| Report Run Date:        | 23-Feb-2022          |
|-------------------------|----------------------|
| Data Lock Date:         | 22-Feb-2022 18:30:04 |
| Earliest Reaction Date: | : 15-Oct-1958        |
| MedDRA Version:         | MedDRA 24.1          |

| Moderna COVID-19     | All UK spontaneous, suspect reports associated with |
|----------------------|---|
| vaccine spontaneous, | the Moderna COVID-19 vaccine from Islington,        |
| suspect reports from | Camden, Haringey, Barnet and Enfield Clinical       |
| Islington, Camden,   | Commissioning Groups up to and including            |
| Haringey, Barnet and | 22/02/2022.   |
| Enfield:             |   |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022Data Lock Date: 22-Feb-2022 18:30:04Earliest Reaction Date: 15-Oct-1958MedDRA Version: MedDRA 24.1

| Earliest Reaction Date: 15-Oct-1958 | Meddra Version: Meddra 24.1 |       |       |
|-------------------------------------|-----------------------------|-------|-------|
| Reaction Name                       |                             | Total | Fatal |
| Blood disorders                     |                             |       |       |
| Lymphatic system disorders NEC      |                             |       |       |
| Lymph node pain                     |                             | 12    | 0     |
| Lymphadenitis                       |                             | 1     | 0     |
| Lymphadenopathy                     |                             | 69    | 0     |
| Neutropenias                        |                             |       |       |
| Neutropenia                         |                             | 1     | 0     |
| Thrombocytopenias                   |                             |       |       |
| Immune thrombocytopenia             |                             | 1     | 0     |
| Thrombocytopenia                    |                             | 1     | 0     |
| Blood disorders SOC TOTAL           |                             | 85    | 0     |

#### Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022 Data Lock Date: 22-Feb-2022 18:30:04 Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.1 Fatal Reaction Name Total Cardiac disorders Cardiac signs and symptoms NEC 33 Palpitations 0 Ischaemic coronary artery disorders Angina pectoris 1 0 Myocardial disorders NEC Left ventricular dysfunction 1 0 Noninfectious myocarditis 9 0 **Myocarditis** Noninfectious pericarditis Pericarditis 5 0 Rate and rhythm disorders NEC Bradycardia 0 1 Cardiac flutter 0 2 0 3 Extrasystoles Tachycardia 13 0 Supraventricular arrhythmias 0 Atrial fibrillation 1 69 0 Cardiac disorders SOC TOTAL

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Popotion Namo                          | Totol | Eatol |
|--|-------|-------|
| Reaction Name                          | Total | Fatal |
| Ear disorders                          |       |       |
| Ear disorders NEC                      |       |       |
| Ear pain                               | 10    | 0     |
| Ear swelling                           | 1     | 0     |
| External ear disorders NEC             |       |       |
| Red ear syndrome                       | 1     | 0     |
| Hearing losses                         |       |       |
| Deafness                               | 2     | 2 0   |
| Hypoacusis                             | 4     | . 0   |
| Inner ear infections and inflammations |       |       |
| Inner ear inflammation                 | 1     | 0     |
| Inner ear signs and symptoms           |       |       |
| Motion sickness                        | 1     | 0     |
| Tinnitus                               | 18    | 0     |
| Vertigo                                | 4     | . 0   |
| Ear disorders SOC TOTAL                | 42    | 0     |

