

## Summary Tabulation 22-06-2021

| Active Substance (High Level)        |  | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) |             |       |
|--------------------------------------|--|--|-------------|-------|
| Reaction SOC                         | Reaction PT                            | Serious  | Non Serious | Total |
| Blood and lymphatic system disorders | Anaemia                                | 3  | 1           | 4     |
|                                      | Autoimmune haemolytic anaemia          | 1  | 0           | 1     |
|                                      | Coagulopathy                           | 61   | 27          | 88    |
|                                      | Coombs negative haemolytic anaemia     | 1  | 0           | 1     |
|                                      | Disseminated intravascular coagulation | 1  | 0           | 1     |
|                                      | Immune thrombocytopenia                | 3  | 1           | 4     |
|                                      | Leukocytosis                           | 1  | 0           | 1     |
|                                      | Leukopenia                             | 1  | 0           | 1     |
|                                      | Lymph node pain                        | 1  | 0           | 1     |
|                                      | Lymphadenopathy                        | 6  | 3           | 9     |
|                                      | Lymphopenia                            | 1  | 0           | 1     |
|                                      | Necrotic lymphadenopathy               | 0  | 1           | 1     |
|                                      | Neutropenia                            | 3  | 1           | 4     |
|                                      | Platelet disorder                      | 1  | 0           | 1     |
|                                      | Splenic embolism                       | 1  | 0           | 1     |
|                                      | Splenic infarction                     | 1  | 0           | 1     |
|                                      | Splenic vein thrombosis                | 1  | 0           | 1     |
|                                      | Spontaneous haematoma                  | 1  | 0           | 1     |
|                                      | Thrombocytopenia                       | 31   | 7           | 38    |
|                                      | Cardiac disorders                      | Acute cardiac event                            | 1           | 0     |
| Angina pectoris                      |  | 3  | 0           | 3     |
| Angina unstable                      |  | 1  | 0           | 1     |
| Arrhythmia                           |  | 6  | 2           | 8     |
| Bradycardia                          |  | 1  | 2           | 3     |
| Cardiac arrest                       |  | 2  | 0           | 2     |
| Cardiac failure                      |  | 2  | 0           | 2     |
| Cardiovascular disorder              |  | 47   | 8           | 55    |
| Extrasystoles                        |  | 0  | 1           | 1     |
| Myocardial depression                |  | 1  | 0           | 1     |
| Myocardial infarction                |  | 2  | 0           | 2     |
| Myocarditis                          |  | 2  | 0           | 2     |
| Palpitations                         |  | 40   | 8           | 48    |
| Pericarditis                         |  | 1  | 0           | 1     |
| Pleuropericarditis                   |  | 1  | 1           | 2     |
| Sinus tachycardia                    |  | 2  | 0           | 2     |

|                             |                                    |    |   |    |
|-----------------------------|------------------------------------|----|---|----|
|                             | Tachycardia                        | 36 | 6 | 42 |
| Ear and labyrinth disorders | Deafness                           | 2  | 3 | 5  |
|                             | Deafness unilateral                | 5  | 1 | 6  |
|                             | Ear congestion                     | 0  | 2 | 2  |
|                             | Ear discomfort                     | 4  | 1 | 5  |
|                             | Ear pain                           | 13 | 4 | 17 |
|                             | Hyperacusis                        | 3  | 0 | 3  |
|                             | Hypoacusis                         | 1  | 0 | 1  |
|                             | Meniere's disease                  | 1  | 1 | 2  |
|                             | Sudden hearing loss                | 0  | 1 | 1  |
|                             | Tinnitus                           | 13 | 3 | 16 |
|                             | Vertigo                            | 38 | 6 | 44 |
| Endocrine disorders         | Adrenocortical insufficiency acute | 1  | 0 | 1  |
|                             | Goitre                             | 2  | 0 | 2  |
| Eye disorders               | Amaurosis fugax                    | 1  | 1 | 2  |
|                             | Asthenopia                         | 3  | 0 | 3  |
|                             | Blindness                          | 5  | 1 | 6  |
|                             | Blindness unilateral               | 4  | 0 | 4  |
|                             | Conjunctival haemorrhage           | 1  | 1 | 2  |
|                             | Diplopia                           | 3  | 1 | 4  |
|                             | Eye disorder                       | 1  | 1 | 2  |
|                             | Eye haemorrhage                    | 2  | 3 | 5  |
|                             | Eye irritation                     | 1  | 0 | 1  |
|                             | Eye oedema                         | 1  | 0 | 1  |
|                             | Eye pain                           | 8  | 4 | 12 |
|                             | Eye swelling                       | 2  | 0 | 2  |
|                             | Macular oedema                     | 1  | 0 | 1  |
|                             | Miosis                             | 1  | 0 | 1  |
|                             | Mydriasis                          | 1  | 0 | 1  |
|                             | Ocular discomfort                  | 1  | 1 | 2  |
|                             | Ocular hyperaemia                  | 2  | 1 | 3  |
|                             | Ophthalmic vein thrombosis         | 1  | 0 | 1  |
|                             | Papilloedema                       | 1  | 0 | 1  |
|                             | Periorbital swelling               | 1  | 0 | 1  |
|                             | Photophobia                        | 5  | 1 | 6  |
|                             | Photopsia                          | 1  | 0 | 1  |
|                             | Pupils unequal                     | 1  | 0 | 1  |
|                             | Retinal artery thrombosis          | 3  | 0 | 3  |
|                             | Retinal haemorrhage                | 0  | 1 | 1  |
|                             | Retinal ischaemia                  | 1  | 0 | 1  |
|                             | Retinal oedema                     | 1  | 0 | 1  |
|                             | Retinal vascular thrombosis        | 0  | 1 | 1  |
|                             | Retinal vein occlusion             | 1  | 0 | 1  |
|                             | Retinal vein thrombosis            | 5  | 0 | 5  |
|                             | Swelling of eyelid                 | 0  | 1 | 1  |
|                             | Uveitis                            | 1  | 0 | 1  |
|                             | Vision blurred                     | 20 | 3 | 23 |
|                             | Visual acuity reduced              | 1  | 0 | 1  |
|                             | Visual field defect                | 1  | 0 | 1  |
|                             | Visual impairment                  | 18 | 4 | 22 |

