

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

-> group == Arm A: 1

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 system disorders	Anaemia		1	96	1	.	.	.
Blood and lymphatic system disorders	Anemia		1	96	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,urethrosocopy 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	.	.

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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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
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	.	.	.
Cardiac 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	.
Infections and infestations	Sepsis	2	95	2	2	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)	Adenocarcinoma 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)	Development 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	.
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

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	Cholecystectomie	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	.	.