

COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021
Data Lock Date: 17-Nov-2021 18:30:04

All UK spontaneous reports received up to and including 17/11/2021 for COVID-19 vaccine Moderna

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

Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

Data Lock Date: 17-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
Mast cell activation syndrome	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	145	0
Lymphadenitis	10	0
Lymphadenopathy	859	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	4	0
Thrombocytopenia	18	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	1052	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	473	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	23	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	2	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial injury	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	101	0
<i>Noninfectious pericarditis</i>		
Pericarditis	57	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	15	0
Bradycardia	9	0
Cardiac fibrillation	1	0
Cardiac flutter	43	0
Extrasystoles	18	0
Tachycardia	89	0
Tachycardia foetal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	7	0
Atrial flutter	3	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	4	0
Ventricular extrasystoles	1	0
Ventricular tachycardia	2	0
Cardiac disorders SOC TOTAL	884	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	125	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	13	0
Tinnitus	192	0
Vertigo	141	0
Vertigo positional	4	0
Ear disorders SOC TOTAL	547	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	6	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	29	0

Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	15	0
Lacrimation increased	6	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
Swelling of eyelid	8	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	2	0
Eye pain	142	0
Eye swelling	41	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	18	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	2	0
Photophobia	62	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

Case Series Drug Analysis Print

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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	11	0
Vision blurred	165	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	26	0
Eye disorders SOC TOTAL	665	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

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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	3	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	513	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	60	0
Epigastric discomfort	1	0
Eructation	7	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	162	0
Abdominal pain lower	14	0
Abdominal pain upper	359	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	17	0

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MedDRA Version: MedDRA 24.1

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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	68	0
Anal incontinence	3	0
Breath odour	4	0
Dysphagia	19	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	6	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	2111	0
Retching	13	0
Vomiting	750	0
Vomiting projectile	3	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	1	0
Haematochezia	5	0
Melaena	1	0
Upper gastrointestinal haemorrhage	3	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	53	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	45	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	69	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	82	0
Mouth swelling	10	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer haemorrhage	2	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	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	44	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	16	0
Swollen tongue	40	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue blistering	1	0
Tongue coated	2	0
Tongue discolouration	2	0
Tongue discomfort	3	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	4773	0

Case Series Drug Analysis Print

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Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	10	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	257	0
Chronic fatigue syndrome	4	0
Fatigue	2803	0
Malaise	488	0
<i>Death and sudden death</i>		
Death	8	8
<i>Febrile disorders</i>		
Pyrexia	3124	1
<i>Feelings and sensations NEC</i>		
Chills	1721	0
Feeling abnormal	246	0
Feeling cold	118	0
Feeling drunk	11	0
Feeling hot	197	0
Feeling jittery	9	0
Feeling of body temperature change	59	0
Hangover	12	0
Hunger	13	0
Sensation of blood flow	1	0
Sensation of foreign body	5	0
Temperature intolerance	17	0
Thirst	52	0
<i>Gait disturbances</i>		
Gait disturbance	17	0
Gait inability	4	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	11	0
Crying	23	0
Discharge	3	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	5	0
Foaming at mouth	2	0

Case Series Drug Analysis Print

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General disorders General disorders cont'd		
General physical health deterioration	1	0
Illness	268	0
Induration	7	0
Influenza like illness	327	0
Irritability postvaccinal	1	0
Local reaction	17	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	1259	0
Screaming	4	0
Secretion discharge	2	0
Swelling	669	0
Swelling face	76	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	90	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	116	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	2	0
Injection site joint erythema	4	0
Injection site joint pain	1	0
Injection site mass	119	0
Injection site oedema	2	0
Injection site pain	399	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	86	0
Injection site rash	156	0
Injection site reaction	15	0
Injection site swelling	60	0
Injection site urticaria	45	0
Injection site vesicles	1	0
Injection site warmth	60	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Interactions</i>		
Alcohol interaction	1	0
Drug interaction	1	0
<i>Mass conditions NEC</i>		
Cyst	4	0
Mass	18	0
Nodule	3	0
<i>Mucosal findings abnormal</i>		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
<i>Oedema NEC</i>		
Face oedema	2	0
Localised oedema	1	0
Oedema	6	0
Oedema peripheral	6	0
<i>Pain and discomfort NEC</i>		
Axillary pain	424	0
Chest discomfort	197	0
Chest pain	574	0
Discomfort	75	0
Facial pain	16	0
Inflammatory pain	2	0
Non-cardiac chest pain	2	0
Pain	1342	0
Tenderness	113	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	9	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	2	0
<i>Ulcers NEC</i>		
Ulcer	3	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	4	0
Vaccination site bruising	12	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	225	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