| Report Run Date: 23-Feb-2022        | Data Lock Date: 22-Feb-2022 18:30:04 |       |       |
|-------------------------------------|--------------------------------------|-------|-------|
| Earliest Reaction Date: 15-Oct-1958 | MedDRA Version: MedDRA 24.1          |       |       |
| Reaction Name                       |                                      | Total | Fatal |
| Endocrine disorders                 |                                      |       |       |
| Endocrine abnormalities of puberty  |                                      |       |       |
| Premature menarche                  |                                      | 1     | 0     |
| Hypoparathyroid disorders           |                                      |       |       |
| Hypoparathyroidism                  |                                      | 1     | 0     |
| Endocrine disorders SOC TOTAL       |                                      | 2     | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Reaction Name  | Total | Fatal |
|--|-------|-------|
| Eye disorders  |       |       |
| Conjunctival and corneal bleeding and vascular disorders         |       |       |
| Conjunctival haemorrhage   | 1     | 0     |
| Eyelid movement disorders  |       |       |
| Blepharospasm  | 4     | 0     |
| Lacrimation disorders  |       |       |
| Lacrimation increased  | 2     | 0     |
| Lid, lash and lacrimal infections, irritations and inflammations |       |       |
| Swelling of eyelid   | 2     | 0     |
| Ocular disorders NEC   |       |       |
| Eye pain   | 14    | 0     |
| Eye swelling   | 2     | 0     |
| Periorbital swelling   | 1     | 0     |
| Ocular sensation disorders                                       |       |       |
| Photophobia  | 3     | 0     |
| Orbital structural change, deposit and degeneration              |       |       |
| Lid sulcus deepened  | 1     | 0     |
| Retinal bleeding and vascular disorders (excl retinopathy)       |       |       |
| Retinal vein occlusion   | 1     | 0     |
| Visual disorders NEC   |       |       |
| Vision blurred   | 11    | 0     |
| Visual impairment and blindness (excl colour blindness)          |       |       |
| Blindness  | 1     | 0     |
| Eve disorders SOC TOTAL  | 43    | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Earliest Reaction Date: 15-Oct-1958 MedDRA Version: MedDRA 24 |          |              |
|---|----------|--------------|
| Reaction Name   | <u> </u> | <u>Fatal</u> |
| Gastrointestinal disorders                                    |          |              |
| Colitis (excl infective)                                      |          |              |
| Colitis   | 1        | 0            |
| Colitis ulcerative  | 1        | 0            |
| Dental pain and sensation disorders                           |          |              |
| Toothache   | 2        | 0            |
| Diarrhoea (excl infective)                                    |          |              |
| Diarrhoea   | 22       | 0            |
| Dyspeptic signs and symptoms                                  |          |              |
| Dyspepsia   | 6        | 0            |
| Epigastric discomfort   | 1        | 0            |
| Eructation  | 1        | 0            |
| Faecal abnormalities NEC                                      |          |              |
| Faeces discoloured  | 1        | 0            |
| Flatulence, bloating and distension                           |          |              |
| Flatulence  | 3        | 0            |
| Gastric ulcers and perforation                                |          |              |
| Gastritis erosive   | 1        | 0            |
| Gastrointestinal and abdominal pains (excl oral and throat)   |          |              |
| Abdominal pain  | 13       | 0            |
| Abdominal pain upper  | 21       | 0            |
| Gastrointestinal pain   | 2        | 0            |
| Gastrointestinal atonic and hypomotility disorders NEC        | -        |              |
| Gastrooesophageal reflux disease                              | 2        | 0            |
| Gastrointestinal signs and symptoms NEC                       | -        |              |
| Breath odour  | 1        | 0            |
| Odynophagia   | 1        | 0            |
| Gastrointestinal spastic and hypermotility disorders          |          |              |
| Irritable bowel syndrome                                      | 1        | 0            |
| Gingival disorders, signs and symptoms NEC                    |          |              |
| Gingival discomfort   | 1        | 0            |
| •   |          |              |
| Intestinal haemorrhages<br>Rectal haemorrhage                 | 1        | 0            |
| •   |          |              |
| Nausea and vomiting symptoms                                  | 117      |              |
| Nausea  | 117      | 0            |
| Retching  | 1        |              |
| Vomiting  | 44       | 0            |
| Oral dryness and saliva altered                               |          |              |
| Dry mouth   | 4        | 0            |
| Oral soft tissue haemorrhages                                 |          |              |
| Oral blood blister  | 1        | 0            |
| Oral soft tissue signs and symptoms                           |          | -            |
| Coating in mouth  | 1        | 0            |
| Hypoaesthesia oral  | 6        | 0            |
| Oral discomfort   | 1        | 0            |
| Paraesthesia oral   | 5        | 0            |
| Oral soft tissue swelling and oedema                          |          |              |
| Lip swelling  | 1        | 0            |
| Stomatitis and ulceration                                     |          |              |
| Mouth ulceration  | 1        | C            |
| Tongue disorders  |          |              |
| Tongue haemorrhage  | 1        | C            |
| Tongue signs and symptoms                                     |          |              |

| Report Run Date: 23-Feb-2022                     | Data Lock Date: 22-Feb-2022 18:30:04 |       |       |
|--|--------------------------------------|-------|-------|
| Earliest Reaction Date: 15-Oct-1958              | MedDRA Version: MedDRA 24.1          |       |       |
| Reaction Name                                    |                                      | Total | Fatal |
| Gastrointestinal disorders ointestinal disorders | cont'd                               |       |       |
| Glossodynia                                      |                                      | 1     | 0     |
| Swollen tongue                                   |                                      | 2     | 0     |
| Tongue oedema                                    |                                      | 1     | 0     |
| Gastrointestinal disorders SOC TOTAL             |                                      | 269   | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022Data Lock Date: 22-Feb-2022 18:30:04Earliest Reaction Date: 15-Oct-1958MedDRA Version: MedDRA 24.1