|                            |  |     |    |     |
|----------------------------|--|-----|----|-----|
|                            | Visual snow syndrome                   | 1   | 0  | 1   |
|                            | Vitreous floaters                      | 0   | 1  | 1   |
| Gastrointestinal disorders | Abdominal discomfort                   | 5   | 1  | 6   |
|                            | Abdominal distension                   | 1   | 0  | 1   |
|                            | Abdominal pain                         | 30  | 10 | 40  |
|                            | Abdominal pain upper                   | 17  | 5  | 22  |
|                            | Abnormal faeces                        | 1   | 0  | 1   |
|                            | Aphthous ulcer                         | 0   | 1  | 1   |
|                            | Colitis ischaemic                      | 2   | 0  | 2   |
|                            | Colitis ulcerative                     | 1   | 0  | 1   |
|                            | Constipation                           | 1   | 0  | 1   |
|                            | Crohn's disease                        | 1   | 0  | 1   |
|                            | Diarrhoea                              | 64  | 10 | 74  |
|                            | Diarrhoea haemorrhagic                 | 1   | 1  | 2   |
|                            | Dry mouth                              | 7   | 0  | 7   |
|                            | Dyspepsia                              | 3   | 0  | 3   |
|                            | Dysphagia                              | 1   | 2  | 3   |
|                            | Eructation                             | 1   | 0  | 1   |
|                            | Faeces discoloured                     | 1   | 0  | 1   |
|                            | Faeces soft                            | 1   | 0  | 1   |
|                            | Flatulence                             | 1   | 0  | 1   |
|                            | Gastrointestinal disorder              | 4   | 0  | 4   |
|                            | Gastrointestinal haemorrhage           | 1   | 0  | 1   |
|                            | Gastrointestinal inflammation          | 1   | 0  | 1   |
|                            | Gastrointestinal pain                  | 1   | 0  | 1   |
|                            | Gastrointestinal vascular malformation | 1   | 0  | 1   |
|                            | Gastrooesophageal reflux disease       | 1   | 0  | 1   |
|                            | Gingival bleeding                      | 2   | 0  | 2   |
|                            | Glossodynia                            | 1   | 1  | 2   |
|                            | Haemoperitoneum                        | 1   | 0  | 1   |
|                            | Haemorrhoidal haemorrhage              | 1   | 0  | 1   |
|                            | Haemorrhoids thrombosed                | 1   | 1  | 2   |
|                            | Hypoaesthesia oral                     | 0   | 1  | 1   |
|                            | Intestinal congestion                  | 1   | 0  | 1   |
|                            | Intestinal infarction                  | 1   | 0  | 1   |
|                            | Intestinal ischaemia                   | 3   | 0  | 3   |
|                            | Lip pain                               | 1   | 0  | 1   |
|                            | Lip swelling                           | 0   | 3  | 3   |
|                            | Melaena                                | 1   | 0  | 1   |
|                            | Mesenteric vein thrombosis             | 2   | 0  | 2   |
|                            | Mouth haemorrhage                      | 0   | 1  | 1   |
|                            | Nausea                                 | 808 | 68 | 876 |
|                            | Oesophageal spasm                      | 1   | 0  | 1   |
|                            | Oral discomfort                        | 2   | 0  | 2   |
| Pancreatic enlargement     | 1                                      | 0   | 1  |     |
| Paraesthesia oral          | 3                                      | 3   | 6  |     |
| Plicated tongue            | 0                                      | 1   | 1  |     |
| Rectal haemorrhage         | 1                                      | 2   | 3  |     |
| Regurgitation              | 1                                      | 0   | 1  |     |
| Retching                   | 3                                      | 0   | 3  |     |

|  |                                       |      |     |       |
|--|---------------------------------------|------|-----|-------|
|  | Splanchnic hypoperfusion              | 1    | 0   | 1     |
|  | Swollen tongue                        | 1    | 1   | 2     |
|  | Thrombosis mesenteric vessel          | 1    | 0   | 1     |
|  | Tongue discomfort                     | 0    | 1   | 1     |
|  | Tongue disorder                       | 0    | 1   | 1     |
|  | Toothache                             | 0    | 1   | 1     |
|  | Vomiting                              | 86   | 10  | 96    |
| General disorders and administration site conditions | Administration site pain              | 0    | 1   | 1     |
|  | Adverse drug reaction                 | 3    | 0   | 3     |
|  | Adverse event                         | 2    | 0   | 2     |
|  | Application site joint warmth         | 1    | 0   | 1     |
|  | Asthenia                              | 42   | 2   | 44    |
|  | Axillary pain                         | 3    | 2   | 5     |
|  | Brain death                           | 1    | 0   | 1     |
|  | Chest discomfort                      | 12   | 3   | 15    |
|  | Chest pain                            | 28   | 7   | 35    |
|  | Chills                                | 1431 | 108 | 1 539 |
|  | Condition aggravated                  | 3    | 0   | 3     |
|  | Death                                 | 19   | 0   | 19    |
|  | Discomfort                            | 1    | 1   | 2     |
|  | Drug ineffective                      | 0    | 4   | 4     |
|  | Exercise tolerance decreased          | 2    | 0   | 2     |
|  | Extensive swelling of vaccinated limb | 93   | 12  | 105   |
|  | Face oedema                           | 3    | 0   | 3     |
|  | Facial pain                           | 0    | 1   | 1     |
|  | Fatigue                               | 1438 | 127 | 1 565 |
|  | Feeling abnormal                      | 22   | 4   | 26    |
|  | Feeling cold                          | 30   | 5   | 35    |
|  | Feeling drunk                         | 2    | 1   | 3     |
|  | Feeling hot                           | 20   | 5   | 25    |
|  | Feeling of body temperature change    | 15   | 2   | 17    |
|  | Gait disturbance                      | 7    | 1   | 8     |
|  | Gait inability                        | 2    | 0   | 2     |
|  | General physical health deterioration | 5    | 0   | 5     |
|  | Hyperpyrexia                          | 0    | 1   | 1     |
|  | Hyperthermia                          | 2    | 1   | 3     |
|  | Hypothermia                           | 2    | 0   | 2     |
|  | Illness                               | 0    | 1   | 1     |
|  | Induration                            | 2    | 1   | 3     |
|  | Inflammation                          | 1    | 0   | 1     |
|  | Influenza like illness                | 163  | 23  | 186   |
|  | Injected limb mobility decreased      | 1    | 0   | 1     |
|  | Injection site bruising               | 0    | 1   | 1     |
|  | Injection site discomfort             | 3    | 0   | 3     |
|  | Injection site erythema               | 16   | 2   | 18    |
|  | Injection site haematoma              | 2    | 0   | 2     |
|  | Injection site haemorrhage            | 1    | 0   | 1     |
|  | Injection site hypoaesthesia          | 2    | 0   | 2     |
| Injection site induration                            | 7                                     | 2    | 9   |       |
| Injection site inflammation                          | 1                                     | 0    | 1   |       |

