

System Organ Class Preferred Term	Immune reaction-related			Infection-related			Infusion-related			Others		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Abdominal Pain Upper	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	6	(1.47)	7
Aphthous Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Constipation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	4
Diarrhoea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(1.71)	7
Dry Mouth	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Dyspepsia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	8	(1.96)	9
Dysphagia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Gastric Mucosal Lesion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Gastric Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Gastritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3
Gastrointestinal Disorder	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Gastrooesophageal Reflux Disease	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Mouth Ulceration	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nausea	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	10	(2.44)	10
Proctalgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Regurgitation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	3
Stomatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Vomiting	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	3	(0.73)	3
General Disorders and Administration Site Conditions	1	(0.24)	1	0	(0.00)	0	3	(0.73)	5	17	(4.16)	19

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	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Asthenia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Chest Discomfort	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Chest Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Chills	0	(0.00)	0	0	(0.00)	0	1	(0.24)	3	3	(0.73)	3
Drug Effect Delayed	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Face Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Fatigue	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Generalised Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3
Oedema Peripheral	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	3	(0.73)	3
Pyrexia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3
Hepatobiliary Disorders	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	3	(0.73)	3
Cholelithiasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Hepatitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1
Liver Disorder	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Immune System Disorders	2	(0.49)	2	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Anaphylactic Reaction	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypersensitivity	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Infections and Infestations	1	(0.24)	1	33	(8.07)	35	0	(0.00)	0	32	(7.82)	36

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	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Abscess	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Arthritis Bacterial	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Body Tinea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Bronchitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	9	(2.20)	9
Candida Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2
Cystitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1
Disseminated Tuberculosis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1
Folliculitis	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Herpes Simplex	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	1	(0.24)	1
Herpes Zoster	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	1	(0.24)	1
Influenza	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Nasopharyngitis	0	(0.00)	0	8	(1.96)	8	0	(0.00)	0	2	(0.49)	2
Otitis Externa	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2
Pneumonia	0	(0.00)	0	1	(0.24)	2	0	(0.00)	0	4	(0.98)	4
Pneumonia Bacterial	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pyelonephritis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pyelonephritis Acute	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	2	(0.49)	2
Rhinitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Sepsis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

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	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Sinusitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Tinea Pedis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Tuberculosis Gastrointestinal	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Upper Respiratory Tract Infection	1	(0.24)	1	6	(1.47)	6	0	(0.00)	0	5	(1.22)	5
Ureteritis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Urinary Tract Infection	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1
Vaginal Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Injury, Poisoning and Procedural Complications	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	8	(1.96)	10
Ankle Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Contusion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Fall	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Foot Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Joint Dislocation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Laceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Perineal Injury	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Road Traffic Accident	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Investigations	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	20	(4.89)	22
Alanine Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(1.22)	5

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Aspartate Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Hepatic Enzyme Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Influenza B Virus Test Positive	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Liver Function Test Abnormal	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	3	(0.73)	4
Serum Ferritin Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Urine Analysis Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Weight Decreased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Weight Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4
Metabolism and Nutrition Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	15	(3.67)	16
Decreased Appetite	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Hypercholesterolaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Hyperglycaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Hyperlipidaemia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	8	(1.96)	8
Hypoglycaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4
Musculoskeletal and Connective Tissue Disorders	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	47	(11.49)	61
Arthralgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	15	(3.67)	16
Atlantoaxial Instability	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Back Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	5

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Bursal Fluid Accumulation	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Fibromyalgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Foot Deformity	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Intervertebral Disc Disorder	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Intervertebral Disc Protrusion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4
Joint Swelling	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4
Lumbar Spinal Stenosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4
Musculoskeletal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4
Myalgia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	4	(0.98)	5
Osteoarthritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Osteoporosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3
Polyarthritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Rheumatoid Arthritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4
Rotator Cuff Syndrome	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Spinal Column Stenosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Synovial Cyst	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Synovitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Tenosynovitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4

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Colon Adenoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Gastric Cancer	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Hypergammaglobulinaemia Benign Monoclonal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Invasive Ductal Breast Carcinoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Nervous System Disorders	1	(0.24)	1	1	(0.24)	1	1	(0.24)	2	34	(8.31)	43
Anosmia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Carotid Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Cerebellar Ataxia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Cerebral Infarction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Diabetic Neuropathy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Dizziness	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	10	(2.44)	10
Headache	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	7	(1.71)	8
Hypoaesthesia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	5	(1.22)	5
Migraine	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Neuropathy Peripheral	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Paraesthesia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	7	(1.71)	8
Subarachnoid Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Tension Headache	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Tremor	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3

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Psychiatric Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4
Insomnia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3
Tic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Reproductive System and Breast Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3
Breast Mass	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Erectile Dysfunction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Menorrhagia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Respiratory, Thoracic and Mediastinal Disorders	1	(0.24)	1	5	(1.22)	5	1	(0.24)	1	15	(3.67)	16
Acute Respiratory Distress Syndrome	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Atelectasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Cough	1	(0.24)	1	3	(0.73)	3	0	(0.00)	0	5	(1.22)	6
Dysphonia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Dyspnoea Exertional	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Interstitial Lung Disease	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Oropharyngeal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Pleural Effusion	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Productive Cough	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Rhinitis Allergic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2

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Vocal Cord Polyp	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Skin and Subcutaneous Tissue Disorders	5	(1.22)	9	0	(0.00)	0	16	(3.91)	28	18	(4.40)	28
Alopecia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3
Dermatitis Acneiform	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Dermatitis Allergic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Dermatitis Contact	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4
Diabetic Foot	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Erythema	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Pruritus	2	(0.49)	2	0	(0.00)	0	7	(1.71)	12	6	(1.47)	8
Pruritus Generalised	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Pseudofolliculitis Barbae	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Rash	2	(0.49)	2	0	(0.00)	0	4	(0.98)	6	1	(0.24)	1
Rash Generalised	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Swelling Face	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3
Systemic Lupus Erythematosus Rash	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2
Urticaria	1	(0.24)	1	0	(0.00)	0	7	(1.71)	8	1	(0.24)	1
Surgical and Medical Procedures	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(1.22)	5

System Organ Class Preferred Term	Immune reaction-related			Infection-related			Infusion-related			Others		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Intervertebral Disc Operation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Joint Arthroplasty	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Removal of Internal Fixation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Spinal Decompression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Tooth Extraction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Vascular Disorders	0	(0.00)	0	0	(0.00)	0	2	(0.49)	3	7	(1.71)	7
Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Flushing	0	(0.00)	0	0	(0.00)	0	2	(0.49)	3	4	(0.98)	4
Hypotension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2

Table 134 Incidence status for classification of Adverse Events type (IBD (N=417))

System Organ Class Preferred Term	Immune reaction-related			Infection-related			Infusion-related			Others		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Total	27	(6.47)	37	21	(5.04)	29	16	(3.84)	18	109	(26.14)	162
Blood and Lymphatic System Disorders	3	(0.72)	3	1	(0.24)	1	0	(0.00)	0	7	(1.68)	7
Anaemia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Iron Deficiency Anaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Leukopenia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	4	(0.96)	4
Lymphadenitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Immune reaction-related			Infection-related			Infusion-related			Others		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Neutropenia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cardiac Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Palpitations	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Ear and Labyrinth Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Otorrhoea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Eye Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Vision Blurred	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Gastrointestinal Disorders	3	(0.72)	5	2	(0.48)	3	1	(0.24)	1	56	(13.43)	80
Abdominal Discomfort	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Abdominal Pain	1	(0.24)	1	2	(0.48)	2	0	(0.00)	0	17	(4.08)	25
Abdominal Pain Lower	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Abdominal Pain Upper	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Anal Fistula	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Aphthous Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Colitis Ulcerative	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Constipation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3
Crohn's Disease	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(1.20)	5
Diarrhoea	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	4	(0.96)	4
Dyspepsia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	4

System Organ Class Preferred Term	Immune reaction-related			Infection-related			Infusion-related			Others		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Enterocutaneous Fistula	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Epigastric Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Frequent Bowel Movements	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Gastrointestinal Inflammation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Haematochezia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(1.68)	7
Ileus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Intestinal Obstruction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Melaena	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Mouth Ulceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Nausea	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	4	(0.96)	6
Protein-Losing Gastroenteropathy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Small Intestinal Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Vomiting	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(1.20)	7
General Disorders and Administration Site Conditions	2	(0.48)	2	2	(0.48)	2	3	(0.72)	3	12	(2.88)	13
Application Site Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Chest Pain	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Disease Progression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Drug Ineffective	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1