| Earliest Reaction Date: 15-Oct-1958         | MedDRA Version: MedDRA 24.1 |              |        |
|---|-----------------------------|--------------|--------|
| Reaction Name                               |                             | <u>Total</u> | Fatal  |
| General disorders                           |                             |              |        |
| Administration site reactions NEC           |                             |              |        |
| Administration site bruise                  |                             | 1            | 0      |
| Application and instillation site reactions |                             |              |        |
| Application site erythema                   |                             | 1            | 0      |
| Application site joint erythema             |                             | 1            | 0      |
| Asthenic conditions                         |                             |              |        |
| Asthenia                                    |                             | 19           | 0      |
| Fatigue                                     |                             | 158          | 0      |
| Malaise                                     |                             | 27           | 0      |
| Febrile disorders                           |                             |              |        |
| Pyrexia                                     |                             | 203          | 0      |
| Feelings and sensations NEC                 |                             |              |        |
| Chills                                      |                             | 115          | 0      |
| Feeling abnormal                            |                             | 17           | 0      |
| Feeling cold                                |                             | 10           | 0      |
| Feeling hot                                 |                             | 9            | 0      |
| Feeling of body temperature change          |                             | 1            | 0      |
| Hangover                                    |                             | 2            | 0      |
| Sensation of foreign body                   |                             | 1            | 0      |
| Temperature intolerance                     |                             | 2            | 0      |
| Thirst                                      |                             | 1            | 0      |
| Gait disturbances                           |                             | '            | 0      |
| Gait disturbance                            |                             | 4            | 0      |
| General signs and symptoms NEC              |                             | 4            | 0      |
| Condition aggravated                        |                             | 1            | 0      |
| General physical health deterioration       |                             | 1            | 0      |
| Illness                                     |                             | 6            | 0      |
| Influenza like illness                      |                             | 11           | 0      |
| Peripheral swelling                         |                             | 49           | 0      |
| Swelling                                    |                             | 49<br>37     | 0      |
|   |                             | 5            | 0      |
| Swelling face<br>Inflammations              |                             | 5            | 0      |
| Inflammation                                |                             | 7            | 0      |
|   |                             | 7            | 0      |
| Injection site reactions                    |                             | 0            | 0      |
| Injection site erythema                     |                             | 6<br>1       | 0      |
| Injection site irritation                   |                             | 1            |        |
| Injection site joint erythema               |                             | 1            | 0<br>0 |
| Injection site mass                         |                             | 3            |        |
| Injection site pain                         |                             | 25           | 0      |
| Injection site pruritus                     |                             | 4            | 0      |
| Injection site rash                         |                             | 8            | 0      |
| Injection site swelling                     |                             | 8            | 0      |
| Injection site urticaria                    |                             | 4            | 0      |
| Injection site warmth                       |                             | 6            | 0      |
| Mass conditions NEC                         |                             |              |        |
| Mass  |                             | 1            | 0      |
| Pain and discomfort NEC                     |                             |              |        |
| Axillary pain                               |                             | 21           | 0      |
| Chest discomfort                            |                             | 13           | 0      |
| Chest pain                                  |                             | 31           | 0      |
| Facial pain                                 |                             | 1            | 0      |
| Non-cardiac chest pain                      |                             | 1            | 0      |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Reaction Name                                     | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd        |       |       |
| Pain  | 86    | 0     |
| Tenderness  | 7     | 0     |
| Therapeutic and nontherapeutic responses          |       |       |
| Adverse drug reaction                             | 2     | 0     |
| Ulcers NEC  |       |       |
| Ulcer   | 1     | 0     |
| Vaccination site reactions                        |       |       |
| Shoulder injury related to vaccine administration | 1     | 0     |
| Vaccination site bruising                         | 1     | 0     |
| Vaccination site erythema                         | 12    | 0     |
| Vaccination site haemorrhage                      | 1     | 0     |
| Vaccination site induration                       | 2     | 0     |
| Vaccination site inflammation                     | 1     | 0     |
| Vaccination site joint pain                       | 1     | 0     |
| Vaccination site mass                             | 3     | 0     |
| Vaccination site pain                             | 10    | 0     |
| Vaccination site pruritus                         | 3     | 0     |
| Vaccination site rash                             | 10    | 0     |
| Vaccination site swelling                         | 11    | 0     |
| Vaccination site warmth                           | 3     | 0     |
| General disorders SOC TOTAL                       | 978   | 0     |

