

COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Data Lock Date: 02-Jun-2021 18:30:03

All UK spontaneous reports received up to and including 02/06/2021 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

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	26	0
Lymphadenitis	3	0
Lymphadenopathy	142	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	174	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
 Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	40	0
<i>Ischaemic coronary artery disorders</i>		
Myocardial infarction	2	0
<i>Noninfectious myocarditis</i>		
Myocarditis	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Bradycardia	1	0
Extrasystoles	1	0
Tachycardia	9	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	0
Cardiac disorders SOC TOTAL	61	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	2	0
Ear pain	21	0
<i>Hearing losses</i>		
Deafness	4	0
Deafness transitory	1	0
Deafness unilateral	2	0
Hypoacusis	3	0
Sudden hearing loss	1	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	3	0
Tinnitus	58	0
Vertigo	29	0
Ear disorders SOC TOTAL	125	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Lacrimation disorders</i>		
Dry eye	3	0
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye pain	16	0
Eye swelling	8	0
Periorbital swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye irritation	2	0
Eye pruritus	4	0
Ocular hyperaemia	7	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Hypoaesthesia eye	1	0
Photophobia	4	0
<i>Orbital infections, inflammations and irritations</i>		
Orbital myositis	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	2	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	35	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Visual impairment	2	0
Eye disorders SOC TOTAL	98	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	2	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
Crohn's disease	2	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	1	0
Toothache	3	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	95	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	5	0
Epigastric discomfort	1	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
Flatulence	5	0
<i>Gastric ulcers and perforation</i>		
Gastritis erosive	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	22	0
Abdominal pain upper	48	0
Gastrointestinal pain	4	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	4	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	8	0
Breath odour	1	0
Dysphagia	1	0
Odynophagia	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival swelling	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	276	0
Vomiting	72	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	16	0
Lip dry	4	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Saliva altered	1	0
Salivary hypersecretion	2	0
<i>Oral soft tissue haemorrhages</i>		
Oral blood blister	2	0
<i>Oral soft tissue signs and symptoms</i>		
Coating in mouth	1	0
Hypoaesthesia oral	16	0
Lip pain	1	0
Oral discomfort	1	0
Paraesthesia oral	28	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	11	0
Mouth swelling	4	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Mouth ulceration	10	0
Stomatitis	1	0
<i>Tongue disorders</i>		
Glossitis	1	0
Tongue disorder	2	0
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	3	0
Swollen tongue	11	0
Tongue blistering	1	0
Tongue dry	2	0
Gastrointestinal disorders SOC TOTAL	689	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site pain	1	0
Puncture site bruise	1	0
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site burn	1	0
Application site erythema	2	0
Application site pain	1	0
Application site pruritus	4	0
Application site rash	1	0
Application site warmth	1	0
<i>Asthenic conditions</i>		
Asthenia	28	0
Fatigue	436	0
Malaise	71	0
<i>Death and sudden death</i>		
Death	2	2
<i>Febrile disorders</i>		
Pyrexia	246	0
<i>Feelings and sensations NEC</i>		
Chills	176	0
Feeling abnormal	35	0
Feeling cold	20	0
Feeling drunk	2	0
Feeling hot	38	0
Feeling jittery	1	0
Feeling of body temperature change	10	0
Hangover	1	0
Hunger	1	0
Sensation of foreign body	1	0
Thirst	14	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	3	0
Crying	7	0
Exercise tolerance decreased	2	0
Illness	25	0
Induration	3	0
Influenza like illness	29	0
Local reaction	4	0
Peripheral swelling	297	0
Screaming	1	0
Swelling	147	0
Swelling face	16	0
<i>Inflammations</i>		
Inflammation	24	0
Soft tissue inflammation	1	0
<i>Infusion site reactions</i>		
Infusion site mass	1	0
Infusion site pain	3	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site urticaria	1	0
Infusion site warmth	1	0
<i>Injection site reactions</i>		
Injection site bruising	3	0
Injection site discolouration	1	0
Injection site erythema	27	0
Injection site hypersensitivity	1	0
Injection site inflammation	2	0
Injection site joint erythema	1	0
Injection site mass	26	0
Injection site pain	68	0
Injection site pruritus	26	0
Injection site rash	47	0
Injection site reaction	4	0
Injection site swelling	6	0
Injection site urticaria	16	0
Injection site warmth	18	0
<i>Mass conditions NEC</i>		
Cyst	1	0
Mass	7	0
Nodule	1	0
<i>Oedema NEC</i>		
Localised oedema	1	0
Oedema	2	0
Oedema peripheral	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	73	0
Chest discomfort	16	0
