

**AdverseEventsDistribution\_AE001.sas: Adverse Event Distribution Validation Program**  
**Use BodySystem or Organ Class, Actual, All event, single event counts**  
**Adverse Events Distribution Counts Table**

| <b>Body System or Organ Class</b>    | <b>Dictionary-Derived Term</b>               | <b>NIC 15</b>  | <b>Placebo</b> | <b>Total</b>   |
|--------------------------------------|--|----------------|----------------|----------------|
| BLOOD AND LYMPHATIC SYSTEM DISORDERS | Anaemia                                      | 145<br>(32.4%) | 167<br>(36.7%) | 312<br>(34.6%) |
|                                      | Coagulopathy                                 | 14 (3.1%)      | 16 (3.5%)      | 30 (3.3%)      |
|                                      | Haemolysis                                   |                | 1 (0.2%)       | 1 (0.1%)       |
|                                      | Leukocytosis                                 | 16 (3.6%)      | 12 (2.6%)      | 28 (3.1%)      |
|                                      | Lymphadenopathy                              | 1 (0.2%)       |                | 1 (0.1%)       |
|                                      | Platelet destruction increased               | 29 (6.5%)      | 16 (3.5%)      | 45 (5%)        |
|                                      | Thrombocythaemia                             | 3 (0.7%)       | 3 (0.7%)       | 6 (0.7%)       |
|                                      |  |                |                |                |
| CARDIAC DISORDERS                    | Angina pectoris                              | 1 (0.2%)       |                | 1 (0.1%)       |
|                                      | Arrhythmia                                   |                | 1 (0.2%)       | 1 (0.1%)       |
|                                      | Atrial fibrillation                          | 18 (4%)        | 17 (3.7%)      | 35 (3.9%)      |
|                                      | Atrial flutter                               | 5 (1.1%)       | 1 (0.2%)       | 6 (0.7%)       |
|                                      | Atrioventricular block first degree          | 3 (0.7%)       | 3 (0.7%)       | 6 (0.7%)       |
|                                      | Atrioventricular block second degree         | 2 (0.4%)       |                | 2 (0.2%)       |
|                                      | Bradycardia                                  |                | 2 (0.4%)       | 2 (0.2%)       |
|                                      | Bundle branch block                          |                | 3 (0.7%)       | 3 (0.3%)       |
|                                      | Cardiac arrest                               | 7 (1.6%)       | 7 (1.5%)       | 14 (1.6%)      |
|                                      | Cardiac asthma                               | 1 (0.2%)       |                | 1 (0.1%)       |
|                                      | Cardiac failure congestive                   | 24 (5.4%)      | 17 (3.7%)      | 41 (4.5%)      |
|                                      | Cardiomegaly                                 |                | 2 (0.4%)       | 2 (0.2%)       |
|                                      | Cardiovascular disorder                      | 2 (0.4%)       | 3 (0.7%)       | 5 (0.6%)       |
|                                      | Intracardiac thrombus                        |                | 1 (0.2%)       | 1 (0.1%)       |
|                                      | Myocardial infarction                        | 4 (0.9%)       | 4 (0.9%)       | 8 (0.9%)       |
|                                      | Myocardial ischaemia                         | 3 (0.7%)       | 2 (0.4%)       | 5 (0.6%)       |
