

***** List of reported SAE's *****

-> group == Arm1: Experimental (1 arm only)

ssoccd Soccod
 aeterm Event term
 affected Subjects affected number
 exposed Subjects exposed number
 occurrences Occurrences all number
 occurrel Occurrences causally related to treatment number
 fatality Fatalities number
 fatalrel Fatalities causally related to treatment number

| | ssoccd | aeterm | affected | exposed | occurrences | occurrel | fatality | fatalrel |
|--|--|--------|----------|---------|-------------|----------|----------|----------|
| Blood and lymphatic disorders | Febrile neutropenia | | 1 | 81 | 1 | 1 | . | . |
| Cardiac disorders | SVT | | 1 | 81 | 1 | 1 | . | . |
| Cardiac disorders | Sinus bradycardia | | 1 | 81 | 1 | . | . | . |
| Gastrointestinal disorders | Constipation | | 1 | 81 | 2 | 2 | . | . |
| Gastrointestinal disorders | Enteritis | | 1 | 81 | 1 | 1 | . | . |
| Gastrointestinal disorders | Nausea and vomiting | | 1 | 81 | 1 | . | . | . |
| General disorders and administration site conditions | Fever | | 3 | 81 | 3 | 3 | . | . |
| General disorders and administration site conditions | Malaise | | 2 | 81 | 2 | 2 | . | . |
| General disorders and administration site conditions | Pain thoracaal | | 1 | 81 | 1 | . | . | . |
| Infections and infestations | Gastro-enteritis | | 1 | 81 | 1 | . | . | . |
| Infections and infestations | Infection lung | | 1 | 81 | 1 | 1 | . | . |
| Infections and infestations | Meesles infection | | 1 | 81 | 1 | . | . | . |
| Infections and infestations | Pneumonia | | 7 | 81 | 7 | 6 | 1 | 1 |
| Infections and infestations | Sepsis (infection-blood) | | 1 | 81 | 1 | 1 | . | . |
| Infections and infestations | Sinusitis | | 1 | 81 | 1 | . | . | . |
| Injury, poisoning and procedural complications | Bone fracture pathologic | | 1 | 81 | 1 | 1 | . | . |
| Injury, poisoning and procedural complications | Contusion brains | | 1 | 81 | 1 | . | . | . |
| Injury, poisoning and procedural complications | Fracture | | 2 | 81 | 2 | . | . | . |
| Injury, poisoning and procedural complications | Increased back pain (due to vertebral collaps L10) | | 1 | 81 | 1 | . | . | . |
| Investigations | Hemoglobin | | 1 | 81 | 1 | 1 | . | . |
| Metabolism and nutrition disorders | Hypercalcemia | | 1 | 81 | 1 | . | . | . |
| Metabolism and nutrition disorders | Hyponatraemia | | 1 | 81 | 1 | . | . | . |
| Musculoskeletal and connective tissue disorders | Myopathy | | 1 | 81 | 1 | 1 | . | . |
| Neoplasms benign, malignant and unspecified | AML (SPM) | | 1 | 81 | 1 | 1 | . | . |
| Neoplasms benign, malignant and unspecified | MDS-RAEB-2 (SPM) | | 1 | 81 | 1 | 1 | . | . |
| Neoplasms benign, malignant and unspecified | Mesothelioma (SPM) | | 2 | 81 | 2 | 1 | . | . |
| Neoplasms benign, malignant and unspecified | Pending spinal injury (due to local plasmacytoma) | | 1 | 81 | 1 | . | . | . |
| Neoplasms benign, malignant and unspecified | SPM: 6x squamous cell carcinoma | | 1 | 81 | 1 | 1 | . | . |
| Neoplasms benign, malignant and unspecified | SPM: Breast (adeno) CA | | 1 | 81 | 1 | 1 | . | . |
| Neoplasms benign, malignant and unspecified | SPM:42x Basal cell carcinoma | | 1 | 81 | 1 | 1 | . | . |
| Neoplasms benign, malignant and unspecified | Squamouscell carcinoma of the skin | | 1 | 81 | 1 | . | . | . |
| Nervous system disorders | (CTC gr.2-3) polyneuropathy | | 1 | 81 | 1 | 1 | . | . |
| Nervous system disorders | Syncope | | 1 | 81 | 1 | 1 | . | . |
| Nervous system disorders | Syncope c collapsing | | 1 | 81 | 1 | . | . | . |
| Psychiatric disorders | Confusion | | 2 | 81 | 2 | 1 | . | . |
| Renal and urinary disorders | Renal failure | | 1 | 81 | 1 | 1 | 1 | 1 |
| Respiratory, thoracic and mediastinal disorders | Cough | | 1 | 81 | 1 | . | . | . |
| Respiratory, thoracic and mediastinal disorders | Dyspnea | | 2 | 81 | 2 | 1 | . | . |
| Respiratory, thoracic and mediastinal disorders | Hyperventilation + dizziness | | 1 | 81 | 1 | 1 | . | . |
| Respiratory, thoracic and mediastinal disorders | Lung-emboli | | 1 | 81 | 1 | 1 | . | . |
| Respiratory, thoracic and mediastinal disorders | Persistent coughing | | 1 | 81 | 1 | . | . | . |
| Skin and subcutaneous tissue disorders | Pyoderma gangnenosum | | 1 | 81 | 1 | 1 | . | . |
| Vascular disorders | Collaps | | 1 | 81 | 1 | . | . | . |
| Vascular disorders | Deep venous thrombosis (DVT) | | 1 | 81 | 1 | 1 | . | . |
| Vascular disorders | Orthostatic hypotension | | 2 | 81 | 2 | 2 | . | . |
| Vascular disorders | Throacic aneurysm | | 1 | 81 | 1 | . | . | . |