Chest pain	30	0
Discomfort	17	0
Facial pain	2	0
Pain	172	0
Tenderness	30	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	7	0
Drug ineffective	2	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	4	0
Vaccination site discolouration	1	0
Vaccination site discomfort	3	0
Vaccination site erythema	78	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	9	0
Vaccination site inflammation	4	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	12	0
Vaccination site movement impairment	1	0
Vaccination site oedema	1	0
Vaccination site pain	63	0
Vaccination site papule	1	0
Vaccination site pruritus	23	0
Vaccination site rash	36	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site reaction	1	0
Vaccination site swelling	39	0
Vaccination site urticaria	1	0
Vaccination site warmth	33	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	1	0
General disorders SOC TOTAL	2585	2

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
Hepatic disorders SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
 Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	47	0
Infusion related hypersensitivity reaction	3	0
Type IV hypersensitivity reaction	4	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	10	0
Anaphylactic shock	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	6	0
Sensitisation	1	0
Immune system disorders SOC TOTAL	78	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Bacterial infection	1	0
Cellulitis	13	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
<i>Breast infections</i>		
Breast abscess	1	0
<i>Candida infections</i>		
Candida infection	1	0
Vulvovaginal candidiasis	4	0
<i>Coronavirus infections</i>		
COVID-19	3	0
Suspected COVID-19	1	0
<i>Coxiella infections</i>		
Q fever	2	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	3	0
<i>Fungal infections NEC</i>		
Fungal skin infection	1	0
<i>Herpes viral infections</i>		
Herpes zoster	16	0
Oral herpes	6	0
<i>Infections NEC</i>		
Abscess limb	1	0
Abscess rupture	1	0
Infection	17	0
Localised infection	3	0
Respiratory tract infection	1	0
Vaccination site infection	1	0
Vestibulitis	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	1	0
<i>Infectious transmissions</i>		
Secondary transmission	2	0
<i>Influenza viral infections</i>		
Influenza	20	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	4	0
Pneumonia	3	0
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	3	0
Rash pustular	1	0
Skin infection	3	0
<i>Tinea infections</i>		
Body tinea	1	0
<i>Tuberculous infections</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Disseminated Bacillus Calmette-Guerin infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	24	0
Peritonsillar abscess	1	0
Rhinitis	1	0
Sinusitis	2	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Urinary tract infection	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Sweating fever	2	0
Viral rash	1	0
Infections SOC TOTAL	159	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Conditions caused by cold</i>		
Chillblains	3	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	42	0
Maternal exposure during pregnancy	21	0
Paternal exposure during pregnancy	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	1	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Wrong schedule	1	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	1	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	1	0
Fall	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
Procedural pain	1	0
<i>Product administration errors and issues</i>		
Incorrect dose administered	1	0
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
Limb injury	1	0
<i>Skin injuries NEC</i>		
Contusion	29	0
Scar	1	0
Subcutaneous haematoma	1	0
<i>Stoma complications</i>		
Stoma site oedema	1	0
<i>Thermal burns</i>		
Thermal burn	3	0
Injuries SOC TOTAL	119	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
<i>ECG investigations</i>		
Electrocardiogram T wave inversion	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	13	0
Heart rate abnormal	1	0
Heart rate increased	16	0
Heart rate irregular	1	0
<i>Liver function analyses</i>		
Liver function test abnormal	2	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	4	0
Body temperature decreased	1	0
Body temperature increased	4	0
Lymph node palpable	1	0
Respiratory rate increased	2	0
Skin temperature	2	0
Weight decreased	2	0
Weight increased	3	0
<i>Platelet analyses</i>		
Platelet count decreased	2	0
<i>Urinary tract function analyses NEC</i>		
Urine output	2	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	2	0
Blood pressure measurement	2	0
<i>Virus identification and serology</i>		
Hepatitis B surface antibody positive	1	0
SARS-CoV-2 antibody test	1	0
<i>White blood cell analyses</i>		
White blood cell count decreased	1	0
Investigations SOC TOTAL	68	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	17	0
Increased appetite	1	0
<i>Disorders of purine metabolism</i>		
Gout	2	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>General nutritional disorders NEC</i>		
Abnormal weight gain	1	0
Feeding disorder	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	3	0
<i>Total fluid volume decreased</i>		
Dehydration	5	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	32	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	3	0