|                                      | Palpitations                                 |                | 1 (0.2%)       | 1 (0.1%)       |
|                                      | Pericardial effusion                         | 1 (0.2%)       |                | 1 (0.1%)       |
|                                      | Sinus bradycardia                            | 20 (4.5%)      | 47 (10.3%)     | 67 (7.4%)      |
|                                      | Supraventricular extrasystoles               | 25 (5.6%)      | 22 (4.8%)      | 47 (5.2%)      |
|                                      | Supraventricular tachycardia                 | 10 (2.2%)      | 7 (1.5%)       | 17 (1.9%)      |
|                                      | Ventricular arrhythmia                       |                | 1 (0.2%)       | 1 (0.1%)       |
| Ventricular extrasystoles            | 42 (9.4%)                                    | 43 (9.5%)      | 85 (9.4%)      |                |
| Ventricular fibrillation             | 2 (0.4%)                                     | 1 (0.2%)       | 3 (0.3%)       |                |
| Ventricular tachycardia              | 3 (0.7%)                                     | 3 (0.7%)       | 6 (0.7%)       |                |
| Withdrawal arrhythmia                |  | 1 (0.2%)       | 1 (0.1%)       |                |
|                                      |  |                |                |                |
| EAR AND LABYRINTH DISORDERS          | Deafness                                     |                | 1 (0.2%)       | 1 (0.1%)       |
|                                      |  |                |                |                |
| ENDOCRINE DISORDERS                  | Diabetes insipidus                           | 13 (2.9%)      | 17 (3.7%)      | 30 (3.3%)      |
|                                      | Inappropriate antidiuretic hormone secretion | 8 (1.8%)       | 13 (2.9%)      | 21 (2.3%)      |
|                                      |  |                |                |                |
| EYE DISORDERS                        | Blindness                                    | 2 (0.4%)       | 2 (0.4%)       | 4 (0.4%)       |
|                                      | Conjunctival deposit                         | 2 (0.4%)       | 2 (0.4%)       | 4 (0.4%)       |
|                                      | Conjunctival haemorrhage                     |                | 1 (0.2%)       | 1 (0.1%)       |

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|---|--------------------------------|---------------|----------------|--------------|
|   | Diplopia                       |               | 1 (0.2%)       | 1 (0.1%)     |
|   | Extraocular muscle paresis     | 3 (0.7%)      | 3 (0.7%)       | 6 (0.7%)     |
|   | Eyelid ptosis                  | 1 (0.2%)      | 2 (0.4%)       | 3 (0.3%)     |
|   | Photophobia                    |               | 1 (0.2%)       | 1 (0.1%)     |
|   | Scotoma                        | 1 (0.2%)      |                | 1 (0.1%)     |
|   | Visual disturbance             | 1 (0.2%)      |                | 1 (0.1%)     |
| <b>GASTROINTESTINAL DISORDERS</b>                           |                                |               |                |              |
|   | Abdominal distension           | 1 (0.2%)      | 1 (0.2%)       | 2 (0.2%)     |
|   | Abdominal pain                 | 1 (0.2%)      |                | 1 (0.1%)     |
|   | Acute abdomen                  |               | 1 (0.2%)       | 1 (0.1%)     |
|   | Anorectal disorder             |               | 1 (0.2%)       | 1 (0.1%)     |
|   | Ascites                        | 1 (0.2%)      |                | 1 (0.1%)     |
