn's disease	7	0
Inflammatory bowel disease	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Teething	1	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	2	0
Hyperaesthesia teeth	4	0
Toothache	13	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	480	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	57	0
Epigastric discomfort	1	0
Eructation	6	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	5	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	36	0
Flatulence	18	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	152	0
Abdominal pain lower	14	0
Abdominal pain upper	338	0
Abdominal rigidity	1	0
Abdominal tenderness	2	0
Gastrointestinal pain	13	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	21	0
Gastrooesophageal reflux disease	15	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
Gastrointestinal disorder	1	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	63	0
Anal incontinence	3	0
Breath odour	4	0
Dysphagia	17	0
Odynophagia	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	4	0
Irritable bowel syndrome	8	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	6	0
Gingival swelling	4	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	5	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	3	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	9	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	1977	0
Retching	12	0
Vomiting	692	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	1	0
Haematochezia	5	0
Melaena	1	0
Upper gastrointestinal haemorrhage	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	52	0
Lip dry	4	0
Saliva altered	2	0
Salivary hypersecretion	6	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Cheilitis	1	0
Enlarged uvula	1	0
Lip blister	2	0
Lip disorder	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	2	0
Oral blood blister	2	0
<i>Oral soft tissue signs and symptoms</i>		
Coating in mouth	2	0
Hypoaesthesia oral	43	0
Lip discolouration	1	0
Lip pain	3	0
Lip pruritus	1	0
Oral discomfort	4	0
Oral mucosal roughening	1	0
Oral pain	10	0
Oral pruritus	1	0
Paraesthesia oral	66	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	76	0
Mouth swelling	10	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer haemorrhage	2	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	1	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	3	0
Lip ulceration	3	0
Mouth ulceration	42	0
Stomatitis	3	0
<i>Tongue disorders</i>		
Glossitis	2	0
Tongue disorder	4	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	15	0
Swollen tongue	39	0
Tongue blistering	1	0
Tongue coated	2	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue discolouration	2	0
Tongue discomfort	2	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	1	0
<i>Tooth missing</i>		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	4481	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site extravasation	1	0
Administration site lymphadenopathy	1	0
Administration site pain	2	0
Puncture site bruise	5	0
Puncture site pain	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	6	0
Application site joint erythema	1	0
Application site pain	1	0
Application site pruritus	9	0
Application site rash	1	0
Application site swelling	2	0
Application site vesicles	4	0
Application site warmth	1	0
Instillation site erythema	1	0
Instillation site warmth	2	0
<i>Asthenic conditions</i>		
Asthenia	243	0
Chronic fatigue syndrome	4	0
Fatigue	2627	0
Malaise	451	0
<i>Death and sudden death</i>		
Death	8	8
<i>Febrile disorders</i>		
Pyrexia	2966	1
<i>Feelings and sensations NEC</i>		
Chills	1602	0
Feeling abnormal	234	0
Feeling cold	109	0
Feeling drunk	11	0
Feeling hot	182	0
Feeling jittery	8	0
Feeling of body temperature change	58	0
Hangover	12	0
Hunger	13	0
Sensation of blood flow	1	0
Sensation of foreign body	5	0
Temperature intolerance	16	0
Thirst	49	0
<i>Gait disturbances</i>		
Gait disturbance	16	0
Gait inability	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	11	0
Crying	22	0
Discharge	3	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	4	0
Foaming at mouth	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
General physical health deterioration	1	0
Illness	250	0
Induration	7	0
Influenza like illness	294	0
Irritability postvaccinal	1	0
Local reaction	14	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	1202	0
Screaming	4	0
Secretion discharge	2	0
Swelling	634	0
Swelling face	73	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	84	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site erythema	1	0
Infusion site mass	1	0
Infusion site pain	4	0
Infusion site pruritus	1	0
Infusion site urticaria	1	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	5	0
Injection site bruising	9	0
Injection site discolouration	1	0
