

AdverseEventsDistribution_AE002.sas: Adverse Event Distribution Validation Program - Incidence Rates
Use BodySystem or Organ Class, Actual, All event, count multiple occurrences, incidence rates, patient
years of exposure, multiplier 100, date variables
Adverse Events Distribution Incidence Rates Table

| | | NIC.15 (PY=13.120708799) | | Placebo (PY=13.985683322) | | |
|--------------------------------------|--|-----------------------------|----------|------------------------------|----------|-------|
| Body System or Organ Class | Dictionary-Derived Term | Count | IR/100PY | Count | IR/100PY | Total |
| BLOOD AND LYMPHATIC SYSTEM DISORDERS | Anaemia | 98 | 746.9 | 122 | 872.3 | 220 |
| | Coagulopathy | 9 | 68.6 | 8 | 57.2 | 17 |
| | Haemolysis | | | 1 | 7.2 | 1 |
| | Leukocytosis | 12 | 91.5 | 6 | 42.9 | 18 |
| | Lymphadenopathy | 1 | 7.6 | | | 1 |
| | Platelet destruction increased | 25 | 190.5 | 13 | 93.0 | 38 |
| | Thrombocythaemia | 3 | 22.9 | 2 | 14.3 | 5 |
| | | | | | | |
| CARDIAC DISORDERS | Angina pectoris | 1 | 7.6 | | | 1 |
| | Atrial fibrillation | 11 | 83.8 | 9 | 64.4 | 20 |
| | Atrial flutter | 4 | 30.5 | 1 | 7.2 | 5 |
| | Atrioventricular block first degree | 1 | 7.6 | 1 | 7.2 | 2 |
| | Atrioventricular block second degree | 1 | 7.6 | | | 1 |
| | Bundle branch block | | | 1 | 7.2 | 1 |
| | Cardiac arrest | 6 | 45.7 | 4 | 28.6 | 10 |
| | Cardiac asthma | 1 | 7.6 | | | 1 |
| | Cardiac failure congestive | 22 | 167.7 | 11 | 78.7 | 33 |
| | Cardiomegaly | | | 2 | 14.3 | 2 |
| | Cardiovascular disorder | 2 | 15.2 | 3 | 21.5 | 5 |
| | Intracardiac thrombus | | | 1 | 7.2 | 1 |
| | Myocardial infarction | 4 | 30.5 | 2 | 14.3 | 6 |
| | Myocardial ischaemia | | | 1 | 7.2 | 1 |
| | Palpitations | | | 1 | 7.2 | 1 |
| | Sinus bradycardia | 5 | 38.1 | 15 | 107.3 | 20 |
| | Supraventricular extrasystoles | 16 | 121.9 | 13 | 93.0 | 29 |
| | Supraventricular tachycardia | 10 | 76.2 | 3 | 21.5 | 13 |
| | Ventricular extrasystoles | 17 | 129.6 | 28 | 200.2 | 45 |
| | Ventricular fibrillation | 1 | 7.6 | 1 | 7.2 | 2 |
| | Ventricular tachycardia | 3 | 22.9 | 1 | 7.2 | 4 |
| | Withdrawal arrhythmia | | | 1 | 7.2 | 1 |
| | | | | | | |
| EAR AND LABYRINTH DISORDERS | Deafness | | | 1 | 7.2 | 1 |
| | | | | | | |
| ENDOCRINE DISORDERS | Diabetes insipidus | 9 | 68.6 | 13 | 93.0 | 22 |
| | Inappropriate antidiuretic hormone secretion | 6 | 45.7 | 12 | 85.8 | 18 |
| | | | | | | |
| EYE DISORDERS | Blindness | 1 | 7.6 | 2 | 14.3 | 3 |
| | Conjunctival deposit | 2 | 15.2 | 1 | 7.2 | 3 |
| | Conjunctival haemorrhage | | | 1 | 7.2 | 1 |