System Organ Class Preferred Term	Immune reaction-related			Infection-related			Infusion-related			Others		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Immediate Post-Injection Reaction	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Large Intestinal Perforation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Non-Cardiac Chest Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Pyrexia	2	(0.48)	2	2	(0.48)	2	1	(0.24)	1	3	(0.72)	4
Hepatobiliary Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3
Hepatic Function Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Hepatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Hyperbilirubinaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Immune System Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anaphylactic Reaction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Infections and Infestations	9	(2.16)	9	18	(4.32)	22	0	(0.00)	0	13	(3.12)	13
Abdominal Abscess	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Anal Abscess	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3
Atypical Pneumonia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Clostridium Difficile Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Cystitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Cytomegalovirus Colitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Infection	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1

System Organ Class Preferred Term	Immune reaction-related			Infection-related			Infusion-related			Others		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Disseminated Tuberculosis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Folliculitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Herpes Virus Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Herpes Zoster	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Lung Abscess	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	5	(1.20)	5
Oral Candidiasis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pneumocystis Jirovecii Pneumonia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pneumonia	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Pseudomembranous Colitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Rhinitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Sepsis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Sialoadenitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Spleen Tuberculosis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tuberculosis	1	(0.24)	1	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Upper Respiratory Tract Infection	4	(0.96)	4	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0
Urinary Tract Infection	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3	1	(0.24)	1

System Organ Class Preferred Term	Immune reaction-related			Infection-related			Infusion-related			Others		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Foot Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Infusion Related Reaction	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0
Investigations	7	(1.68)	7	0	(0.00)	0	0	(0.00)	0	6	(1.44)	8
Alanine Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2
Aspartate Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Blood Alkaline Phosphatase Increase	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
C-Reactive Protein Increased	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Eosinophil Count Increased	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Liver Function Test Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Occult Blood	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
White Blood Cell Count Decreased	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Metabolism and Nutrition Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Decreased Appetite	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Musculoskeletal and Connective Tissue Disorders	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	4	(0.96)	4
Arthralgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Flank Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Musculoskeletal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2

System Organ Class Preferred Term	Immune reaction-related			Infection-related			Infusion-related			Others		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Musculoskeletal Stiffness	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Myalgia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nervous System Disorders	2	(0.48)	2	0	(0.00)	0	1	(0.24)	1	2	(0.48)	2
Dizziness	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	2	(0.48)	2
Hypoaesthesia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tremor	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Psychiatric Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2
Depression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Insomnia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Renal and Urinary Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Calculus Ureteric	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Respiratory, Thoracic and Mediastinal Disorders	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	7	(1.68)	8
Cough	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Dyspnoea	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	3	(0.72)	3
Epistaxis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Oropharyngeal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Respiratory Distress	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Skin and Subcutaneous Tissue Disorders	6	(1.44)	6	1	(0.24)	1	9	(2.16)	9	11	(2.64)	11

System Organ Class Preferred Term	Immune reaction-related			Infection-related			Infusion-related			Others		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Acne	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Dermatitis Acneiform	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Erythema Nodosum	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Pain of Skin	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Photosensitivity Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Pruritus	0	(0.00)	0	0	(0.00)	0	4	(0.96)	4	3	(0.72)	3
Rash	2	(0.48)	2	0	(0.00)	0	1	(0.24)	1	2	(0.48)	2
Seborrhoeic Dermatitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1
Skin Exfoliation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Skin Lesion	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Swelling Face	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Urticaria	1	(0.24)	1	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0
Surgical and Medical Procedures	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3
Ileostomy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Ileostomy Closure	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Vascular Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Deep Vein Thrombosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Renovascular Hypertension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1

B. Classification of Adverse Events by Severity

The severity of adverse events was categorized as ‘mild’, ‘moderate’ and ‘severe’; 770 events of “mild” in 31.25% (424/1357 subjects), 204 events of “moderate” in 10.46% (142/1357 subjects) and 32 events of “severe” in 1.69% (23/1357 subjects) (Table 136).

Classification of adverse events by severity for each indication is presented in Table 136, Table 137 and Table 138.

Table 135 Incidence status for classification of Adverse Events by severity (total (N=1357))

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Total	424	(31.25)	770	142	(10.46)	204	23	(1.69)	32
Blood and Lymphatic System Disorders	10	(0.74)	11	6	(0.44)	6	1	(0.07)	1
Anaemia	2	(0.15)	2	2	(0.15)	2	0	(0.00)	0
Iron Deficiency Anaemia	3	(0.22)	3	1	(0.07)	1	0	(0.00)	0
Leukopenia	3	(0.22)	3	2	(0.15)	2	0	(0.00)	0
Lymphadenitis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Lymphadenopathy	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Neutropenia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pancytopenia	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Cardiac Disorders	5	(0.37)	5	2	(0.15)	2	1	(0.07)	1
Atrial Fibrillation	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Cardiac Arrest	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Palpitations	5	(0.37)	5	1	(0.07)	1	0	(0.00)	0
Ear and Labyrinth Disorders	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0
Otorrhoea	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tinnitus	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Vertigo	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Eye Disorders	9	(0.66)	9	2	(0.15)	2	0	(0.00)	0
Blepharitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dry Eye	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Glaucoma	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Uveitis	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0
Vision Blurred	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Visual Acuity Reduced	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorders	113	(8.33)	144	28	(2.06)	43	5	(0.37)	5
Abdominal Discomfort	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0
Abdominal Distension	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Abdominal Pain	18	(1.33)	22	6	(0.44)	8	2	(0.15)	2
Abdominal Pain Lower	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Abdominal Pain Upper	11	(0.81)	12	2	(0.15)	2	0	(0.00)	0
Anal Fistula	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Aphthous Ulcer	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Colitis Ulcerative	1	(0.07)	1	2	(0.15)	2	1	(0.07)	1
Constipation	10	(0.74)	11	0	(0.00)	0	0	(0.00)	0
Crohn's Disease	1	(0.07)	1	4	(0.29)	4	0	(0.00)	0
Diarrhoea	18	(1.33)	18	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Dry Mouth	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Dyspepsia	14	(1.03)	16	0	(0.00)	0	0	(0.00)	0
Dysphagia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Enterocutaneous Fistula	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Epigastric Discomfort	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Frequent Bowel Movements	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Gastric Mucosal Lesion	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer Haemorrhage	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Gastritis	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0
Gastroduodenitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorder	3	(0.22)	3	0	(0.00)	0	1	(0.07)	1
Gastrointestinal Inflammation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastrooesophageal Reflux Disease	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Haematochezia	4	(0.29)	4	3	(0.22)	3	0	(0.00)	0
Ileus	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Intestinal Obstruction	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Large Intestin Polyp	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Melaena	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Mouth Haemorrhage	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Mouth Ulceration	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0
Nausea	13	(0.96)	13	6	(0.44)	8	0	(0.00)	0
Proctalgia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Protein-Losing Gastroenteropathy	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Regurgitation	2	(0.15)	3	0	(0.00)	0	0	(0.00)	0
Small Intestinal Haemorrhage	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Stomatitis	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Vomiting	5	(0.37)	5	3	(0.22)	5	1	(0.07)	1
General Disorders and Administration Site Conditions	38	(2.80)	43	10	(0.74)	10	3	(0.22)	3
Application Site Haemorrhage	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Asthenia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Chest Discomfort	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Chest Pain	3	(0.22)	3	1	(0.07)	1	0	(0.00)	0
Chills	4	(0.29)	6	0	(0.00)	0	0	(0.00)	0
Disease Progression	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2
Drug Effect Delayed	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Drug Ineffective	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Face Oedema	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Fatigue	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0
Generalised Oedema	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Immediate Post-Injection Reaction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Influenza Like Illness	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Large Intestinal Perforation	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Non-Cardiac Chest Pain	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Oedema	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0
Oedema Peripheral	3	(0.22)	3	1	(0.07)	1	0	(0.00)	0
Pain	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pyrexia	10	(0.74)	11	3	(0.22)	3	0	(0.00)	0
Swelling	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	8	(0.59)	8	1	(0.07)	1	0	(0.00)	0
Cholelithiasis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Drug-Induced Liver Injury	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hepatic Function Abnormal	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hepatitis	3	(0.22)	3	1	(0.07)	1	0	(0.00)	0
Hyperbilirubinaemia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Liver Disorder	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Immune System Disorders	4	(0.29)	4	6	(0.44)	6	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Anaphylactic Reaction	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0
Anaphylactic Shock	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Hypersensitivity	3	(0.22)	3	2	(0.15)	2	0	(0.00)	0
Infections and Infestations	104	(7.66)	113	35	(2.58)	38	7	(0.52)	11
Abdominal Abscess	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Abscess	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Anal Abscess	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0
Arthritis Bacterial	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Atypical Pneumonia	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Body Tinea	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Bronchiolitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Bronchitis	11	(0.81)	11	1	(0.07)	1	0	(0.00)	0
Candida Infection	1	(0.07)	2	0	(0.00)	0	0	(0.00)	0
Cellulitis	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Clostridium Difficile Infection	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Cystitis	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Colitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Infection	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Disseminated Tuberculosis	0	(0.00)	0	2	(0.15)	2	1	(0.07)	1