Injection site erythema	110	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	5	0
Injection site indentation	2	0
Injection site inflammation	9	0
Injection site irritation	1	0
Injection site joint erythema	4	0
Injection site mass	116	0
Injection site oedema	2	0
Injection site pain	382	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	85	0
Injection site rash	153	0
Injection site reaction	14	0
Injection site swelling	55	0
Injection site urticaria	43	0
Injection site vesicles	1	0
Injection site warmth	57	0
Interactions		

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General disorders General disorders cont'd		
Alcohol interaction	1	0
Drug interaction	1	0
Mass conditions NEC		
Cyst	4	0
Mass	18	0
Nodule	3	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema NEC		
Face oedema	2	0
Localised oedema	1	0
Oedema	5	0
Oedema peripheral	6	0
Pain and discomfort NEC		
Axillary pain	413	0
Chest discomfort	182	0
Chest pain	520	0
Discomfort	75	0
Facial pain	14	0
Inflammatory pain	2	0
Non-cardiac chest pain	2	0
Pain	1277	0
Tenderness	108	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	3	0
Adverse event	1	0
Drug ineffective	11	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	2	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	2	0
Treatment failure	1	0
Vaccination failure	1	0
Ulcers NEC		
Ulcer	3	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	3	0
Vaccination site bruising	11	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	218	0
Vaccination site haemorrhage	2	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	15	0
Vaccination site inflammation	9	0
Vaccination site irritation	1	0
Vaccination site joint erythema	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	2	0
Vaccination site mass	50	0
Vaccination site movement impairment	7	0
Vaccination site oedema	1	0
Vaccination site pain	202	0
Vaccination site papule	2	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	56	0
Vaccination site rash	117	0
Vaccination site reaction	4	0
Vaccination site scar	1	0
Vaccination site swelling	137	0
Vaccination site urticaria	10	0
Vaccination site vesicles	1	0
Vaccination site warmth	99	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	3	0
General disorders SOC TOTAL	15988	10

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Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	4	0
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
Jaundice cholestatic	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	2	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Hepatic steatosis	1	0
Hepatic disorders SOC TOTAL	13	0

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Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	186	0
Infusion related hypersensitivity reaction	11	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	13	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	1	0
Allergy to vaccine	8	0
Drug hypersensitivity	8	0
Milk allergy	1	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	35	0
Anaphylactic shock	4	0
Anaphylactoid reaction	2	0
<i>Atopic disorders</i>		
Seasonal allergy	14	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	31	0
Immune-mediated adverse reaction	1	0
Sensitisation	3	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	332	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	4	0
Diverticulitis	2	0
Gastroenteritis	2	0
<i>Bacterial infections NEC</i>		
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	48	0
Folliculitis	1	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	3	0
<i>Candida infections</i>		
Candida infection	4	0
Oral candidiasis	1	0
Vulvovaginal candidiasis	7	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Meningitis	2	0
<i>Coronavirus infections</i>		
COVID-19	69	0
COVID-19 pneumonia	3	0
Suspected COVID-19	1	0
<i>Coxiella infections</i>		
Q fever	3	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	1	0
Cytomegalovirus infection reactivation	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
Tooth abscess	1	0
Tooth infection	1	0
<i>Ear infections</i>		
Ear infection	3	0
Labyrinthitis	2	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	9	0
Eye infection	2	0
Eyelid boil	1	0
Hordeolum	1	0
<i>Female reproductive tract infections</i>		
Vaginal infection	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Flaviviral infections</i>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<i>Fungal infections NEC</i>		
Fungal infection	2	0
Fungal skin infection	2	0
Overgrowth fungal	1	1
Pneumonia fungal	1	0
<i>Fusobacterium infections</i>		
Necrotising ulcerative gingivostomatitis	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	1	0
Genital herpes	8	0
Herpes ophthalmic	1	0
Herpes simplex	1	0
Herpes zoster	43	0
Herpes zoster oticus	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	38	0
Varicella	1	0