|                         |                                      |      |     |       |
|-------------------------|--------------------------------------|------|-----|-------|
|                         | Injection site movement impairment   | 2    | 1   | 3     |
|                         | Injection site necrosis              | 1    | 0   | 1     |
|                         | Injection site oedema                | 1    | 0   | 1     |
|                         | Injection site pain                  | 109  | 10  | 119   |
|                         | Injection site paraesthesia          | 1    | 0   | 1     |
|                         | Injection site phlebitis             | 0    | 1   | 1     |
|                         | Injection site pruritus              | 0    | 3   | 3     |
|                         | Injection site rash                  | 1    | 0   | 1     |
|                         | Injection site reaction              | 701  | 51  | 752   |
|                         | Injection site swelling              | 19   | 3   | 22    |
|                         | Injection site warmth                | 10   | 0   | 10    |
|                         | Local reaction                       | 1    | 0   | 1     |
|                         | Localised oedema                     | 1    | 0   | 1     |
|                         | Malaise                              | 827  | 76  | 903   |
|                         | Mucosal inflammation                 | 0    | 1   | 1     |
|                         | Multiple organ dysfunction syndrome  | 1    | 0   | 1     |
|                         | No adverse event                     | 1    | 0   | 1     |
|                         | Oedema                               | 3    | 0   | 3     |
|                         | Oedema peripheral                    | 3    | 2   | 5     |
|                         | Pain                                 | 25   | 13  | 38    |
|                         | Peripheral swelling                  | 64   | 7   | 71    |
|                         | Puncture site pain                   | 0    | 1   | 1     |
|                         | Pyrexia                              | 1438 | 131 | 1 569 |
|                         | Secretion discharge                  | 1    | 0   | 1     |
|                         | Sensation of foreign body            | 1    | 0   | 1     |
|                         | Sense of oppression                  | 1    | 0   | 1     |
|                         | Sick building syndrome               | 0    | 2   | 2     |
|                         | Sudden death                         | 8    | 0   | 8     |
|                         | Swelling                             | 6    | 4   | 10    |
|                         | Swelling face                        | 2    | 0   | 2     |
|                         | Tenderness                           | 2    | 1   | 3     |
|                         | Therapeutic response unexpected      | 0    | 1   | 1     |
|                         | Thirst                               | 6    | 0   | 6     |
|                         | Tissue infiltration                  | 0    | 1   | 1     |
|                         | Unevaluable event                    | 1    | 1   | 2     |
|                         | Vaccination site discharge           | 0    | 1   | 1     |
|                         | Vaccination site erythema            | 1    | 0   | 1     |
|                         | Vaccination site haematoma           | 1    | 0   | 1     |
|                         | Vaccination site movement impairment | 1    | 0   | 1     |
|                         | Vaccination site pain                | 2    | 5   | 7     |
| Hepatobiliary disorders | Gallbladder necrosis                 | 1    | 0   | 1     |
|                         | Hepatic failure                      | 1    | 0   | 1     |
|                         | Hepatic steatosis                    | 1    | 0   | 1     |
|                         | Hepatitis                            | 1    | 0   | 1     |
|                         | Hyperbilirubinaemia                  | 1    | 0   | 1     |
|                         | Liver disorder                       | 2    | 0   | 2     |
|                         | Portal vein occlusion                | 1    | 0   | 1     |
|                         | Portal vein thrombosis               | 4    | 0   | 4     |
|                         | Venoocclusive liver disease          | 1    | 0   | 1     |
| Immune system disorders | Anaphylactic reaction                | 8    | 4   | 12    |