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General disorders General disorders cont'd		
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	2	0
Vaccination site mass	53	0
Vaccination site movement impairment	7	0
Vaccination site oedema	1	0
Vaccination site pain	216	0
Vaccination site papule	2	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	57	0
Vaccination site rash	118	0
Vaccination site reaction	4	0
Vaccination site scar	1	0
Vaccination site swelling	142	0
Vaccination site urticaria	10	0
Vaccination site vesicles	1	0
Vaccination site warmth	101	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	4	0
General disorders SOC TOTAL	16933	10

Case Series Drug Analysis Print

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Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	5	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 enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Hepatic steatosis	1	0
Hepatic disorders SOC TOTAL	16	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
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	194	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	10	0
Drug hypersensitivity	8	0
Milk allergy	1	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	36	0
Anaphylactic shock	4	0
Anaphylactoid reaction	3	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 system disorder	2	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	346	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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	51	0
Folliculitis	1	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
Vaccination site cellulitis	2	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	71	0
COVID-19 pneumonia	4	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
Otitis externa	1	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>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Vaginal infection	1	0
Flaviviral infections		
Dengue fever	2	0
Encephalitis Japanese B	1	0
Fungal infections NEC		
Fungal infection	3	0
Fungal skin infection	2	0
Overgrowth fungal	1	1
Pneumonia fungal	1	0
Fusobacterium infections		
Necrotising ulcerative gingivostomatitis	1	0
Herpes viral infections		
Eczema herpeticum	1	0
Genital herpes	8	0
Herpes ophthalmic	1	0
Herpes simplex	1	0
Herpes zoster	46	0
Herpes zoster oticus	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	40	0
Varicella	1	0
Infections NEC		
Abscess limb	1	0
Abscess rupture	1	0
Infection	56	0
Injection site infection	1	0
Localised infection	13	0
Respiratory tract infection	1	0
Vaccination site abscess	1	0
Vaccination site infection	4	0
Vestibulitis	1	0
Infectious disorders carrier		
SARS-CoV-2 carrier	2	0
Infectious transmissions		
Secondary transmission	2	0
Influenza viral infections		
Influenza	250	0
Lower respiratory tract and lung infections		
Atypical pneumonia	1	0
Bronchitis	3	0
Lower respiratory tract infection	22	1
Pneumonia	9	1
Male reproductive tract infections		
Epididymitis	1	0
Orchitis	1	0
Mumps viral infections		
Mumps	1	0
Nematode infections		
Enterobiasis	1	0
Rabies viral infections		
Rabies	1	1
Rubella viral infections		
Rubella	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
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	5	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	160	0
Peritonsillar abscess	1	0
Pharyngitis	2	0
Rhinitis	3	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	27	0
Viral infection	2	0
Viral labyrinthitis	1	0
Viral pharyngitis	2	0
Viral rash	5	0
Infections SOC TOTAL	977	4