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|---|--|-----------------------------|----------|------------------------------|----------|-------|
| Body System or Organ Class | Dictionary-Derived Term | Count | IR/100PY | Count | IR/100PY | Total |
| | Extraocular muscle paresis | 2 | 15.2 | 3 | 21.5 | 5 |
| | Eyelid ptosis | | | 2 | 14.3 | 2 |
| | Photophobia | | | 1 | 7.2 | 1 |
| | Visual disturbance | 1 | 7.6 | | | 1 |
| | | | | | | |
| GASTROINTESTINAL DISORDERS | Abdominal distension | 1 | 7.6 | 1 | 7.2 | 2 |
| | Abdominal pain | 1 | 7.6 | | | 1 |
| | Acute abdomen | | | 1 | 7.2 | 1 |
| | Ascites | 1 | 7.6 | | | 1 |
| | Constipation | 2 | 15.2 | 2 | 14.3 | 4 |
| | Diarrhoea | 5 | 38.1 | 2 | 14.3 | 7 |
| | Dyspepsia | 2 | 15.2 | | | 2 |
| | Gastrointestinal haemorrhage | 14 | 106.7 | 3 | 21.5 | 17 |
| | Gastrointestinal necrosis | 1 | 7.6 | 1 | 7.2 | 2 |
| | Ileus paralytic | 3 | 22.9 | 9 | 64.4 | 12 |
| | Intestinal obstruction | | | 1 | 7.2 | 1 |
| | Intestinal perforation | | | 1 | 7.2 | 1 |
| | Pancreatitis acute | | | 1 | 7.2 | 1 |
| | Vomiting | 40 | 304.9 | 49 | 350.4 | 89 |
| | | | | | | |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | Asthenia | 2 | 15.2 | | | 2 |
| | Chest pain | 6 | 45.7 | 4 | 28.6 | 10 |
| | Enanthema | 27 | 205.8 | 25 | 178.8 | 52 |
| | Infusion site haemorrhage | 1 | 7.6 | 6 | 42.9 | 7 |
| | Oedema peripheral | 60 | 457.3 | 65 | 464.8 | 125 |
| | Pyrexia | 72 | 548.8 | 85 | 607.8 | 157 |
| | Surgical failure | | | 1 | 7.2 | 1 |
| | | | | | | |
| HEPATOBIILIARY DISORDERS | Hepatic function abnormal | 103 | 785.0 | 82 | 586.3 | 185 |
| | Hepatitis | 3 | 22.9 | 1 | 7.2 | 4 |
| | Hepatomegaly | 1 | 7.6 | | | 1 |
| | Hyperbilirubinaemia | | | 1 | 7.2 | 1 |
| | Jaundice | | | 1 | 7.2 | 1 |
| | | | | | | |
| IMMUNE SYSTEM DISORDERS | Type III immune complex mediated reaction | 4 | 30.5 | 4 | 28.6 | 8 |
| | | | | | | |
| INFECTIONS AND INFESTATIONS | Cellulitis | | | 3 | 21.5 | 3 |
| | Ependymitis | | | 4 | 28.6 | 4 |
| | Infection | 10 | 76.2 | 17 | 121.6 | 27 |
| | Injection site abscess | 2 | 15.2 | | | 2 |
| | Meningitis | 3 | 22.9 | 10 | 71.5 | 13 |