|  |                             |    |    |    |
|--|-----------------------------|----|----|----|
|  | Anaphylactic shock          | 1  | 0  | 1  |
|  | Autoimmune disorder         | 9  | 0  | 9  |
|  | Hypersensitivity            | 27 | 11 | 38 |
|  | Seasonal allergy            | 1  | 0  | 1  |
| Infections and infestations                    | Abscess                     | 0  | 1  | 1  |
|  | Brain abscess               | 1  | 0  | 1  |
|  | Brain empyema               | 1  | 0  | 1  |
|  | Bronchitis                  | 1  | 0  | 1  |
|  | COVID-19                    | 48 | 7  | 55 |
|  | COVID-19 pneumonia          | 1  | 0  | 1  |
|  | Cavernous sinus thrombosis  | 1  | 0  | 1  |
|  | Chronic sinusitis           | 1  | 0  | 1  |
|  | Conjunctivitis              | 1  | 1  | 2  |
|  | Conjunctivitis viral        | 0  | 1  | 1  |
|  | Cystitis                    | 1  | 1  | 2  |
|  | Diverticulitis              | 1  | 0  | 1  |
|  | Ear infection               | 0  | 1  | 1  |
|  | Encephalitis                | 3  | 0  | 3  |
|  | Erysipelas                  | 0  | 2  | 2  |
|  | Eye infection               | 1  | 0  | 1  |
|  | Gastrointestinal infection  | 0  | 1  | 1  |
|  | Herpes zoster               | 2  | 11 | 13 |
|  | Infection                   | 0  | 1  | 1  |
|  | Influenza                   | 14 | 11 | 25 |
|  | Injection site cellulitis   | 0  | 1  | 1  |
|  | Laryngitis                  | 1  | 0  | 1  |
|  | Lymphangitis                | 0  | 1  | 1  |
|  | Meningitis bacterial        | 1  | 0  | 1  |
|  | Nasopharyngitis             | 16 | 5  | 21 |
|  | Ophthalmic herpes zoster    | 0  | 1  | 1  |
|  | Oral herpes                 | 1  | 0  | 1  |
|  | Pharyngitis                 | 0  | 2  | 2  |
|  | Pneumonia                   | 1  | 0  | 1  |
|  | Pneumonia bacterial         | 1  | 0  | 1  |
|  | Pyelonephritis              | 1  | 0  | 1  |
|  | Pyelonephritis acute        | 1  | 0  | 1  |
|  | Respiratory tract infection | 1  | 0  | 1  |
|  | Sepsis                      | 2  | 0  | 2  |
|  | Septic shock                | 2  | 0  | 2  |
|  | Sinusitis                   | 2  | 0  | 2  |
|  | Streptococcal infection     | 1  | 0  | 1  |
|  | Subcutaneous abscess        | 0  | 1  | 1  |
|  | Suspected COVID-19          | 0  | 1  | 1  |
|  | Sweating fever              | 0  | 1  | 1  |
|  | Tooth abscess               | 1  | 0  | 1  |
| Urinary tract infection                        | 2                           | 1  | 3  |    |
| Vestibular neuronitis                          | 1                           | 0  | 1  |    |
| Viral myocarditis                              | 1                           | 0  | 1  |    |
| Injury, poisoning and procedural complications | Contusion                   | 7  | 8  | 15 |
|  | Epicondylitis               | 1  | 0  | 1  |

|                |   |    |   |    |
|----------------|---|----|---|----|
|                | Exposure during pregnancy                       | 0  | 2 | 2  |
|                | Exposure via breast milk                        | 0  | 1 | 1  |
|                | Fall  | 9  | 1 | 10 |
|                | Head injury                                     | 1  | 0 | 1  |
|                | Inappropriate schedule of product               | 0  | 1 | 1  |
|                | Incorrect route of product administration       | 1  | 4 | 5  |
|                | Intentional dose omission                       | 1  | 0 | 1  |
|                | Kidney rupture                                  | 1  | 0 | 1  |
|                | Limb injury                                     | 0  | 1 | 1  |
|                | Maternal exposure during breast feeding         | 2  | 4 | 6  |
|                | Medication error                                | 1  | 3 | 4  |
|                | Off label use                                   | 1  | 2 | 3  |
|                | Product administered at inappropriate site      | 0  | 1 | 1  |
|                | Product administration error                    | 0  | 1 | 1  |
|                | Synovial rupture                                | 1  | 0 | 1  |
|                | Vascular injury                                 | 1  | 0 | 1  |
|                | Vasoplegia syndrome                             | 1  | 0 | 1  |
|                | Venous injury                                   | 0  | 1 | 1  |
|                | Wrong product administered                      | 0  | 1 | 1  |
| Investigations | Activated partial thromboplastin time prolonged | 1  | 0 | 1  |
|                | Alanine aminotransferase increased              | 1  | 0 | 1  |
|                | Anti-platelet antibody                          | 1  | 0 | 1  |
|                | Antibody test negative                          | 0  | 1 | 1  |
|                | Aspartate aminotransferase increased            | 1  | 0 | 1  |
|                | Babinski reflex test                            | 1  | 0 | 1  |
|                | Blood albumin decreased                         | 1  | 0 | 1  |
|                | Blood alkaline phosphatase increased            | 1  | 0 | 1  |
|                | Blood bilirubin increased                       | 1  | 0 | 1  |
|                | Blood fibrinogen decreased                      | 2  | 0 | 2  |
|                | Blood fibrinogen increased                      | 1  | 0 | 1  |
|                | Blood glucose abnormal                          | 1  | 0 | 1  |
|                | Blood glucose increased                         | 1  | 0 | 1  |
|                | Blood pressure decreased                        | 12 | 1 | 13 |
|                | Blood pressure diastolic increased              | 0  | 1 | 1  |
|                | Blood pressure increased                        | 9  | 2 | 11 |
|                | Body temperature abnormal                       | 0  | 1 | 1  |
|                | Body temperature decreased                      | 2  | 1 | 3  |
|                | Body temperature increased                      | 6  | 3 | 9  |
|                | C-reactive protein increased                    | 13 | 1 | 14 |
|                | Capillary nail refill test abnormal             | 1  | 0 | 1  |
|                | Coagulation factor increased                    | 1  | 0 | 1  |
|                | Ejection fraction decreased                     | 1  | 0 | 1  |
|                | Fibrin D dimer decreased                        | 0  | 1 | 1  |
|                | Fibrin D dimer increased                        | 20 | 3 | 23 |
|                | Gamma-glutamyltransferase increased             | 1  | 0 | 1  |
|                | General physical condition abnormal             | 2  | 0 | 2  |
|                | Haematocrit decreased                           | 1  | 0 | 1  |
|                | Haematocrit increased                           | 1  | 0 | 1  |
|                | Haemoglobin decreased                           | 1  | 0 | 1  |
|                | Heart rate abnormal                             | 0  | 1 | 1  |