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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 before pregnancy	1	0
Maternal exposure during breast feeding	362	0
Maternal exposure during pregnancy	179	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	2	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	19	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Injury	3	0
Nervous system injury	1	0
Wound complication	2	0
Wound haemorrhage	1	0
Non-site specific procedural complications		
Injection related reaction	3	0
Post procedural erythema	1	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	6	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	15	0
Incorrect dose administered	1	0
Incorrect route of product administration	1	0
Poor quality product administered	1	0
Product administered at inappropriate site	2	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	11	0
Site specific injuries NEC		
Back injury	1	0
Head injury	5	0
Limb injury	17	0
Skin injuries NEC		
Contusion	176	0
Scar	9	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	2	0
Cold burn	1	0
Thermal burn	9	0
Thermal burns of eye	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Thoracic cage fractures and dislocations</i>		
Sternal fracture	1	0
<i>Vaccination related complications</i>		
Vaccination complication	4	0
Injuries SOC TOTAL	964	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Campylobacter test positive	1	0
<i>Blood counts NEC</i>		
Full blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen consumption decreased	1	0
Oxygen saturation decreased	6	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	1	0
Blood glucose decreased	1	0
Blood glucose increased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
Heart sounds	3	0
<i>Cardiac function diagnostic procedures</i>		
Ejection fraction decreased	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	1	0
<i>Cholesterol analyses</i>		
Low density lipoprotein increased	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
<i>ECG investigations</i>		
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
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	7	0
<i>Fertility analyses</i>		
Semen analysis abnormal	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
X-ray with contrast upper gastrointestinal tract	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	93	0
Heart rate abnormal	9	0
Heart rate decreased	7	0
Heart rate increased	155	0
Heart rate irregular	26	0
Heart rate variability decreased	1	0
<i>Investigations NEC</i>		
Blood test abnormal	3	0
<i>Liver function analyses</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Alanine aminotransferase increased	4	0
Aspartate aminotransferase	2	0
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
Musculoskeletal and soft tissue imaging procedures		
Bone scan	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	2	0
Sensory level	1	0
Ophthalmic function diagnostic procedures		
Visual tracking test abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	41	0
Body temperature abnormal	3	0
Body temperature decreased	3	0
Body temperature fluctuation	12	0
Body temperature increased	41	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	13	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	4	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		

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood creatine phosphokinase increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	2	0
Therapeutic drug monitoring analyses		
Analgesic drug level	3	0
Tissue enzyme analyses NEC		
Blood lactate dehydrogenase increased	1	0
Urinalysis NEC		
Blood urine present	7	0
Protein urine	1	0
Urinary tract function analyses NEC		
Urine output	3	0
Urine output decreased	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	6	0
Blood pressure diastolic increased	1	0
Blood pressure increased	12	0
Blood pressure measurement	3	0
Virus identification and serology		
Coronavirus test	4	0
Influenza A virus test	1	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
Vitamin analyses		
Blood folate decreased	1	0
White blood cell analyses		
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	591	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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	176	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	24	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	49	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	318	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	17	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	36	0
Bone swelling	1	0
Pain in jaw	40	0
Spinal pain	8	0
<i>Bursal disorders</i>		
Bursitis	7	0
<i>Cartilage disorders</i>		
Costochondritis	12	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	4	0
Periarthritis	18	0
Rotator cuff syndrome	3	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	988	0
Joint noise	3	0
Joint stiffness	32	0
Joint swelling	32	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	12	0
Myalgia	1507	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle fatigue	49	0
Muscle haemorrhage	1	0
Muscle spasms	264	0
Muscle swelling	9	0
Muscle tightness	17	0
Muscle twitching	50	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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	95	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Mastication disorder	2	0
Mobility decreased	7	0
Muscle contracture	1	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	227	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	355	0
Flank pain	7	0
Limb discomfort	208	0
Musculoskeletal chest pain	22	0
Musculoskeletal discomfort	9	0
Musculoskeletal pain	8	0
Neck pain	183	0
Pain in extremity	2014	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	24	0
Groin pain	11	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	4	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	6354	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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	2	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>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	2	0
Neoplasms SOC TOTAL	24	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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	12	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	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	2	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	26	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	230	0
Loss of consciousness	135	0
Somnolence	136	0
Stupor	1	0
Syncope	620	0
<i>Disturbances in sleep phase rhythm</i>		
Delayed sleep phase	1	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	6	0
Movement disorder	5	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Psychomotor hyperactivity	1	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	39	0
Facial paralysis	25	0
Facial paresis	4	0
Facial spasm	4	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cluster headache	29	0
Cold-stimulus headache	3	0
Drug withdrawal headache	2	0
Headache	3472	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Sinus headache	37	0
Tension headache	70	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	22	0
Memory impairment	17	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	11	0
Disturbance in attention	47	0
Mental impairment	6	0
<i>Migraine headaches</i>		
Hemiplegic migraine	3	0
Migraine	384	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