|   | Constipation                   | 2 (0.4%)      | 1 (0.2%)       | 3 (0.3%)     |
|   | Diarrhoea                      | 6 (1.3%)      | 2 (0.4%)       | 8 (0.9%)     |
|   | Dyspepsia                      | 2 (0.4%)      |                | 2 (0.2%)     |
|   | Gastrointestinal haemorrhage   | 18 (4%)       | 10 (2.2%)      | 28 (3.1%)    |
|   | Gastrointestinal necrosis      | 1 (0.2%)      | 1 (0.2%)       | 2 (0.2%)     |
|   | Ileus paralytic                | 4 (0.9%)      | 9 (2%)         | 13 (1.4%)    |
|   | Intestinal obstruction         |               | 1 (0.2%)       | 1 (0.1%)     |
|   | Intestinal perforation         |               | 1 (0.2%)       | 1 (0.1%)     |
|   | Melaena                        |               | 1 (0.2%)       | 1 (0.1%)     |
|   | Nausea                         | 1 (0.2%)      |                | 1 (0.1%)     |
|   | Pancreatitis acute             |               | 1 (0.2%)       | 1 (0.1%)     |
|   | Peptic ulcer                   | 1 (0.2%)      |                | 1 (0.1%)     |
|   | Vomiting                       | 63 (14.1%)    | 64 (14.1%)     | 127 (14.1%)  |
| <b>GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS</b> |                                |               |                |              |
|   | Asthenia                       | 3 (0.7%)      | 1 (0.2%)       | 4 (0.4%)     |
|   | Chest pain                     | 7 (1.6%)      | 4 (0.9%)       | 11 (1.2%)    |
|   | Enanthema                      | 32 (7.2%)     | 31 (6.8%)      | 63 (7%)      |
|   | Infusion site haemorrhage      | 3 (0.7%)      | 6 (1.3%)       | 9 (1%)       |
|   | Oedema peripheral              | 94 (21%)      | 91 (20%)       | 185 (20.5%)  |
|   | Pyrexia                        | 117 (26.2%)   | 130 (28.6%)    | 247 (27.4%)  |
|   | Surgical failure               |               | 1 (0.2%)       | 1 (0.1%)     |
| <b>HEPATOBIILIARY DISORDERS</b>                             |                                |               |                |              |
|   | Hepatic function abnormal      | 126 (28.2%)   | 111 (24.4%)    | 237 (26.3%)  |
|   | Hepatitis                      | 2 (0.4%)      | 1 (0.2%)       | 3 (0.3%)     |
|   | Hepatomegaly                   | 1 (0.2%)      |                | 1 (0.1%)     |
|   | Hyperbilirubinaemia            |               | 1 (0.2%)       | 1 (0.1%)     |
|   | Jaundice                       |               | 1 (0.2%)       | 1 (0.1%)     |

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| IMMUNE SYSTEM DISORDERS                        | Type III immune complex mediated reaction    | 5 (1.1%)      | 3 (0.7%)       | 8 (0.9%)     |
| INFECTIONS AND INFESTATIONS                    | Cellulitis                                   |               | 4 (0.9%)       | 4 (0.4%)     |
|  | Ependymitis                                  | 1 (0.2%)      | 5 (1.1%)       | 6 (0.7%)     |
|  | Gangrene                                     | 1 (0.2%)      |                | 1 (0.1%)     |
|  | Infection                                    | 11 (2.5%)     | 18 (4%)        | 29 (3.2%)    |
|  | Injection site abscess                       | 2 (0.4%)      |                | 2 (0.2%)     |
|  | Meningitis                                   | 3 (0.7%)      | 10 (2.2%)      | 13 (1.4%)    |
|  | Nasopharyngitis                              | 2 (0.4%)      |                | 2 (0.2%)     |
|  | Oral candidiasis                             | 2 (0.4%)      |                | 2 (0.2%)     |
|  | Otitis media                                 | 1 (0.2%)      |                | 1 (0.1%)     |
|  | Pulmonary tuberculosis                       | 1 (0.2%)      |                | 1 (0.1%)     |