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| Body System or Organ Class | Dictionary-Derived Term | NIC.15 (PY=13.120708799) | | Placebo (PY=13.985683322) | | Total |
|--|--|-----------------------------|----------|------------------------------|----------|-------|
| | | Count | IR/100PY | Count | IR/100PY | |
| | Oral candidiasis | 2 | 15.2 | | | 2 |
| | Otitis media | 1 | 7.6 | | | 1 |
| | Pulmonary tuberculosis | 1 | 7.6 | | | 1 |
| | Sepsis neonatal | 31 | 236.3 | 27 | 193.1 | 58 |
| | Sialoadenitis | 1 | 7.6 | 1 | 7.2 | 2 |
| | Sinusitis | 2 | 15.2 | 1 | 7.2 | 3 |
| | Skin candida | | | 1 | 7.2 | 1 |
| | Tracheobronchitis | | | 1 | 7.2 | 1 |
| | Urinary tract infection | 60 | 457.3 | 67 | 479.1 | 127 |
| | Vaginal infection | 2 | 15.2 | | | 2 |
| | | | | | | |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | Extradural haematoma | 2 | 15.2 | 1 | 7.2 | 3 |
| | Overdose | 4 | 30.5 | | | 4 |
| | Subdural haematoma | 2 | 15.2 | 2 | 14.3 | 4 |
| | | | | | | |
| INVESTIGATIONS | Blood amylase increased | | | 1 | 7.2 | 1 |
| | Blood creatine phosphokinase increased | 9 | 68.6 | 6 | 42.9 | 15 |
| | Blood lactate dehydrogenase increased | 15 | 114.3 | 11 | 78.7 | 26 |
| | Coombs direct test positive | 1 | 7.6 | | | 1 |
| | Electrocardiogram T wave amplitude decreased | 1 | 7.6 | | | 1 |
| | Electrocardiogram T wave inversion | 3 | 22.9 | 1 | 7.2 | 4 |
| | Heart rate increased | 29 | 221.0 | 36 | 257.4 | 65 |
| | Xanthochromia | 6 | 45.7 | 4 | 28.6 | 10 |
| | | | | | | |
| METABOLISM AND NUTRITION DISORDERS | Acidosis | | | 1 | 7.2 | 1 |
| | Alkalosis | 2 | 15.2 | 1 | 7.2 | 3 |
| | Hyperchloraemia | 2 | 15.2 | 2 | 14.3 | 4 |
| | Hyperglycaemia | 53 | 403.9 | 45 | 321.8 | 98 |
| | Hyperkalaemia | 4 | 30.5 | 2 | 14.3 | 6 |
| | Hypernatraemia | 27 | 205.8 | 17 | 121.6 | 44 |
| | Hypervolaemia | 2 | 15.2 | 1 | 7.2 | 3 |
| | Hypocalcaemia | 1 | 7.6 | 1 | 7.2 | 2 |
| | Hypochloraemia | 1 | 7.6 | 1 | 7.2 | 2 |
| | Hypoglycaemia | 1 | 7.6 | 1 | 7.2 | 2 |
| | Hypokalaemia | 39 | 297.2 | 41 | 293.2 | 80 |
| | Hypomagnesaemia | | | 1 | 7.2 | 1 |
| | Hyponatraemia | 16 | 121.9 | 36 | 257.4 | 52 |
| | Hypophosphataemia | | | 1 | 7.2 | 1 |

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| | Hypovolaemia | | | 1 | 7.2 | 1 |
| | | | | | | |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | Arthralgia | | | 1 | 7.2 | 1 |
| | Back pain | 1 | 7.6 | | | 1 |
| | Joint stiffness | 1 | 7.6 | | | 1 |
| | | | | | | |
| NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) | Cerebral hygroma | 5 | 38.1 | 5 | 35.8 | 10 |
| | | | | | | |
| NERVOUS SYSTEM DISORDERS | Agraphia | 2 | 15.2 | | | 2 |
| | Brain oedema | 38 | 289.6 | 64 | 457.6 | 102 |
| | Carotid artery thrombosis | | | 1 | 7.2 | 1 |
| | Cerebral haemorrhage | 6 | 45.7 | 11 | 78.7 | 17 |
| | Cerebral hypoperfusion | 1 | 7.6 | | | 1 |
| | Cerebral infarction | 32 | 243.9 | 39 | 278.9 | 71 |
| | Cerebral ischaemia | 1 | 7.6 | 1 | 7.2 | 2 |
| | Clumsiness | 1 | 7.6 | 1 | 7.2 | 2 |
| | Coma | 6 | 45.7 | 5 | 35.8 | 11 |
| | Convulsion | 12 | 91.5 | 12 | 85.8 | 24 |
| | Dizziness exertional | 9 | 68.6 | 2 | 14.3 | 11 |
| | Hemiparesis | | | 2 | 14.3 | 2 |
| | Hydrocephalus | 31 | 236.3 | 46 | 328.9 | 77 |
| | Intention tremor | 2 | 15.2 | | | 2 |
| | Intracranial pressure increased | 57 | 434.4 | 106 | 757.9 | 163 |
| | Lethargy | 5 | 38.1 | 4 | 28.6 | 9 |
| | Oculofacial paralysis | 1 | 7.6 | 1 | 7.2 | 2 |
| | Pneumocephalus | | | 1 | 7.2 | 1 |
| | Sinus headache | 11 | 83.8 | 13 | 93.0 | 24 |
| | Stupor | | | 2 | 14.3 | 2 |
| | Subarachnoid haemorrhage | 15 | 114.3 | 25 | 178.8 | 40 |
| | Vocal cord paralysis | 1 | 7.6 | | | 1 |
| | | | | | | |
| PSYCHIATRIC DISORDERS | Agitation | 9 | 68.6 | | | 9 |
| | Delirium | 6 | 45.7 | | | 6 |
| | Disorientation | 6 | 45.7 | 3 | 21.5 | 9 |
| | Hallucination | 2 | 15.2 | 1 | 7.2 | 3 |
| | Paranoia | 3 | 22.9 | | | 3 |
| | Personality disorder | 1 | 7.6 | | | 1 |
| | Psychotic disorder | 1 | 7.6 | | | 1 |