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Folliculitis	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Furuncle	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastritis Bacterial	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Hepatitis B	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Herpes Simplex	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0
Herpes Virus Infection	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Herpes Zoster	3	(0.22)	3	4	(0.29)	4	0	(0.00)	0
Hordeolum	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Influenza	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Lung Abscess	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Nasopharyngitis	24	(1.77)	25	3	(0.22)	3	0	(0.00)	0
Onychomycosis	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Oral Candidiasis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Otitis Externa	1	(0.07)	2	0	(0.00)	0	0	(0.00)	0
Pharyngitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pharyngotonsillitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pneumocystis Jirovecii Pneumonia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pneumonia	3	(0.22)	3	4	(0.29)	4	2	(0.15)	2
Pneumonia Bacterial	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Postoperative Wound Infection	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Pseudomembranous Colitis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Pulmonary Tuberculosis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pyelonephritis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Pyelonephritis Acute	2	(0.15)	2	2	(0.15)	2	0	(0.00)	0
Rhinitis	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Sepsis	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2
Sialoadenitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Sinusitis	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Spleen Tuberculosis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tinea Pedis	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Tonsillitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tuberculosis	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0
Tuberculosis Gastrointestinal	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Upper Respiratory Tract Infection	22	(1.62)	25	2	(0.15)	2	0	(0.00)	0
Ureteritis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Urinary Tract Infection	1	(0.07)	1	2	(0.15)	2	1	(0.07)	1
Vaginal Infection	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	9	(0.66)	12	7	(0.52)	9	2	(0.15)	2

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Ankle Fracture	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Auricular Haematoma	0	(0.00)	0	1	(0.07)	3	0	(0.00)	0
Compression Fracture	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Contusion	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Facial Bones Fracture	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Fall	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Foot Fracture	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Fracture	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hand Fracture	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Infusion Related Reaction	1	(0.07)	1	1	(0.07)	1	1	(0.07)	1
Joint Dislocation	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Laceration	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Perineal Injury	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Road Traffic Accident	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Investigations	50	(3.68)	61	11	(0.81)	13	0	(0.00)	0
Alanine Aminotransferase Increased	19	(1.40)	20	2	(0.15)	2	0	(0.00)	0
Aspartate Aminotransferase Increased	10	(0.74)	10	3	(0.22)	3	0	(0.00)	0
Blood Alkaline Phosphatase Increase	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Blood Creatine Phosphokinase Increased	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
C-Reactive Protein Increased	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Eosinophil Count Increased	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hepatic Enzyme Increased	4	(0.29)	4	1	(0.07)	1	0	(0.00)	0
Influenza B Virus Test Positive	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Liver Function Test Abnormal	6	(0.44)	7	2	(0.15)	2	0	(0.00)	0
Occult Blood	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Serum Ferritin Increased	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Transaminases Increased	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0
Urine Analysis Abnormal	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Weight Decreased	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Weight Increased	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0
White Blood Cell Count Decreased	4	(0.29)	4	2	(0.15)	2	0	(0.00)	0
Metabolism and Nutrition Disorders	23	(1.69)	24	2	(0.15)	2	0	(0.00)	0
Decreased Appetite	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Diabetes Mellitus	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hypercholesterolaemia	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Hyperglycaemia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Hyperlipidaemia	12	(0.88)	12	0	(0.00)	0	0	(0.00)	0
Hypoglycaemia	2	(0.15)	2	2	(0.15)	2	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	67	(4.94)	90	21	(1.55)	27	1	(0.07)	1
Ankylosing Spondylitis	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0
Arthralgia	21	(1.55)	24	5	(0.37)	6	1	(0.07)	1
Atlantoaxial Instability	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Back Pain	11	(0.81)	12	2	(0.15)	2	0	(0.00)	0
Bursal Fluid Accumulation	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Fibromyalgia	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Flank Pain	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Foot Deformity	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Disorder	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Intervertebral Disc Protrusion	2	(0.15)	2	2	(0.15)	2	0	(0.00)	0
Joint Swelling	5	(0.37)	5	2	(0.15)	2	0	(0.00)	0
Lumbar Spinal Stenosis	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Pain	5	(0.37)	5	2	(0.15)	2	0	(0.00)	0
Musculoskeletal Stiffness	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Myalgia	5	(0.37)	6	3	(0.22)	3	0	(0.00)	0
Osteoarthritis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Osteoporosis	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Pain in Extremity	8	(0.59)	9	1	(0.07)	1	0	(0.00)	0
Polyarthrititis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Rheumatoid Arthritis	3	(0.22)	3	1	(0.07)	1	0	(0.00)	0
Rotator Cuff Syndrome	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Spinal Column Stenosis	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Synovial Cyst	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Synovitis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Tendonitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tenosynovitis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)	1	(0.07)	1	1	(0.07)	1	3	(0.22)	3
Colon Adenoma	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastric Cancer	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1
Hypergammaglobulinaemia Benign Monoclonal	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Invasive Ductal Breast Carcinoma	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Nervous System Disorders	49	(3.61)	61	8	(0.59)	8	1	(0.07)	1
Anosmia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Carotid Arteriosclerosis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Cerebellar Ataxia	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Cerebellar Infarction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cerebral Infarction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cervical Radiculopathy	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Diabetic Neuropathy	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dizziness	15	(1.11)	16	1	(0.07)	1	0	(0.00)	0
Headache	11	(0.81)	12	1	(0.07)	1	0	(0.00)	0
Hypoaesthesia	9	(0.66)	9	0	(0.00)	0	0	(0.00)	0
Migraine	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0
Neuropathy Peripheral	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Paraesthesia	10	(0.74)	11	0	(0.00)	0	0	(0.00)	0
Sciatica	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Subarachnoid Haemorrhage	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Syncope	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tension Headache	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tremor	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Psychiatric Disorders	6	(0.44)	7	1	(0.07)	1	0	(0.00)	0
Depression	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Insomnia	4	(0.29)	4	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Tic	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Renal and Urinary Disorders	4	(0.29)	4	1	(0.07)	1	0	(0.00)	0
Calculus Ureteric	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Dysuria	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Pollakiuria	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Proteinuria	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Reproductive System and Breast Disorders	7	(0.52)	7	0	(0.00)	0	0	(0.00)	0
Breast Mass	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Erectile Dysfunction	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Menorrhagia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pelvic Pain	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Varicocele	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	40	(2.95)	43	3	(0.22)	5	1	(0.07)	2
Acute Respiratory Distress Syndrome	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Atelectasis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cough	15	(1.11)	16	2	(0.15)	2	0	(0.00)	0
Dysphonia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dyspnoea	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Dyspnoea Exertional	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Epistaxis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Interstitial Lung Disease	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1
Laryngeal Oedema	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Nasal Septum Deviation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Oropharyngeal Pain	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Pleural Effusion	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Productive Cough	6	(0.44)	6	1	(0.07)	1	0	(0.00)	0
Respiratory Distress	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Rhinitis Allergic	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Rhinorrhoea	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Sputum Increased	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Vocal Cord Polyp	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Skin and Subcutaneous Tissue Disorders	76	(5.60)	102	17	(1.25)	21	0	(0.00)	0
Acne	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0
Alopecia	3	(0.22)	3	1	(0.07)	1	0	(0.00)	0
Androgenetic Alopecia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Decubitus Ulcer	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dermatitis Acneiform	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Dermatitis Allergic	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dermatitis Contact	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Diabetic Foot	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Eczema	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Erythema	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Erythema Nodosum	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Hyperkeratosis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hypersensitivity Vasculitis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Pain of Skin	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Papule	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Photosensitivity Reaction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pruritus	25	(1.84)	32	4	(0.29)	4	0	(0.00)	0
Pruritus Generalised	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0
Pseudofolliculitis Barbae	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Psoriasis	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Rash	15	(1.11)	17	3	(0.22)	3	0	(0.00)	0
Rash Generalised	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Seborrhoeic Dermatitis	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Skin Exfoliation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Skin Lesion	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Swelling Face	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0
Systemic Lupus Erythematosus Rash	1	(0.07)	2	0	(0.00)	0	0	(0.00)	0
Urticaria	9	(0.66)	10	6	(0.44)	6	0	(0.00)	0
Xeroderma	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Social Circumstances	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Andropause	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Surgical and Medical Procedures	1	(0.07)	1	6	(0.44)	6	2	(0.15)	2
Arthrotomy	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Ileostomy	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Ileostomy Closure	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Intervertebral Disc Operation	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Joint Arthroplasty	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Removal of Internal Fixation	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Spinal Decompression	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Tooth Extraction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	13	(0.96)	14	2	(0.15)	2	0	(0.00)	0
Arteriosclerosis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Deep Vein Thrombosis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Flushing	6	(0.44)	7	0	(0.00)	0	0	(0.00)	0
Hypertension	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0
Hypotension	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Orthostatic Hypotension	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Renovascular Hypertension	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