<i>Infections NEC</i>		
Abscess limb	1	0
Abscess rupture	1	0
Infection	54	0
Injection site infection	1	0
Localised infection	13	0
Respiratory tract infection	1	0
Vaccination site infection	3	0
Vestibulitis	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	2	0
<i>Infectious transmissions</i>		
Secondary transmission	2	0
<i>Influenza viral infections</i>		
Influenza	224	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	1	0
Bronchitis	3	0
Lower respiratory tract infection	17	1
Pneumonia	9	1
<i>Male reproductive tract infections</i>		
Epididymitis	1	0
Orchitis	1	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Nematode infections</i>		
Enterobiasis	1	0
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Rubella viral infections</i>		
Rubella	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Septic shock	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Eczema infected	1	0
Impetigo	2	0
Pustule	9	0
Pyoderma	1	0
Rash pustular	2	0
Skin infection	9	0
<i>Staphylococcal infections</i>		
Furuncle	4	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea infection	1	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	151	0
Peritonsillar abscess	1	0
Pharyngitis	2	0
Rhinitis	2	0
Sinusitis	8	0
Tonsillitis	10	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	5	0
Kidney infection	2	0
Urinary tract infection	18	0
<i>Vascular infections</i>		
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Gastroenteritis viral	1	0
Meningitis viral	1	0
Post viral fatigue syndrome	4	0
Sweating fever	25	0
Viral infection	2	0
Viral labyrinthitis	1	0
Viral pharyngitis	2	0
Viral rash	4	0
Infections SOC TOTAL	914	4

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Concussion	6	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	8	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	10	0
Foetal exposure during pregnancy	7	0
Maternal exposure during breast feeding	360	0
Maternal exposure during pregnancy	177	0
Maternal exposure timing unspecified	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	2	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	3	0
Heat stroke	6	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	6	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	2	0
Muscle injury	1	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	9	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	3	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	3	0
Bite	1	0
Electric shock	4	0
Fall	15	0
Injury	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 03-Nov-2021 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Nervous system injury	1	0
Wound complication	2	0
Wound haemorrhage	1	0
Non-site specific procedural complications		
Injection related reaction	3	0
Procedural pain	1	0
Occupational exposures		
Occupational exposure to toxic agent	1	0
Off label uses		
Off label use	1	0
Overdoses NEC		
Overdose	5	0
Peripheral nerve injuries		
Sciatic nerve injury	1	0
Poisoning and toxicity		
Toxicity to various agents	1	0
Product administration errors and issues		
Expired product administered	20	0
Inappropriate schedule of product administration	14	0
Incorrect dose administered	1	0
Incorrect route of product administration	1	0
Poor quality product administered	1	0
Product administered at inappropriate site	1	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	1	0
Product dispensing errors and issues		
Product dispensing error	1	0
Radiation injuries		
Sunburn	10	0
Site specific injuries NEC		
Head injury	5	0
Limb injury	17	0
Skin injuries NEC		
Contusion	171	0
Scar	8	0
Scratch	1	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Stoma complications		
Stoma site oedema	1	0
Thermal burns		
Burn oesophageal	1	0
Burns third degree	1	0
Cold burn	1	0
Thermal burn	6	0
Thermal burns of eye	1	0
Vaccination related complications		
Vaccination complication	4	0
Injuries SOC TOTAL	936	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Adrenal medulla tests		
Norepinephrine increased	2	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		
Oxygen consumption decreased	1	0
Oxygen saturation decreased	4	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	1	0
Blood glucose decreased	1	0
Blood glucose increased	2	0
Cardiac auscultatory investigations		
Cardiac murmur	1	0
Heart sounds	3	0
Central nervous system imaging procedures		
Computerised tomogram head	1	0
Cholesterol analyses		
Low density lipoprotein increased	1	0
Coagulation and bleeding analyses		
Fibrin D dimer increased	1	0
ECG investigations		
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	1	0
Electrocardiogram change	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	5	0
Fertility analyses		
Semen analysis abnormal	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
Fungus identification and serology		