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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>Muscle tone abnormal</i>		
Hypotonia	3	0
Stiff leg syndrome	2	0
<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	6	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Clonus	1	0
Dizziness	1710	0
Dizziness exertional	4	0
Dizziness postural	77	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	35	0
Inability to crawl	1	0
Neurological symptom	5	0
Persistent postural-perceptual dizziness	1	0
Presyncope	148	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	17	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	60	0
Formication	2	0
Hemianaesthesia	2	0
Hyperaesthesia	32	0
Hypoaesthesia	349	0
Paraesthesia	490	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	4	0
Hemiplegia	5	0
Monoparesis	10	0
Monoplegia	14	0
Paralysis	14	0
Paresis	2	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
Reduced facial expression	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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>Peripheral neuropathies NEC</i>		
Autoimmune neuropathy	1	0
Neuralgic amyotrophy	1	0
Neuritis	1	0
Neuropathy peripheral	5	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	9	0
Febrile convulsion	2	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	103	0
Seizure anoxic	1	0
Status epilepticus	24	0
Tonic clonic movements	3	0
Tonic convulsion	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	37	0
Allodynia	1	0
Complex regional pain syndrome	1	0
Dysgeusia	111	0
Electric shock sensation	4	0
Hypogeusia	1	0
Neuralgia	48	0
Post herpetic neuralgia	2	0
Restless legs syndrome	25	0
Sensory disturbance	8	0
Sensory loss	13	0
Taste disorder	20	0
Vibratory sense increased	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	2	0
<i>Speech and language abnormalities</i>		
Dysarthria	19	0
Incoherent	7	0
Slow speech	3	0
Speech disorder	10	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculopathy	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	6	0
<i>Tremor (excl congenital)</i>		
Tremor	233	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	2	0
Nervous system disorders SOC TOTAL	9222	2

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	39	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
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	66	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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: 18-Nov-2021

Data Lock Date: 17-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	13	0
Anxiety	159	0
Nervousness	24	0
Stress	14	0
Tension	7	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	5	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	87	0
Disorientation	38	0
<i>Deliria</i>		
Delirium	16	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	186	0
Middle insomnia	9	0
Terminal insomnia	10	0
<i>Dyssomnias</i>		
Poor quality sleep	41	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	8	0
Euphoric mood	7	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Irritability	35	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	12	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	54	0
Hallucination, auditory	2	0
Hallucination, visual	1	0
Somatic hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	31	0
<i>Mental disorders NEC</i>		
Mental disorder	3	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	55	0
Feeling of despair	3	0
Tearfulness	2	0
<i>Mood alterations with manic symptoms</i>		
Mania	4	0
<i>Mood disorders NEC</i>		
Apathy	6	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 inertia	1	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

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic disorder	1	0
<i>Sexual desire disorders</i>		
Libido decreased	4	0
Libido increased	1	0
Loss of libido	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	27	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	2	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	1169	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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	4	0
Micturition urgency	4	0
Pollakiuria	19	0
Urethral pain	1	0
Urinary incontinence	7	0
Urinary retention	2	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	9	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	45	0
Renal & urinary disorders SOC TOTAL	127	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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	10	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	67	0
Breast swelling	8	0
Breast tenderness	9	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	10	0
Nocturnal emission	1	0
Organic erectile dysfunction	6	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	8	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	300	0
Intermenstrual bleeding	145	0
Menstrual discomfort	2	0
Menstrual disorder	254	0
Menstruation irregular	411	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	13	0
Premenstrual syndrome	13	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	59	0
Hypomenorrhoea	83	0
Menstruation delayed	541	0
Oligomenorrhoea	20	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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	696	0
Menometrorrhagia	5	0
Polymenorrhoea	100	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	3	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>		
Haemospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	10	0
Testicular swelling	4	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometriosis	10	0
Uterine haemorrhage	6	0
Uterine pain	3	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	197	0
Vaginal ulceration	1	0
Vulval haemorrhage	6	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
<i>Vulvovaginal signs and symptoms</i>		
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	3147	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	509	0
Dyspnoea exertional	4	0
Hyperventilation	4	0
Hypopnoea	11	0
Hypoventilation	1	0
Irregular breathing	1	0
Respiration abnormal	9	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	30	0
Asthma late onset	1	0
Childhood asthma	1	0
Chronic obstructive pulmonary disease	1	0
Wheezing	46	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	237	0
Productive cough	17	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	10	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	30	0
<i>Nasal disorders NEC</i>		
Epistaxis	85	0
Nasal oedema	1	0
Nasal pruritus	3	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: 18-Nov-2021