Table 136 Incidence status for classification of Adverse Events by severity (AS (N=531))

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Total	150	(28.25)	224	43	(8.10)	60	4	(0.75)	5
Blood and Lymphatic System Disorders	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0
Anaemia	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Iron Deficiency Anaemia	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Ear and Labyrinth Disorders	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Vertigo	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Eye Disorders	4	(0.75)	4	1	(0.19)	1	0	(0.00)	0
Dry Eye	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Uveitis	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0
Gastrointestinal Disorders	23	(4.33)	29	2	(0.38)	2	1	(0.19)	1
Abdominal Discomfort	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Upper	5	(0.94)	5	1	(0.19)	1	0	(0.00)	0
Constipation	4	(0.75)	4	0	(0.00)	0	0	(0.00)	0
Diarrhoea	7	(1.32)	7	0	(0.00)	0	0	(0.00)	0
Dry Mouth	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Dyspepsia	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Epigastric Discomfort	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer Haemorrhage	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Gastritis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Gastroduodenitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorder	1	(0.19)	1	0	(0.00)	0	1	(0.19)	1
Lartge Intestin Polyp	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Mouth Haemorrhage	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Mouth Ulceration	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Nausea	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
General Disorders and Administration Site Conditions	9	(1.69)	9	2	(0.38)	2	0	(0.00)	0
Chest Discomfort	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Chest Pain	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Fatigue	4	(0.75)	4	0	(0.00)	0	0	(0.00)	0
Influenza Like Illness	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Pain	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pyrexia	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Swelling	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Drug-Induced Liver Injury	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hepatitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Immune System Disorders	2	(0.38)	2	3	(0.56)	3	0	(0.00)	0
Anaphylactic Reaction	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Anaphylactic Shock	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Hypersensitivity	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0
Infections and Infestations	31	(5.84)	37	6	(1.13)	7	1	(0.19)	2
Body Tinea	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Bronchiolitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Bronchitis	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Cellulitis	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0
Furuncle	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Gastritis Bacterial	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Hepatitis B	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Herpes Virus Infection	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Herpes Zoster	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0
Hordeolum	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	9	(1.69)	10	2	(0.38)	2	0	(0.00)	0
Onychomycosis	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Pharyngitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pharyngotonsillitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pneumonia	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Postoperative Wound Infection	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Pulmonary Tuberculosis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Sinusitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Tinea Pedis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Tonsillitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Tuberculosis	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Upper Respiratory Tract Infection	4	(0.75)	7	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	3	(0.56)	4	2	(0.38)	4	1	(0.19)	1
Auricular Haematoma	0	(0.00)	0	1	(0.19)	3	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Compression Fracture	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Facial Bones Fracture	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Fracture	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hand Fracture	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Joint Dislocation	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Road Traffic Accident	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Investigations	22	(4.14)	29	5	(0.94)	7	0	(0.00)	0
Alanine Aminotransferase Increased	13	(2.45)	13	2	(0.38)	2	0	(0.00)	0
Aspartate Aminotransferase Increased	7	(1.32)	7	3	(0.56)	3	0	(0.00)	0
Blood Creatine Phosphokinase Increased	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hepatic Enzyme Increased	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0
Liver Function Test Abnormal	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Transaminases Increased	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0
Weight Increased	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Metabolism and Nutrition Disorders	8	(1.51)	8	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Diabetes Mellitus	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hypercholesterolaemia	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Hyperlipidaemia	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	26	(4.90)	37	9	(1.69)	12	0	(0.00)	0
Ankylosing Spondylitis	1	(0.19)	1	2	(0.38)	2	0	(0.00)	0
Arthralgia	8	(1.51)	10	3	(0.56)	4	0	(0.00)	0
Back Pain	8	(1.51)	8	1	(0.19)	1	0	(0.00)	0
Fibromyalgia	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Foot Deformity	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Joint Swelling	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0
Musculoskeletal Pain	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Musculoskeletal Stiffness	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Myalgia	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0
Pain in Extremity	8	(1.51)	9	1	(0.19)	1	0	(0.00)	0
Spinal Column Stenosis	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Tendonitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Nervous System Disorders	12	(2.26)	14	3	(0.56)	3	1	(0.19)	1
Cerebellar Infarction	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Cervical Radiculopathy	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Dizziness	2	(0.38)	3	0	(0.00)	0	0	(0.00)	0
Headache	4	(0.75)	4	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Hypoaesthesia	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Migraine	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0
Neuropathy Peripheral	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Paraesthesia	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Sciatica	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Syncope	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Psychiatric Disorders	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0
Depression	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Insomnia	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Renal and Urinary Disorders	3	(0.56)	3	1	(0.19)	1	0	(0.00)	0
Calculus Ureteric	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Dysuria	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Pollakiuria	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Proteinuria	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Reproductive System and Breast Disorders	4	(0.75)	4	0	(0.00)	0	0	(0.00)	0
Erectile Dysfunction	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pelvic Pain	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Varicocele	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Respiratory, Thoracic and Mediastinal Disorders	14	(2.64)	14	2	(0.38)	4	0	(0.00)	0
Cough	4	(0.75)	4	2	(0.38)	2	0	(0.00)	0
Dyspnoea	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Laryngeal Oedema	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Nasal Septum Deviation	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Oropharyngeal Pain	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Productive Cough	4	(0.75)	4	1	(0.19)	1	0	(0.00)	0
Rhinitis Allergic	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Rhinorrhoea	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Sputum Increased	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Skin and Subcutaneous Tissue Disorders	20	(3.77)	21	8	(1.51)	10	0	(0.00)	0
Acne	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Alopecia	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Androgenetic Alopecia	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Decubitus Ulcer	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Eczema	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hyperkeratosis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Hypersensitivity Vasculitis	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Papule	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pruritus	6	(1.13)	6	1	(0.19)	1	0	(0.00)	0
Pruritus Generalised	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Psoriasis	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0
Rash	5	(0.94)	5	1	(0.19)	1	0	(0.00)	0
Seborrhoeic Dermatitis	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Swelling Face	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Urticaria	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0
Xeroderma	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Social Circumstances	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Andropause	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Surgical and Medical Procedures	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Arthrotomy	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Vascular Disorders	3	(0.56)	3	1	(0.19)	1	0	(0.00)	0
Hypertension	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0
Orthostatic Hypotension	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0

Table 137 Incidence status for classification of Adverse Events by severity (RA/PA/PS (N=409))

System Organ Class	Mild			Moderate			Severe		
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Preferred Term	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Total	170	(41.56)	387	50	(12.22)	73	8	(1.96)	11
Blood and Lymphatic System Disorders	4	(0.98)	4	1	(0.24)	1	0	(0.00)	0
Iron Deficiency Anaemia	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Lymphadenopathy	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Pancytopenia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Cardiac Disorders	4	(0.98)	4	2	(0.49)	2	1	(0.24)	1
Atrial Fibrillation	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Cardiac Arrest	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Palpitations	4	(0.98)	4	1	(0.24)	1	0	(0.00)	0
Ear and Labyrinth Disorders	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Tinnitus	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Eye Disorders	4	(0.98)	4	1	(0.24)	1	0	(0.00)	0
Blepharitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dry Eye	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Glaucoma	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Visual Acuity Reduced	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorders	49	(11.98)	64	5	(1.22)	7	0	(0.00)	0
Abdominal Discomfort	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Abdominal Distension	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Abdominal Pain	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Abdominal Pain Upper	6	(1.47)	7	0	(0.00)	0	0	(0.00)	0
Aphthous Ulcer	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Constipation	3	(0.73)	4	0	(0.00)	0	0	(0.00)	0
Diarrhoea	7	(1.71)	7	0	(0.00)	0	0	(0.00)	0
Dry Mouth	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dyspepsia	9	(2.20)	10	0	(0.00)	0	0	(0.00)	0
Dysphagia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastric Mucosal Lesion	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Gastritis	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorder	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Gastroesophageal Reflux Disease	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Mouth Ulceration	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Nausea	8	(1.96)	8	4	(0.98)	4	0	(0.00)	0
Proctalgia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Regurgitation	2	(0.49)	3	0	(0.00)	0	0	(0.00)	0
Stomatitis	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Vomiting	2	(0.49)	2	2	(0.49)	2	0	(0.00)	0
General Disorders and Administration Site Conditions	19	(4.65)	23	2	(0.49)	2	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Asthenia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Chest Discomfort	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Chest Pain	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Chills	4	(0.98)	6	0	(0.00)	0	0	(0.00)	0
Drug Effect Delayed	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Face Oedema	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Fatigue	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Generalised Oedema	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Oedema	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Oedema Peripheral	3	(0.73)	3	1	(0.24)	1	0	(0.00)	0
Pyrexia	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	3	(0.73)	3	1	(0.24)	1	0	(0.00)	0
Cholelithiasis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hepatitis	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Liver Disorder	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Immune System Disorders	2	(0.49)	2	2	(0.49)	2	0	(0.00)	0
Anaphylactic Reaction	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Hypersensitivity	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Infections and Infestations	48	(11.74)	50	18	(4.40)	20	2	(0.49)	2

