

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
Intervertebral Disc Operation	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 Arthroplasty	1	(0.24)	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	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Spinal Decompression	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tooth Extraction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	8	(1.96)	9	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
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
Flushing	6	(1.47)	7	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypotension	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

Table 142 Incidence status for classification of Adverse Events by outcome (IBD (N=417))

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	132	(31.65)	221	2	(0.48)	2	5	(1.20)	7	11	(2.64)	11	1	(0.24)	4	1	(0.24)	1
Blood and Lymphatic System Disorders	8	(1.92)	9	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Anaemia	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Iron Deficiency Anaemia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Leukopenia	5	(1.20)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Lymphadenitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

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Neutropenia	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	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Palpitations	1	(0.24)	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	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Otorrhoea	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Eye Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vision Blurred	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	58	(13.91)	85	0	(0.00)	0	0	(0.00)	0	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0
Abdominal Discomfort	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Pain	20	(4.80)	28	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Lower	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Upper	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	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	(0.24)	1	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
Colitis Ulcerative	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Constipation	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Crohn's Disease	5	(1.20)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Diarrhoea	5	(1.20)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dyspepsia	3	(0.72)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

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Enterocutaneous Fistula	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Epigastric Discomfort	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Frequent Bowel Movements	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastritis	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 Inflammation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Haematochezia	5	(1.20)	5	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Ileus	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Intestinal Obstruction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Melaena	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Mouth Ulceration	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nausea	5	(1.20)	7	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Protein-Losing Gastroenteropathy	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Small Intestinal Haemorrhage	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vomiting	5	(1.20)	7	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	17	(4.08)	18	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Application Site 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
Chest Pain	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Disease Progression	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Drug Ineffective	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

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Immediate Post-Injection Reaction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Large Intestinal Perforation	1	(0.24)	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	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Oedema	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pyrexia	8	(1.92)	9	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hepatic Function 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
Hepatitis	1	(0.24)	1	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	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Immune System Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Infections and Infestations	31	(7.43)	34	2	(0.48)	2	2	(0.48)	2	2	(0.48)	2	1	(0.24)	4	0	(0.00)	0
Abdominal 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
Anal Abscess	2	(0.48)	2	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Atypical Pneumonia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Clostridium Difficile Infection	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cystitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Colitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Infection	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

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Disseminated Tuberculosis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Folliculitis	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Herpes Virus 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
Herpes Zoster	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Lung Abscess	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	5	(1.20)	5	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Oral Candidiasis	1	(0.24)	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	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pneumonia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Pseudomembranous Colitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	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
Sialoadenitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Spleen Tuberculosis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tuberculosis	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Upper Respiratory Tract Infection	8	(1.92)	8	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urinary Tract Infection	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Injury, Poisoning and Procedural Complications	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

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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
Infusion Related Reaction	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Investigations	10	(2.40)	12	0	(0.00)	0	2	(0.48)	2	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Alanine Aminotransferase Increased	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Aspartate Aminotransferase 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
Blood Alkaline Phosphatase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
C-Reactive Protein Increased	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Eosinophil Count 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
Liver Function Test 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
Occult Blood	1	(0.24)	1	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	(1.20)	5	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Metabolism and Nutrition Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	1	(0.24)	1	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	6	(1.44)	6	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Arthralgia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Flank 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

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Musculoskeletal Pain	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Stiffness	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Nervous System Disorders	5	(1.20)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dizziness	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypoaesthesia	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Psychiatric Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Depression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Renal and Urinary Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Calculus Ureteric	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	8	(1.92)	9	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cough	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dyspnoea	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Epistaxis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Oropharyngeal Pain	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Respiratory Distress	1	(0.24)	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
Skin and Subcutaneous Tissue Disorders	25	(6.00)	26	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Acne	2	(0.48)	2	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
Erythema Nodosum	1	(0.24)	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	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Photosensitivity Reaction	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pruritus	7	(1.68)	7	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rash	5	(1.20)	5	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Seborrhoeic Dermatitis	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Skin Exfoliation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Skin Lesion	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Swelling Face	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urticaria	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Surgical and Medical Procedures	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ileostomy	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ileostomy Closure	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Deep Vein Thrombosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Renovascular Hypertension	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

D. Classification of Causal Relationship to the Surveillance Drug

The relationship of adverse event to the surveillance drug was categorized as the following 6 categories, 'certain', 'probable/likely', 'possible', 'unlikely', 'conditional/unclassified' and 'unassessable/unclassifiable'; 745 events of 'unlikely' in 29.92% (406/1357 subjects), 181 events of 'possible' in 9.58% (130/1357 subjects), 37 events of 'probable/likely' in 1.69% (23/1357 subjects), 19 events of 'conditional/unclassified' in 1.18% (16/1357 subjects), 13 events of 'unassessable/unclassifiable' in 0.81% (11/1357 subjects) and 11 events of 'certain' in 0.81% (11/1357 subjects)(Table 143).

Classification of causal relationship to the surveillance drug by indication is presented in Table 144, Table 145 and Table 146.

Table 143 Incidence status status for classification of causal relationship to the surveillance drug (Total (N=1357))

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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	11	(0.81)	11	23	(1.69)	37	130	(9.58)	181	406	(29.92)	745	16	(1.18)	19	11	(0.81)	13
Blood and Lymphatic System Disorders	0	(0.00)	0	1	(0.07)	1	3	(0.22)	4	13	(0.96)	13	0	(0.00)	0	0	(0.00)	0
Anaemia	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Iron Deficiency Anaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Leukopenia	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Lymphadenitis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Lymphadenopathy	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Neutropenia	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pancytopenia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cardiac Disorders	0	(0.00)	0	2	(0.15)	2	2	(0.15)	2	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Atrial Fibrillation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cardiac Arrest	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Palpitations	0	(0.00)	0	2	(0.15)	2	2	(0.15)	2	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Ear and Labyrinth Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0
Otorrhoea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tinnitus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Vertigo	0	(0.00)	0	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	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Eye Disorders	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	8	(0.59)	9	1	(0.07)	1	0	(0.00)	0
Blepharitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dry Eye	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Glaucoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Uveitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0
Vision Blurred	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Visual Acuity Reduced	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 Disorders	0	(0.00)	0	1	(0.07)	1	13	(0.96)	14	127	(9.36)	176	0	(0.00)	0	1	(0.07)	1
Abdominal Discomfort	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Abdominal Distension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Abdominal Pain	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	23	(1.69)	31	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Lower	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Upper	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	12	(0.88)	13	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Colitis Ulcerative	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Constipation	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	8	(0.59)	9	0	(0.00)	0	1	(0.07)	1
Crohn's Disease	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Diarrhoea	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	18	(1.33)	18	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Dry Mouth	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Dyspepsia	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	12	(0.88)	14	0	(0.00)	0	0	(0.00)	0
Dysphagia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Frequent Bowel Movements	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastric Mucosal Lesion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(0.37)	5	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	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Inflammation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastroesophageal Reflux Disease	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Haematochezia	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0
Ileus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Intestinal Obstruction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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	0	(0.00)	0	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	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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 Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Mouth Ulceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Nausea	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	17	(1.25)	19	0	(0.00)	0	0	(0.00)	0
Proctalgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Protein-Losing Gastroenteropathy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Regurgitation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	3	0	(0.00)	0	0	(0.00)	0
Small Intestinal Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Stomatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Vomiting	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	9	(0.66)	11	0	(0.00)	0	0	(0.00)	0
General Disorders and Administration Site Conditions	0	(0.00)	0	2	(0.15)	2	9	(0.66)	11	38	(2.80)	41	2	(0.15)	2	0	(0.00)	0
Application Site Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Asthenia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Chest Discomfort	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Chest Pain	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Chills	0	(0.00)	0	0	(0.00)	0	1	(0.07)	3	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Disease Progression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Drug Effect Delayed	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Drug Ineffective	0	(0.00)	0	0	(0.00)	0	1	(0.07)	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	(0.07)	1	0	(0.00)	0	0	(0.00)	0

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Fatigue	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Generalised Oedema	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Immediate Post-Injection Reaction	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Influenza Like Illness	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Large Intestinal Perforation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Non-Cardiac Chest Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	2	(0.15)	2	0	(0.00)	0
Oedema Peripheral	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pyrexia	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	12	(0.88)	13	0	(0.00)	0	0	(0.00)	0
Swelling	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	8	(0.59)	8	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	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatic Function Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hepatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	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	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Immune System Disorders	3	(0.22)	3	4	(0.29)	4	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