|   |     |    |     |
|---|-----|----|-----|
| Heart rate decreased                            | 1   | 0  | 1   |
| Heart rate increased                            | 25  | 7  | 32  |
| Heart rate irregular                            | 0   | 1  | 1   |
| Heart rate normal                               | 1   | 0  | 1   |
| Heparin-induced thrombocytopenia test positive  | 5   | 0  | 5   |
| Homans' sign negative                           | 0   | 1  | 1   |
| Interleukin level increased                     | 1   | 0  | 1   |
| International normalised ratio increased        | 1   | 0  | 1   |
| Intestinal transit time abnormal                | 0   | 1  | 1   |
| Liver function test abnormal                    | 2   | 0  | 2   |
| Lymphocyte count decreased                      | 0   | 1  | 1   |
| Neurological examination abnormal               | 1   | 0  | 1   |
| Oxygen saturation decreased                     | 3   | 0  | 3   |
| Platelet count decreased                        | 5   | 0  | 5   |
| Platelet count increased                        | 1   | 0  | 1   |
| Platelet factor 4 increased                     | 0   | 1  | 1   |
| Procalcitonin increased                         | 1   | 0  | 1   |
| Progesterone decreased                          | 0   | 1  | 1   |
| Red blood cell count decreased                  | 1   | 1  | 2   |
| Red blood cell count increased                  | 0   | 1  | 1   |
| Red blood cell sedimentation rate increased     | 1   | 0  | 1   |
| Respiratory rate decreased                      | 0   | 1  | 1   |
| SARS-CoV-2 antibody test negative               | 0   | 3  | 3   |
| SARS-CoV-2 test negative                        | 0   | 1  | 1   |
| SARS-CoV-2 test positive                        | 0   | 1  | 1   |
| Troponin T increased                            | 1   | 0  | 1   |
| Troponin increased                              | 2   | 0  | 2   |
| Venous pressure increased                       | 1   | 0  | 1   |
| Weight decreased                                | 5   | 1  | 6   |
| White blood cell count decreased                | 0   | 1  | 1   |
| Metabolism and nutrition disorders              |     |    |     |
| Decreased appetite                              | 69  | 7  | 76  |
| Dehydration                                     | 2   | 0  | 2   |
| Feeding disorder                                | 1   | 0  | 1   |
| Fluid retention                                 | 1   | 1  | 2   |
| Gout  | 1   | 0  | 1   |
| Hyperglycaemia                                  | 1   | 0  | 1   |
| Hyperkalaemia                                   | 1   | 0  | 1   |
| Hypoglycaemia                                   | 1   | 0  | 1   |
| Hypovolaemia                                    | 1   | 0  | 1   |
| Lactic acidosis                                 | 2   | 0  | 2   |
| Mineral deficiency                              | 1   | 0  | 1   |
| Oligodipsia                                     | 1   | 0  | 1   |
| Vitamin D deficiency                            | 1   | 0  | 1   |
| Musculoskeletal and connective tissue disorders |     |    |     |
| Acute aseptic arthritis                         | 1   | 0  | 1   |
| Arthralgia                                      | 651 | 57 | 708 |
| Arthritis                                       | 4   | 0  | 4   |
| Back pain                                       | 30  | 8  | 38  |
| Bone pain                                       | 2   | 0  | 2   |
| Connective tissue disorder                      | 0   | 1  | 1   |
| Fibromyalgia                                    | 1   | 0  | 1   |



|   |                                  |      |     |       |
|---|----------------------------------|------|-----|-------|
|   | Jaw disorder                     | 0    | 1   | 1     |
|   | Joint stiffness                  | 1    | 1   | 2     |
|   | Joint swelling                   | 0    | 2   | 2     |
|   | Limb discomfort                  | 15   | 3   | 18    |
|   | Muscle contracture               | 1    | 0   | 1     |
|   | Muscle discomfort                | 1    | 0   | 1     |
|   | Muscle spasms                    | 16   | 1   | 17    |
|   | Muscle swelling                  | 1    | 0   | 1     |
|   | Muscle twitching                 | 2    | 0   | 2     |
|   | Muscular weakness                | 15   | 6   | 21    |
|   | Musculoskeletal pain             | 0    | 1   | 1     |
|   | Musculoskeletal stiffness        | 64   | 6   | 70    |
|   | Myalgia                          | 1221 | 114 | 1 335 |
|   | Myosclerosis                     | 1    | 0   | 1     |
|   | Neck pain                        | 20   | 3   | 23    |
|   | Osteoarthritis                   | 2    | 1   | 3     |
|   | Pain in extremity                | 77   | 24  | 101   |
|   | Polyarthritis                    | 1    | 0   | 1     |
|   | Polymyalgia rheumatica           | 1    | 0   | 1     |
|   | Spinal deformity                 | 0    | 1   | 1     |
|   | Spinal pain                      | 0    | 1   | 1     |
|   | Still's disease                  | 1    | 0   | 1     |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Haemangioma of liver             | 1    | 0   | 1     |
|   | Neoplasm malignant               | 1    | 0   | 1     |
| Nervous system disorders  | Ageusia                          | 4    | 0   | 4     |
|   | Altered state of consciousness   | 4    | 1   | 5     |
|   | Amnesia                          | 6    | 0   | 6     |
|   | Anosmia                          | 3    | 0   | 3     |
|   | Aphasia                          | 7    | 0   | 7     |
|   | Areflexia                        | 1    | 0   | 1     |
|   | Balance disorder                 | 10   | 2   | 12    |
|   | Bell's palsy                     | 1    | 0   | 1     |
|   | Brain oedema                     | 3    | 0   | 3     |
|   | Burning sensation                | 4    | 0   | 4     |
|   | Carotid artery thrombosis        | 1    | 0   | 1     |
|   | Cerebellar infarction            | 1    | 0   | 1     |
|   | Cerebellar stroke                | 1    | 0   | 1     |
|   | Cerebral haemorrhage             | 10   | 0   | 10    |
|   | Cerebral infarction              | 4    | 0   | 4     |
|   | Cerebral ischaemia               | 2    | 0   | 2     |
|   | Cerebral mass effect             | 1    | 0   | 1     |
|   | Cerebral thrombosis              | 4    | 0   | 4     |
|   | Cerebral venous sinus thrombosis | 1    | 0   | 1     |
|   | Cerebrovascular accident         | 10   | 0   | 10    |
|   | Cervical radiculopathy           | 0    | 1   | 1     |
|   | Coma                             | 3    | 0   | 3     |
|   | Dementia Alzheimer's type        | 1    | 0   | 1     |
|   | Depressed level of consciousness | 4    | 0   | 4     |
|   | Diplegia                         | 2    | 0   | 2     |
|   | Disturbance in attention         | 9    | 2   | 11    |