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Abscess	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Arthritis Bacterial	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Body Tinea	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Bronchitis	8	(1.96)	8	1	(0.24)	1	0	(0.00)	0
Candida Infection	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0
Cystitis	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Disseminated Tuberculosis	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Folliculitis	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Herpes Simplex	1	(0.24)	1	2	(0.49)	2	0	(0.00)	0
Herpes Zoster	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0
Influenza	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Nasopharyngitis	10	(2.44)	10	0	(0.00)	0	0	(0.00)	0
Otitis Externa	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0
Pneumonia	3	(0.73)	3	2	(0.49)	2	1	(0.24)	1
Pneumonia Bacterial	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Pyelonephritis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Pyelonephritis Acute	2	(0.49)	2	2	(0.49)	2	0	(0.00)	0
Rhinitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Sepsis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Sinusitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Tinea Pedis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Tuberculosis Gastrointestinal	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Upper Respiratory Tract Infection	12	(2.93)	12	0	(0.00)	0	0	(0.00)	0
Ureteritis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Urinary Tract Infection	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Vaginal Infection	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	5	(1.22)	7	3	(0.73)	3	0	(0.00)	0
Ankle Fracture	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Contusion	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Fall	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Foot Fracture	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Joint Dislocation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Laceration	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Perineal Injury	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Road Traffic Accident	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Investigations	19	(4.65)	21	2	(0.49)	2	0	(0.00)	0
Alanine Aminotransferase Increased	5	(1.22)	5	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Aspartate Aminotransferase Increased	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Hepatic Enzyme Increased	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Influenza B Virus Test Positive	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Liver Function Test Abnormal	3	(0.73)	4	1	(0.24)	1	0	(0.00)	0
Serum Ferritin Increased	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Urine Analysis Abnormal	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Weight Decreased	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Weight Increased	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Metabolism and Nutrition Disorders	14	(3.42)	15	2	(0.49)	2	0	(0.00)	0
Decreased Appetite	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Hypercholesterolaemia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hyperglycaemia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hyperlipidaemia	9	(2.20)	9	0	(0.00)	0	0	(0.00)	0
Hypoglycaemia	2	(0.49)	2	2	(0.49)	2	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	36	(8.80)	48	11	(2.69)	14	1	(0.24)	1
Arthralgia	12	(2.93)	13	2	(0.49)	2	1	(0.24)	1
Atlantoaxial Instability	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Back Pain	3	(0.73)	4	1	(0.24)	1	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Bursal Fluid Accumulation	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Fibromyalgia	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Foot Deformity	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Disorder	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Intervertebral Disc Protrusion	2	(0.49)	2	2	(0.49)	2	0	(0.00)	0
Joint Swelling	3	(0.73)	3	1	(0.24)	1	0	(0.00)	0
Lumbar Spinal Stenosis	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Pain	3	(0.73)	3	1	(0.24)	1	0	(0.00)	0
Myalgia	4	(0.98)	5	1	(0.24)	1	0	(0.00)	0
Osteoarthritis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Osteoporosis	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Polyarthritis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Rheumatoid Arthritis	3	(0.73)	3	1	(0.24)	1	0	(0.00)	0
Rotator Cuff Syndrome	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Spinal Column Stenosis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Synovial Cyst	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Synovitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Tenosynovitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)	1	(0.24)	1	1	(0.24)	1	3	(0.73)	3

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Colon Adenoma	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastric Cancer	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Hypergammaglobulinaemia Benign Monoclonal	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Invasive Ductal Breast Carcinoma	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Nervous System Disorders	32	(7.82)	42	5	(1.22)	5	0	(0.00)	0
Anosmia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Carotid Arteriosclerosis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Cerebellar Ataxia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Cerebral Infarction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Diabetic Neuropathy	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dizziness	10	(2.44)	10	1	(0.24)	1	0	(0.00)	0
Headache	7	(1.71)	8	1	(0.24)	1	0	(0.00)	0
Hypoaesthesia	6	(1.47)	6	0	(0.00)	0	0	(0.00)	0
Migraine	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Neuropathy Peripheral	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Paraesthesia	8	(1.96)	9	0	(0.00)	0	0	(0.00)	0
Subarachnoid Haemorrhage	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Tension Headache	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Tremor	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Psychiatric Disorders	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Insomnia	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Tic	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Reproductive System and Breast Disorders	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Breast Mass	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Erectile Dysfunction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Menorrhagia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	19	(4.65)	21	0	(0.00)	0	1	(0.24)	2
Acute Respiratory Distress Syndrome	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Atelectasis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Cough	9	(2.20)	10	0	(0.00)	0	0	(0.00)	0
Dysphonia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dyspnoea Exertional	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Interstitial Lung Disease	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1
Oropharyngeal Pain	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pleural Effusion	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Productive Cough	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Rhinitis Allergic	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Vocal Cord Polyp	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Skin and Subcutaneous Tissue Disorders	33	(8.07)	57	6	(1.47)	8	0	(0.00)	0
Alopecia	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Dermatitis Acneiform	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dermatitis Allergic	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dermatitis Contact	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Diabetic Foot	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Erythema	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Pruritus	14	(3.42)	21	1	(0.24)	1	0	(0.00)	0
Pruritus Generalised	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Pseudofolliculitis Barbae	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Rash	5	(1.22)	7	2	(0.49)	2	0	(0.00)	0
Rash Generalised	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Swelling Face	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Systemic Lupus Erythematosus Rash	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0
Urticaria	6	(1.47)	7	3	(0.73)	3	0	(0.00)	0
Surgical and Medical Procedures	1	(0.24)	1	2	(0.49)	2	2	(0.49)	2

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Intervertebral Disc Operation	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Joint Arthroplasty	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Removal of Internal Fixation	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Spinal Decompression	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Tooth Extraction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	9	(2.20)	10	0	(0.00)	0	0	(0.00)	0
Arteriosclerosis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Flushing	6	(1.47)	7	0	(0.00)	0	0	(0.00)	0
Hypotension	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0

Table 138 Incidence status for classification of Adverse Events by severity(IBD (N=417))