| Report Run Date: 23-Feb-2022        | Data Lock Date: 22-Feb-2022 18:3 | 0:04  |       |
|-------------------------------------|----------------------------------|-------|-------|
| Earliest Reaction Date: 15-Oct-1958 | MedDRA Version: MedDRA 24.1      |       |       |
| Reaction Name                       |                                  | Total | Fatal |
| Hepatic disorders                   |                                  |       |       |
| Hepatobiliary signs and symptoms    |                                  |       |       |
| Hepatic pain                        |                                  | 1     | 0     |
| Hepatic disorders SOC TOTAL         |                                  | 1     | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Reaction Name   | Total | Fatal |
|---|-------|-------|
|   | Total | ralai |
| Immune system disorders                                       |       |       |
| Acute and chronic sarcoidosis                                 |       |       |
| Sarcoidosis   | 1     | 0     |
| Allergic conditions NEC                                       |       |       |
| Hypersensitivity  | 15    | 0     |
| Allergies to foods, food additives, drugs and other chemicals |       |       |
| Reaction to excipient   | 1     | 0     |
| Anaphylactic and anaphylactoid responses                      |       |       |
| Anaphylactic reaction   | 5     | 0     |
| Atopic disorders  |       |       |
| Seasonal allergy  | 2     | 0     |
| Immune and associated conditions NEC                          |       |       |
| Bacille Calmette-Guerin scar reactivation                     | 2     | 0     |
| Immune system disorders SOC TOTAL                             | 26    | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Reaction Name MedDRA Version: MedDRA 24.1   | Total | Fatal  |
|---|-------|--------|
| Infections                                  |       | i atai |
| Abdominal and gastrointestinal infections   |       |        |
| Appendicitis                                | 1     | 0      |
| Bacterial infections NEC                    |       | -      |
| Cellulitis                                  | 1     | 0      |
| Candida infections                          |       |        |
| Candida infection                           | 1     | 0      |
| Vulvovaginal candidiasis                    | 1     | 0      |
| Coronavirus infections                      |       |        |
| COVID-19                                    | 5     | 0      |
| Ear infections                              |       |        |
| Ear infection                               | 1     | 0      |
| Epstein-Barr viral infections               |       |        |
| Epstein-Barr virus infection                | 1     | 0      |
| Flaviviral infections                       |       |        |
| Encephalitis Japanese B                     | 1     | 0      |
| Herpes viral infections                     |       |        |
| Genital herpes                              | 2     | 0      |
| Herpes ophthalmic                           | 1     | 0      |
| Herpes zoster                               | 3     | 0      |
| Herpes zoster oticus                        | 1     | 0      |
| Oral herpes                                 | 1     | 0      |
| Infections NEC                              |       |        |
| Infection                                   | 4     | 0      |
| Localised infection                         | 2     | 0      |
| Influenza viral infections                  |       |        |
| Influenza                                   | 10    | 0      |
| Lower respiratory tract and lung infections |       |        |
| Lower respiratory tract infection           | 2     | 0      |
| Pneumonia                                   | 1     | 1      |
| Skin structures and soft tissue infections  |       |        |
| Pyoderma                                    | 1     | 0      |
| Skin infection                              | 3     | 0      |
| Upper respiratory tract infections          |       |        |
| Nasopharyngitis                             | 7     | 0      |
| Rhinitis                                    | 1     | 0      |
| Sinusitis                                   | 2     | 0      |
| Viral infections NEC                        |       |        |
| Post viral fatigue syndrome                 | 1     | 0      |
| Sweating fever                              | 1     | 0      |
| Infections SOC TOTAL                        | 55    | 1      |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Reaction Name   | Total | Fatal |
|---|-------|-------|
| Injuries  |       |       |
| Exposures associated with pregnancy, delivery and lactation |       |       |
| Maternal exposure during breast feeding                     | 16    | 0     |
| Maternal exposure during pregnancy                          | 10    | 0     |
| Medication errors, product use errors and issues NEC        |       |       |
| Medication error  | 1     | 0     |
| Nerve injuries NEC  |       |       |
| Nerve injury  | 1     | 0     |
| Overdoses NEC   |       |       |
| Overdose  | 1     | 0     |
| Product administration errors and issues                    |       |       |
| Incorrect product administration duration                   | 1     | 0     |
| Skin injuries NEC   |       |       |
| Contusion   | 11    | 0     |
| Spinal cord injuries NEC                                    |       |       |
| Spinal cord injury cervical                                 | 1     | 0     |
| Injuries SOC TOTAL  | 42    | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Reaction Name   | Total | Fatal |
|---|-------|-------|
| Investigations  |       |       |
| Carbohydrate tolerance analyses (incl diabetes)         |       |       |
| Blood glucose   | 1     | 0     |
| Blood glucose increased                                 | 1     | 0     |
| Cardiac auscultatory investigations                     |       |       |
| Cardiac murmur  | 1     | 0     |
| ECG investigations                                      |       |       |
| Electrocardiogram T wave inversion                      | 1     | 0     |
| Endocrine analyses and imaging NEC                      |       |       |
| Hormone level abnormal                                  | 2     | 0     |
| Heart rate and pulse investigations                     |       |       |
| Heart rate  | 6     | 0     |
| Heart rate abnormal                                     | 1     | 0     |
| Heart rate decreased                                    | 1     | 0     |
| Heart rate increased                                    | 8     | 0     |
| Heart rate irregular                                    | 2     | 0     |
| Physical examination procedures and organ system status |       |       |
| Body temperature  | 1     | 0     |
| Body temperature increased                              | 1     | 0     |
| Weight decreased  | 1     | 0     |
| Weight increased  | 1     | 0     |
| Platelet analyses                                       |       |       |
| Platelet count decreased                                | 1     | 0     |
| Protein analyses NEC                                    |       |       |
| C-reactive protein increased                            | 1     | 0     |
| Reproductive hormone analyses                           |       |       |
| Pregnancy test  | 1     | 0     |
| Skeletal and cardiac muscle analyses                    |       |       |
| Troponin increased                                      | 1     | 0     |
| Urinalysis NEC  |       |       |
| Blood urine present                                     | 1     | 0     |
| Urinary tract imaging procedures                        |       |       |
| Bladder scan  | 1     | 0     |
| Vascular tests NEC (incl blood pressure)                |       |       |
| Blood pressure increased                                | 2     | 0     |
| Investigations SOC TOTAL                                | 36    | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

|                                   |      | _  |       |
|-----------------------------------|------|----|-------|
| Reaction Name                     | Tota | l_ | Fatal |
| Metabolic disorders               |      |    |       |
| Appetite disorders                |      |    |       |
| Appetite disorder                 |      | 1  | 0     |
| Decreased appetite                |      | 10 | 0     |
| Hyperphagia                       |      | 1  | 0     |
| Fluid intake increased            |      |    |       |
| Polydipsia                        |      | 1  | 0     |
| General nutritional disorders NEC |      |    |       |
| Feeding disorder                  |      | 3  | 0     |
| Total fluid volume decreased      |      |    |       |
| Dehydration                       |      | 1  | 0     |
| Total fluid volume increased      |      |    |       |
| Fluid retention                   |      | 1  | 0     |
| Metabolic disorders SOC TOTAL     |      | 18 | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