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Anaphylactic Reaction	1	(0.07)	1	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anaphylactic Shock	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypersensitivity	2	(0.15)	2	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Infections and Infestations	2	(0.15)	2	3	(0.22)	4	42	(3.10)	49	87	(6.41)	98	2	(0.15)	2	7	(0.52)	7
Abdominal Abscess	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Abscess	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anal Abscess	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Arthritis Bacterial	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Atypical Pneumonia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Body Tinea	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Bronchiolitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Bronchitis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	11	(0.81)	11	0	(0.00)	0	0	(0.00)	0
Candida Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	2	0	(0.00)	0	0	(0.00)	0
Cellulitis	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Clostridium Difficile Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cystitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Colitis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Disseminated Tuberculosis	0	(0.00)	0	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

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Folliculitis	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Furuncle	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastritis Bacterial	0	(0.00)	0	1	(0.07)	1	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	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2
Herpes Virus Infection	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Herpes Zoster	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	4	(0.29)	4	0	(0.00)	0	1	(0.07)	1
Hordeolum	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Influenza	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Lung Abscess	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	0	(0.00)	0	0	(0.00)	0	10	(0.74)	10	17	(1.25)	18	0	(0.00)	0	0	(0.00)	0
Onychomycosis	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Oral Candidiasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Otitis Externa	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	2	0	(0.00)	0	0	(0.00)	0
Pharyngitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pharyngotonsillitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pneumocystis Jirovecii Pneumonia	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pneumonia	0	(0.00)	0	0	(0.00)	0	4	(0.29)	5	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Pneumonia Bacterial	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

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Postoperative Wound Infection	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pseudomembranous Colitis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pulmonary 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
Pyelonephritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pyelonephritis Acute	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	1	(0.07)	1
Rhinitis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Sepsis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Sialoadenitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Sinusitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Tonsillitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tuberculosis	2	(0.15)	2	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	18	(1.33)	21	0	(0.00)	0	2	(0.15)	2
Ureteritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Urinary Tract Infection	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0
Vaginal Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0	13	(0.96)	18	0	(0.00)	0	1	(0.07)	2

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Ankle 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
Auricular Haematoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	3	0	(0.00)	0	0	(0.00)	0
Compression 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
Contusion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Facial Bones Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Fall	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Foot Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
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
Hand Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Infusion Related Reaction	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Joint Dislocation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Laceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Perineal Injury	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Road Traffic Accident	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Investigations	0	(0.00)	0	3	(0.22)	3	10	(0.74)	14	42	(3.10)	49	5	(0.37)	8	0	(0.00)	0
Alanine Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	5	(0.37)	5	12	(0.88)	13	4	(0.29)	4	0	(0.00)	0
Aspartate Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	6	(0.44)	6	3	(0.22)	3	0	(0.00)	0
Blood Alkaline Phosphatase 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

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Blood Creatine 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
C-Reactive Protein Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0
Eosinophil Count 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
Hepatic Enzyme Increased	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Influenza B Virus Test Positive	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 Function Test Abnormal	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	7	(0.52)	8	0	(0.00)	0	0	(0.00)	0
Occult Blood	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Serum Ferritin 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
Transaminases Increased	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urine Analysis Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Weight Decreased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Weight Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0
White Blood Cell Count Decreased	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Metabolism and Nutrition Disorders	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	24	(1.77)	25	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Hyperglycaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

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Hyperlipidaemia	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	11	(0.81)	11	0	(0.00)	0	0	(0.00)	0
Hypoglycaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	0	(0.00)	0	0	(0.00)	0	7	(0.52)	9	80	(5.90)	108	1	(0.07)	1	0	(0.00)	0
Ankylosing Spondylitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Arthralgia	0	(0.00)	0	0	(0.00)	0	2	(0.15)	3	25	(1.84)	28	0	(0.00)	0	0	(0.00)	0
Atlantoaxial Instability	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Back Pain	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	12	(0.88)	13	0	(0.00)	0	0	(0.00)	0
Bursal Fluid Accumulation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Fibromyalgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Flank Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Protrusion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Joint Swelling	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(0.52)	7	0	(0.00)	0	0	(0.00)	0
Lumbar Spinal Stenosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Pain	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Stiffness	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Myalgia	0	(0.00)	0	0	(0.00)	0	2	(0.15)	3	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0
Osteoarthritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

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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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	9	(0.66)	10	0	(0.00)	0	0	(0.00)	0
Polyarthritits	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Rheumatoid Arthritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Rotator Cuff Syndrome	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Spinal Column Stenosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Synovial Cyst	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Synovitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tendonitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tenosynovitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Colon Adenoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastric Cancer	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Nervous System Disorders	0	(0.00)	0	0	(0.00)	0	8	(0.59)	9	48	(3.54)	59	1	(0.07)	1	1	(0.07)	1
Anosmia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Carotid Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

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Cerebellar Ataxia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Cerebellar Infarction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cerebral Infarction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cervical Radiculopathy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	13	(0.96)	14	0	(0.00)	0	0	(0.00)	0
Headache	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	9	(0.66)	10	1	(0.07)	1	0	(0.00)	0
Hypoaesthesia	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	7	(0.52)	7	0	(0.00)	0	0	(0.00)	0
Migraine	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Neuropathy Peripheral	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Paraesthesia	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	9	(0.66)	10	0	(0.00)	0	0	(0.00)	0
Sciatica	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Subarachnoid Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Syncope	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tension Headache	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tremor	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Psychiatric Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(0.52)	8	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0

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Tic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Renal and Urinary Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0
Calculus Ureteric	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Dysuria	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pollakiuria	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(0.52)	7	0	(0.00)	0	0	(0.00)	0
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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Menorrhagia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Pelvic Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Varicocele	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	0	(0.00)	0	3	(0.22)	3	6	(0.44)	8	36	(2.65)	39	0	(0.00)	0	0	(0.00)	0
Acute Respiratory Distress Syndrome	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Atelectasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cough	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	16	(1.18)	17	0	(0.00)	0	0	(0.00)	0
Dysphonia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dyspnoea	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0

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Dyspnoea Exertional	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Epistaxis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Interstitial Lung Disease	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Laryngeal Oedema	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nasal Septum Deviation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Oropharyngeal Pain	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Pleural Effusion	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Productive Cough	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	5	(0.37)	5	0	(0.00)	0	0	(0.00)	0
Respiratory Distress	0	(0.00)	0	1	(0.07)	1	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	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Rhinorrhoea	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sputum 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
Vocal Cord 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
Skin and Subcutaneous Tissue Disorders	4	(0.29)	4	6	(0.44)	14	45	(3.32)	53	37	(2.73)	47	3	(0.22)	3	2	(0.15)	2
Acne	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Alopecia	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Androgenetic Alopecia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Decubitus Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dermatitis Acneiform	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

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Dermatitis Allergic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Dermatitis Contact	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0
Diabetic Foot	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Eczema	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Erythema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Erythema Nodosum	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Hyperkeratosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Papule	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Photosensitivity Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Pruritus	1	(0.07)	1	3	(0.22)	6	16	(1.18)	17	10	(0.74)	12	0	(0.00)	0	0	(0.00)	0
Pruritus Generalised	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pseudofolliculitis Barbae	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Psoriasis	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rash	2	(0.15)	2	3	(0.22)	5	7	(0.52)	7	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0
Rash Generalised	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Seborrhoeic Dermatitis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Skin Exfoliation	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Skin Lesion	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0
Systemic Lupus Erythematosus Rash	0	(0.00)	0	0	(0.00)	0	1	(0.07)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urticaria	0	(0.00)	0	2	(0.15)	2	13	(0.96)	13	0	(0.00)	0	1	(0.07)	1	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	9	(0.66)	9	0	(0.00)	0	0	(0.00)	0
Arthrotomy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Ileostomy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Ileostomy Closure	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Operation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Joint Arthroplasty	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Removal of Internal Fixation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Spinal Decompression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Tooth Extraction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	0	(0.00)	0	1	(0.07)	2	1	(0.07)	1	12	(0.88)	12	1	(0.07)	1	0	(0.00)	0
Arteriosclerosis	0	(0.00)	0	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	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Deep Vein Thrombosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Flushing	0	(0.00)	0	1	(0.07)	2	1	(0.07)	1	3	(0.22)	3	1	(0.07)	1	0	(0.00)	0
Hypertension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0
Hypotension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0
Orthostatic Hypotension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Renovascular Hypertension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0

Table 144 Incidence status for classification of causal relationship to the surveillance drug (AS (N=531))

