

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

-> group == Arm A: 1

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| ssoccd | Soccode |
| 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 system disorders | Anaemia | | 1 | 96 | 1 | . | . | . |
| Blood and lymphatic system disorders | Anemia | | 1 | 96 | 1 | 1 | . | . |
| Blood and lymphatic system disorders | Febrile neutropenia | | 1 | 96 | 1 | 1 | . | . |
| Blood and lymphatic system disorders | Fever, neutropenic | | 1 | 96 | 1 | 1 | . | . |
| Blood and lymphatic system disorders | Pancytopenia | | 1 | 96 | 1 | 1 | . | . |
| Blood and lymphatic system disorders | Symptomatic anaemia | | 1 | 96 | 2 | 1 | . | . |
| Cardiac disorders | Acute coronary syndrome | | 1 | 96 | 2 | . | . | . |
| Cardiac disorders | Angina Pectoris | | 1 | 96 | 1 | . | . | . |
| Cardiac disorders | Angina Pectoris iv | | 1 | 96 | 1 | . | . | . |
| Cardiac disorders | Angina pectoris | | 1 | 96 | 1 | . | . | . |
| Cardiac disorders | Cardiac arrest | | 1 | 96 | 1 | . | 1 | . |
| Cardiac disorders | Decompensatio cordis | | 1 | 96 | 1 | 1 | . | . |
| Gastrointestinal disorders | Abdominal pain | | 1 | 96 | 1 | 1 | . | . |
| Gastrointestinal disorders | Diarrhea | | 1 | 96 | 1 | . | . | . |
| Gastrointestinal disorders | Ileus due to obstruction in bowel | | 1 | 96 | 1 | . | . | . |
| Gastrointestinal disorders | Peptic ulcer with hemorrhage | | 1 | 96 | 1 | 1 | . | . |
| Gastrointestinal disorders | Vomiting | | 1 | 96 | 1 | . | . | . |
| General disorders and administration site conditions | Death | | 1 | 96 | 1 | 1 | 1 | 1 |
| General disorders and administration site conditions | Disease progression NOS | | 1 | 96 | 1 | . | 1 | . |
| General disorders and administration site conditions | Fever | | 1 | 96 | 1 | 1 | . | . |
| General disorders and administration site conditions | General malaise | | 1 | 96 | 1 | . | . | . |
| General disorders and administration site conditions | Subfebrile fever | | 1 | 96 | 1 | . | . | . |
| Hepatobiliary disorders | Cholangitis (CTC??) | | 1 | 96 | 1 | . | . | . |
| Immune system disorders | Allergic reaction | | 1 | 96 | 1 | . | . | . |
| Infections and infestations | Cystitis | | 1 | 96 | 1 | . | . | . |
| Infections and infestations | Erysipelas | | 1 | 96 | 1 | . | . | . |
| Infections and infestations | Fasciitis necroticans | | 1 | 96 | 1 | 1 | . | . |
| Infections and infestations | Herpes Zoster in face | | 1 | 96 | 1 | 1 | . | . |
| Infections and infestations | Infection nefrolithiasis,urethrososcopy w/ laser litharips | | 1 | 96 | 1 | . | . | . |
| Infections and infestations | Infiltration pneumoniae | | 1 | 96 | 1 | 1 | . | . |
| Infections and infestations | Lung infection | | 1 | 96 | 1 | . | . | . |
| Infections and infestations | Mastitis | | 1 | 96 | 1 | . | . | . |
| Infections and infestations | Parotitis | | 1 | 96 | 1 | 1 | . | . |
| Infections and infestations | Pneumonia | | 3 | 96 | 4 | 4 | . | . |
| Infections and infestations | Pulmonary abscess | | 1 | 96 | 1 | 1 | 1 | 1 |
| Infections and infestations | Septic shock | | 1 | 96 | 1 | . | . | . |
| Infections and infestations | Upper airway infection | | 1 | 96 | 1 | 1 | . | . |
| Injury, poisoning and procedural complications | Fall | | 1 | 96 | 1 | . | . | . |
| Injury, poisoning and procedural complications | Tibia fracture | | 1 | 96 | 1 | . | . | . |
| Investigations | Long QT time on ECG | | 1 | 96 | 1 | . | . | . |
| Musculoskeletal and connective tissue disorders | Back pain | | 1 | 96 | 1 | . | . | . |
| Musculoskeletal and connective tissue disorders | Pain in extremity | | 1 | 96 | 1 | . | . | . |
| Musculoskeletal and connective tissue disorders | Pain muskuloskeletal | | 1 | 96 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Basal cell carcinoma | | 1 | 96 | 1 | . | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Breast Carcinoma | | 1 | 96 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Colorectal adenocarcinoma | | 1 | 96 | 1 | 1 | 1 | 1 |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Esophagus carcinoma (with brain metastasis) (SPM) | | 1 | 96 | 1 | 1 | 1 | 1 |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Low grade liposarcoma left | | 1 | 96 | 1 | . | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | MGUS | | 1 | 96 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Metastasis melignant melanoma | | 1 | 96 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Prostate carcinoma | | 1 | 96 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Renal cell carcinoma | | 1 | 96 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Second primary malignancies | | 1 | 96 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Squa cell carcinoma | | 1 | 96 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Squamous Cell Carcinoma of the Skin | | 1 | 96 | 1 | . | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Squamous cell carcinoma (SPM) | | 1 | 96 | 1 | 1 | 1 | 1 |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Supraglottic larynxcarcinoma | | 1 | 96 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Urothelial cell carcinoma (bladder) | | 1 | 96 | 1 | 1 | . | . |
| Respiratory, thoracic and mediastinal disorders | Pulmonal Embolism Right | | 1 | 96 | 1 | 1 | . | . |
| Respiratory, thoracic and mediastinal disorders | Pulmonary embolism | | 1 | 96 | 1 | 1 | . | . |
| Skin and subcutaneous tissue disorders | Dermatology / skin other | | 1 | 96 | 1 | 1 | . | . |
| Skin and subcutaneous tissue disorders | Rash maculo-papular | | 1 | 96 | 1 | 1 | . | . |