Fungal test	1	0
Gastrointestinal and abdominal imaging procedures		
X-ray with contrast upper gastrointestinal tract	1	0
Heart rate and pulse investigations		
Heart rate	84	0
Heart rate abnormal	7	0
Heart rate decreased	7	0
Heart rate increased	142	0
Heart rate irregular	24	0
Heart rate variability decreased	1	0
Investigations NEC		
Blood test abnormal	3	0
Liver function analyses		
Alanine aminotransferase increased	4	0
Aspartate aminotransferase	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood bilirubin increased	1	0
Liver function test abnormal	6	0
Liver function test increased	1	0
Mineral and electrolyte analyses		
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	1	0
Sensory level	1	0
Ophthalmic function diagnostic procedures		
Visual tracking test abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	40	0
Body temperature abnormal	2	0
Body temperature decreased	3	0
Body temperature fluctuation	11	0
Body temperature increased	38	0
Grip strength	1	0
Grip strength decreased	1	0
Lymph node palpable	1	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	2	0
Respiratory rate decreased	2	0
Respiratory rate increased	6	0
Skin temperature	8	0
Temperature difference of extremities	1	0
Weight decreased	11	0
Weight increased	6	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone increased	1	0
Platelet analyses		
Platelet count decreased	7	0
Protein analyses NEC		
C-reactive protein increased	3	0
Red blood cell analyses		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
Renal function analyses		
Blood creatinine increased	1	0
Reproductive hormone analyses		
Pregnancy test	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	3	0
<i>Tissue enzyme analyses NEC</i>		
Blood lactate dehydrogenase increased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	7	0
Protein urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	3	0
Urine output decreased	1	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	6	0
Blood pressure diastolic increased	1	0
Blood pressure increased	11	0
Blood pressure measurement	3	0
<i>Virus identification and serology</i>		
Coronavirus test	4	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	2	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	3	0
SARS-CoV-2 test positive	2	0
<i>Vitamin analyses</i>		
Blood folate decreased	1	0
<i>White blood cell analyses</i>		
Neutrophil count	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	547	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	165	0
Food craving	1	0
Food refusal	1	0
Hyperphagia	5	0
Hypophagia	1	0
Increased appetite	6	0
Salt craving	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	3	0
Diabetes mellitus inadequate control	1	0
Type 1 diabetes mellitus	1	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	0
<i>Disorders of purine metabolism</i>		
Gout	10	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Food intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Abnormal weight gain	5	0
Feeding disorder	20	0
Food aversion	3	0
Neonatal insufficient breast milk syndrome	4	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	5	0
<i>Potassium imbalance</i>		
Hypokalaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	44	0
<i>Total fluid volume increased</i>		
Fluid retention	8	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	298	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	13	0
Arthritis enteropathic	1	0
Arthropathy	5	0
Autoimmune arthritis	1	0
<i>Bone disorders NEC</i>		
Jaw cyst	1	0
Jaw disorder	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	33	0
Bone swelling	1	0
Pain in jaw	38	0
Spinal pain	7	0
<i>Bursal disorders</i>		
Bursitis	7	0
<i>Cartilage disorders</i>		
Costochondritis	10	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	1	0
Reynold's syndrome	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	2	0
<i>Joint related disorders NEC</i>		
Joint lock	3	0
Periarthritis	17	0
Rotator cuff syndrome	3	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	911	0
Joint noise	3	0
Joint stiffness	32	0
Joint swelling	30	0
Joint vibration	1	0
Joint warmth	2	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
<i>Muscle infections and inflammations</i>		
Myositis	5	0
<i>Muscle pains</i>		
Fibromyalgia	7	0
Myalgia	1417	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle fatigue	45	0
Muscle haemorrhage	1	0
Muscle spasms	256	0
Muscle swelling	8	0
Muscle tightness	17	0
Muscle twitching	48	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle rigidity	2	0
Nuchal rigidity	3	0
Trismus	3	0
<i>Muscle weakness conditions</i>		
Muscular weakness	93	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Mastication disorder	2	0
Mobility decreased	5	0