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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	3	(0.56)	3	4	(0.75)	5	49	(9.23)	66	132	(24.86)	202	7	(1.32)	10	2	(0.38)	3
Blood and Lymphatic System Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Ear and Labyrinth Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Vertigo	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Eye Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.75)	4	1	(0.19)	1	0	(0.00)	0
Dry Eye	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Uveitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0
Gastrointestinal Disorders	0	(0.00)	0	0	(0.00)	0	4	(0.75)	4	21	(3.95)	27	0	(0.00)	0	1	(0.19)	1
Abdominal Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Upper	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	5	(0.94)	5	0	(0.00)	0	0	(0.00)	0
Constipation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	1	(0.19)	1
Diarrhoea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(1.32)	7	0	(0.00)	0	0	(0.00)	0
Dry Mouth	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Dyspepsia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Epigastric Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	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	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	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	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 Ulceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Nausea	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
General Disorders and Administration Site Conditions	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	10	(1.88)	10	0	(0.00)	0	0	(0.00)	0
Chest Discomfort	0	(0.00)	0	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	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Chest Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Fatigue	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Influenza Like Illness	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pyrexia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Swelling	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hepatobiliary 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
Drug-Induced Liver Injury	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Immune System Disorders	1	(0.19)	1	1	(0.19)	1	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anaphylactic Reaction	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anaphylactic Shock	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypersensitivity	1	(0.19)	1	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Infections and Infestations	1	(0.19)	1	1	(0.19)	2	14	(2.64)	16	22	(4.14)	27	0	(0.00)	0	0	(0.00)	0
Body Tinea	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Bronchiolitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Bronchitis	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Cellulitis	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Furuncle	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0

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Gastritis Bacterial	0	(0.00)	0	1	(0.19)	1	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	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 Zoster	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Hordeolum	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	8	(1.51)	9	0	(0.00)	0	0	(0.00)	0
Onychomycosis	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pharyngitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pharyngotonsillitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pneumonia	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Postoperative Wound Infection	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pulmonary Tuberculosis	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sinusitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Tinea Pedis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Tonsillitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
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
Upper Respiratory Tract Infection	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	2	(0.38)	5	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.75)	7	0	(0.00)	0	1	(0.19)	2
Auricular Haematoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	3	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
Compression 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
Facial Bones Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
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
Hand Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Joint Dislocation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Road Traffic Accident	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Investigations	0	(0.00)	0	1	(0.19)	1	7	(1.32)	10	14	(2.64)	18	4	(0.75)	7	0	(0.00)	0
Alanine Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	8	(1.51)	8	4	(0.75)	4	0	(0.00)	0
Aspartate Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	4	(0.75)	4	3	(0.56)	3	0	(0.00)	0
Blood Creatine Phosphokinase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hepatic Enzyme Increased	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Liver Function Test Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Transaminases Increased	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Weight Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Metabolism and Nutrition Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	8	(1.51)	8	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	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

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Hypercholesterolaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Hyperlipidaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	0	(0.00)	0	0	(0.00)	0	4	(0.75)	5	30	(5.65)	44	0	(0.00)	0	0	(0.00)	0
Ankylosing Spondylitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Arthralgia	0	(0.00)	0	0	(0.00)	0	2	(0.38)	3	9	(1.69)	11	0	(0.00)	0	0	(0.00)	0
Back Pain	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	8	(1.51)	8	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Pain	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Stiffness	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Myalgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Pain in Extremity	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	9	(1.69)	10	0	(0.00)	0	0	(0.00)	0
Spinal Column Stenosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Tendonitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Nervous System Disorders	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	12	(2.26)	14	1	(0.19)	1	0	(0.00)	0
Cerebellar Infarction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Cervical Radiculopathy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Dizziness	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	1	(0.19)	2	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Headache	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0
Hypoaesthesia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Migraine	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Sciatica	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Syncope	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Psychiatric Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	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	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Renal and Urinary Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.75)	4	0	(0.00)	0	0	(0.00)	0
Calculus Ureteric	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Dysuria	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pollakiuria	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.75)	4	0	(0.00)	0	0	(0.00)	0
Erectile Dysfunction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Pelvic Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Varicocele	0	(0.00)	0	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	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Respiratory, Thoracic and Mediastinal Disorders	0	(0.00)	0	1	(0.19)	1	3	(0.56)	5	12	(2.26)	12	0	(0.00)	0	0	(0.00)	0
Cough	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	5	(0.94)	5	0	(0.00)	0	0	(0.00)	0
Dyspnoea	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Laryngeal Oedema	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nasal Septum Deviation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Oropharyngeal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Productive Cough	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Rhinitis Allergic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Rhinorrhoea	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sputum Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Skin and Subcutaneous Tissue Disorders	1	(0.19)	1	0	(0.00)	0	15	(2.82)	18	11	(2.07)	11	1	(0.19)	1	0	(0.00)	0
Acne	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Alopecia	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Androgenetic 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
Decubitus Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Eczema	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Hyperkeratosis	0	(0.00)	0	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	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Pruritus	0	(0.00)	0	0	(0.00)	0	5	(0.94)	5	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0
Pruritus Generalised	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Psoriasis	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rash	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0
Seborrhoeic Dermatitis	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	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	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Urticaria	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Arthrotomy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.75)	4	0	(0.00)	0	0	(0.00)	0
Hypertension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	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 145 Incidence status for classification of causal relationship to the surveillance drug (RA/PA/PS (N=409))

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessable/unclassifiable		
	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	4	(0.98)	4	12	(2.93)	24	53	(12.96)	74	161	(39.36)	356	8	(1.96)	8	5	(1.22)	5
Blood and Lymphatic System Disorders	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Iron Deficiency Anaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Lymphadenopathy	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pancytopenia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Cardiac Disorders	0	(0.00)	0	2	(0.49)	2	2	(0.49)	2	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Atrial Fibrillation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Cardiac Arrest	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Palpitations	0	(0.00)	0	2	(0.49)	2	2	(0.49)	2	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Ear and Labyrinth Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Tinnitus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Eye Disorders	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	3	(0.73)	4	0	(0.00)	0	0	(0.00)	0
Blepharitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dry Eye	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Glaucoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Visual Acuity Reduced	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorders	0	(0.00)	0	0	(0.00)	0	6	(1.47)	7	48	(11.74)	64	0	(0.00)	0	0	(0.00)	0
Abdominal Discomfort	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Abdominal Distension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Upper	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	6	(1.47)	7	0	(0.00)	0	0	(0.00)	0
Aphthous Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Constipation	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	2	(0.49)	3	0	(0.00)	0	0	(0.00)	0
Diarrhoea	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	6	(1.47)	6	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	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	7	(1.71)	8	0	(0.00)	0	0	(0.00)	0
Dysphagia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastric Mucosal Lesion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastric Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Gastritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorder	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Gastroesophageal Reflux Disease	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Mouth Ulceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Nausea	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	11	(2.69)	11	0	(0.00)	0	0	(0.00)	0
Proctalgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Regurgitation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	3	0	(0.00)	0	0	(0.00)	0
Stomatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Vomiting	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0

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General Disorders and Administration Site Conditions	0	(0.00)	0	2	(0.49)	2	4	(0.98)	6	13	(3.18)	15	2	(0.49)	2	0	(0.00)	0
Asthenia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Chest Discomfort	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chest Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Chills	0	(0.00)	0	0	(0.00)	0	1	(0.24)	3	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Drug Effect Delayed	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Fatigue	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Generalised Oedema	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	2	(0.49)	2	0	(0.00)	0
Oedema Peripheral	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Pyrexia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Liver Disorder	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anaphylactic Reaction	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hypersensitivity	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

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Infections and Infestations	0	(0.00)	0	2	(0.49)	2	19	(4.65)	20	40	(9.78)	44	2	(0.49)	2	4	(0.98)	4
Abscess	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Arthritis Bacterial	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Bronchitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	9	(2.20)	9	0	(0.00)	0	0	(0.00)	0
Candida Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0
Cystitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Disseminated Tuberculosis	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Folliculitis	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Herpes Simplex	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Herpes Zoster	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Influenza	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	0	(0.00)	0	0	(0.00)	0	7	(1.71)	7	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Otitis Externa	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0
Pneumonia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Pneumonia Bacterial	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pyelonephritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pyelonephritis Acute	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	2	(0.49)	2	0	(0.00)	0	1	(0.24)	1
Rhinitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

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Sepsis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	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	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	9	(2.20)	9	0	(0.00)	0	1	(0.24)	1
Ureteritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Urinary Tract Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Vaginal Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	8	(1.96)	10	0	(0.00)	0	0	(0.00)	0
Ankle Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Contusion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Fall	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Foot Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Joint Dislocation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Laceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Perineal Injury	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Road Traffic Accident	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Investigations	0	(0.00)	0	0	(0.00)	0	3	(0.73)	4	18	(4.40)	19	0	(0.00)	0	0	(0.00)	0
Alanine Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0

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Aspartate Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hepatic Enzyme Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Influenza B Virus Test Positive	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Liver Function Test Abnormal	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	3	(0.73)	4	0	(0.00)	0	0	(0.00)	0
Serum Ferritin Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Urine Analysis Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Weight Decreased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Weight Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Metabolism and Nutrition Disorders	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	15	(3.67)	16	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Hypercholesterolaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hyperglycaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hyperlipidaemia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	8	(1.96)	8	0	(0.00)	0	0	(0.00)	0
Hypoglycaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	46	(11.25)	60	1	(0.24)	1	0	(0.00)	0
Arthralgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	15	(3.67)	16	0	(0.00)	0	0	(0.00)	0
Atlantoaxial Instability	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Back Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	5	0	(0.00)	0	0	(0.00)	0