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Total	104	(24.94)	159	49	(11.75)	71	11	(2.64)	16
Blood and Lymphatic System Disorders	5	(1.20)	6	4	(0.96)	4	1	(0.24)	1
Anaemia	1	(0.24)	1	2	(0.48)	2	0	(0.00)	0
Iron Deficiency Anaemia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Leukopenia	3	(0.72)	3	2	(0.48)	2	0	(0.00)	0
Lymphadenitis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Neutropenia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Cardiac Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Palpitations	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Ear and Labyrinth Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Otorrhoea	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Eye Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Vision Blurred	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorders	41	(9.83)	51	21	(5.04)	34	4	(0.96)	4
Abdominal Discomfort	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Abdominal Pain	14	(3.36)	18	6	(1.44)	8	2	(0.48)	2
Abdominal Pain Lower	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Abdominal Pain Upper	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Anal Fistula	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Aphthous Ulcer	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Colitis Ulcerative	1	(0.24)	1	2	(0.48)	2	1	(0.24)	1
Constipation	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0
Crohn's Disease	1	(0.24)	1	4	(0.96)	4	0	(0.00)	0
Diarrhoea	4	(0.96)	4	1	(0.24)	1	0	(0.00)	0
Dyspepsia	3	(0.72)	4	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Enterocutaneous Fistula	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Epigastric Discomfort	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Frequent Bowel Movements	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Gastritis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Inflammation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Haematochezia	4	(0.96)	4	3	(0.72)	3	0	(0.00)	0
Ileus	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Intestinal Obstruction	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Melaena	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Mouth Ulceration	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Nausea	3	(0.72)	3	2	(0.48)	4	0	(0.00)	0
Protein-Losing Gastroenteropathy	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Small Intestinal Haemorrhage	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Vomiting	3	(0.72)	3	1	(0.24)	3	1	(0.24)	1
General Disorders and Administration Site Conditions	10	(2.40)	11	6	(1.44)	6	3	(0.72)	3
Application Site Haemorrhage	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Chest Pain	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Disease Progression	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Drug Ineffective	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Immediate Post-Injection Reaction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Large Intestinal Perforation	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Non-Cardiac Chest Pain	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Oedema	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Pyrexia	5	(1.20)	6	3	(0.72)	3	0	(0.00)	0
Hepatobiliary Disorders	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0
Hepatic Function Abnormal	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hepatitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hyperbilirubinaemia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Immune System Disorders	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Anaphylactic Reaction	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Infections and Infestations	25	(6.00)	26	11	(2.64)	11	4	(0.96)	7
Abdominal Abscess	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Anal Abscess	2	(0.48)	2	1	(0.24)	1	0	(0.00)	0
Atypical Pneumonia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Clostridium Difficile Infection	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Cystitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Colitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Cytomegalovirus Infection	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Disseminated Tuberculosis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Folliculitis	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Herpes Virus Infection	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Herpes Zoster	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Lung Abscess	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Nasopharyngitis	5	(1.20)	5	1	(0.24)	1	0	(0.00)	0
Oral Candidiasis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pneumocystis Jirovecii Pneumonia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pneumonia	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Pseudomembranous Colitis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Rhinitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Sepsis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Sialoadenitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Spleen Tuberculosis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Tuberculosis	1	(0.24)	1	2	(0.48)	2	0	(0.00)	0
Upper Respiratory Tract Infection	6	(1.44)	6	2	(0.48)	2	0	(0.00)	0
Urinary Tract Infection	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Injury, Poisoning and Procedural Complications	1	(0.24)	1	2	(0.48)	2	1	(0.24)	1
Foot Fracture	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Infusion Related Reaction	1	(0.24)	1	1	(0.24)	1	1	(0.24)	1
Investigations	9	(2.16)	11	4	(0.96)	4	0	(0.00)	0
Alanine Aminotransferase Increased	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0
Aspartate Aminotransferase Increased	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Blood Alkaline Phosphatase Increased	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
C-Reactive Protein Increased	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Eosinophil Count Increased	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Liver Function Test Abnormal	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Occult Blood	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
White Blood Cell Count Decreased	4	(0.96)	4	2	(0.48)	2	0	(0.00)	0
Metabolism and Nutrition Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	5	(1.20)	5	1	(0.24)	1	0	(0.00)	0
Arthralgia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Flank Pain	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Pain	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Stiffness	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Myalgia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Nervous System Disorders	5	(1.20)	5	0	(0.00)	0	0	(0.00)	0
Dizziness	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0
Hypoaesthesia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Tremor	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Psychiatric Disorders	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0
Depression	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Insomnia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Renal and Urinary Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Calculus Ureteric	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	7	(1.68)	8	1	(0.24)	1	0	(0.00)	0
Cough	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Dyspnoea	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0
Epistaxis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Oropharyngeal Pain	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Respiratory Distress	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0

System Organ Class Preferred Term	Mild			Moderate			Severe		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Skin and Subcutaneous Tissue Disorders	23	(5.52)	24	3	(0.72)	3	0	(0.00)	0
Acne	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Dermatitis Acneiform	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Erythema Nodosum	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pain of Skin	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Photosensitivity Reaction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pruritus	5	(1.20)	5	2	(0.48)	2	0	(0.00)	0
Rash	5	(1.20)	5	0	(0.00)	0	0	(0.00)	0
Seborrhoeic Dermatitis	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Skin Exfoliation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Skin Lesion	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Swelling Face	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Urticaria	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0
Surgical and Medical Procedures	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0
Ileostomy	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0
Ileostomy Closure	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Vascular Disorders	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Deep Vein Thrombosis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Renovascular Hypertension	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

C. Classification by Adverse Events Outcomes

The outcomes of adverse events were categorized as ‘resolved’, ‘resolved with sequela’, ‘improved’, ‘continuing’, ‘death’ and ‘unknown’; 862 events of ‘resolved’ in 35.00% (475/1357 subjects) , 68 events of “continuing” in 3.98% (54/1375 subjects), 54 events of ‘improved’ in 3.17% (43/1357 subjects) , 8 events of “unknown” in 0.59% (8/1357 subjects), 9 events of “Death” in 0.22% (3/1357 subjects) and 5 events “Resolved with sequelae” in 0.29% (4/1357 subjects) (Table 139).

Classification of adverse events by outcome for each indication is presented in Table 140, Table 141 and Table 142.

Table 139 Incidence status for classification of Adverse Events by outcome (total (N=1357))

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Total	475	(35.00)	862	4	(0.29)	5	43	(3.17)	54	54	(3.98)	68	3	(0.22)	9	8	(0.59)	8
Blood and Lymphatic System Disorders	13	(0.96)	14	0	(0.00)	0	2	(0.15)	2	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Anaemia	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Iron Deficiency Anaemia	3	(0.22)	3	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Leukopenia	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Lymphadenitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Lymphadenopathy	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Neutropenia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pancytopenia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cardiac Disorders	7	(0.52)	7	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Atrial Fibrillation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cardiac Arrest	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Palpitations	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ear and Labyrinth Disorders	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Otorrhoea	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tinnitus	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vertigo	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Eye Disorders	10	(0.74)	11	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Blepharitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dry Eye	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Glaucoma	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Uveitis	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vision Blurred	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Visual Acuity Reduced	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorders	126	(9.29)	173	1	(0.07)	1	7	(0.52)	7	8	(0.59)	10	0	(0.00)	0	1	(0.07)	1
Abdominal Discomfort	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Distension	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Pain	24	(1.77)	32	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Lower	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Upper	11	(0.81)	12	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anal Fistula	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Aphthous Ulcer	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Colitis Ulcerative	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Constipation	9	(0.66)	10	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Crohn's Disease	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Diarrhoea	18	(1.33)	18	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dry Mouth	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Dyspepsia	13	(0.96)	15	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dysphagia	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Enterocutaneous Fistula	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Epigastric Discomfort	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Frequent Bowel Movements	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastric Mucosal Lesion	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Gastric Ulcer Haemorrhage	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastritis	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastroduodenitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorder	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Inflammation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastroesophageal Reflux Disease	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Haematochezia	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Ileus	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Intestinal Obstruction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Large Intestine Polyp	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Melaena	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Mouth Haemorrhage	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Mouth Ulceration	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nausea	19	(1.40)	21	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Proctalgia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Protein-Losing Gastroenteropathy	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Regurgitation	2	(0.15)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Small Intestinal Haemorrhage	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Stomatitis	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vomiting	9	(0.66)	11	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
General Disorders and Administration Site Conditions	48	(3.54)	52	0	(0.00)	0	3	(0.22)	3	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Application Site Haemorrhage	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Asthenia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chest Discomfort	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chest Pain	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chills	4	(0.29)	6	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Disease Progression	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Drug Effect Delayed	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Drug Ineffective	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Face Oedema	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Fatigue	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Generalised Oedema	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Immediate Post-Injection Reaction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Influenza Like Illness	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Large Intestinal Perforation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Non-Cardiac Chest Pain	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Oedema	4	(0.29)	4	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Oedema Peripheral	3	(0.22)	3	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pain	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pyrexia	13	(0.96)	14	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Swelling	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	6	(0.44)	6	0	(0.00)	0	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Cholelithiasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Drug-Induced Liver Injury	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatic Function Abnormal	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatitis	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperbilirubinaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Liver Disorder	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Immune System Disorders	10	(0.74)	10	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anaphylactic Reaction	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Anaphylactic Shock	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypersensitivity	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Infections and Infestations	125	(9.21)	139	2	(0.15)	2	7	(0.52)	8	6	(0.44)	7	3	(0.22)	6	0	(0.00)	0
Abdominal Abscess	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abscess	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anal Abscess	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Arthritis Bacterial	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Atypical Pneumonia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Body Tinea	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Bronchiolitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Bronchitis	12	(0.88)	12	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Candida Infection	1	(0.07)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cellulitis	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Clostridium Difficile Infection	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cystitis	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Colitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Infection	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Disseminated Tuberculosis	1	(0.07)	1	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Folliculitis	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Furuncle	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastritis Bacterial	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatitis B	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Herpes Simplex	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Herpes Virus Infection	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Herpes Zoster	7	(0.52)	7	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hordeolum	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Influenza	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Lung Abscess	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	26	(1.92)	27	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Onychomycosis	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Oral Candidiasis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Otitis Externa	0	(0.00)	0	0	(0.00)	0	1	(0.07)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pharyngitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pharyngotonsillitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pneumocystis Jirovecii Pneumonia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pneumonia	7	(0.52)	7	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Pneumonia Bacterial	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Postoperative Wound Infection	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Pseudomembranous Colitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Pulmonary Tuberculosis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pyelonephritis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pyelonephritis Acute	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rhinitis	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sepsis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Sialoadenitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sinusitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Spleen Tuberculosis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tinea Pedis	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tonsillitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tuberculosis	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Tuberculosis Gastrointestinal	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Upper Respiratory Tract Infection	24	(1.77)	27	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ureteritis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urinary Tract Infection	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Vaginal Infection	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	17	(1.25)	22	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Ankle Fracture	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Auricular Haematoma	1	(0.07)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Compression Fracture	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Contusion	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Facial Bones Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Fall	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Foot Fracture	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Fracture	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hand Fracture	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Infusion Related Reaction	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Joint Dislocation	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Laceration	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Perineal Injury	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Road Traffic Accident	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Investigations	54	(3.98)	66	0	(0.00)	0	2	(0.15)	2	5	(0.37)	6	0	(0.00)	0	0	(0.00)	0
Alanine Aminotransferase Increased	20	(1.47)	21	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Aspartate Aminotransferase Increased	11	(0.81)	11	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Blood Alkaline Phosphokinase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Blood Creatine Phosphokinase Increased	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
C-Reactive Protein Increased	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Eosinophil Count Increased	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatic Enzyme Increased	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Influenza B Virus Test Positive	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Liver Function Test Abnormal	7	(0.52)	8	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Occult Blood	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Serum Ferritin Increased	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Transaminases Increased	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urine Analysis Abnormal	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Weight Decreased	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Weight Increased	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
White Blood Cell Count Decreased	5	(0.37)	5	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Metabolism and Nutrition Disorders	15	(1.11)	16	0	(0.00)	0	7	(0.52)	7	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Diabetes Mellitus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hypercholesterolaemia	3	(0.22)	3	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperglycaemia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperlipidaemia	4	(0.29)	4	0	(0.00)	0	6	(0.44)	6	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Hypoglycaemia	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Musculoskeletal and Connective Tissue Disorders	72	(5.31)	94	1	(0.07)	1	8	(0.59)	10	11	(0.81)	12	0	(0.00)	0	1	(0.07)	1
Ankylosing Spondylitis	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Arthralgia	23	(1.69)	27	0	(0.00)	0	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	1	(0.07)	1
Atlantoaxial Instability	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Back Pain	12	(0.88)	13	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Bursal Fluid Accumulation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Fibromyalgia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Flank Pain	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Foot Deformity	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Disorder	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Protrusion	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Joint Swelling	6	(0.44)	6	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Lumbar Spinal Stenosis	1	(0.07)	1	0	(0.00)	0	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Pain	6	(0.44)	6	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Stiffness	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Myalgia	7	(0.52)	8	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Osteoarthritis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Osteoporosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Pain in Extremity	8	(0.59)	9	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