Muscle contracture	1	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	219	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dupuytren's contracture	1	0
Fasciitis	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	340	0
Flank pain	6	0
Limb discomfort	202	0
Musculoskeletal chest pain	20	0
Musculoskeletal discomfort	9	0
Musculoskeletal pain	8	0
Neck pain	176	0
Pain in extremity	1937	0
Sacral pain	1	0
<i>Myopathies</i>		
Rhabdomyolysis	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	2	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	4	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	23	0
Groin pain	10	0
Neck mass	5	0
Soft tissue swelling	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	2	0
Arthritis reactive	4	0
Axial spondyloarthritis	1	0
<i>Synovial disorders</i>		
Synovial cyst	3	0
<i>Tendon disorders</i>		
Tendon pain	1	0
Trigger finger	2	0
<i>Trunk deformities</i>		
Shoulder deformity	1	0
Muscle & tissue disorders SOC TOTAL	6028	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma stage III	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	4	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Metastases to specified sites</i>		
Metastases to lymph nodes	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Skin neoplasms benign</i>		
Anogenital warts	1	0
Haemangioma of skin	3	0
Skin papilloma	3	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	21	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	2	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	5	0
<i>Autonomic nervous system disorders</i>		
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral haemorrhage	2	1
Cerebral infarction	1	0
Cerebrovascular accident	10	1
Haemorrhage intracranial	1	0
Intracranial haematoma	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	2	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	1	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	25	0
Coordination abnormal	1	0
Dysstasia	4	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	8	0
Lethargy	212	0
Loss of consciousness	122	0
Somnolence	129	0
Stupor	1	0
Syncope	594	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	2	0
Clumsiness	2	0
Dyskinesia	5	0
Extrapyramidal disorder	1	0
Fine motor delay	1	0
Fine motor skill dysfunction	3	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	5	0
Movement disorder	5	0
Psychomotor hyperactivity	1	0
<i>Dystonias</i>		
Dystonia	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	36	0
Facial paralysis	25	0
Facial paresis	3	0
Facial spasm	4	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cluster headache	27	0
Cold-stimulus headache	3	0
Drug withdrawal headache	2	0
Headache	3252	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Sinus headache	35	0
Tension headache	65	0
Thunderclap headache	1	0
Vascular headache	2	0
<i>Increased intracranial pressure disorders</i>		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	3	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	3	0
<i>Memory loss (excl dementia)</i>		
Amnesia	20	0
Memory impairment	17	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	10	0
Disturbance in attention	45	0
Mental impairment	6	0
<i>Migraine headaches</i>		
Hemiplegic migraine	3	0
Migraine	366	0
Migraine with aura	28	0
Migraine without aura	2	0
Retinal migraine	2	0
Typical aura without headache	1	0
Vestibular migraine	2	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	1	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
Multiple sclerosis	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	3	0
Stiff leg syndrome	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	10	0
Narcolepsy	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	2	0
Psychomotor skills impaired	1	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	5	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Dizziness	1654	0
Dizziness exertional	3	0
Dizziness postural	73	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	32	0
Inability to crawl	1	0
Neurological symptom	5	0
Persistent postural-perceptual dizziness	1	0
Presyncope	147	0
Unresponsive to stimuli	9	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	2	0
Muscle spasticity	3	0
<i>Olfactory nerve disorders</i>		
Anosmia	16	0
Parosmia	15	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	1	0
Burning sensation	57	0
Formication	2	0
Hemianaesthesia	2	0
Hyperaesthesia	30	0
Hypoaesthesia	335	0
Paraesthesia	477	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	4	0
Hemiplegia	5	0
Monoparesis	9	0
Monoplegia	13	0
Paralysis	13	0
Paresis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
Reduced facial expression	1	0
<i>Peripheral neuropathies NEC</i>		
Autoimmune neuropathy	1	0
Neuralgic amyotrophy	1	0
Neuritis	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Neuropathy peripheral	6	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0