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Bursal Fluid Accumulation	0	(0.00)	0	0	(0.00)	0	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	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	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 Protrusion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Joint Swelling	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Lumbar Spinal Stenosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Myalgia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Osteoarthritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Rheumatoid Arthritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Rotator Cuff Syndrome	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Spinal Column Stenosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Synovial Cyst	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Synovitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Tenosynovitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0

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Colon Adenoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastric Cancer	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Nervous System Disorders	0	(0.00)	0	0	(0.00)	0	3	(0.73)	4	33	(8.07)	42	0	(0.00)	0	1	(0.24)	1
Anosmia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Carotid Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Cerebellar Ataxia	0	(0.00)	0	0	(0.00)	0	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	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	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	9	(2.20)	9	0	(0.00)	0	0	(0.00)	0
Headache	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	8	(1.96)	9	0	(0.00)	0	0	(0.00)	0
Hypoaesthesia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	5	(1.22)	5	0	(0.00)	0	0	(0.00)	0
Migraine	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Neuropathy Peripheral	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Paraesthesia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	7	(1.71)	8	0	(0.00)	0	0	(0.00)	0
Subarachnoid Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Tension Headache	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Tremor	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Insomnia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Tic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Reproductive System and Breast Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Menorrhagia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	18	(4.40)	20	0	(0.00)	0	0	(0.00)	0
Acute Respiratory Distress Syndrome	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Cough	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	9	(2.20)	10	0	(0.00)	0	0	(0.00)	0
Dysphonia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dyspnoea Exertional	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Interstitial Lung Disease	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Rhinitis Allergic	0	(0.00)	0	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	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Skin and Subcutaneous Tissue Disorders	2	(0.49)	2	6	(1.47)	14	17	(4.16)	21	16	(3.91)	26	2	(0.49)	2	0	(0.00)	0
Alopecia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Dermatitis Acneiform	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dermatitis Allergic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Dermatitis Contact	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0	0	(0.00)	0
Diabetic Foot	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Erythema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Pruritus	1	(0.24)	1	3	(0.73)	6	6	(1.47)	7	6	(1.47)	8	0	(0.00)	0	0	(0.00)	0
Pruritus Generalised	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pseudofolliculitis Barbae	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0
Rash	1	(0.24)	1	3	(0.73)	5	2	(0.49)	2	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Rash Generalised	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Swelling Face	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0
Systemic Lupus Erythematosus Rash	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urticaria	0	(0.00)	0	2	(0.49)	2	7	(1.71)	7	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Surgical and Medical Procedures	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(1.22)	5	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Intervertebral Disc Operation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Joint Arthroplasty	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Removal of Internal Fixation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Spinal Decompression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Tooth Extraction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	0	(0.00)	0	1	(0.24)	2	1	(0.24)	1	6	(1.47)	6	1	(0.24)	1	0	(0.00)	0
Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Flushing	0	(0.00)	0	1	(0.24)	2	1	(0.24)	1	3	(0.73)	3	1	(0.24)	1	0	(0.00)	0
Hypotension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0

Table 146 Incidence status for classification of causal relationship to the surveillance drug (IBD (N=417))

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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	4	(0.96)	4	7	(1.68)	8	28	(6.71)	41	113	(27.10)	187	1	(0.24)	1	4	(0.96)	5
Blood and Lymphatic System Disorders	0	(0.00)	0	1	(0.24)	1	2	(0.48)	3	7	(1.68)	7	0	(0.00)	0	0	(0.00)	0
Anaemia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Iron Deficiency Anaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Leukopenia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0
Lymphadenitis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Neutropenia	0	(0.00)	0	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	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Cardiac Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Palpitations	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Ear and Labyrinth Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Otorrhoea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Eye Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Vision Blurred	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Disorders	0	(0.00)	0	1	(0.24)	1	3	(0.72)	3	58	(13.91)	85	0	(0.00)	0	0	(0.00)	0
Abdominal Discomfort	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Abdominal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	20	(4.80)	28	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Lower	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Upper	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Anal Fistula	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Aphthous Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Colitis Ulcerative	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0
Constipation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0
Crohn's Disease	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0
Diarrhoea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(1.20)	5	0	(0.00)	0	0	(0.00)	0
Dyspepsia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	4	0	(0.00)	0	0	(0.00)	0
Enterocutaneous Fistula	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Epigastric Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Frequent Bowel Movements	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	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	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Inflammation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Haematochezia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	6	(1.44)	6	0	(0.00)	0	0	(0.00)	0
Ileus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Intestinal Obstruction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Melaena	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Mouth Ulceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Nausea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(1.20)	7	0	(0.00)	0	0	(0.00)	0
Protein-Losing Gastroenteropathy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Small Intestinal Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Vomiting	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(1.20)	7	0	(0.00)	0	0	(0.00)	0
General Disorders and Administration Site Conditions	0	(0.00)	0	0	(0.00)	0	4	(0.96)	4	15	(3.60)	16	0	(0.00)	0	0	(0.00)	0
Application Site Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Chest Pain	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Disease Progression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Drug Ineffective	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Immediate Post-Injection Reaction	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	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
Large Intestinal Perforation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Non-Cardiac Chest Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Pyrexia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	7	(1.68)	8	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0
Hepatic Function Abnormal	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hyperbilirubinaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anaphylactic Reaction	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Infections and Infestations	1	(0.24)	1	0	(0.00)	0	9	(2.16)	13	25	(6.00)	27	0	(0.00)	0	3	(0.72)	3
Abdominal Abscess	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Atypical Pneumonia	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Cystitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Colitis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Disseminated Tuberculosis	0	(0.00)	0	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	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Folliculitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Herpes Virus Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Herpes Zoster	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Lung Abscess	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	6	(1.44)	6	0	(0.00)	0	0	(0.00)	0
Oral Candidiasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Pneumocystis Jirovecii Pneumonia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pneumonia	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pseudomembranous Colitis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rhinitis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sepsis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sialoadenitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Spleen Tuberculosis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tuberculosis	1	(0.24)	1	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Upper Respiratory Tract Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(1.68)	7	0	(0.00)	0	1	(0.24)	1
Urinary Tract Infection	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Injury, Poisoning and Procedural Complications	2	(0.48)	2	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Foot Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Infusion Related Reaction	2	(0.48)	2	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Investigations	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	10	(2.40)	12	1	(0.24)	1	0	(0.00)	0
Alanine Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0
Aspartate Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Blood Alkaline Phosphatase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
C-Reactive Protein Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Eosinophil Count Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	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	0	(0.00)	0	0	(0.00)	0
Occult Blood	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
White Blood Cell Count Decreased	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0
Metabolism and Nutrition Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0
Arthralgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Flank Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Stiffness	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Myalgia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Nervous System Disorders	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Dizziness	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0
Hypoaesthesia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tremor	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Depression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Insomnia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Renal and Urinary Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Calculus Ureteric	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	6	(1.44)	7	0	(0.00)	0	0	(0.00)	0
Cough	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Dyspnoea	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0
Epistaxis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Oropharyngeal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Skin and Subcutaneous Tissue Disorders	1	(0.24)	1	0	(0.00)	0	13	(3.12)	14	10	(2.40)	10	0	(0.00)	0	2	(0.48)	2
Acne	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Dermatitis Acneiform	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Pain of Skin	0	(0.00)	0	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	Certain			Probable/likely			Possible			Unlikely			Conditional/unclassified			Unassessible/unclassifiable		
	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
Photosensitivity Reaction	0	(0.00)	0	0	(0.00)	0	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	5	(1.20)	5	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Rash	1	(0.24)	1	0	(0.00)	0	2	(0.48)	2	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Seborrhoeic Dermatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1
Skin Exfoliation	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Swelling Face	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Urticaria	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Surgical and Medical Procedures	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0
Ileostomy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Ileostomy Closure	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0
Deep Vein Thrombosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Renovascular Hypertension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0

E. Classification of Causal relationship except the surveillance drug

Causal relationship except the surveillance drug was categorized as “Concomitant medication”, “Underlying disease”, “Others”, “Not applicable” and “Unknown”, 567 events of “Not applicable” in 23.73% (322/1357 subjects), 216 events of “Underlying disease” in 10.91% (148/1357 subjects), 112 events of “Unknown” in 6.04% (82/1357 subjects), 94 events of “Concomitant medication” in 5.60% (76/1357 subjects) and 17 events of “Others” in 1.18% (16/1357 subjects) (Table 147).

Classification of causal relationship except the surveillance drug by indication is presented in Table 148, Table 149 and Table 150.

