

**Table 4. Incidence of Serious Adverse Events
By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)**

System Organ Class Preferred Term	Total (N = 129)
Number of Subjects With Any Serious Adverse Event	61 (47.3%)
Infections and infestations	23 (17.8%)
Pneumonia	10 (7.8%)
Infection	4 (3.1%)
Bronchitis	3 (2.3%)
Sepsis	2 (1.6%)
Bronchitis bacterial	1 (0.8%)
Bronchopneumonia	1 (0.8%)
Device related infection	1 (0.8%)
Endocarditis	1 (0.8%)
Gastrointestinal fungal infection	1 (0.8%)
Lung infection	1 (0.8%)
Pharyngitis	1 (0.8%)
Septic shock	1 (0.8%)
Upper respiratory tract infection	1 (0.8%)
Urosepsis	1 (0.8%)
General disorders and administration site conditions	18 (14.0%)
Pyrexia	6 (4.7%)
Multi-organ failure	3 (2.3%)
Fatigue	2 (1.6%)
Asthenia	1 (0.8%)
Chills	1 (0.8%)
Disease progression	1 (0.8%)
Euthanasia	1 (0.8%)
General physical health deterioration	1 (0.8%)
Malaise	1 (0.8%)
Pain	1 (0.8%)
Vascular disorders	9 (7.0%)
Deep vein thrombosis	3 (2.3%)
Hypotension	2 (1.6%)

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Extremity necrosis	1 (0.8%)
Iliac artery thrombosis	1 (0.8%)
Shock	1 (0.8%)
Vasculitis	1 (0.8%)
Venous thrombosis limb	1 (0.8%)
Blood and lymphatic system disorders	8 (6.2%)
Anaemia	3 (2.3%)
Thrombocytopenia	3 (2.3%)
Febrile neutropenia	2 (1.6%)
Anaemia haemolytic autoimmune	1 (0.8%)
Haemolytic anaemia	1 (0.8%)
Pancytopenia	1 (0.8%)
Splenomegaly	1 (0.8%)
Respiratory, thoracic and mediastinal disorders	8 (6.2%)
Pulmonary embolism	3 (2.3%)
Alveolitis	1 (0.8%)
Chylothorax	1 (0.8%)
Hypoxia	1 (0.8%)
Pulmonary haemorrhage	1 (0.8%)
Pulmonary mass	1 (0.8%)
Respiratory failure	1 (0.8%)
Metabolism and nutrition disorders	7 (5.4%)
Tumour lysis syndrome	2 (1.6%)
Decreased appetite	1 (0.8%)
Dehydration	1 (0.8%)
Hypercalcaemia	1 (0.8%)
Hyperglycaemia	1 (0.8%)
Hypoglycaemia	1 (0.8%)
Investigations	6 (4.7%)

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Blood creatinine increased	3 (2.3%)
Alanine aminotransferase increased	1 (0.8%)
Aspartate aminotransferase increased	1 (0.8%)
Gamma-glutamyltransferase increased	1 (0.8%)
Liver function test abnormal	1 (0.8%)
Platelet count decreased	1 (0.8%)
Cardiac disorders	3 (2.3%)
Cardiac failure	2 (1.6%)
Atrial fibrillation	1 (0.8%)
Gastrointestinal disorders	2 (1.6%)
Constipation	1 (0.8%)
Gastrointestinal haemorrhage	1 (0.8%)
Hepatobiliary disorders	2 (1.6%)
Hepatic failure	1 (0.8%)
Hyperbilirubinaemia	1 (0.8%)
Injury, poisoning and procedural complications	2 (1.6%)
Lower limb fracture	1 (0.8%)
Multiple fractures	1 (0.8%)
Musculoskeletal and connective tissue disorders	2 (1.6%)
Arthralgia	1 (0.8%)
Pathological fracture	1 (0.8%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (1.6%)
Tumour associated fever	1 (0.8%)
Tumour haemorrhage	1 (0.8%)
Psychiatric disorders	2 (1.6%)

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Anxiety	1 (0.8%)
Impaired self-care	1 (0.8%)
Skin and subcutaneous tissue disorders	2 (1.6%)
Actinic keratosis	1 (0.8%)
Pain of skin	1 (0.8%)
Rash	1 (0.8%)
Eye disorders	1 (0.8%)
Toxic cataract	1 (0.8%)
Nervous system disorders	1 (0.8%)
Peripheral sensory neuropathy	1 (0.8%)
Renal and urinary disorders	1 (0.8%)
Renal failure	1 (0.8%)
Surgical and medical procedures	1 (0.8%)
Central venous catheterisation	1 (0.8%)