Seizures and seizure disorders NEC		
Epilepsy	9	0
Febrile convulsion	2	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	102	0
Seizure anoxic	1	0
Status epilepticus	24	0
Tonic clonic movements	2	0
Tonic convulsion	2	0
Sensory abnormalities NEC		
Ageusia	35	0
Allodynia	1	0
Complex regional pain syndrome	1	0
Dysgeusia	106	0
Electric shock sensation	4	0
Hypogeusia	1	0
Neuralgia	46	0
Post herpetic neuralgia	2	0
Restless legs syndrome	24	0
Sensory disturbance	8	0
Sensory loss	13	0
Taste disorder	19	0
Vibratory sense increased	1	0
Sleep disturbances NEC		
Sleep deficit	2	0
Speech and language abnormalities		
Dysarthria	18	0
Incoherent	5	0
Slow speech	3	0
Speech disorder	10	0
Spinal cord and nerve root disorders NEC		
Radiculopathy	1	0
Transient cerebrovascular events		
Transient ischaemic attack	5	0
Tremor (excl congenital)		
Tremor	218	0
Trigeminal disorders		
Trigeminal neuralgia	2	0
Nervous system disorders SOC TOTAL	8758	2

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	36	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	3	0
Hydrops foetalis	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	3	0
<i>Maternal complications of labour NEC</i>		
Uterine atony	1	0
Uterine hypertonus	2	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Somatic symptom disorder of pregnancy	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	4	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	1
Pregnancy conditions SOC TOTAL	62	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Device malfunction events NEC</i>		
Thrombosis in device	1	0
<i>Manufacturing materials issues</i>		
Manufacturing materials issue	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	8	0
<i>Product physical issues</i>		
Product after taste	1	0
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product impurity	1	0
Product quality issue	1	0
<i>Product supply and availability issues</i>		
Product availability issue	2	0
null SOC TOTAL	18	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
<i>Affect alterations NEC</i>		
Affect lability	2	0
Flat affect	3	0
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Agitation	12	0
Anxiety	155	0
Nervousness	24	0
Stress	14	0
Tension	6	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	3	0
<i>Behaviour and socialisation disturbances</i>		
Disinhibition	1	0
Paranoia	4	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	27	0
<i>Confusion and disorientation</i>		
Confusional state	81	0
Disorientation	34	0
<i>Deliria</i>		
Delirium	15	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	48	0
Depression suicidal	3	0
Major depression	1	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
Dissociation	8	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	2	0
Insomnia	177	0
Middle insomnia	9	0
Terminal insomnia	9	0
<i>Dyssomnias</i>		
Poor quality sleep	39	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	7	0
Emotional disorder	14	0
Emotional distress	6	0
Euphoric mood	7	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Irritability	34	0
Mood altered	8	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
Fear of death	1	0
Fear of injection	6	0
Paruresis	1	0
Phobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	11	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	51	0
Hallucination, auditory	2	0
Hallucination, visual	1	0
Somatic hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	30	0
<i>Mental disorders NEC</i>		
Mental disorder	3	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	52	0
Feeling of despair	2	0
Tearfulness	2	0
<i>Mood alterations with manic symptoms</i>		
Mania	4	0
<i>Mood disorders NEC</i>		
Apathy	5	0
Listless	2	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	1	0
<i>Orgasmic disorders and disturbances</i>		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	36	0
Panic reaction	7	0
<i>Parasomnias</i>		
Abnormal dreams	20	0
Nightmare	24	0
Sleep talking	2	0
Sleep terror	3	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	3	0
Derealisation	2	0
Illusion	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	7	0
<i>Psychiatric symptoms NEC</i>		
Psychiatric symptom	1	0
Psychological trauma	1	0
<i>Psychotic disorder NEC</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Acute psychosis	1	0
Psychotic disorder	1	0
<i>Sexual desire disorders</i>		
Libido decreased	3	0
Libido increased	1	0
Loss of libido	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	24	0
<i>Somatic symptom disorders</i>		
Conversion disorder	3	0
Habit cough	4	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	3	0
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	1	0
Head banging	1	0
<i>Substance related and addictive disorders</i>		
Alcoholism	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	8	0