|   | ersion: MedDRA 24.1 | Fotol |
|---|---------------------|-------|
| Reaction Name   | Total               | Fatal |
| Muscle & tissue disorders                               |                     |       |
| Arthropathies NEC                                       |                     |       |
| Arthritis   | 1                   | l C   |
| Bone related signs and symptoms                         |                     |       |
| Bone pain   | 2                   |       |
| Bone swelling   | 1                   | l C   |
| Pain in jaw   | 3                   | 3 C   |
| Bursal disorders  |                     |       |
| Bursitis  | 1                   | C     |
| Cartilage disorders                                     |                     |       |
| Costochondritis   | 1                   | 1 C   |
| Joint related disorders NEC                             |                     |       |
| Joint lock  | 1                   | C     |
| Periarthritis   | 1                   | I C   |
| Joint related signs and symptoms                        |                     |       |
| Arthralgia  | 56                  | 6 C   |
| Joint stiffness   | 1                   | I C   |
| Joint swelling  | 5                   | 5 0   |
| Joint warmth  | 1                   |       |
| Muscle infections and inflammations                     |                     |       |
| Myositis  | 1                   |       |
| Muscle pains  |                     |       |
| Myalgia   | 87                  |       |
| Muscle related signs and symptoms NEC                   |                     |       |
| Muscle fatigue  | 1                   |       |
| Muscle spasms   | 12                  |       |
| Muscle swelling   | 1                   |       |
| Muscle tightness  | 2                   |       |
| Muscle twitching  |                     |       |
| Muscle tone abnormalities                               |                     |       |
| Nuchal rigidity   | 1                   |       |
| Muscle weakness conditions                              |                     |       |
| Muscular weakness                                       | 5                   | 5 0   |
| Musculoskeletal and connective tissue conditions NEC    |                     |       |
| Musculoskeletal stiffness                               | 14                  | 1 C   |
| Musculoskeletal and connective tissue infections and in |                     |       |
| Fasciitis   |                     |       |
| Musculoskeletal and connective tissue pain and discom   |                     |       |
| Back pain   | 21                  |       |
| Flank pain  | 2                   |       |
| Limb discomfort   | g                   |       |
| Neck pain   | 17                  |       |
|   | 107                 |       |
| Pain in extremity                                       | 107                 | 7 (   |
| Rheumatoid arthropathies                                |                     |       |
| Rheumatoid arthritis                                    | 1                   | (     |
| Soft tissue disorders NEC                               |                     |       |
| Axillary mass   | 2                   |       |
| Groin pain  | 1                   | (     |
| Neck mass   | 2                   |       |
| Muscle & tissue disorders SOC TOTAL                     | 367                 | 7 (   |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Earliest Reaction Date: 15-Oct-1958 MedDRA Version: MedDRA 24.1   | -     |       |
|---|-------|-------|
| Reaction Name   | Total | Fatal |
| Nervous system disorders  |       |       |
| Central nervous system haemorrhages and cerebrovascular accidents |       |       |
| Cerebrovascular accident  | 1     | 0     |
| Disturbances in consciousness NEC                                 |       |       |
| Lethargy  | 7     | 0     |
| Loss of consciousness   | 6     | 0     |
| Somnolence  | 7     | 0     |
| Syncope   | 33    | 0     |
| Dyskinesias and movement disorders NEC                            |       |       |
| Hypokinesia   | 1     | 0     |
| Facial cranial nerve disorders                                    |       |       |
| Bell's palsy  | 2     | 0     |
| Facial paralysis  | 2     | 0     |
| Facial spasm  | 1     | 0     |
| Generalised tonic-clonic seizures                                 |       |       |
| Generalised tonic-clonic seizure                                  | 1     | 0     |
| Headaches NEC   |       |       |
| Headache  | 182   | 0     |
| Sinus headache  | 2     |       |
| Tension headache  | 4     |       |
| Lumbar spinal cord and nerve root disorders                       |       |       |
| Sciatica  | 1     | 0     |
| Memory loss (excl dementia)                                       |       | -     |
| Memory impairment   | 1     | 0     |
| Mental impairment (excl dementia and memory loss)                 |       | Ŭ     |
| Cognitive disorder  | 3     | 0     |
| Disturbance in attention  | 3     |       |
| Mental impairment   | 2     | 0     |
| Migraine headaches  |       | -     |
| Migraine  | 22    | 0     |
| Migraine with aura  | 2     | 0     |
| Narcolepsy and hypersomnia  |       |       |
| Hypersomnia   | 1     | 0     |
| Neurological signs and symptoms NEC                               |       |       |
| Dizziness   | 65    | 0     |
| Dizziness postural  | 4     | 0     |
| Head discomfort   | 2     | 0     |
| Presyncope  | 7     | 0     |
| Olfactory nerve disorders   |       | Ŭ     |
| Anosmia   | 4     | 0     |
| Hyposmia  | 1     | 0     |
| Parosmia  | 1     | 0     |
| Paraesthesias and dysaesthesias                                   |       | Ű     |
| Burning sensation   | 5     | 0     |
| Hypoaesthesia   | 21    | 0     |
| Paraesthesia  | 32    |       |
| Paralysis and paresis (excl cranial nerve)                        | 52    |       |
| Hemiparesis   | 1     | 0     |
| Hemiplegia  | 1     | 0     |
| Monoparesis   | 2     |       |
|   | 2     | 0     |
| Paralysis Parinhard neuropathian NEC                              | 2     | 0     |
| Peripheral neuropathies NEC                                       |       |       |
| Neuropathy peripheral   | 1     | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Reaction Name                                | Tota   | <u>al</u> | Fatal |
|--|--------|-----------|-------|
| Nervous system disorders us system disorders | cont'd |           |       |
| Seizures and seizure disorders NEC           |        |           |       |
| Epilepsy                                     |        | 1         | 0     |
| Febrile convulsion                           |        | 1         | 0     |
| Seizure                                      |        | 6         | 0     |
| Sensory abnormalities NEC                    |        |           |       |
| Ageusia                                      |        | 5         | 0     |
| Dysgeusia                                    |        | 8         | 0     |
| Electric shock sensation                     |        | 1         | 0     |
| Neuralgia                                    |        | 2         | 0     |
| Sensory disturbance                          |        | 1         | 0     |
| Speech and language abnormalities            |        |           |       |
| Speech disorder                              |        | 1         | 0     |
| Tremor (excl congenital)                     |        |           |       |
| Tremor                                       |        | 21        | 0     |
| Nervous system disorders SOC TOTAL           | 4      | 80        | 0     |