Data Lock Date: 17-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	4	0
Pharyngeal swelling	39	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	8	0
<i>Pleural infections and inflammations</i>		
Pleurisy	5	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	2	0
Pulmonary oedema	3	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	16	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
Respiratory symptom	2	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	3	0
Dry throat	15	0
Dysphonia	7	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	3	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	270	0
Paranasal sinus discomfort	5	0
Rhinalgia	2	0
Rhinorrhoea	72	0
Sinus pain	30	0
Sneezing	19	0
Throat irritation	21	0
Throat tightness	34	0
Upper-airway cough syndrome	1	0
Yawning	4	0
Respiratory disorders SOC TOTAL	1631	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	27	0
<i>Alopecias</i>		
Alopecia	34	0
Alopecia areata	5	0
Alopecia totalis	1	0
<i>Angioedemas</i>		
Angioedema	22	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	162	0
Hidradenitis	1	0
Hyperhidrosis	505	0
Miliaria	46	0
Night sweats	107	0
<i>Bullous conditions</i>		
Blister	41	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	59	0
Pain of skin	55	0
Papule	20	0
Scab	4	0
Scar pain	2	0
Sensitive skin	78	0
Skin burning sensation	37	0
Skin discolouration	20	0
Skin induration	6	0
Skin lesion	21	0
Skin reaction	81	0
Skin sensitisation	9	0
Skin swelling	13	0
Skin tightness	4	0
Skin warm	159	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	19	0
Dermatitis allergic	75	0
Dermatitis atopic	11	0
Dermatitis contact	5	0
Dyshidrotic eczema	9	0
Eczema	43	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: 18-Nov-2021

Data Lock Date: 17-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	2	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	760	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	1627	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	1887	0
Rash erythematous	739	0
Rash macular	124	0
Rash maculo-papular	2	0
Rash morbilliform	4	0
Rash papular	133	0
Rash pruritic	421	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>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Cutaneous symptom	3	0
Skin mass	4	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	1	0
Skin ulcer	2	0
<i>Skin cysts and polyps</i>		
Dermal cyst	6	0
<i>Skin dystrophies</i>		
Keloid scar	1	0
Skin wrinkling	1	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	2	0
<i>Skin injuries and mechanical dermatoses</i>		
Needle track marks	1	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	2	0
Vasculitic rash	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	3	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	287	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	2	0
Skin disorders SOC TOTAL	7849	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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
Loss of personal independence in daily activities	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	23	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-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>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	2	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	2	0
<i>Immunisations</i>		
COVID-19 immunisation	16	0
Immunisation	21	0
<i>Joint therapeutic procedures</i>		
Joint injection	2	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	3	0
Injection	16	0
Interchange of vaccine products	1	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	76	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

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	151	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	10	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Embolism venous	1	0
Thrombosis	30	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	11	0
Superficial vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	6	0
Flushing	30	0
Hot flush	175	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	42	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	61	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	49	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Hypotension	58	0
Orthostatic hypotension	5	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	669	0
TOTAL REACTIONS FOR DRUG	58476	19
TOTAL REPORTS	18116	
TOTAL FATAL OUTCOME REPORTS		19