

AdverseEventsDistribution_AE001.sas: Adverse Event Distribution Validation Program
Use BodySystem or Organ Class, Actual, All event, single event counts
Adverse Events Distribution Counts Table

Body System or Organ Class	Dictionary-Derived Term	NIC 15	Placebo	Total
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia	145 (32.4%)	167 (36.7%)	312 (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%)
GASTROINTESTINAL DISORDERS	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%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	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%)
HEPATOBIILIARY DISORDERS	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 (16.3%)	73 (16%)	146 (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%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	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%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	Cerebral hygroma	5 (1.1%)	5 (1.1%)	10 (1.1%)
NERVOUS SYSTEM DISORDERS	Agaphia	3 (0.7%)	1 (0.2%)	4 (0.4%)
	Brain oedema	80 (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 (10.1%)	49 (10.8%)	94 (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 (29.1%)	129 (28.4%)	259 (28.7%)
	Intention tremor	2 (0.4%)		2 (0.2%)
	Intracranial pressure increased	126 (28.2%)	149 (32.7%)	275 (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%)
PSYCHIATRIC DISORDERS	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%)
RENAL AND URINARY DISORDERS	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%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	Pruritus genital	1 (0.2%)	3 (0.7%)	4 (0.4%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	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%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	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%)
VASCULAR DISORDERS	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%)