|  | Sepsis neonatal                              | 37 (8.3%)     | 33 (7.3%)      | 70 (7.8%)    |
|  | Sialoadenitis                                | 1 (0.2%)      | 1 (0.2%)       | 2 (0.2%)     |
|  | Sinusitis                                    | 2 (0.4%)      | 1 (0.2%)       | 3 (0.3%)     |
|  | Skin candida                                 |               | 1 (0.2%)       | 1 (0.1%)     |
|  | Tracheobronchitis                            |               | 1 (0.2%)       | 1 (0.1%)     |
|  | Urinary tract infection                      | 78 (17.4%)    | 74 (16.3%)     | 152 (16.9%)  |
|  | Vaginal infection                            | 2 (0.4%)      |                | 2 (0.2%)     |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | Extradural haematoma                         | 2 (0.4%)      | 1 (0.2%)       | 3 (0.3%)     |
|  | Overdose                                     | 5 (1.1%)      |                | 5 (0.6%)     |
|  | Subdural haematoma                           | 2 (0.4%)      | 2 (0.4%)       | 4 (0.4%)     |
| INVESTIGATIONS                                 | Blood amylase increased                      |               | 1 (0.2%)       | 1 (0.1%)     |
|  | Blood creatine phosphokinase increased       | 20 (4.5%)     | 24 (5.3%)      | 44 (4.9%)    |
|  | Blood lactate dehydrogenase increased        | 22 (4.9%)     | 21 (4.6%)      | 43 (4.8%)    |
|  | Coombs direct test positive                  | 1 (0.2%)      |                | 1 (0.1%)     |
|  | Electrocardiogram T wave amplitude decreased | 1 (0.2%)      |                | 1 (0.1%)     |
|  | Electrocardiogram T wave inversion           | 6 (1.3%)      | 1 (0.2%)       | 7 (0.8%)     |
|  | Heart rate increased                         | 58 (13%)      | 52 (11.4%)     | 110 (12.2%)  |
|  | Xanthochromia                                | 6 (1.3%)      | 4 (0.9%)       | 10 (1.1%)    |
| METABOLISM AND NUTRITION DISORDERS             | Acidosis                                     |               | 2 (0.4%)       | 2 (0.2%)     |
|  | Alkalosis                                    | 2 (0.4%)      | 1 (0.2%)       | 3 (0.3%)     |
|  | Hypercalcaemia                               | 1 (0.2%)      |                | 1 (0.1%)     |
|  | Hyperchloraemia                              | 3 (0.7%)      | 2 (0.4%)       | 5 (0.6%)     |
|  | Hyperglycaemia                               | 114 (25.5%)   | 96 (21.1%)     | 210 (23.3%)  |
|  | Hyperkalaemia                                | 6 (1.3%)      | 3 (0.7%)       | 9 (1%)       |

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|  | Hypernatraemia                  | 32 (7.2%)      | 20 (4.4%)      | 52 (5.8%)      |
|  | Hypervolaemia                   | 2 (0.4%)       | 1 (0.2%)       | 3 (0.3%)       |
|  | Hypocalcaemia                   | 3 (0.7%)       | 2 (0.4%)       | 5 (0.6%)       |
|  | Hypochloraemia                  | 4 (0.9%)       | 3 (0.7%)       | 7 (0.8%)       |
|  | Hypoglycaemia                   | 1 (0.2%)       | 1 (0.2%)       | 2 (0.2%)       |
|  | Hypokalaemia                    | 73<br>(16.3%)  | 73 (16%)       | 146<br>(16.2%) |
|  | Hypomagnesaemia                 |                | 1 (0.2%)       | 1 (0.1%)       |
|  | Hyponatraemia                   | 24 (5.4%)      | 40 (8.8%)      | 64 (7.1%)      |
|  | Hypophosphataemia               | 2 (0.4%)       | 3 (0.7%)       | 5 (0.6%)       |
|  | Hypovolaemia                    |                | 3 (0.7%)       | 3 (0.3%)       |
| <b>MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS</b>                     | Arthralgia                      |                | 1 (0.2%)       | 1 (0.1%)       |
|  | Back pain                       | 1 (0.2%)       | 1 (0.2%)       | 2 (0.2%)       |