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|--|------------------------------|---|----|---|---|---|---|
| Skin and subcutaneous tissue disorders | Toxicodermia | 1 | 96 | 1 | . | . | . |
| Skin and subcutaneous tissue disorders | Ulcers of extremities | 1 | 96 | 1 | 1 | . | . |
| Surgical and medical procedures | Surgery: total hip prothesis | 1 | 96 | 1 | . | . | . |
| Vascular disorders | Circulatory collaps | 1 | 96 | 1 | 1 | . | . |
| Vascular disorders | Hypotension | 1 | 96 | 1 | 1 | . | . |

-> group == Arm B: 1

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| ssoccd | Soccode |
| 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 system disorders | Anemia and thrombopenia | 1 | 95 | 1 | 1 | . | . | . |
| Blood and lymphatic system disorders | Anemia | 3 | 95 | 4 | 4 | . | . | . |
| Blood and lymphatic system disorders | Anemia (symptomatic) | 1 | 95 | 1 | . | . | . | . |
| Blood and lymphatic system disorders | Hemolytic Anemia | 1 | 95 | 1 | 1 | . | . | . |
| Blood and lymphatic system disorders | Neutropenic fever | 1 | 95 | 1 | . | . | . | . |
| Blood and lymphatic system disorders | Thrombopenie | 1 | 95 | 1 | 1 | . | . | . |
| Cardiac disorders | Angina pectoris | 1 | 95 | 1 | . | . | . | . |
| Cardiac disorders | Atrial fibrillation | 1 | 95 | 1 | 1 | . | . | . |
| Cardiac disorders | Bradycardiy | 1 | 95 | 1 | 1 | . | . | . |
| Cardiac disorders | Cardiac arrest | 1 | 95 | 1 | . | 1 | . | . |
| Cardiac disorders | Cardiac ischemia | 2 | 95 | 2 | . | 1 | . | . |
| Cardiac disorders | Cardiac ischemia (angina pectoris) | 1 | 95 | 1 | . | . | . | . |
| Cardiac disorders | Cardiac ischemia, grade 3 | 1 | 95 | 1 | . | . | . | . |
| Cardiac disorders | Coronary insufficiency | 1 | 95 | 2 | . | . | . | . |
| Cardiac disorders | Decompensatio cordis | 2 | 95 | 2 | 1 | . | . | . |
| Cardiac disorders | Dysfunctional ventricle wire of pacemaker | 1 | 95 | 1 | . | . | . | . |
| Cardiac disorders | Heart failure | 1 | 95 | 1 | . | 1 | . | . |
| Cardiac disorders | Myocardial infarction | 1 | 95 | 1 | 1 | . | . | . |
| Eye disorders | Amaurosis fugax | 1 | 95 | 1 | 1 | . | . | . |
| Gastrointestinal disorders | Admission due to fissura ani | 1 | 95 | 1 | . | . | . | . |
| Gastrointestinal disorders | Diarrhea | 1 | 95 | 1 | 1 | . | . | . |
| Gastrointestinal disorders | Intestinal perforation | 1 | 95 | 1 | . | . | . | . |
| General disorders and administration site conditions | Chest pain NOS | 1 | 95 | 2 | . | . | . | . |
| General disorders and administration site conditions | Fever | 6 | 95 | 6 | 2 | 1 | . | . |
| General disorders and administration site conditions | General malaise | 1 | 95 | 1 | 1 | . | . | . |
| General disorders and administration site conditions | Malaise | 1 | 95 | 1 | 1 | . | . | . |
| General disorders and administration site conditions | Malaise progressive | 1 | 95 | 1 | 1 | . | . | . |
| General disorders and administration site conditions | Necrosis dig II left foot | 1 | 95 | 1 | . | . | . | . |