Suicide attempt	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	1120	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	4	0
Dysuria	6	0
Incontinence	2	0
Micturition urgency	4	0
Pollakiuria	17	0
Urethral pain	1	0
Urinary incontinence	6	0
Urinary retention	1	0
Urinary straining	1	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
Urinary bladder haemorrhage	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	4	0
Oliguria	1	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	8	0
Haematuria	2	0
Urine abnormality	4	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	5	0
Renal pain	44	0
Renal & urinary disorders SOC TOTAL	119	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	3	0
<i>Breast disorders NEC</i>		
Breast enlargement	3	0
Breast mass	9	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	1	0
Breast discomfort	1	0
Breast pain	65	0
Breast swelling	8	0
Breast tenderness	8	0
Nipple pain	1	0
Nipple swelling	2	0
<i>Cervix disorders NEC</i>		
Ectropion of cervix	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	9	0
Nocturnal emission	1	0
Organic erectile dysfunction	5	0
Painful ejaculation	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Galactorrhoea	1	0
Lactation puerperal increased	2	0
Suppressed lactation	5	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	6	0
Premature menopause	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	7	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	290	0
Intermenstrual bleeding	142	0
Menstrual discomfort	2	0
Menstrual disorder	251	0
Menstruation irregular	409	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	11	0
Premenstrual syndrome	12	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	59	0
Hypomenorrhoea	83	0
Menstruation delayed	536	0
Oligomenorrhoea	20	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	688	0
Menometrorrhagia	5	0
Polymenorrhoea	98	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	5	0
Polycystic ovaries	5	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	14	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	10	0
Pelvic haemorrhage	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile pain	1	0
Penis disorder	3	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	2	0
Genital paraesthesia	1	0
Genital ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	14	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	2	0
Varicocele	1	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	3	0
Sexual dysfunction	1	0
<i>Spermatogenesis and semen disorders</i>		
Haematospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	9	0
Testicular swelling	4	0
<i>Uterine disorders NEC</i>		
Endometriosis	10	0
Uterine haemorrhage	6	0
Uterine pain	2	0
<i>Uterine tone disorders</i>		
Uterine spasm	11	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	194	0
Vaginal ulceration	1	0
Vulval haemorrhage	6	0
<i>Vulvovaginal signs and symptoms</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<small>Reproductive & breast disorders cont'd</small>		
Labia enlarged	1	0
Vaginal discharge	11	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	5	0
Reproductive & breast disorders SOC TOTAL	3097	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	459	0
Dyspnoea exertional	4	0
Hyperventilation	4	0
Hypopnoea	10	0
Hypoventilation	1	0
Irregular breathing	1	0
Respiration abnormal	8	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	27	0
Asthma late onset	1	0
Childhood asthma	1	0
Chronic obstructive pulmonary disease	1	0
Wheezing	42	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	218	0
Productive cough	16	0
Sputum discoloured	2	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	2	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	14	0
Pulmonary haemorrhage	1	0
Pulmonary pain	9	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	29	0
<i>Nasal disorders NEC</i>		
Epistaxis	82	0
Nasal oedema	1	0
Nasal pruritus	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	1	0
Sinus congestion	5	0
Sinus disorder	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal hypoesthesia	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	3	0
Pharyngeal swelling	38	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	8	0
<i>Pleural infections and inflammations</i>		
Pleurisy	4	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	2	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
Pulmonary oedema	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	15	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
Respiratory symptom	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	6	0
Catarrh	1	0
Choking	2	0
Dry throat	15	0
Dysphonia	6	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	3	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	258	0
Paranasal sinus discomfort	5	0