<i>Bone related signs and symptoms</i>		
Bone pain	5	0
Pain in jaw	9	0
Spinal pain	2	0
<i>Bursal disorders</i>		
Bursitis	2	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Connective tissue disorders NEC</i>		
Reynold's syndrome	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	2	0
Rotator cuff syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	122	0
Joint noise	1	0
Joint stiffness	6	0
Joint swelling	6	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	173	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	6	0
Muscle haemorrhage	1	0
Muscle spasms	25	0
Muscle swelling	3	0
Muscle tightness	4	0
Muscle twitching	4	0
<i>Muscle tone abnormalities</i>		
Nuchal rigidity	1	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	13	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	44	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dupuytren's contracture	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	34	0
Flank pain	1	0
Limb discomfort	47	0
Musculoskeletal discomfort	2	0
Neck pain	21	0
Pain in extremity	443	0
<i>Myopathies</i>		
Rhabdomyolysis	1	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	5	0
Groin pain	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Soft tissue swelling	1	0
<i>Tendon disorders</i>		
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	998	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Neoplasms		
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	3	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	2	1
Cerebrovascular accident	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	2	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
Coordination abnormal	1	0
Dysstasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	37	0
Loss of consciousness	12	0
Somnolence	24	0
Syncope	65	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	1	0
Hypokinesia	1	0
Movement disorder	1	0
Psychomotor hyperactivity	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	6	0
Facial paralysis	10	0
Facial paresis	1	0
<i>Headaches NEC</i>		
Cluster headache	5	0
Drug withdrawal headache	1	0
Headache	434	0
Sinus headache	5	0
Tension headache	4	0
Thunderclap headache	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	11	0
<i>Migraine headaches</i>		
Migraine	38	0
Migraine with aura	5	0
Retinal migraine	1	0
<i>Mononeuropathies</i>		
Cubital tunnel syndrome	1	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	283	0
Dizziness postural	12	0
Drooling	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Head discomfort	7	0
Neurological symptom	1	0
Presyncope	13	0
Unresponsive to stimuli	1	0
Olfactory nerve disorders		
Anosmia	2	0
Parosmia	3	0
Paraesthesias and dysaesthesias		
Burning sensation	17	0
Hyperaesthesia	5	0
Hypoaesthesia	70	0
Paraesthesia	120	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	1	0
Hemiplegia	1	0
Monoparesis	2	0
Monoplegia	1	0
Paralysis	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	1	0
Seizures and seizure disorders NEC		
Febrile convulsion	1	0
Partial seizures	1	0
Seizure	5	0
Status epilepticus	14	0
Sensory abnormalities NEC		
Ageusia	5	0
Dysgeusia	41	0
Electric shock sensation	1	0
Neuralgia	6	0
Post herpetic neuralgia	2	0
Restless legs syndrome	3	0
Sensory disturbance	2	0
Taste disorder	5	0
Sleep disturbances NEC		
Sleep deficit	1	0
Speech and language abnormalities		
Dysarthria	5	0
Incoherent	2	0
Slow speech	1	0
Transient cerebrovascular events		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Tremor	27	0
Nervous system disorders SOC TOTAL	1349	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	2	0
<i>Stillbirth and foetal death</i>		
Stillbirth	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	8	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device leakage	1	0
null SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Affect alterations NEC</i>		
Flat affect	1	0
<i>Anxiety symptoms</i>		
Agitation	2	0
Anxiety	20	0
Nervousness	7	0
Stress	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	4	0
<i>Confusion and disorientation</i>		
Confusional state	16	0
Disorientation	6	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	5	0
<i>Dissociative states</i>		
Dissociation	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	23	0
Middle insomnia	1	0
Terminal insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	3	0
<i>Emotional and mood disturbances NEC</i>		
Anger	4	0
Emotional disorder	5	0
Emotional distress	2	0
Euphoric mood	1	0
Irritability	4	0
Mood altered	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear of injection	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	7	0
<i>Increased physical activity levels</i>		
Restlessness	3	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	4	0
<i>Mood disorders NEC</i>		
Apathy	2	0
Listless	1	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
Panic reaction	1	0
<i>Parasomnias</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Abnormal dreams	6	0
Nightmare	7	0
Sleep terror	1	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	1	0
Sexual desire disorders		
Libido decreased	1	0
Sleep disorders NEC		
Sleep disorder	3	0
Suicidal and self-injurious behaviour		
Suicidal ideation	3	0
Thinking disturbances		
Bradyphrenia	1	0
Psychiatric disorders SOC TOTAL	162	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	2	0