| Report Run Date: 23-Feb-2022            | Data Lock Date: 22-Feb-2022 18:3 | 0:04  |       |
|---|----------------------------------|-------|-------|
| Earliest Reaction Date: 15-Oct-1958     | MedDRA Version: MedDRA 24.1      |       |       |
| Reaction Name                           |                                  | Total | Fatal |
| Pregnancy conditions                    |                                  |       |       |
| Abortions spontaneous                   |                                  |       |       |
| Abortion spontaneous                    |                                  | 4     | 0     |
| Maternal complications of pregnancy NEC |                                  |       |       |
| Ectopic pregnancy                       |                                  | 1     | 0     |
| Pregnancy conditions SOC TOTAL          |                                  | 5     | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Earliest Reaction Date: 15-Oct-1958            | MedDRA Version: MedDRA 24.1 |              |       |
|--|-----------------------------|--------------|-------|
| Reaction Name                                  |                             | <u>Total</u> | Fatal |
| Psychiatric disorders                          |                             |              |       |
| Anxiety symptoms                               |                             |              |       |
| Anxiety  |                             | 8            | 0     |
| Tension  |                             | 1            | C     |
| Cognitive and attention disorders and distur   | bances NEC                  |              |       |
| Mental fatigue                                 |                             | 5            | C     |
| Confusion and disorientation                   |                             |              |       |
| Confusional state                              |                             | 3            | C     |
| Disorientation                                 |                             | 1            | C     |
| Deliria  |                             |              |       |
| Delirium                                       |                             | 4            | 0     |
| Depressive disorders                           |                             |              |       |
| Depression                                     |                             | 3            | 0     |
| Disturbances in initiating and maintaining sle | eep 🛛                       |              |       |
| Insomnia                                       |                             | 9            | 0     |
| Dyssomnias                                     |                             |              |       |
| Poor quality sleep                             |                             | 1            | 0     |
| Emotional and mood disturbances NEC            |                             |              |       |
| Anger  |                             | 2            | C     |
| Emotional disorder                             |                             | 2            | C     |
| Irritability                                   |                             | 1            | 0     |
| Hallucinations (excl sleep-related)            |                             |              |       |
| Hallucination                                  |                             | 5            | C     |
| Hallucinations, mixed                          |                             | 1            | C     |
| Mood alterations with depressive symptoms      |                             |              |       |
| Depressed mood                                 |                             | 2            | C     |
| Sense of a foreshortened future                |                             | 1            | C     |
| Mood disorders NEC                             |                             |              |       |
| Apathy   |                             | 1            | C     |
| Listless                                       |                             | 1            | C     |
| Panic attacks and disorders                    |                             |              |       |
| Panic attack                                   |                             | 3            | C     |
| Parasomnias                                    |                             |              |       |
| Abnormal dreams                                |                             | 1            | C     |
| Sleep disorders NEC                            |                             |              |       |
| Sleep disorder                                 |                             | 1            | (     |
| Suicidal and self-injurious behaviour          |                             |              |       |
| Suicidal ideation                              |                             | 1            | (     |
| Thinking disturbances                          |                             |              |       |
| Thinking abnormal                              |                             | 1            | (     |
| Psychiatric disorders SOC TOTAL                |                             | 58           | C     |