Rhinalgia	2	0
Rhinorrhoea	67	0
Sinus pain	29	0
Sneezing	18	0
Throat irritation	20	0
Throat tightness	33	0
Upper-airway cough syndrome	1	0
Yawning	4	0
Respiratory disorders SOC TOTAL	1516	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	24	0
<i>Alopecias</i>		
Alopecia	31	0
Alopecia areata	4	0
Alopecia totalis	1	0
<i>Angioedemas</i>		
Angioedema	22	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	153	0
Hidradenitis	1	0
Hyperhidrosis	477	0
Miliaria	46	0
Night sweats	102	0
<i>Bullous conditions</i>		
Blister	39	0
Blister rupture	1	0
Blood blister	1	0
Dermatitis bullous	1	0
Erythema multiforme	11	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	56	0
Pain of skin	53	0
Papule	20	0
Scab	4	0
Scar pain	2	0
Sensitive skin	76	0
Skin burning sensation	33	0
Skin discolouration	19	0
Skin induration	6	0
Skin lesion	21	0
Skin reaction	78	0
Skin sensitisation	9	0
Skin swelling	13	0
Skin tightness	4	0
Skin warm	152	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	18	0
Dermatitis allergic	73	0
Dermatitis atopic	9	0
Dermatitis contact	5	0
Dyshidrotic eczema	9	0
Eczema	38	0
Eczema nummular	2	0
Neurodermatitis	1	0
Skin irritation	17	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	742	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	9	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Vitiligo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Papulosquamous conditions</i>		
Lichen planus	2	0
Pityriasis rosea	8	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	13	0
<i>Pilar disorders NEC</i>		
Piloerection	8	0
<i>Pruritus NEC</i>		
Itching scar	3	0
Pruritus	1581	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	16	0
<i>Purpura and related conditions</i>		
Petechiae	14	0
Purpura	8	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	1845	0
Rash erythematous	721	0
Rash macular	121	0
Rash maculo-papular	2	0
Rash morbilliform	4	0
Rash papular	129	0
Rash pruritic	415	0
Rash vesicular	5	0
<i>Rosaceas</i>		
Rosacea	2	0
<i>Scaly conditions</i>		
Pityriasis	1	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	3	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin mass	4	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin ulcer	2	0
Skin cysts and polyps		
Dermal cyst	6	0
Skin dystrophies		
Keloid scar	1	0
Skin haemorrhages		
Skin haemorrhage	1	0
Skin hypoplasias and atrophies		
Skin atrophy	2	0
Skin injuries and mechanical dermatoses		
Needle track marks	1	0
Skin vasculitides		
Cutaneous vasculitis	2	0
Skin vasomotor conditions		
Livedo reticularis	3	0
Telangiectasia and related conditions		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	271	0
Urticaria cholinergic	1	0
Urticaria chronic	2	0
Skin disorders SOC TOTAL	7607	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menarche	1	0
Menopause	5	0
<i>Disability issues</i>		
Bedridden	3	0
Immobile	2	0
Impaired driving ability	1	0
Sight disability	1	0
<i>Employment issues</i>		
Retirement	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	5	0
<i>Social issues NEC</i>		
Social problem	1	0
Social circumstances SOC TOTAL	22	0

Case Series Drug Analysis Print

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Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	1	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	2	0
<i>Immunisations</i>		
COVID-19 immunisation	13	0
Immunisation	16	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
Joint stabilisation	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	4	0
<i>Therapeutic procedures NEC</i>		
Bed rest	2	0
Botulinum toxin injection	1	0
Hospitalisation	2	0
Injection	16	0
Interchange of vaccine products	1	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	64	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive urgency	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Neurogenic shock	1	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	4	0
Haemorrhage	149	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	9	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Embolism venous	1	0
Thrombosis	29	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	1	0
Infarction	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	5	0
Vasodilatation	2	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	2	0
Deep vein thrombosis	9	0
Superficial vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	6	0
Flushing	28	0
Hot flush	172	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	35	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	58	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	47	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Hypotension	57	0
Orthostatic hypotension	5	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	645	0
TOTAL REACTIONS FOR DRUG	55564	19
TOTAL REPORTS	17321	
TOTAL FATAL OUTCOME REPORTS		19