Dysuria	1	0
Pollakiuria	2	0
Urinary retention	1	0
<i>Urinary abnormalities</i>		
Chromaturia	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	1	0
Renal pain	4	0
Renal & urinary disorders SOC TOTAL	13	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	1	0
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
Fibrocystic breast disease	1	0
<i>Breast signs and symptoms</i>		
Breast pain	7	0
Nipple swelling	1	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	2	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	20	0
Intermenstrual bleeding	19	0
Menstrual disorder	24	0
Menstruation irregular	43	0
Premenstrual syndrome	3	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	6	0
Hypomenorrhoea	4	0
Menstruation delayed	24	0
Oligomenorrhoea	3	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	65	0
Menometrorrhagia	1	0
Polymenorrhoea	6	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
Polycystic ovaries	1	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Premature ovulation	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile curvature	1	0
Penis disorder	1	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	2	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular swelling	1	0
<i>Uterine disorders NEC</i>		
Uterine haemorrhage	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	29	0
Vulval haemorrhage	1	0
<i>Vulvovaginal signs and symptoms</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vulvovaginal discomfort	1	0
Reproductive & breast disorders SOC TOTAL	277	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	45	0
Hypopnoea	2	0
Hypoventilation	1	0
Respiration abnormal	1	0
Respiratory distress	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	4	0
Wheezing	7	0
<i>Coughing and associated symptoms</i>		
Cough	26	0
Haemoptysis	1	0
Productive cough	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	7	0
Pulmonary haemorrhage	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	6	0
<i>Nasal disorders NEC</i>		
Epistaxis	19	0
Nasal oedema	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	1	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	10	0
Tonsillar hypertrophy	3	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Pulmonary oedema	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	2	0
Catarrh	1	0
Dry throat	3	0
Dysphonia	1	0
Increased viscosity of upper respiratory secretion	1	0
Nasal discomfort	2	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	53	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	12	0
Sinus pain	7	0
Sneezing	2	0
Throat irritation	6	0
Throat tightness	3	0
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	241	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Alopecias</i>		
Alopecia	4	0
<i>Angioedemas</i>		
Angioedema	6	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	16	0
Hyperhidrosis	26	0
Miliaria	9	0
Night sweats	8	0
<i>Bullous conditions</i>		
Blister	11	0
Erythema multiforme	3	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	10	0
Pain of skin	7	0
Papule	5	0
Sensitive skin	6	0
Skin burning sensation	12	0
Skin discolouration	1	0
Skin induration	2	0
Skin lesion	6	0
Skin reaction	23	0
Skin sensitisation	1	0
Skin swelling	4	0
Skin tightness	1	0
Skin warm	38	0
Yellow skin	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	3	0
Dermatitis allergic	26	0
Dermatitis atopic	2	0
Dyshidrotic eczema	1	0
Eczema	6	0
Skin irritation	6	0
<i>Erythemas</i>		
Erythema	205	0
<i>Exfoliative conditions</i>		
Skin exfoliation	2	0
<i>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	3	0
<i>Pruritus NEC</i>		
Pruritus	509	0
<i>Psoriatic conditions</i>		
Psoriasis	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Purpura and related conditions</i>		
Petechiae	2	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	440	0
Rash erythematous	210	0
Rash macular	25	0
Rash morbilliform	1	0
Rash papular	30	0
Rash pruritic	122	0
<i>Rosaceas</i>		
Rosacea	2	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	2	0
<i>Skin cysts and polyps</i>		
Dermal cyst	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	1	0
<i>Urticarias</i>		
Urticaria	61	0
Skin disorders SOC TOTAL	1870	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	4	0
<i>Disability issues</i>		
Immobile	1	0
<i>Employment issues</i>		
Retirement	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	2	0
Social circumstances SOC TOTAL	8	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

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>Immunisations</i>		
COVID-19 immunisation	2	0
Immunisation	1	0
<i>Therapeutic procedures NEC</i>		
Injection	1	0
Surgical & medical procedures SOC TOTAL	6	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haemorrhage	15	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	5	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Flushing	7	0
Hot flush	29	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	6	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	11	0
<i>Varicose veins NEC</i>		
Varicose vein	2	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	17	0
<i>Vascular hypotensive disorders</i>		
Hypotension	14	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	117	0
TOTAL REACTIONS FOR DRUG	9243	4
TOTAL REPORTS	3278	
TOTAL FATAL OUTCOME REPORTS		4