|                                 |      |     |       |
|---------------------------------|------|-----|-------|
| Dizziness                       | 60   | 14  | 74    |
| Dizziness postural              | 1    | 0   | 1     |
| Dysarthria                      | 5    | 0   | 5     |
| Dysgeusia                       | 6    | 1   | 7     |
| Dyskinesia                      | 2    | 0   | 2     |
| Dysstasia                       | 0    | 1   | 1     |
| Electric shock sensation        | 1    | 0   | 1     |
| Epilepsy                        | 3    | 0   | 3     |
| Facial nerve disorder           | 1    | 0   | 1     |
| Facial paralysis                | 10   | 1   | 11    |
| Formication                     | 0    | 1   | 1     |
| Guillain-Barre syndrome         | 7    | 0   | 7     |
| Head discomfort                 | 6    | 4   | 10    |
| Headache                        | 1495 | 153 | 1 648 |
| Hemianopia                      | 1    | 0   | 1     |
| Hemiparaesthesia                | 0    | 1   | 1     |
| Hemiparesis                     | 2    | 1   | 3     |
| Hemiplegia                      | 6    | 0   | 6     |
| Hyperaesthesia                  | 4    | 0   | 4     |
| Hyperreflexia                   | 1    | 0   | 1     |
| Hypersomnia                     | 0    | 1   | 1     |
| Hypoaesthesia                   | 17   | 8   | 25    |
| Hypokinesia                     | 1    | 0   | 1     |
| Intracranial pressure increased | 1    | 0   | 1     |
| Ischaemic cerebral infarction   | 1    | 0   | 1     |
| Ischaemic stroke                | 3    | 0   | 3     |
| Leukoencephalopathy             | 1    | 0   | 1     |
| Loss of consciousness           | 12   | 2   | 14    |
| Memory impairment               | 4    | 2   | 6     |
| Meningism                       | 0    | 1   | 1     |
| Migraine                        | 26   | 1   | 27    |
| Migraine with aura              | 1    | 0   | 1     |
| Monoplegia                      | 3    | 0   | 3     |
| Motor dysfunction               | 1    | 0   | 1     |
| Muscle contractions involuntary | 1    | 0   | 1     |
| Muscle tone disorder            | 1    | 0   | 1     |
| Nervous system disorder         | 46   | 9   | 55    |
| Neuralgia                       | 3    | 0   | 3     |
| Neuropathy peripheral           | 1    | 0   | 1     |
| Nystagmus                       | 1    | 0   | 1     |
| Pachymeningitis                 | 1    | 0   | 1     |
| Paraesthesia                    | 22   | 8   | 30    |
| Paralysis                       | 1    | 0   | 1     |
| Paraparesis                     | 1    | 0   | 1     |
| Paraplegia                      | 1    | 0   | 1     |
| Paresis                         | 2    | 0   | 2     |
| Petit mal epilepsy              | 1    | 0   | 1     |
| Presyncope                      | 1    | 1   | 2     |
| Restless legs syndrome          | 4    | 0   | 4     |
| Retrograde amnesia              | 1    | 0   | 1     |

|  |  |    |   |    |
|--|--|----|---|----|
|  | Sedation                               | 1  | 0 | 1  |
|  | Seizure                                | 17 | 6 | 23 |
|  | Sensory loss                           | 2  | 1 | 3  |
|  | Somnolence                             | 12 | 2 | 14 |
|  | Speech disorder                        | 4  | 1 | 5  |
|  | Spinal cord infarction                 | 1  | 0 | 1  |
|  | Spinal cord ischaemia                  | 1  | 0 | 1  |
|  | Superior sagittal sinus thrombosis     | 1  | 0 | 1  |
|  | Syncope                                | 16 | 8 | 24 |
|  | Taste disorder                         | 2  | 3 | 5  |
|  | Transient ischaemic attack             | 3  | 0 | 3  |
|  | Transverse sinus thrombosis            | 3  | 0 | 3  |
|  | Tremor                                 | 22 | 7 | 29 |
|  | Unresponsive to stimuli                | 5  | 0 | 5  |
| Pregnancy, puerperium and perinatal conditions | Abortion spontaneous                   | 2  | 0 | 2  |
|  | Foetal death                           | 1  | 0 | 1  |
|  | Preterm premature rupture of membranes | 1  | 0 | 1  |
| Product issues                                 | Oversensing                            | 2  | 0 | 2  |
| Psychiatric disorders                          | Agitation                              | 5  | 0 | 5  |
|  | Anxiety                                | 3  | 1 | 4  |
|  | Apathy                                 | 2  | 0 | 2  |
|  | Confusional state                      | 19 | 0 | 19 |
|  | Daydreaming                            | 2  | 2 | 4  |
|  | Delirium                               | 2  | 0 | 2  |
|  | Delusion                               | 0  | 1 | 1  |
|  | Depressed mood                         | 0  | 2 | 2  |
|  | Depression                             | 1  | 0 | 1  |
|  | Disorientation                         | 2  | 0 | 2  |
|  | Dissociation                           | 0  | 1 | 1  |
|  | Eating disorder                        | 1  | 0 | 1  |
|  | Emotional poverty                      | 1  | 0 | 1  |
|  | Fear of death                          | 1  | 0 | 1  |
|  | Feeling of despair                     | 1  | 0 | 1  |
|  | Hallucination                          | 1  | 1 | 2  |
|  | Hallucination, visual                  | 1  | 0 | 1  |
|  | Initial insomnia                       | 1  | 0 | 1  |
|  | Insomnia                               | 32 | 4 | 36 |
|  | Nervousness                            | 1  | 0 | 1  |
|  | Nightmare                              | 1  | 1 | 2  |
|  | Panic attack                           | 1  | 0 | 1  |
|  | Phonophobia                            | 1  | 0 | 1  |
|  | Psychomotor retardation                | 1  | 0 | 1  |
|  | Restlessness                           | 3  | 0 | 3  |
|  | Sleep disorder                         | 1  | 0 | 1  |
|  | Stress                                 | 1  | 0 | 1  |
|  | Tension                                | 0  | 1 | 1  |
| Renal and urinary disorders                    | Acute kidney injury                    | 4  | 0 | 4  |
|  | Bladder dysfunction                    | 1  | 0 | 1  |
|  | Calculus urinary                       | 1  | 0 | 1  |
|  | Chromaturia                            | 1  | 0 | 1  |