| General disorders and administration site conditions | Pain chest | 1 | 95 | 1 | . | . | . | . |
| General disorders and administration site conditions | Sudden death | 1 | 95 | 1 | . | 1 | . | . |
| Hepatobiliary disorders | Calculous cholecystitis | 1 | 95 | 1 | . | . | . | . |
| Hepatobiliary disorders | Cholangitis | 1 | 95 | 1 | . | . | . | . |
| Hepatobiliary disorders | Choledocholithiasis | 1 | 95 | 1 | . | . | . | . |
| Infections and infestations | Diverticulitis | 1 | 95 | 1 | . | . | . | . |
| Infections and infestations | E Coli sepsis | 1 | 95 | 1 | 1 | . | . | . |
| Infections and infestations | Emphysemateus pyelonefritis | 1 | 95 | 1 | . | 1 | . | . |
| Infections and infestations | Gastro-enteritis | 1 | 95 | 1 | 1 | . | . | . |
| Infections and infestations | Gastroenteritis | 1 | 95 | 1 | . | . | . | . |
| Infections and infestations | Infection | 3 | 95 | 3 | 2 | 1 | . | . |
| Infections and infestations | Pneumonia | 4 | 95 | 4 | 4 | . | . | . |
| Infections and infestations | Pulmonary infection | 2 | 95 | 2 | 2 | 1 | 1 | 1 |
| Infections and infestations | Sepsis | 2 | 95 | 2 | 2 | 1 | 1 | 1 |
| Infections and infestations | Skin atheroma (right arm) infected | 1 | 95 | 1 | 1 | . | . | . |
| Infections and infestations | Urinary tract infection | 1 | 95 | 1 | 1 | . | . | . |
| Infections and infestations | Viral infection upper airway | 1 | 95 | 1 | 1 | . | . | . |
| Infections and infestations | Wound infection left foot dig-11 | 1 | 95 | 1 | 1 | . | . | . |
| Injury, poisoning and procedural complications | Contusion Costae 4-6 | 1 | 95 | 1 | . | . | . | . |
| Injury, poisoning and procedural complications | Fracture subcapital humerus,sinus maxillaris and orbita left | 1 | 95 | 1 | . | . | . | . |
| Injury, poisoning and procedural complications | Spleen rupture | 1 | 95 | 1 | 1 | . | . | . |
| Metabolism and nutrition disorders | Hyponatriemie | 1 | 95 | 1 | 1 | . | . | . |
| Musculoskeletal and connective tissue disorders | Pain left foot | 1 | 95 | 1 | . | . | . | . |
| Musculoskeletal and connective tissue disorders | Polymyalgia rheumatica | 1 | 95 | 1 | 1 | . | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Adenocarcimona upper gi tract | 1 | 95 | 1 | . | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Basal cell carcinoma | 2 | 95 | 3 | 2 | . | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Develoement to acute myeloid leukemia | 1 | 95 | 1 | 1 | . | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Melanoma | 1 | 95 | 1 | 1 | . | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Oesophagus carcinoma | 1 | 95 | 1 | 1 | 1 | 1 | 1 |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Second primary malignancy/mamma-carcinoma | 1 | 95 | 1 | 1 | . | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Second primary- lung cancer (probably) | 1 | 95 | 1 | 1 | 1 | 1 | 1 |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Secondary malignancy prostate Cancer | 1 | 95 | 1 | . | . | . | . |