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| RENAL AND URINARY DISORDERS | Bladder pain | | | 1 | 7.2 | 1 |
| | Haematuria | 1 | 7.6 | 5 | 35.8 | 6 |
| | Isosthenuria | 66 | 503.0 | 26 | 185.9 | 92 |
| | Oliguria | | | 1 | 7.2 | 1 |
| | Polyuria | 1 | 7.6 | | | 1 |
| | Proteinuria | | | 1 | 7.2 | 1 |
| | Urinary retention | 1 | 7.6 | 1 | 7.2 | 2 |
| REPRODUCTIVE SYSTEM AND BREAST DISORDERS | Pruritus genital | 1 | 7.6 | 3 | 21.5 | 4 |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | Alveolitis | 70 | 533.5 | 80 | 572.0 | 150 |
| | Anoxia | 9 | 68.6 | 2 | 14.3 | 11 |
| | Apnoea | 2 | 15.2 | 5 | 35.8 | 7 |
| | Atelectasis | 63 | 480.2 | 47 | 336.1 | 110 |
| | Choking | 1 | 7.6 | | | 1 |
| | Cough | | | 1 | 7.2 | 1 |
| | Cyanosis neonatal | 1 | 7.6 | 1 | 7.2 | 2 |
| | Dyspnoea | 2 | 15.2 | | | 2 |
| | Epistaxis | | | 1 | 7.2 | 1 |
| | Haemoptysis | 1 | 7.6 | | | 1 |
| | Hydrothorax | | | 1 | 7.2 | 1 |
| | Hyperventilation | 1 | 7.6 | 1 | 7.2 | 2 |
| | Hypoxia | | | 1 | 7.2 | 1 |
| | Laryngeal oedema | 1 | 7.6 | 1 | 7.2 | 2 |
| | Pleural effusion | 15 | 114.3 | 2 | 14.3 | 17 |
| | Pneumomediastinum | 1 | 7.6 | | | 1 |
| | Pneumothorax | 9 | 68.6 | 7 | 50.1 | 16 |
| | Pulmonary embolism | 4 | 30.5 | 1 | 7.2 | 5 |
| | Pulmonary oedema | 102 | 777.4 | 78 | 557.7 | 180 |
| | Respiratory disorder | 23 | 175.3 | 12 | 85.8 | 35 |
| | Status asthmaticus | 2 | 15.2 | | | 2 |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | Ecchymosis | 1 | 7.6 | | | 1 |
| | Hyperhidrosis | | | 1 | 7.2 | 1 |
| | Petechiae | | | 1 | 7.2 | 1 |
| | Subcutaneous emphysema | 5 | 38.1 | | | 5 |
| | Urticaria vesiculosa | 1 | 7.6 | 1 | 7.2 | 2 |

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| VASCULAR DISORDERS | Circulatory failure neonatal | | | 1 | 7.2 | 1 |
| | Embolism | | | 1 | 7.2 | 1 |
| | Haemorrhage | 1 | 7.6 | 2 | 14.3 | 3 |
| | Hypertension | 36 | 274.4 | 80 | 572.0 | 116 |
| | Hypotension | 136 | 1036.5 | 69 | 493.4 | 205 |
| | Phlebitis | 124 | 945.1 | 25 | 178.8 | 149 |
| | Thrombophlebitis | 8 | 61.0 | 7 | 50.1 | 15 |
| | Vascular occlusion | | | 2 | 14.3 | 2 |
| | Vasoconstriction | 174 | 1326.1 | 288 | 2059.2 | 462 |
| | Vasodilatation | 5 | 38.1 | 5 | 35.8 | 10 |
| | | | | | | |