Table 147 Incidence status for classification of casual relationship except the surveillance drug (total (N=1357))

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Total	76	(5.60)	94	148	(10.91)	216	16	(1.18)	17	322	(23.73)	567	82	(6.04)	112
Blood and Lymphatic System Disorders	5	(0.37)	5	2	(0.15)	2	0	(0.00)	0	9	(0.66)	9	2	(0.15)	2
Anaemia	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Iron Deficiency Anaemia	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Leukopenia	4	(0.29)	4	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Lymphadenitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Lymphadenopathy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Neutropenia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Pancytopenia	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cardiac Disorders	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	4	(0.29)	4	2	(0.15)	2
Atrial Fibrillation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Cardiac Arrest	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Palpitations	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	4	(0.29)	4	1	(0.07)	1
Ear and Labyrinth Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(0.37)	5	0	(0.00)	0
Otorrhoea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Tinnitus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Vertigo	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Eye Disorders	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	8	(0.59)	9	1	(0.07)	1

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Blepharitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Dry Eye	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0
Glaucoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Uveitis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1
Vision Blurred	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Visual Acuity Reduced	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Gastrointestinal Disorders	19	(1.40)	21	41	(3.02)	59	4	(0.29)	4	71	(5.23)	90	13	(0.96)	18
Abdominal Discomfort	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	4	(0.29)	4	0	(0.00)	0
Abdominal Distension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Abdominal Pain	1	(0.07)	1	15	(1.11)	20	0	(0.00)	0	7	(0.52)	9	2	(0.15)	2
Abdominal Pain Lower	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Upper	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	9	(0.66)	10	1	(0.07)	1
Anal Fistula	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Aphthous Ulcer	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Colitis Ulcerative	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3
Constipation	3	(0.22)	3	2	(0.15)	2	0	(0.00)	0	4	(0.29)	5	1	(0.07)	1
Crohn's Disease	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Diarrhoea	3	(0.22)	3	4	(0.29)	4	0	(0.00)	0	10	(0.74)	10	2	(0.15)	2
Dry Mouth	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Dyspepsia	4	(0.29)	4	1	(0.07)	1	0	(0.00)	0	9	(0.66)	11	0	(0.00)	0
Dysphagia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Enterocutaneous Fistula	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Epigastric Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Frequent Bowel Movements	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Gastric Mucosal Lesion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Gastric Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Gastric Ulcer Haemorrhage	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastritis	1	(0.07)	1	2	(0.15)	2	0	(0.00)	0	2	(0.15)	2	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
Gastrointestinal Disorder	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1
Gastrointestinal Inflammation	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Gastroesophageal Reflux Disease	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Haematochezia	0	(0.00)	0	6	(0.44)	6	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Ileus	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Large Intestine Polyp	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Melaena	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Mouth Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Mouth Ulceration	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Nausea	2	(0.15)	2	3	(0.22)	5	1	(0.07)	1	9	(0.66)	9	4	(0.29)	4
Proctalgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Protein-Losing Gastroenteropathy	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Regurgitation	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	2	0	(0.00)	0
Small Intestinal Haemorrhage	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Stomatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Vomiting	0	(0.00)	0	2	(0.15)	4	0	(0.00)	0	5	(0.37)	5	2	(0.15)	2
General Disorders and Administration Site Conditions	7	(0.52)	7	13	(0.96)	14	4	(0.29)	4	21	(1.55)	23	7	(0.52)	8
Application Site Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Asthenia	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chest Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Chest Pain	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	2	(0.15)	2
Chills	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	2	(0.15)	4	1	(0.07)	1
Disease Progression	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	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
Drug Ineffective	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Face Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Fatigue	2	(0.15)	2	2	(0.15)	2	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Generalised Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1
Immediate Post-Injection Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Influenza Like Illness	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Non-Cardiac Chest Pain	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Oedema	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Oedema Peripheral	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	2	(0.15)	2	1	(0.07)	1
Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Pyrexia	1	(0.07)	1	4	(0.29)	5	2	(0.15)	2	5	(0.37)	5	1	(0.07)	1
Swelling	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatobiliary Disorders	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	4	(0.29)	4	3	(0.22)	3
Cholelithiasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Drug-Induced Liver Injury	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Hepatic Function Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Hepatitis	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	1	(0.07)	1
Hyperbilirubinaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Liver Disorder	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Immune System Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	9	(0.66)	9	1	(0.07)	1
Anaphylactic Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Anaphylactic Shock	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Hypersensitivity	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	1	(0.07)	1
Infections and Infestations	7	(0.52)	7	23	(1.69)	29	3	(0.22)	3	88	(6.48)	98	24	(1.77)	25
Abdominal Abscess	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abscess	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anal Abscess	0	(0.00)	0	3	(0.22)	3	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
Atypical Pneumonia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Body Tinea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Bronchiolitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Bronchitis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	11	(0.81)	11	0	(0.00)	0
Candida Infection	0	(0.00)	0	1	(0.07)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cellulitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2
Clostridium Difficile Infection	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Cystitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	1	(0.07)	1
Cytomegalovirus Colitis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Infection	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Disseminated Tuberculosis	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1	1	(0.07)	1
Folliculitis	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Furuncle	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Gastritis Bacterial	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatitis B	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Herpes Simplex	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	2	(0.15)	2
Herpes Virus Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Herpes Zoster	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	4	(0.29)	4
Hordeolum	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Influenza	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Lung Abscess	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Nasopharyngitis	2	(0.15)	2	5	(0.37)	5	0	(0.00)	0	18	(1.33)	19	2	(0.15)	2
Onychomycosis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Oral Candidiasis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Otitis Externa	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	2	0	(0.00)	0
Pharyngitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Pharyngotonsillitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Pneumocystis Jirovecii Pneumonia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Pneumonia	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	5	(0.37)	5	0	(0.00)	0
Pneumonia Bacterial	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Postoperative Wound Infection	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Pseudomembranous Colitis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	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
Pyelonephritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Pyelonephritis Acute	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	1	(0.07)	1
Rhinitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Sepsis	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sialoadenitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Sinusitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Spleen Tuberculosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Tinea Pedis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Tonsillitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Tuberculosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	1	(0.07)	1
Tuberculosis Gastrointestinal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Upper Respiratory Tract Infection	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	20	(1.47)	23	3	(0.22)	3
Ureteritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Urinary Tract Infection	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Vaginal Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Injury, Poisoning and Procedural Complications	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	15	(1.11)	18	2	(0.15)	4
Ankle Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Auricular Haematoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	3
Compression Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Contusion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Facial Bones Fracture	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0
Fall	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Foot Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Hand Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Infusion Related Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Joint Dislocation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Laceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Perineal Injury	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Road Traffic Accident	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Investigations	20	(1.47)	25	4	(0.29)	4	1	(0.07)	2	24	(1.77)	30	11	(0.81)	13
Alanine Aminotransferase Increased	8	(0.59)	8	0	(0.00)	0	1	(0.07)	1	8	(0.59)	9	4	(0.29)	4
Aspartate Aminotransferase Increased	4	(0.29)	4	0	(0.00)	0	1	(0.07)	1	7	(0.52)	7	1	(0.07)	1
Blood Alkaline Phosphatase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Blood Creatine Phosphokinase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
C-Reactive Protein Increased	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Eosinophil Count Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Hepatic Enzyme Increased	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	2	(0.15)	2
Influenza B Virus Test Positive	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Liver Function Test Abnormal	5	(0.37)	6	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Occult Blood	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Serum Ferritin Increased	0	(0.00)	0	1	(0.07)	1	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
Urine Analysis Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Weight Decreased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Weight Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	1	(0.07)	1
White Blood Cell Count Decreased	3	(0.22)	3	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1
Metabolism and Nutrition Disorders	2	(0.15)	2	5	(0.37)	5	0	(0.00)	0	18	(1.33)	19	0	(0.00)	0
Decreased Appetite	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	2	(0.15)	2	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
Hypercholesterolaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0
Hyperglycaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Hyperlipidaemia	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	10	(0.74)	10	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Hypoglycaemia	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	3	(0.22)	3	40	(2.95)	55	0	(0.00)	0	42	(3.10)	56	4	(0.29)	4
Ankylosing Spondylitis	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1
Arthralgia	0	(0.00)	0	15	(1.11)	18	0	(0.00)	0	12	(0.88)	13	0	(0.00)	0
Atlantoaxial Instability	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Back Pain	1	(0.07)	1	8	(0.59)	9	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0
Bursal Fluid Accumulation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Fibromyalgia	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Flank Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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
Intervertebral Disc Disorder	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Protrusion	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Joint Swelling	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Lumbar Spinal Stenosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0
Musculoskeletal Pain	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	3	(0.22)	3	1	(0.07)	1
Musculoskeletal Stiffness	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Myalgia	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	6	(0.44)	7	0	(0.00)	0
Osteoarthritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Pain in Extremity	0	(0.00)	0	5	(0.37)	5	0	(0.00)	0	3	(0.22)	4	1	(0.07)	1
Polyarthrititis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rheumatoid Arthritis	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Rotator Cuff Syndrome	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Spinal Column Stenosis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Synovial Cyst	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Synovitis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tendonitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Tenosynovitis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	3	(0.22)	3
Colon Adenoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Gastric Cancer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2
Hypergammaglobulinaemia Benign Monoclonal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Invasive Ductal Breast Carcinoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Nervous System Disorders	2	(0.15)	2	19	(1.40)	21	0	(0.00)	0	37	(2.73)	44	3	(0.22)	3
Anosmia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Carotid Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Cerebellar Ataxia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Cerebellar Infarction	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cerebral Infarction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Cervical Radiculopathy	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Diabetic Neuropathy	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dizziness	2	(0.15)	2	1	(0.07)	1	0	(0.00)	0	13	(0.96)	14	0	(0.00)	0
Headache	0	(0.00)	0	3	(0.22)	4	0	(0.00)	0	9	(0.66)	9	0	(0.00)	0
Hypoesthesia	0	(0.00)	0	6	(0.44)	6	0	(0.00)	0	2	(0.15)	2	1	(0.07)	1
Migraine	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	1	(0.07)	1
Neuropathy Peripheral	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Paraesthesia	0	(0.00)	0	6	(0.44)	7	0	(0.00)	0	3	(0.22)	3	1	(0.07)	1
Sciatica	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Subarachnoid Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Syncope	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Tension Headache	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Tremor	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0
Psychiatric Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(0.52)	7	1	(0.07)	1
Depression	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1
Insomnia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(0.37)	5	0	(0.00)	0
Tic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Renal and Urinary Disorders	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Calculus Ureteric	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dysuria	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Pollakiuria	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	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Reproductive System and Breast Disorders	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	4	(0.29)	4	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
Erectile Dysfunction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1
Menorrhagia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Pelvic Pain	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Varicocele	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	3	(0.22)	5	6	(0.44)	7	0	(0.00)	0	31	(2.28)	32	5	(0.37)	6
Acute Respiratory Distress Syndrome	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Atelectasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Cough	1	(0.07)	1	3	(0.22)	3	0	(0.00)	0	13	(0.96)	13	1	(0.07)	1
Dysphonia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Dyspnoea	1	(0.07)	1	1	(0.07)	1	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Dyspnoea Exertional	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Epistaxis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Interstitial Lung Disease	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Laryngeal Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Nasal Septum Deviation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Oropharyngeal Pain	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	1	(0.07)	1
Pleural Effusion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Productive Cough	2	(0.15)	2	0	(0.00)	0	0	(0.00)	0	5	(0.37)	5	0	(0.00)	0
Respiratory Distress	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Rhinitis Allergic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	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
Sputum Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Vocal Cord Polyp	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Skin and Subcutaneous Tissue Disorders	11	(0.81)	12	7	(0.52)	7	0	(0.00)	0	63	(4.64)	88	15	(1.11)	16
Acne	2	(0.15)	2	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
Androgenetic Alopecia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Decubitus Ulcer	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dermatitis Acneiform	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Dermatitis Allergic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Dermatitis Contact	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0
Diabetic Foot	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Eczema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Erythema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Erythema Nodosum	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hyperhidrosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Hyperkeratosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Hypersensitivity Vasculitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Pain of Skin	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Papule	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Photosensitivity Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Pruritus	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	28	(2.06)	35	0	(0.00)	0
Pruritus Generalised	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	1	(0.07)	1
Pseudofolliculitis Barbae	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Psoriasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.15)	2	0	(0.00)	0
Rash	4	(0.29)	4	1	(0.07)	1	0	(0.00)	0	9	(0.66)	11	4	(0.29)	4
Rash Generalised	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1
Seborrhoeic Dermatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Skin Exfoliation	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	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Skin Lesion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Swelling Face	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	4	(0.29)	4	1	(0.07)	1
Systemic Lupus Erythematosus Rash	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Urticaria	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	10	(0.74)	11	4	(0.29)	4
Xeroderma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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
Andropause	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Surgical and Medical Procedures	0	(0.00)	0	5	(0.37)	5	0	(0.00)	0	4	(0.29)	4	0	(0.00)	0
Arthrotomy	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ileostomy	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Ileostomy Closure	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Intervertebral Disc Operation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Joint Arthroplasty	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Spinal Decompression	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tooth Extraction	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	3	(0.22)	3	1	(0.07)	1	1	(0.07)	1	10	(0.74)	11	0	(0.00)	0
Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0
Deep Vein Thrombosis	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			Unknown		
	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	N of events	No. of subjects	(%)	No. of Events	No. of subjects	(%)	No. of Events
Flushing	2	(0.15)	2	0	(0.00)	0	1	(0.07)	1	3	(0.22)	4	0	(0.00)	0
Hypertension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.22)	3	0	(0.00)	0
Hypotension	1	(0.07)	1	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	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
Renovascular Hypertension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.07)	1	0	(0.00)	0