|   |                                       |    |   |    |
|---|---------------------------------------|----|---|----|
|   | Dysuria                               | 1  | 0 | 1  |
|   | Haematuria                            | 1  | 1 | 2  |
|   | Hydronephrosis                        | 1  | 0 | 1  |
|   | Incontinence                          | 1  | 0 | 1  |
|   | Neurogenic bladder                    | 1  | 0 | 1  |
|   | Pollakiuria                           | 1  | 0 | 1  |
|   | Polyuria                              | 1  | 0 | 1  |
|   | Renal colic                           | 2  | 0 | 2  |
|   | Renal disorder                        | 8  | 0 | 8  |
|   | Renal failure                         | 1  | 0 | 1  |
|   | Renal pain                            | 4  | 0 | 4  |
|   | Renal tubular disorder                | 1  | 0 | 1  |
|   | Renal vascular thrombosis             | 1  | 0 | 1  |
|   | Urge incontinence                     | 1  | 0 | 1  |
|   | Urinary incontinence                  | 4  | 0 | 4  |
|   | Urinary retention                     | 2  | 0 | 2  |
| Reproductive system and breast disorders        | Amenorrhoea                           | 1  | 0 | 1  |
|   | Breast cyst                           | 1  | 0 | 1  |
|   | Breast inflammation                   | 1  | 0 | 1  |
|   | Breast pain                           | 2  | 2 | 4  |
|   | Breast swelling                       | 0  | 1 | 1  |
|   | Dysmenorrhoea                         | 2  | 0 | 2  |
|   | Ejaculation disorder                  | 0  | 1 | 1  |
|   | Erectile dysfunction                  | 1  | 0 | 1  |
|   | Heavy menstrual bleeding              | 2  | 3 | 5  |
|   | Menstrual disorder                    | 5  | 1 | 6  |
|   | Menstruation delayed                  | 0  | 1 | 1  |
|   | Menstruation irregular                | 1  | 0 | 1  |
|   | Polymenorrhoea                        | 1  | 0 | 1  |
|   | Postmenopausal haemorrhage            | 0  | 1 | 1  |
|   | Vaginal haemorrhage                   | 3  | 1 | 4  |
|   | Varicose veins pelvic                 | 1  | 0 | 1  |
|   | Vulval haematoma                      | 0  | 1 | 1  |
| Respiratory, thoracic and mediastinal disorders | Acute pulmonary oedema                | 1  | 0 | 1  |
|   | Apparent life threatening event       | 1  | 0 | 1  |
|   | Asthma                                | 7  | 2 | 9  |
|   | Choking                               | 1  | 0 | 1  |
|   | Choking sensation                     | 1  | 0 | 1  |
|   | Chronic obstructive pulmonary disease | 1  | 0 | 1  |
|   | Cough                                 | 29 | 1 | 30 |
|   | Dysphonia                             | 2  | 1 | 3  |
|   | Dyspnoea                              | 74 | 5 | 79 |
|   | Dyspnoea exertional                   | 5  | 0 | 5  |
|   | Epistaxis                             | 15 | 6 | 21 |
|   | Hyperventilation                      | 7  | 0 | 7  |
|   | Lung disorder                         | 2  | 1 | 3  |
|   | Nasal congestion                      | 3  | 0 | 3  |
|   | Nasal inflammation                    | 0  | 1 | 1  |
|   | Oropharyngeal pain                    | 15 | 4 | 19 |
|   | Painful respiration                   | 2  | 0 | 2  |

|                           |    |    |     |
|---------------------------|----|----|-----|
| Pharyngeal paraesthesia   | 0  | 1  | 1   |
| Pharyngeal swelling       | 1  | 2  | 3   |
| Pleural effusion          | 2  | 0  | 2   |
| Pleurisy                  | 1  | 0  | 1   |
| Productive cough          | 1  | 0  | 1   |
| Pulmonary embolism        | 33 | 1  | 34  |
| Pulmonary hypertension    | 1  | 0  | 1   |
| Pulmonary microemboli     | 1  | 0  | 1   |
| Pulmonary oedema          | 2  | 0  | 2   |
| Pulmonary pain            | 1  | 2  | 3   |
| Pulmonary thrombosis      | 1  | 0  | 1   |
| Rales                     | 1  | 0  | 1   |
| Respiration abnormal      | 1  | 0  | 1   |
| Respiratory depression    | 1  | 0  | 1   |
| Respiratory disorder      | 95 | 14 | 109 |
| Respiratory distress      | 3  | 0  | 3   |
| Respiratory failure       | 1  | 0  | 1   |
| Rhinorrhoea               | 3  | 3  | 6   |
| Sneezing                  | 1  | 0  | 1   |
| Snoring                   | 1  | 0  | 1   |
| Stridor                   | 1  | 0  | 1   |
| Tachypnoea                | 1  | 0  | 1   |
| Throat irritation         | 1  | 1  | 2   |
| Tonsillar erythema        | 0  | 1  | 1   |
| Tonsillar hypertrophy     | 1  | 0  | 1   |
| Tracheal pain             | 0  | 1  | 1   |
| Wheezing                  | 2  | 0  | 2   |
| Angioedema                | 4  | 2  | 6   |
| Blister                   | 2  | 0  | 2   |
| Cold sweat                | 3  | 1  | 4   |
| Dermatitis allergic       | 1  | 0  | 1   |
| Ecchymosis                | 2  | 0  | 2   |
| Eczema                    | 1  | 1  | 2   |
| Erythema                  | 15 | 5  | 20  |
| Erythema multiforme       | 0  | 1  | 1   |
| Hyperhidrosis             | 74 | 4  | 78  |
| Macule                    | 0  | 1  | 1   |
| Miliaria                  | 2  | 0  | 2   |
| Night sweats              | 1  | 2  | 3   |
| Pain of skin              | 10 | 0  | 10  |
| Pemphigoid                | 1  | 0  | 1   |
| Petechiae                 | 7  | 4  | 11  |
| Photosensitivity reaction | 3  | 0  | 3   |
| Pruritus                  | 14 | 4  | 18  |
| Pseudofolliculitis        | 0  | 1  | 1   |
| Psoriasis                 | 1  | 0  | 1   |
| Purpura                   | 1  | 1  | 2   |
| Rash                      | 5  | 2  | 7   |
| Rash erythematous         | 4  | 1  | 5   |
| Rash macular              | 2  | 1  | 3   |