| Report Run Date: 23-Feb-2022         | Data Lock Date: 22-Feb-2022 18:3 | 0:04  |       |
|--------------------------------------|----------------------------------|-------|-------|
| Earliest Reaction Date: 15-Oct-1958  | MedDRA Version: MedDRA 24.1      |       |       |
| Reaction Name                        |                                  | Total | Fatal |
| Renal & urinary disorders            |                                  |       |       |
| Urinary tract signs and symptoms NEC |                                  |       |       |
| Renal pain                           |                                  | 1     | 0     |
| Renal & urinary disorders SOC TOTAL  |                                  | 1     | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Earliest Reaction Date: 15-Oct-1958 MedDRA Version: MedDRA 24. Reaction Name | Total | Fatal        |
|--|-------|--------------|
| Reproductive & breast disorders  |       | <u>ralar</u> |
| Breast disorders NEC   | -     |              |
| Breast mass  | 3     |              |
| Breast signs and symptoms  | 5     |              |
| Breast discharge   | 1     |              |
| Breast discharge<br>Breast pain  | 6     |              |
| Breast tenderness  | 3     |              |
| Lactation disorders  | 3     |              |
| Galactorrhoea  | 1     |              |
| Menstruation and uterine bleeding NEC  |       |              |
| Dysmenorrhoea  | 17    |              |
| Intermenstrual bleeding  | 10    |              |
| Menstrual disorder   | 15    |              |
|  | 19    |              |
| Menstruation irregular   | 2     |              |
| Premenstrual pain<br>Menstruation with decreased bleeding                    | 2     |              |
| Amenorrhoea  | 1     |              |
|  | 4     |              |
| Hypomenorrhoea<br>Monotruction delayed                                       | 25    |              |
| Menstruation delayed<br>Menstruation with increased bleeding                 | 20    | l (          |
|  | 39    |              |
| Heavy menstrual bleeding<br>Menometrorrhagia                                 | 39    |              |
| Polymenorrhoea   | 6     |              |
| Polymenormoea<br>Pelvis and broad ligament disorders NEC                     | 0     |              |
| Adnexa uteri pain  | 1     |              |
| Prostate and seminal vesicles infections and inflammations                   |       |              |
| Prostatitis  | 1     |              |
|  |       |              |
| Prostatic signs, symptoms and disorders NEC<br>Prostatic pain                | 1     |              |
| Reproductive tract signs and symptoms NEC                                    |       |              |
| Pelvic pain  | 1     |              |
| Scrotal disorders NEC  |       |              |
| Scrotal pain   | 1     |              |
| Testicular and epididymal disorders NEC                                      |       |              |
| Testicular pain  | 1     |              |
| Uterine disorders NEC  |       |              |
| Endometriosis  | 2     |              |
| Uterine haemorrhage  | 2     |              |
|  | 2     |              |
| Vulvovaginal disorders NEC   | G     |              |
| Vaginal haemorrhage  | 6     |              |
| Vulvovaginal signs and symptoms  | 4     |              |
| Vaginal discharge  | 1     |              |
| Vulvovaginal discomfort  | 1     |              |
| Reproductive & breast disorders SOC TOTAL                                    | 171   |              |

## Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Earliest Reaction Date: 15-Oct-1958 MedDRA Version: MedDRA 24.1 |              |       |
|---|--------------|-------|
| Reaction Name   | <u>Total</u> | Fatal |
| Respiratory disorders   |              |       |
| Breathing abnormalities   |              |       |
| Dyspnoea  | 29           | 0     |
| Hyperventilation  | 1            | 0     |
| Respiration abnormal  | 1            | 0     |
| Bronchospasm and obstruction                                    |              |       |
| Asthma  | 3            | 0     |
| Coughing and associated symptoms                                |              |       |
| Cough   | 15           | 0     |
| Productive cough  | 1            | 0     |
| Lower respiratory tract inflammatory and immunologic conditions |              |       |
| Pulmonary sarcoidosis   | 1            | 0     |
| Lower respiratory tract signs and symptoms                      |              |       |
| Hiccups   | 1            | 0     |
| Pulmonary haemorrhage   | 1            | 0     |
| Nasal congestion and inflammations                              |              |       |
| Nasal congestion  | 2            | 0     |
| Nasal disorders NEC   |              |       |
| Epistaxis   | 10           | 0     |
| Nasal oedema  | 1            | 0     |
| Pharyngeal disorders (excl infections and neoplasms)            |              |       |
| Pharyngeal swelling   | 2            | 0     |
| Pulmonary thrombotic and embolic conditions                     |              |       |
| Pulmonary embolism  | 1            | 0     |
| Upper respiratory tract signs and symptoms                      |              |       |
| Dysphonia   | 2            | 0     |
| Increased viscosity of upper respiratory secretion              | 1            | 0     |
| Nasal discomfort  | 2            | 0     |
| Oropharyngeal pain  | 17           | 0     |
| Rhinorrhoea   | 8            | 0     |
| Sinus pain  | 1            | 0     |
| Sneezing  | 2            | 0     |
| Throat irritation   | 2            | 0     |
| Throat tightness  | 1            | 0     |
| Yawning   | 1            | 0     |
| Respiratory disorders SOC TOTAL                                 | 106          | 0     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Earliest Reaction Date: 15-Oct-1958 MedDRA Version: MedDRA 24.1 Reaction Name | Total | Fatal |
|---|-------|-------|
|   | Total | ratai |
| Skin disorders  |       |       |
| Acnes   | 0     | ~     |
|   | 3     | C     |
| Alopecias   | 0     | 0     |
| Alopecia  | 3     | 0     |
| Alopecia areata   | 1     | C     |
| Angioedemas   |       |       |
| Angioedema  | 2     | C     |
| Apocrine and eccrine gland disorders  |       |       |
| Cold sweat  | 12    | 0     |
| Hyperhidrosis   | 17    | 0     |
| Miliaria  | 2     | 0     |
| Night sweats  | 11    | C     |
| Bullous conditions  |       | -     |
| Erythema multiforme   | 1     | 0     |
| Pemphigus   | 1     | C     |
| Dermal and epidermal conditions NEC   |       |       |
| Dry skin  | 3     | 0     |
| Pain of skin  | 4     | 0     |
| Papule  | 1     | 0     |
| Sensitive skin  | 1     | 0     |
| Skin burning sensation  | 1     | 0     |
| Skin discolouration   | 2     | 0     |
| Skin lesion   | 1     | 0     |
| Skin reaction   | 1     | 0     |
| Skin tightness  | 1     | C     |
| Skin warm   | 1     | 0     |
| Dermatitis and eczema   |       |       |
| Dermatitis  | 1     | 0     |
| Dermatitis allergic   | 8     | 0     |
| Dermatitis atopic   | 1     | 0     |
| Eczema  | 1     | C     |
| Erythemas   |       | _     |
| Erythema  | 39    | C     |
| Exfoliative conditions  |       | _     |
| Skin exfoliation  | 1     | C     |
| Panniculitides  |       | _     |
| Erythema nodosum  | 1     | C     |
| Papulosquamous conditions   |       |       |
| Pityriasis rosea  | 1     | C     |
| Photosensitivity and photodermatosis conditions                               |       |       |
| Photosensitivity reaction   | 1     | C     |
| Pilar disorders NEC   |       |       |
| Hair growth abnormal  | 2     | C     |
| Pruritus NEC  |       |       |
| Pruritus  | 97    | 0     |
| Purpura and related conditions  |       |       |
| Petechiae   | 1     | C     |
| Rashes, eruptions and exanthems NEC   |       |       |
| Rash  | 116   |       |
| Rash erythematous   | 41    | C     |
| Rash macular  | 5     | C     |
| Rash papular  | 8     | C     |

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Reaction Name                           | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd    |       |       |
| Rash pruritic                           | 27    | 0     |
| Skin and subcutaneous conditions NEC    |       |       |
| Cutaneous symptom                       | 1     | 0     |
| Skin haemorrhages                       |       |       |
| Skin haemorrhage                        | 1     | 0     |
| Skin injuries and mechanical dermatoses |       |       |
| Needle track marks                      | 1     | 0     |
| Skin vasculitides                       |       |       |
| Cutaneous vasculitis                    | 1     | 0     |
| Urticarias                              |       |       |
| Urticaria                               | 20    | 0     |
| Skin disorders SOC TOTAL                | 444   | 0     |

### Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

 Report Run Date: 23-Feb-2022
 Data Lock Date: 22-Feb-2022 18:30:04

 Earliest Reaction Date: 15-Oct-1958
 MedDRA Version: MedDRA 24.1

 Reaction Name
 Total Fatal

 Surgical & medical procedures
 Immunisations

 Immunisations
 Immunisations

Immunisation10Skin and subcutaneous tissue therapeutic procedures NEC10Dermal filler injection10Surgical & medical procedures SOC TOTAL20

# Name: Moderna COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield Data Lock Date: 22-Feb-2022 18:30:04

Report Run Date: 23-Feb-2022 Earliest Reaction Date: 15-Oct-1958

| Reaction Name   | Total | Fatal |
|---|-------|-------|
| Vascular disorders  |       |       |
| Arterial infections and inflammations                           |       |       |
| Giant cell arteritis  | 1     | 0     |
| Haemorrhages NEC  |       |       |
| Haematoma   | 1     | 0     |
| Haemorrhage   | 11    | 0     |
| Lymphoedemas  |       |       |
| Lymphoedema   | 2     | 0     |
| Non-site specific embolism and thrombosis                       |       |       |
| Thrombosis  | 2     | 0     |
| Peripheral embolism and thrombosis                              |       |       |
| Blue toe syndrome   | 1     | 0     |
| Deep vein thrombosis  | 1     | 0     |
| Peripheral vascular disorders NEC                               |       |       |
| Hot flush   | 7     | 0     |
| Peripheral vasoconstriction, necrosis and vascular insufficient | cy    |       |
| Peripheral coldness   | 2     | 0     |
| Vascular hypertensive disorders NEC                             |       |       |
| Hypertension  | 8     | 0     |
| Vascular hypotensive disorders                                  |       |       |
| Hypotension   | 10    | 0     |
| Orthostatic hypotension   | 2     | 0     |
| Vascular disorders SOC TOTAL                                    | 48    | 0     |
| TOTAL REACTIONS FOR DRUG  | 3348  | 1     |
|   |       |       |
| TOTAL REPORTS   | 1022  |       |
| TOTAL FATAL OUTCOME REPORTS                                     |       | 1     |