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	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Polyarthrititis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rheumatoid Arthritis	3	(0.22)	3	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rotator Cuff Syndrome	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Spinal Column Stenosis	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Synovial Cyst	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Synovitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tendonitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tenosynovitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)	3	(0.22)	3	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Colon Adenoma	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastric Cancer	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypergammaglobulinaemia Benign Monoclonal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Invasive Ductal Breast Carcinoma	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nervous System Disorders	52	(3.83)	59	1	(0.07)	1	3	(0.22)	4	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0
Anosmia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Carotid Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cerebellar Ataxia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cerebellar Infarction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Cerebral Infarction	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cervical Radiculopathy	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Diabetic Neuropathy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dizziness	15	(1.11)	15	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Headache	12	(0.88)	13	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypoaesthesia	8	(0.59)	8	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Migraine	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Neuropathy Peripheral	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Paraesthesia	9	(0.66)	10	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sciatica	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Subarachnoid Haemorrhage	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Syncope	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tension Headache	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tremor	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Psychiatric Disorders	4	(0.29)	4	0	(0.00)	0	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Depression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Insomnia	3	(0.22)	3	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tic	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Renal and Urinary Disorders	2	(0.15)	2	0	(0.00)	0	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Calculus Ureteric	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dysuria	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pollakiuria	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Proteinuria	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Reproductive System and Breast Disorders	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1
Breast Mass	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Erectile Dysfunction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Menorrhagia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pelvic Pain	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Varicocele	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	39	(2.87)	43	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	1	(0.07)	2	2	(0.15)	2
Acute Respiratory Distress Syndrome	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Atelectasis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cough	17	(1.25)	18	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dysphonia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dyspnoea	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dyspnoea Exertional	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Epistaxis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Interstitial Lung Disease	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Laryngeal Oedema	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nasal Septum Deviation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Oropharyngeal Pain	2	(0.15)	2	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pleural Effusion	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Productive Cough	7	(0.52)	7	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Respiratory Distress	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rhinitis Allergic	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Rhinorrhoea	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sputum Increased	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vocal Cord Polyp	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Skin and Subcutaneous Tissue Disorders	84	(6.19)	111	0	(0.00)	0	2	(0.15)	2	6	(0.44)	8	0	(0.00)	0	2	(0.15)	2
Acne	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Alopecia	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Androgenetic Alopecia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Decubitus Ulcer	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dermatitis Acneiform	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dermatitis Allergic	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dermatitis Contact	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Diabetic Foot	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Eczema	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Erythema	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Erythema Nodosum	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperkeratosis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypersensitivity Vasculitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pain of Skin	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Papule	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Photosensitivity Reaction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pruritus	27	(1.99)	34	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Pruritus Generalised	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pseudofolliculitis Barbae	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Psoriasis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Rash	16	(1.18)	18	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Rash Generalised	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Seborrhoeic Dermatitis	2	(0.15)	2	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Skin Exfoliation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Skin Lesion	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Swelling Face	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Systemic Lupus Erythematosus Rash	1	(0.07)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urticaria	14	(1.03)	15	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Xeroderma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Social Circumstances	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Andropause	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Surgical and Medical Procedures	9	(0.66)	9	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Arthrotomy	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ileostomy	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ileostomy Closure	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Operation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Joint Arthroplasty	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Removal of Internal Fixation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Spinal Decompression	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tooth Extraction	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	10	(0.74)	11	0	(0.00)	0	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	1	(0.07)	1
Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Deep Vein Thrombosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Flushing	6	(0.44)	7	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Hypertension	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Hypotension	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Orthostatic Hypotension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Renovascular Hypertension	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

Table 140 Incidence status for classification of Adverse Events by outcome (AS (N=531))

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Total	158	(29.76)	240	0	(0.00)	0	10	(1.88)	11	23	(4.33)	35	0	(0.00)	0	3	(0.56)	3
Blood and Lymphatic System Disorders	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Anaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Iron Deficiency Anaemia	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ear and Labyrinth Disorders	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vertigo	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Eye Disorders	5	(0.94)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dry Eye	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Uveitis	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorders	22	(4.14)	26	0	(0.00)	0	2	(0.38)	2	2	(0.38)	4	0	(0.00)	0	0	(0.00)	0
Abdominal Discomfort	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Abdominal Pain Upper	5	(0.94)	5	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Constipation	3	(0.56)	3	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Diarrhoea	6	(1.13)	6	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Dry Mouth	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dyspepsia	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Epigastric Discomfort	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer Haemorrhage	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Gastroduodenitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorder	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Large Intestine Polyp	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Mouth Haemorrhage	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Mouth Ulceration	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nausea	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
General Disorders and Administration Site Conditions	10	(1.88)	10	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chest Discomfort	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chest Pain	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Fatigue	4	(0.75)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Influenza Like Illness	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Pain	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pyrexia	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Swelling	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Drug-Induced Liver Injury	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Immune System Disorders	5	(0.94)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anaphylactic Reaction	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anaphylactic Shock	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypersensitivity	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Infections and Infestations	34	(6.40)	42	0	(0.00)	0	1	(0.19)	1	2	(0.38)	3	0	(0.00)	0	0	(0.00)	0
Body Tinea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Bronchiolitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Bronchitis	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cellulitis	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Furuncle	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastritis Bacterial	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatitis B	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Herpes Virus Infection	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Herpes Zoster	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hordeolum	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	11	(2.07)	12	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Onychomycosis	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pharyngitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pharyngotonsillitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pneumonia	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Postoperative Wound Infection	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pulmonary Tuberculosis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sinusitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tinea Pedis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tonsillitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tuberculosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Upper Respiratory Tract Infection	4	(0.75)	7	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	5	(0.94)	8	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Auricular Haematoma	1	(0.19)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Compression Fracture	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Facial Bones Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Fracture	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Hand Fracture	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Joint Dislocation	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Road Traffic Accident	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Investigations	23	(4.33)	31	0	(0.00)	0	0	(0.00)	0	4	(0.75)	5	0	(0.00)	0	0	(0.00)	0
Alanine Aminotransferase Increased	14	(2.64)	14	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Aspartate Aminotransferase Increased	8	(1.51)	8	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Blood Creatine Phosphokinase Increased	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatic Enzyme Increased	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Liver Function Test Abnormal	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Transaminases Increased	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Weight Increased	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Metabolism and Nutrition Disorders	3	(0.56)	3	0	(0.00)	0	2	(0.38)	2	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Diabetes Mellitus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hypercholesterolaemia	2	(0.38)	2	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperlipidaemia	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	31	(5.84)	43	0	(0.00)	0	1	(0.19)	1	3	(0.56)	4	0	(0.00)	0	1	(0.19)	1