Skin and subcutaneous tissue disorders

|                                 |                                 |    |    |     |
|---------------------------------|---------------------------------|----|----|-----|
|                                 | Rash papular                    | 0  | 1  | 1   |
|                                 | Rash pruritic                   | 1  | 1  | 2   |
|                                 | Sensitive skin                  | 3  | 0  | 3   |
|                                 | Skin discolouration             | 1  | 2  | 3   |
|                                 | Skin disorder                   | 76 | 34 | 110 |
|                                 | Skin lesion                     | 0  | 1  | 1   |
|                                 | Skin lesion inflammation        | 1  | 0  | 1   |
|                                 | Skin mass                       | 1  | 0  | 1   |
|                                 | Skin odour abnormal             | 1  | 0  | 1   |
|                                 | Skin reaction                   | 0  | 1  | 1   |
|                                 | Urticaria                       | 7  | 4  | 11  |
| Social circumstances            | Bedridden                       | 0  | 1  | 1   |
|                                 | Disability                      | 0  | 1  | 1   |
|                                 | Impaired work ability           | 1  | 1  | 2   |
|                                 | Sitting disability              | 1  | 0  | 1   |
|                                 | Walking disability              | 1  | 0  | 1   |
| Surgical and medical procedures | Bed rest                        | 1  | 0  | 1   |
|                                 | Chemotherapy                    | 1  | 0  | 1   |
|                                 | Dialysis                        | 1  | 0  | 1   |
|                                 | Explorative laparotomy          | 1  | 0  | 1   |
|                                 | Eye laser surgery               | 1  | 0  | 1   |
|                                 | Hospitalisation                 | 1  | 1  | 2   |
|                                 | Interchange of vaccine products | 1  | 1  | 2   |
|                                 | Thrombectomy                    | 1  | 0  | 1   |
|                                 | Thromboembolectomy              | 1  | 0  | 1   |
| Vascular disorders              | Arteriosclerosis                | 0  | 1  | 1   |
|                                 | Axillary vein thrombosis        | 1  | 0  | 1   |
|                                 | Blood pressure fluctuation      | 1  | 0  | 1   |
|                                 | Bloody discharge                | 1  | 0  | 1   |
|                                 | Capillary leak syndrome         | 1  | 0  | 1   |
|                                 | Cyanosis                        | 2  | 3  | 5   |
|                                 | Deep vein thrombosis            | 19 | 7  | 26  |
|                                 | Flushing                        | 1  | 0  | 1   |
|                                 | Giant cell arteritis            | 1  | 0  | 1   |
|                                 | Haematoma                       | 6  | 7  | 13  |
|                                 | Haemodynamic instability        | 1  | 0  | 1   |
|                                 | Haemorrhage                     | 1  | 2  | 3   |
|                                 | Hot flush                       | 13 | 1  | 14  |
|                                 | Hypertension                    | 31 | 5  | 36  |
|                                 | Hypertensive crisis             | 2  | 0  | 2   |
|                                 | Hypotension                     | 21 | 5  | 26  |
|                                 | Hypovolaemic shock              | 2  | 0  | 2   |
|                                 | Infarction                      | 1  | 0  | 1   |
|                                 | Ischaemia                       | 1  | 0  | 1   |
|                                 | Jugular vein thrombosis         | 4  | 0  | 4   |
|                                 | Lymphoedema                     | 1  | 0  | 1   |
|                                 | Pallor                          | 1  | 0  | 1   |
|                                 | Pelvic venous thrombosis        | 0  | 1  | 1   |
|                                 | Peripheral coldness             | 5  | 2  | 7   |
|                                 | Peripheral ischaemia            | 1  | 0  | 1   |

|                              |              |             |               |
|------------------------------|--------------|-------------|---------------|
| Peripheral vascular disorder | 1            | 0           | 1             |
| Peripheral venous disease    | 1            | 1           | 2             |
| Periphlebitis                | 0            | 1           | 1             |
| Phlebitis                    | 2            | 4           | 6             |
| Phlebitis superficial        | 0            | 1           | 1             |
| Subclavian artery thrombosis | 1            | 0           | 1             |
| Subclavian vein thrombosis   | 1            | 0           | 1             |
| Thrombophlebitis             | 2            | 0           | 2             |
| Thrombophlebitis superficial | 5            | 5           | 10            |
| Thrombosis                   | 20           | 5           | 25            |
| Varicose vein                | 1            | 2           | 3             |
| Vascular pain                | 1            | 1           | 2             |
| Vascular rupture             | 1            | 0           | 1             |
| Vasculitis                   | 1            | 0           | 1             |
| Vasodilatation               | 2            | 1           | 3             |
| Vein disorder                | 1            | 0           | 1             |
| Vein rupture                 | 1            | 1           | 2             |
| Venous aneurysm              | 0            | 1           | 1             |
| Venous occlusion             | 0            | 1           | 1             |
| Venous thrombosis            | 3            | 1           | 4             |
| Venous thrombosis limb       | 1            | 1           | 2             |
| <b>Total</b>                 | <b>13558</b> | <b>1710</b> | <b>15 268</b> |