|  | Joint stiffness                 | 1 (0.2%)       | 1 (0.2%)       | 2 (0.2%)       |
|  | Tenosynovitis                   | 1 (0.2%)       |                | 1 (0.1%)       |
| <b>NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)</b> | Cerebral hygroma                | 5 (1.1%)       | 5 (1.1%)       | 10 (1.1%)      |
| <b>NERVOUS SYSTEM DISORDERS</b>  | Agaphia                         | 3 (0.7%)       | 1 (0.2%)       | 4 (0.4%)       |
|  | Brain oedema                    | 80<br>(17.9%)  | 100 (22%)      | 180 (20%)      |
|  | Carotid artery thrombosis       |                | 1 (0.2%)       | 1 (0.1%)       |
|  | Cerebral haemorrhage            | 17 (3.8%)      | 28 (6.2%)      | 45 (5%)        |
|  | Cerebral hypoperfusion          | 2 (0.4%)       |                | 2 (0.2%)       |
|  | Cerebral infarction             | 45<br>(10.1%)  | 49 (10.8%)     | 94<br>(10.4%)  |
|  | Cerebral ischaemia              | 2 (0.4%)       | 1 (0.2%)       | 3 (0.3%)       |
|  | Clumsiness                      | 1 (0.2%)       | 2 (0.4%)       | 3 (0.3%)       |
|  | Coma                            | 14 (3.1%)      | 7 (1.5%)       | 21 (2.3%)      |
|  | Convulsion                      | 19 (4.3%)      | 19 (4.2%)      | 38 (4.2%)      |
|  | Dizziness exertional            | 7 (1.6%)       | 4 (0.9%)       | 11 (1.2%)      |
|  | Hemiparesis                     | 2 (0.4%)       | 3 (0.7%)       | 5 (0.6%)       |
|  | Hydrocephalus                   | 130<br>(29.1%) | 129<br>(28.4%) | 259<br>(28.7%) |
|  | Intention tremor                | 2 (0.4%)       |                | 2 (0.2%)       |
|  | Intracranial pressure increased | 126<br>(28.2%) | 149<br>(32.7%) | 275<br>(30.5%) |
|  | Lethargy                        | 6 (1.3%)       | 6 (1.3%)       | 12 (1.3%)      |
|  | Oculofacial paralysis           | 1 (0.2%)       | 3 (0.7%)       | 4 (0.4%)       |
|  | Paralysis                       |                | 1 (0.2%)       | 1 (0.1%)       |
|  | Pneumocephalus                  | 1 (0.2%)       | 2 (0.4%)       | 3 (0.3%)       |
|  | Sinus headache                  | 21 (4.7%)      | 24 (5.3%)      | 45 (5%)        |
|  | Stupor                          | 1 (0.2%)       | 3 (0.7%)       | 4 (0.4%)       |
|  | Subarachnoid haemorrhage        | 26 (5.8%)      | 35 (7.7%)      | 61 (6.8%)      |

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|  | Vocal cord paralysis    | 1 (0.2%)    |             | 1 (0.1%)    |
| <b>PSYCHIATRIC DISORDERS</b>                           | Agitation               | 10 (2.2%)   |             | 10 (1.1%)   |
|  | Delirium                | 7 (1.6%)    | 1 (0.2%)    | 8 (0.9%)    |
|  | Disorientation          | 8 (1.8%)    | 3 (0.7%)    | 11 (1.2%)   |
|  | Hallucination           | 2 (0.4%)    | 1 (0.2%)    | 3 (0.3%)    |
|  | Paranoia                | 3 (0.7%)    |             | 3 (0.3%)    |
|  | Personality disorder    | 1 (0.2%)    |             | 1 (0.1%)    |
|  | Psychotic disorder      | 1 (0.2%)    |             | 1 (0.1%)    |
| <b>RENAL AND URINARY DISORDERS</b>                     | Bladder pain            |             | 1 (0.2%)    | 1 (0.1%)    |
|  | Haematuria              | 1 (0.2%)    | 5 (1.1%)    | 6 (0.7%)    |
|  | Isosthenuria            | 72 (16.1%)  | 33 (7.3%)   | 105 (11.6%) |
|  | Oliguria                |             | 1 (0.2%)    | 1 (0.1%)    |
|  | Polyuria                | 2 (0.4%)    |             | 2 (0.2%)    |
|  | Proteinuria             |             | 1 (0.2%)    | 1 (0.1%)    |
|  | Urinary retention       | 1 (0.2%)    | 1 (0.2%)    | 2 (0.2%)    |
| <b>REPRODUCTIVE SYSTEM AND BREAST DISORDERS</b>        | Pruritus genital        | 1 (0.2%)    | 3 (0.7%)    | 4 (0.4%)    |