Table 148 Incidence status for classification of causal relationship except the surveillance drug (AS (N=531))

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Total	26	(4.90)	34	35	(6.59)	51	4	(0.75)	5	112	(21.09)	159	29	(5.46)	40
Blood and Lymphatic System Disorders	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	1	(0.19)	1	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
Iron Deficiency Anaemia	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Ear and Labyrinth Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Vertigo	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Eye Disorders	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	3	(0.56)	3	1	(0.19)	1
Dry Eye	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0
Uveitis	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1
Gastrointestinal Disorders	7	(1.32)	8	3	(0.56)	5	0	(0.00)	0	13	(2.45)	15	3	(0.56)	4

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Abdominal Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Abdominal Pain Upper	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	4	(0.75)	4	1	(0.19)	1
Constipation	1	(0.19)	1	1	(0.19)	1	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1
Diarrhoea	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0	4	(0.75)	4	0	(0.00)	0
Dry Mouth	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dyspepsia	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Epigastric Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	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
Gastritis	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	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
Gastrointestinal Disorder	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Large Intestine Polyp	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Mouth Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	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
Nausea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1
General Disorders and Administration Site Conditions	3	(0.56)	3	2	(0.38)	2	2	(0.38)	2	3	(0.56)	3	1	(0.19)	1
Chest Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Chest Pain	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0
Fatigue	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Influenza Like Illness	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Pyrexia	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1	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
Hepatobiliary Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1
Drug-Induced Liver Injury	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Hepatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Immune System Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.75)	4	1	(0.19)	1
Anaphylactic Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Anaphylactic Shock	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Hypersensitivity	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	1	(0.19)	1
Infections and Infestations	2	(0.38)	2	3	(0.56)	4	0	(0.00)	0	24	(4.52)	30	9	(1.69)	10
Body Tinea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Bronchiolitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Bronchitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0
Cellulitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2
Furuncle	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Gastritis Bacterial	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Hepatitis B	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Herpes Virus Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Herpes Zoster	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3
Hordeolum	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Nasopharyngitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	8	(1.51)	9	2	(0.38)	2
Onychomycosis	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0
Pharyngitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Pharyngotonsillitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Pneumonia	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Postoperative Wound Infection	0	(0.00)	0	1	(0.19)	1	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
Sinusitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Tinea Pedis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Tonsillitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Tuberculosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Upper Respiratory Tract Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	6	1	(0.19)	1
Injury, Poisoning and Procedural Complications	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	3	(0.56)	4	2	(0.38)	4
Auricular Haematoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	3
Compression Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Facial Bones Fracture	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	Concomitant medication			Underlying disease			Others			Not applicable			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
Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Hand Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Joint Dislocation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Road Traffic Accident	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Investigations	9	(1.69)	12	0	(0.00)	0	1	(0.19)	2	10	(1.88)	14	6	(1.13)	8
Alanine Aminotransferase Increased	5	(0.94)	5	0	(0.00)	0	1	(0.19)	1	6	(1.13)	6	3	(0.56)	3
Aspartate Aminotransferase Increased	3	(0.56)	3	0	(0.00)	0	1	(0.19)	1	5	(0.94)	5	1	(0.19)	1
Blood Creatine Phosphokinase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Hepatic Enzyme Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	2	(0.38)	2
Liver Function Test Abnormal	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	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
Weight Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Metabolism and Nutrition Disorders	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	7	(1.32)	7	0	(0.00)	0
Decreased Appetite	0	(0.00)	0	1	(0.19)	1	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
Hypercholesterolaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0
Hyperlipidaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Musculoskeletal and Connective Tissue Disorders	3	(0.56)	3	15	(2.82)	24	0	(0.00)	0	13	(2.45)	19	3	(0.56)	3
Ankylosing Spondylitis	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1
Arthralgia	0	(0.00)	0	6	(1.13)	8	0	(0.00)	0	5	(0.94)	6	0	(0.00)	0
Back Pain	1	(0.19)	1	6	(1.13)	6	0	(0.00)	0	2	(0.38)	2	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
Foot Deformity	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Joint Swelling	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0
Musculoskeletal Pain	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Musculoskeletal Stiffness	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Myalgia	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Pain in Extremity	0	(0.00)	0	5	(0.94)	5	0	(0.00)	0	3	(0.56)	4	1	(0.19)	1
Spinal Column Stenosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Tendonitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Nervous System Disorders	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	13	(2.45)	15	0	(0.00)	0
Cerebellar Infarction	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cervical Radiculopathy	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dizziness	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	3	0	(0.00)	0
Headache	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.75)	4	0	(0.00)	0
Hypoaesthesia	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Migraine	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0
Neuropathy Peripheral	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Paraesthesia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0
Sciatica	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Syncope	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Psychiatric Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	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
Insomnia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Renal and Urinary Disorders	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Calculus Ureteric	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dysuria	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Pollakiuria	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	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Reproductive System and Breast Disorders	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	1	(0.19)	1	1	(0.19)	1
Erectile Dysfunction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Pelvic Pain	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Varicocele	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	2	(0.38)	4	2	(0.38)	2	0	(0.00)	0	11	(2.07)	11	1	(0.19)	1