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Ankylosing Spondylitis	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Arthralgia	9	(1.69)	12	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	1	(0.19)	1
Back Pain	9	(1.69)	9	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Fibromyalgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Foot Deformity	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Joint Swelling	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Pain	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Stiffness	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Myalgia	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pain in Extremity	8	(1.51)	9	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Spinal Column Stenosis	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tendonitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nervous System Disorders	15	(2.82)	16	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Cerebellar Infarction	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cervical Radiculopathy	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dizziness	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Headache	4	(0.75)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypoaesthesia	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Migraine	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Neuropathy Peripheral	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Paraesthesia	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sciatica	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Syncope	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Psychiatric Disorders	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Depression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Insomnia	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Renal and Urinary Disorders	1	(0.19)	1	0	(0.00)	0	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Calculus Ureteric	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dysuria	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pollakiuria	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Proteinuria	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Reproductive System and Breast Disorders	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Erectile Dysfunction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Pelvic Pain	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Varicocele	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	16	(3.01)	18	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cough	6	(1.13)	6	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Dyspnoea	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Laryngeal Oedema	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nasal Septum Deviation	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Oropharyngeal Pain	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Productive Cough	5	(0.94)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rhinitis Allergic	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rhinorrhoea	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sputum Increased	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Skin and Subcutaneous Tissue Disorders	23	(4.33)	23	0	(0.00)	0	1	(0.19)	1	4	(0.75)	6	0	(0.00)	0	1	(0.19)	1
Acne	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Alopecia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Androgenetic Alopecia	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Decubitus Ulcer	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Eczema	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperkeratosis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypersensitivity Vasculitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Papule	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pruritus	6	(1.13)	6	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Pruritus Generalised	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Psoriasis	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Rash	4	(0.75)	4	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Seborrhoeic Dermatitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Swelling Face	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urticaria	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Xeroderma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Social Circumstances	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Andropause	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Surgical and Medical Procedures	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Arthrotomy	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Hypertension	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Orthostatic Hypotension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0

Table 141 Incidence status for classification of Adverse Events by outcome (RA/PA/PS (N=409))

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Total	185	(45.23)	401	2	(0.49)	3	28	(6.85)	36	20	(4.89)	22	2	(0.49)	5	4	(0.98)	4

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Blood and Lymphatic System Disorders	4	(0.98)	4	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Iron Deficiency Anaemia	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Lymphadenopathy	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pancytopenia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cardiac Disorders	6	(1.47)	6	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Atrial Fibrillation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cardiac Arrest	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Palpitations	5	(1.22)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ear and Labyrinth Disorders	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tinnitus	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Eye Disorders	4	(0.98)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Blepharitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dry Eye	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Glaucoma	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Visual Acuity Reduced	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorders	46	(11.25)	62	1	(0.24)	1	5	(1.22)	5	2	(0.49)	2	0	(0.00)	0	1	(0.24)	1
Abdominal Discomfort	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Distension	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Pain	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Abdominal Pain Upper	5	(1.22)	6	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Aphthous Ulcer	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Constipation	3	(0.73)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Diarrhoea	7	(1.71)	7	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dry Mouth	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dyspepsia	8	(1.96)	9	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dysphagia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastric Mucosal Lesion	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Gastritis	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorder	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastroesophageal Reflux Disease	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Mouth Ulceration	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nausea	12	(2.93)	12	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Proctalgia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Regurgitation	2	(0.49)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Stomatitis	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vomiting	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
General Disorders and Administration Site Conditions	21	(5.13)	24	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Asthenia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chest Discomfort	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chest Pain	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chills	4	(0.98)	6	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Drug Effect Delayed	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Face Oedema	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Fatigue	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Generalised Oedema	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Oedema	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Oedema Peripheral	3	(0.73)	3	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pyrexia	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	2	(0.49)	2	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Cholelithiasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hepatitis	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Liver Disorder	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Immune System Disorders	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anaphylactic Reaction	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypersensitivity	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Infections and Infestations	60	(14.67)	63	0	(0.00)	0	4	(0.98)	5	2	(0.49)	2	2	(0.49)	2	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Abscess	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Arthritis Bacterial	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Body Tinea	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Bronchitis	9	(2.20)	9	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Candida Infection	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cystitis	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Disseminated Tuberculosis	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Folliculitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Herpes Simplex	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Herpes Zoster	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Influenza	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	10	(2.44)	10	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Otitis Externa	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pneumonia	5	(1.22)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Pneumonia Bacterial	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pyelonephritis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pyelonephritis Acute	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rhinitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sepsis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Sinusitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Tinea Pedis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tuberculosis Gastrointestinal	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Upper Respiratory Tract Infection	12	(2.93)	12	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ureteritis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urinary Tract Infection	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vaginal Infection	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	8	(1.96)	10	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ankle Fracture	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Contusion	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Fall	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Foot Fracture	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Joint Dislocation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Laceration	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Perineal Injury	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Road Traffic Accident	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Investigations	21	(5.13)	23	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Alanine Aminotransferase Increased	5	(1.22)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Aspartate Aminotransferase Increased	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatic Enzyme Increased	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Influenza B Virus Test Positive	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Liver Function Test Abnormal	4	(0.98)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Serum Ferritin Increased	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urine Analysis Abnormal	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Weight Decreased	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Weight Increased	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Metabolism and Nutrition Disorders	11	(2.69)	12	0	(0.00)	0	5	(1.22)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypercholesterolaemia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperglycaemia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperlipidaemia	4	(0.98)	4	0	(0.00)	0	5	(1.22)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypoglycaemia	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	35	(8.56)	45	1	(0.24)	1	7	(1.71)	9	8	(1.96)	8	0	(0.00)	0	0	(0.00)	0
Arthralgia	13	(3.18)	14	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Atlantoaxial Instability	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Back Pain	3	(0.73)	4	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Bursal Fluid Accumulation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Fibromyalgia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Foot Deformity	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Disorder	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Protrusion	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Joint Swelling	3	(0.73)	3	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Lumbar Spinal Stenosis	1	(0.24)	1	0	(0.00)	0	2	(0.49)	2	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Pain	3	(0.73)	3	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Myalgia	4	(0.98)	5	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Osteoarthritis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Osteoporosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Polyarthritits	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rheumatoid Arthritis	3	(0.73)	3	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rotator Cuff Syndrome	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Spinal Column Stenosis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Synovial Cyst	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Synovitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tenosynovitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)	3	(0.73)	3	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Colon Adenoma	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastric Cancer	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypergammaglobulinaemia Benign Monoclonal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Invasive Ductal Breast Carcinoma	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nervous System Disorders	32	(7.82)	38	1	(0.24)	1	3	(0.73)	4	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Anosmia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Carotid Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cerebellar Ataxia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cerebral Infarction	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Diabetic Neuropathy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dizziness	10	(2.44)	10	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Headache	8	(1.96)	9	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypoaesthesia	5	(1.22)	5	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Migraine	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Neuropathy Peripheral	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Paraesthesia	7	(1.71)	8	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Subarachnoid Haemorrhage	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tension Headache	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tremor	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Psychiatric Disorders	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Insomnia	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Tic	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Reproductive System and Breast Disorders	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Breast Mass	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Erectile Dysfunction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Menorrhagia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	15	(3.67)	16	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	1	(0.24)	2	2	(0.49)	2
Acute Respiratory Distress Syndrome	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Atelectasis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cough	9	(2.20)	10	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dysphonia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dyspnoea Exertional	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Interstitial Lung Disease	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Oropharyngeal Pain	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pleural Effusion	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Productive Cough	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rhinitis Allergic	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1

System Organ Class Preferred Term	Resolved			Resolved with sequela			Improved			Continuing			Death			Unknown		
	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events	No. of Subjects	(%)	No. of Events
Vocal Cord Polyp	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Skin and Subcutaneous Tissue Disorders	36	(8.80)	62	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	1	(0.24)	1
Alopecia	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dermatitis Acneiform	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dermatitis Allergic	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dermatitis Contact	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Diabetic Foot	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Erythema	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pruritus	14	(3.42)	21	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pruritus Generalised	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pseudofolliculitis Barbae	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rash	7	(1.71)	9	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rash Generalised	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Swelling Face	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Systemic Lupus Erythematosus Rash	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urticaria	8	(1.96)	9	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Surgical and Medical Procedures	5	(1.22)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0