| <b>RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS</b> | Alveolitis              | 96 (21.5%)  | 102 (22.4%) | 198 (22%)   |
|  | Anoxia                  | 10 (2.2%)   | 2 (0.4%)    | 12 (1.3%)   |
|  | Apnoea                  | 3 (0.7%)    | 8 (1.8%)    | 11 (1.2%)   |
|  | Atelectasis             | 94 (21%)    | 72 (15.8%)  | 166 (18.4%) |
|  | Choking                 | 1 (0.2%)    |             | 1 (0.1%)    |
|  | Cough                   |             | 1 (0.2%)    | 1 (0.1%)    |
|  | Cyanosis neonatal       | 1 (0.2%)    | 2 (0.4%)    | 3 (0.3%)    |
|  | Dyspnoea                | 2 (0.4%)    |             | 2 (0.2%)    |
|  | Epistaxis               |             | 1 (0.2%)    | 1 (0.1%)    |
|  | Haemoptysis             | 1 (0.2%)    | 1 (0.2%)    | 2 (0.2%)    |
|  | Hydrothorax             |             | 1 (0.2%)    | 1 (0.1%)    |
|  | Hyperventilation        | 1 (0.2%)    | 1 (0.2%)    | 2 (0.2%)    |
|  | Hypoxia                 | 1 (0.2%)    | 1 (0.2%)    | 2 (0.2%)    |
|  | Laryngeal oedema        | 1 (0.2%)    | 1 (0.2%)    | 2 (0.2%)    |
|  | Lung disorder           |             | 1 (0.2%)    | 1 (0.1%)    |
|  | Pleural effusion        | 15 (3.4%)   | 4 (0.9%)    | 19 (2.1%)   |
|  | Pneumomediastinum       | 1 (0.2%)    |             | 1 (0.1%)    |
|  | Pneumothorax            | 10 (2.2%)   | 12 (2.6%)   | 22 (2.4%)   |
|  | Pulmonary embolism      | 4 (0.9%)    | 1 (0.2%)    | 5 (0.6%)    |
|  | Pulmonary oedema        | 132 (29.5%) | 104 (22.9%) | 236 (26.2%) |
|  | Respiratory disorder    | 28 (6.3%)   | 18 (4%)     | 46 (5.1%)   |
|  | Status asthmaticus      | 4 (0.9%)    | 4 (0.9%)    | 8 (0.9%)    |
| <b>SKIN AND SUBCUTANEOUS TISSUE DISORDERS</b>          | Ecchymosis              | 1 (0.2%)    |             | 1 (0.1%)    |
|  | Hyperhidrosis           |             | 1 (0.2%)    | 1 (0.1%)    |

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|                                   | Petechiae                      |               | 1 (0.2%)       | 1 (0.1%)     |
|                                   | Subcutaneous emphysema         | 5 (1.1%)      |                | 5 (0.6%)     |
|                                   | Urticaria vesiculosa           | 1 (0.2%)      | 1 (0.2%)       | 2 (0.2%)     |
| <b>VASCULAR DISORDERS</b>         |                                |               |                |              |
|                                   | Circulatory failure neonatal   |               | 1 (0.2%)       | 1 (0.1%)     |
|                                   | Embolism                       |               | 1 (0.2%)       | 1 (0.1%)     |
|                                   | Haemorrhage                    | 1 (0.2%)      | 2 (0.4%)       | 3 (0.3%)     |
|                                   | Hypertension                   | 91 (20.4%)    | 163 (35.8%)    | 254 (28.2%)  |
|                                   | Hypotension                    | 155 (34.7%)   | 80 (17.6%)     | 235 (26.1%)  |
|                                   | Peripheral vascular disorder   |               | 1 (0.2%)       | 1 (0.1%)     |
|                                   | Phlebitis                      | 99 (22.1%)    | 23 (5.1%)      | 122 (13.5%)  |
|                                   | Thrombophlebitis               | 10 (2.2%)     | 8 (1.8%)       | 18 (2%)      |
|                                   | Vascular occlusion             |               | 2 (0.4%)       | 2 (0.2%)     |
|                                   | Vasoconstriction               | 246 (55%)     | 314 (69%)      | 560 (62.1%)  |
|                                   | Vasodilatation                 | 6 (1.3%)      | 6 (1.3%)       | 12 (1.3%)    |