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Cough	1	(0.19)	1	2	(0.38)	2	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0
Dyspnoea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Laryngeal Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Nasal Septum Deviation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Oropharyngeal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Productive Cough	2	(0.38)	2	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0
Rhinitis Allergic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	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
Sputum Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1
Skin and Subcutaneous Tissue Disorders	2	(0.38)	2	2	(0.38)	2	0	(0.00)	0	21	(3.95)	23	4	(0.75)	4
Acne	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
Androgenetic Alopecia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Decubitus Ulcer	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Eczema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Hyperhidrosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Hyperkeratosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Hypersensitivity Vasculitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Papule	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Pruritus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(1.32)	7	0	(0.00)	0
Pruritus Generalised	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Psoriasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.38)	2	0	(0.00)	0
Rash	2	(0.38)	2	1	(0.19)	1	0	(0.00)	0	3	(0.56)	3	0	(0.00)	0
Seborrhoeic Dermatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Swelling Face	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Urticaria	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	2	(0.38)	2
Xerodema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	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
Andropause	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0
Surgical and Medical Procedures	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Arthrotomy	0	(0.00)	0	1	(0.19)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.75)	4	0	(0.00)	0
Hypertension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.56)	3	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

Table 149 Incidence status for classification of causal relationship except the surveillance drug (RA/PA/PS (N=409))

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Total	31	(7.58)	38	61	(14.91)	87	5	(1.22)	5	143	(34.96)	308	25	(6.11)	33

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Blood and Lymphatic System Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0
Iron Deficiency Anaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Lymphadenopathy	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	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
Cardiac Disorders	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	3	(0.73)	3	2	(0.49)	2
Atrial Fibrillation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Cardiac Arrest	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Palpitations	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	3	(0.73)	3	1	(0.24)	1
Ear and Labyrinth Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0
Tinnitus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0
Eye Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	5	0	(0.00)	0
Blepharitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Dry Eye	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Glaucoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Visual Acuity Reduced	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Gastrointestinal Disorders	8	(1.96)	9	4	(0.98)	4	1	(0.24)	1	42	(10.27)	52	3	(0.73)	5
Abdominal Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Abdominal Distension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Abdominal Pain	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	1	(0.24)	1

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Abdominal Pain Upper	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	5	(1.22)	6	0	(0.00)	0
Aphthous Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Constipation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	2	(0.49)	3	0	(0.00)	0
Diarrhoea	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	2	(0.49)	2
Dry Mouth	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dyspepsia	2	(0.49)	2	1	(0.24)	1	0	(0.00)	0	6	(1.47)	7	0	(0.00)	0
Dysphagia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Gastric Mucosal Lesion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Gastric Ulcer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Gastritis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	2	(0.49)	2	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
Gastroesophageal Reflux Disease	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Mouth Ulceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Nausea	1	(0.24)	1	1	(0.24)	1	1	(0.24)	1	8	(1.96)	8	1	(0.24)	1
Proctalgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Regurgitation	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	0	(0.00)	0
Stomatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Vomiting	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	1	(0.24)	1
General Disorders and Administration Site Conditions	2	(0.49)	2	5	(1.22)	5	1	(0.24)	1	11	(2.69)	13	3	(0.73)	4

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Asthenia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Chest Discomfort	0	(0.00)	0	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	0	(0.00)	0
Chills	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	2	(0.49)	4	1	(0.24)	1
Drug Effect Delayed	1	(0.24)	1	0	(0.00)	0	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	0	(0.00)	0
Fatigue	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Generalised Oedema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Oedema	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Oedema Peripheral	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	2	(0.49)	2	1	(0.24)	1
Pyrexia	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	1	(0.24)	1
Hepatobiliary Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	1	(0.24)	1
Cholelithiasis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Hepatitis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0
Immune System Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0
Anaphylactic Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Hypersensitivity	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Infections and Infestations	4	(0.98)	4	11	(2.69)	12	1	(0.24)	1	45	(11.00)	48	7	(1.71)	7

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Abscess	0	(0.00)	0	1	(0.24)	1	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
Body Tinea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Bronchitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	8	(1.96)	8	0	(0.00)	0
Candida Infection	0	(0.00)	0	1	(0.24)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cystitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Disseminated Tuberculosis	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	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
Herpes Simplex	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	2	(0.49)	2
Herpes Zoster	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0
Influenza	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Nasopharyngitis	1	(0.24)	1	4	(0.98)	4	0	(0.00)	0	5	(1.22)	5	0	(0.00)	0
Otitis Externa	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	0	(0.00)	0
Pneumonia	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0
Pneumonia Bacterial	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Pyelonephritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Pyelonephritis Acute	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	1	(0.24)	1
Rhinitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Sepsis	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	Concomitant medication			Underlying disease			Others			Not applicable			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
Sinusitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Tinea Pedis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Tuberculosis Gastrointestinal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Upper Respiratory Tract Infection	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	10	(2.44)	10	1	(0.24)	1
Ureteritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Urinary Tract Infection	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Vaginal Infection	0	(0.00)	0	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	0	(0.00)	0
Ankle Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Contusion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Fall	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Foot Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Joint Dislocation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Laceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Perineal Injury	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Road Traffic Accident	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Investigations	8	(1.96)	10	2	(0.49)	2	0	(0.00)	0	10	(2.44)	10	1	(0.24)	1
Alanine Aminotransferase Increased	3	(0.73)	3	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Aspartate Aminotransferase Increased	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Hepatic Enzyme Increased	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Influenza B Virus Test Positive	0	(0.00)	0	1	(0.24)	1	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
Serum Ferritin Increased	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Urine Analysis Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Weight Decreased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Weight Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0
Metabolism and Nutrition Disorders	2	(0.49)	2	3	(0.73)	3	0	(0.00)	0	11	(2.69)	12	0	(0.00)	0
Decreased Appetite	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Hypercholesterolaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Hyperglycaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Hyperlipidaemia	2	(0.49)	2	0	(0.00)	0	0	(0.00)	0	7	(1.71)	7	0	(0.00)	0
Hypoglycaemia	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	0	(0.00)	0	25	(6.11)	31	0	(0.00)	0	24	(5.87)	32	0	(0.00)	0
Arthralgia	0	(0.00)	0	9	(2.20)	10	0	(0.00)	0	6	(1.47)	6	0	(0.00)	0
Atlantoaxial Instability	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Back Pain	0	(0.00)	0	2	(0.49)	3	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Bursal Fluid Accumulation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Fibromyalgia	0	(0.00)	0	2	(0.49)	2	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	1	(0.24)	1	0	(0.00)	0
Intervertebral Disc Disorder	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Intervertebral Disc Protrusion	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0
Joint Swelling	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Lumbar Spinal Stenosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0
Musculoskeletal Pain	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Myalgia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	4	(0.98)	5	0	(0.00)	0
Osteoarthritis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	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
Polyarthritis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rheumatoid Arthritis	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Rotator Cuff Syndrome	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Spinal Column Stenosis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Synovial Cyst	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Synovitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tenosynovitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	3	(0.73)	3