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| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Squamous cell lip second primary | 1 | 95 | 1 | . | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | T-cell large granular lymphocytic leukemia | 1 | 95 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Urothelial Cell CA. (SPM) | 1 | 95 | 1 | 1 | . | . |
| Nervous system disorder | CVA | 1 | 95 | 1 | 1 | 1 | 1 |
| Nervous system disorder | Cerebrovasculair ischemia | 1 | 95 | 1 | 1 | . | . |
| Nervous system disorder | Episode of ataxia | 1 | 95 | 1 | . | . | . |
| Nervous system disorder | Minor stroke (TIA) | 1 | 95 | 1 | 1 | . | . |
| Nervous system disorder | Seizure | 1 | 95 | 1 | . | . | . |
| Nervous system disorder | T.I.A. Ischemic Cerebrovascular | 1 | 95 | 1 | 1 | . | . |
| Nervous system disorder | Vasovagal reaction | 1 | 95 | 1 | . | . | . |
| Psychiatric disorders | Delier - Confusion | 1 | 95 | 1 | 1 | . | . |
| Renal and urinary disorders | Acute renal insufficiency | 1 | 95 | 1 | 1 | . | . |
| Renal and urinary disorders | Haematuria | 1 | 95 | 1 | 1 | . | . |
| Renal and urinary disorders | Hematurie | 1 | 95 | 1 | . | . | . |
| Renal and urinary disorders | Renal other: kidney failure | 1 | 95 | 1 | 1 | 1 | 1 |
| Respiratory, thoracic and mediastinal disorders | Dyspnoea | 1 | 95 | 1 | 1 | 1 | 1 |
| Respiratory, thoracic and mediastinal disorders | Pneumonitis | 3 | 95 | 3 | 2 | . | . |
| Respiratory, thoracic and mediastinal disorders | Pulmonary embolism | 1 | 95 | 1 | 1 | . | . |
| Skin and subcutaneous tissue disorders | Hydradenitis | 1 | 95 | 1 | 1 | . | . |
| Skin and subcutaneous tissue disorders | Psoriasis-deterioration | 1 | 95 | 1 | . | . | . |
| Skin and subcutaneous tissue disorders | Urticaria | 1 | 95 | 1 | 1 | . | . |
| Surgical and medical procedures | Blood transfusion | 1 | 95 | 1 | . | . | . |
| Surgical and medical procedures | Cholecystectomy | 1 | 95 | 1 | . | . | . |
| Surgical and medical procedures | Orchidectomy | 1 | 95 | 1 | . | . | . |
| Surgical and medical procedures | Stent placement | 1 | 95 | 1 | . | . | . |
| Surgical and medical procedures | Total knee prothesis | 1 | 95 | 1 | . | . | . |
| Vascular disorders | Deep vein thrombosis | 1 | 95 | 1 | 1 | . | . |