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Colon Adenoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Gastric Cancer	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2
Hypergammaglobulinaemia Benign Monoclonal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Invasive Ductal Breast Carcinoma	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Nervous System Disorders	1	(0.24)	1	16	(3.91)	18	0	(0.00)	0	21	(5.13)	26	2	(0.49)	2
Anosmia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Carotid Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Cerebellar Ataxia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Cerebral Infarction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Diabetic Neuropathy	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dizziness	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	9	(2.20)	9	0	(0.00)	0
Headache	0	(0.00)	0	3	(0.73)	4	0	(0.00)	0	5	(1.22)	5	0	(0.00)	0
Hypoaesthesia	0	(0.00)	0	5	(1.22)	5	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Migraine	0	(0.00)	0	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	0	(0.00)	0
Paraesthesia	0	(0.00)	0	6	(1.47)	7	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Subarachnoid Haemorrhage	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Tension Headache	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Tremor	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Psychiatric Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0
Insomnia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0
Tic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Reproductive System and Breast Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	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
Erectile Dysfunction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Menorrhagia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	0	(0.00)	0	3	(0.73)	4	0	(0.00)	0	16	(3.91)	17	2	(0.49)	2
Acute Respiratory Distress Syndrome	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	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	0	(0.00)	0
Cough	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	9	(2.20)	9	0	(0.00)	0
Dysphonia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Dyspnoea Exertional	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Interstitial Lung Disease	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Oropharyngeal Pain	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pleural Effusion	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Productive Cough	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Rhinitis Allergic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Vocal Cord Polyp	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Skin and Subcutaneous Tissue Disorders	4	(0.98)	5	4	(0.98)	4	0	(0.00)	0	28	(6.85)	50	5	(1.22)	6
Alopecia	3	(0.73)	3	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
Dermatitis Allergic	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Dermatitis Contact	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.98)	4	0	(0.00)	0
Diabetic Foot	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Erythema	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Hyperhidrosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Pruritus	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	14	(3.42)	21	0	(0.00)	0
Pruritus Generalised	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Pseudofolliculitis Barbae	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0
Rash	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(1.22)	7	2	(0.49)	2
Rash Generalised	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Swelling Face	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0
Systemic Lupus Erythematosus Rash	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Urticaria	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	6	(1.47)	7	2	(0.49)	2
Surgical and Medical Procedures	0	(0.00)	0	3	(0.73)	3	0	(0.00)	0	2	(0.49)	2	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Intervertebral Disc Operation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Joint Arthroplasty	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Spinal Decompression	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Tooth Extraction	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vascular Disorders	3	(0.73)	3	0	(0.00)	0	1	(0.24)	1	5	(1.22)	6	0	(0.00)	0
Arteriosclerosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Flushing	2	(0.49)	2	0	(0.00)	0	1	(0.24)	1	3	(0.73)	4	0	(0.00)	0
Hypotension	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0

Table 150 Incidence status for classification of causal relationship except the surveillance drug (IBD (N=417))

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Total	19	(4.56)	22	52	(12.47)	78	7	(1.68)	7	67	(16.07)	100	28	(6.71)	39
Blood and Lymphatic System Disorders	4	(0.96)	4	1	(0.24)	1	0	(0.00)	0	4	(0.96)	4	2	(0.48)	2
Anaemia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0
Iron Deficiency Anaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Leukopenia	4	(0.96)	4	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Lymphadenitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Neutropenia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Cardiac Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Palpitations	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Ear and Labyrinth Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Otorrhoea	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Eye Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Vision Blurred	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Gastrointestinal Disorders	4	(0.96)	4	34	(8.15)	50	3	(0.72)	3	16	(3.84)	23	7	(1.68)	9
Abdominal Discomfort	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0
Abdominal Pain	0	(0.00)	0	15	(3.60)	20	0	(0.00)	0	5	(1.20)	7	1	(0.24)	1
Abdominal Pain Lower	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Abdominal Pain Upper	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anal Fistula	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Aphthous Ulcer	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Colitis Ulcerative	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3
Constipation	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Crohn's Disease	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0
Diarrhoea	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0
Dyspepsia	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	2	(0.48)	3	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Enterocutaneous Fistula	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Epigastric Discomfort	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0
Frequent Bowel Movements	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Gastritis	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Gastrointestinal Inflammation	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Haematochezia	0	(0.00)	0	6	(1.44)	6	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Ileus	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Melaena	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Mouth Ulceration	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Nausea	1	(0.24)	1	2	(0.48)	4	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2
Protein-Losing Gastroenteropathy	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Small Intestinal Haemorrhage	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Vomiting	0	(0.00)	0	2	(0.48)	4	0	(0.00)	0	2	(0.48)	2	1	(0.24)	1
General Disorders and Administration Site Conditions	2	(0.48)	2	6	(1.44)	7	1	(0.24)	1	7	(1.68)	7	3	(0.72)	3
Application Site Haemorrhage	0	(0.00)	0	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	0	(0.00)	0	2	(0.48)	2
Disease Progression	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Drug Ineffective	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Immediate Post-Injection Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Large Intestinal Perforation	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Non-Cardiac Chest Pain	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Oedema	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Pyrexia	1	(0.24)	1	3	(0.72)	4	0	(0.00)	0	4	(0.96)	4	0	(0.00)	0
Hepatobiliary Disorders	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1	1	(0.24)	1
Hepatic Function Abnormal	0	(0.00)	0	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	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0
Hyperbilirubinaemia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Immune System Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Anaphylactic Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Infections and Infestations	1	(0.24)	1	9	(2.16)	13	2	(0.48)	2	19	(4.56)	20	8	(1.92)	8
Abdominal Abscess	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Anal Abscess	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Atypical Pneumonia	0	(0.00)	0	0	(0.00)	0	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	0	(0.00)	0	0	(0.00)	0
Cystitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Cytomegalovirus Colitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Cytomegalovirus Infection	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Disseminated Tuberculosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Folliculitis	1	(0.24)	1	0	(0.00)	0	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	0	(0.00)	0
Herpes Zoster	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Lung Abscess	0	(0.00)	0	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	0	(0.00)	0
Oral Candidiasis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pneumocystis Jirovecii Pneumonia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Pneumonia	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Pseudomembranous Colitis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Rhinitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Sepsis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Sialoadenitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Spleen Tuberculosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Tuberculosis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	1	(0.24)	1
Upper Respiratory Tract Infection	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(1.68)	7	1	(0.24)	1
Urinary Tract Infection	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Injury, Poisoning and Procedural Complications	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	4	(0.96)	4	0	(0.00)	0

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Foot Fracture	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Infusion Related Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0
Investigations	3	(0.72)	3	2	(0.48)	2	0	(0.00)	0	4	(0.96)	6	4	(0.96)	4
Alanine Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	2	0	(0.00)	0
Aspartate Aminotransferase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Blood Alkaline Phosphatase Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
C-Reactive Protein Increased	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Eosinophil Count Increased	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Liver Function Test Abnormal	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Occult Blood	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
White Blood Cell Count Decreased	3	(0.72)	3	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Metabolism and Nutrition Disorders	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Decreased Appetite	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Musculoskeletal and Connective Tissue Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	5	(1.20)	5	1	(0.24)	1
Arthralgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Flank Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Musculoskeletal Pain	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Musculoskeletal Stiffness	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Myalgia	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Nervous System Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3	1	(0.24)	1
Dizziness	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0
Hypoaesthesia	0	(0.00)	0	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	1	(0.24)	1	0	(0.00)	0
Psychiatric Disorders	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Depression	0	(0.00)	0	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	0	(0.00)	0
Renal and Urinary Disorders	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Calculus Ureteric	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Respiratory, Thoracic and Mediastinal Disorders	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	4	(0.96)	4	2	(0.48)	3
Cough	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	1	(0.24)	1
Dyspnoea	1	(0.24)	1	1	(0.24)	1	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0
Epistaxis	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	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Rhinitis Hypertrophic	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	5	(1.20)	5	1	(0.24)	1	0	(0.00)	0	14	(3.36)	15	6	(1.44)	6

System Organ Class Preferred Term	Concomitant medication			Underlying disease			Others			Not applicable			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
Acne	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Dermatitis Acneiform	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Erythema Nodosum	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Pain of Skin	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Photosensitivity Reaction	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Pruritus	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	7	(1.68)	7	0	(0.00)	0
Rash	2	(0.48)	2	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	2	(0.48)	2
Seborrhoeic Dermatitis	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0
Skin Exfoliation	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1
Skin Lesion	0	(0.00)	0	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	0	(0.00)	0	1	(0.24)	1
Urticaria	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	3	(0.72)	3	0	(0.00)	0
Surgical and Medical Procedures	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	2	(0.48)	2	0	(0.00)	0
Ileostomy	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Ileostomy Closure	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Vascular Disorders	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0
Deep Vein Thrombosis	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0
Renovascular Hypertension	0	(0.00)	0	0	(0.00)	0	0	(0.00)	0	1	(0.24)	1	0	(0.00)	0

F. Action taken for the surveillance drug

Actions taken to the surveillance drug were categorized in the 6 categories, “Permanently Stopped administration”, “Temporarily Stopped administration”, “Decreased dosage”, “Increased dosage”, “Maintained dosage” and “Unknown”, 856 events of “Maintained dosage” in 33.31% (452/1357 subjects), 81 events of “Permanently Stopped administration” in 5.01% (68/1357 subjects), 40 events of “Temporarily Stopped administration” in 2.36% (32/1357 subjects), 21 events of “Increased dosage” in 1.18% (16/1357 subjects), 5 events of “Decreased dosage” in 0.29% (4/1357 subjects), and 3 events of “Unknown” in 0.15% (2/1357 subjects) (Table 151).

Classification of Action taken to the surveillance drug due to AE by indication is presented in Table 152, Table 153 and Table 154.