

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

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

ssoccd SOC code
 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	(Symptomatic) Anemia		1	234	1	1	.	.
Blood and lymphatic system disorders	Anemia		5	234	5	3	.	.
Blood and lymphatic system disorders	Anemia / thrombocytopenia		1	234	1	1	.	.
Blood and lymphatic system disorders	Febrile neutropenia		2	234	2	2	.	.
Blood and lymphatic system disorders	Neutropenic fever		3	234	3	3	1	1
Blood and lymphatic system disorders	Thrombopenia		1	234	1	1	.	.
Cardiac disorders	Acuut coronair syndroom		1	234	1	.	.	.
Cardiac disorders	Atrial Fibrillation		1	234	1	1	.	.
Cardiac disorders	Atrial fibrillation (AF)		1	234	1	.	1	.
Cardiac disorders	Cardiac arrest		1	234	1	1	1	1
Cardiac disorders	Cardiac failure		1	234	1	.	1	.
Cardiac disorders	Congestive heart failure		2	234	2	2	.	.
Cardiac disorders	Decompensatio cordis		1	234	1	1	.	.
Cardiac disorders	Decompensation cardiac		1	234	1	.	.	.
Cardiac disorders	Flutter		1	234	1	1	.	.
Cardiac disorders	Heart failure		4	234	4	2	.	.
Cardiac disorders	Mitralis insufficiency		1	234	1	.	.	.
Cardiac disorders	Myocardial infarction		1	234	1	.	.	.
Cardiac disorders	NSTEMI		1	234	1	1	.	.
Cardiac disorders	Right ventricular dysfunction		1	234	1	1	.	.
Cardiac disorders	STEMI		1	234	1	.	.	.
Cardiac disorders	Unstable angina pectoris		1	234	1	.	.	.
Gastrointestinal disorders	Constipation		4	234	4	4	.	.
Gastrointestinal disorders	Diarrhea		2	234	2	2	.	.
Gastrointestinal disorders	Emesis		1	234	1	.	.	.
Gastrointestinal disorders	Gastritis		1	234	1	.	.	.
Gastrointestinal disorders	Gastrointestinal disorders other		1	234	1	1	.	.
Gastrointestinal disorders	Nausea and vomiting		2	234	2	1	.	.
Gastrointestinal disorders	Nausea and vomitting		1	234	1	1	.	.
Gastrointestinal disorders	Rectal bleeding		1	234	1	1	.	.
Gastrointestinal disorders	Vomiting and diarrhea		1	234	1	.	.	.
General disorders and administration site conditions	Admission pain		1	234	1	.	.	.
General disorders and administration site conditions	Atypical thoracal/precordial pain		1	234	1	.	.	.
General disorders and administration site conditions	Backpain		1	234	1	.	.	.
General disorders and administration site conditions	Disease progression		1	234	1	.	1	.
General disorders and administration site conditions	Exacerbarion pain		1	234	1	.	.	.
General disorders and administration site conditions	Exacerbation pain		1	234	1	.	.	.
General disorders and administration site conditions	Fever		9	234	14	8	.	.
General disorders and administration site conditions	Fever, unknown cause		1	234	1	1	.	.
General disorders and administration site conditions	Malaise		4	234	4	4	.	.
General disorders and administration site conditions	Non-neutropenic fever		1	234	1	.	.	.
General disorders and administration site conditions	Oedema		1	234	1	.	.	.
General disorders and administration site conditions	Overall weekness		1	234	1	.	.	.
General disorders and administration site conditions	Pain		3	234	3	.	.	.
General disorders and administration site conditions	Recurrent bleeding along catheter vena jugularis		1	234	1	1	.	.
General disorders and administration site conditions	Sudden death NOS		1	234	1	.	1	.
Hepatobiliary disorders	Cholecystitis		2	234	2	.	.	.
Infections and infestations	Airway infection		1	234	1	.	.	.
Infections and infestations	Catheter related infection		1	234	1	.	.	.
Infections and infestations	Cellulitis		1	234	1	1	.	.
Infections and infestations	Cellulitis of her right leg		1	234	1	.	.	.
Infections and infestations	Erysipelas		1	234	1	.	.	.
Infections and infestations	Gastro-enterits		1	234	1	.	.	.
Infections and infestations	Gastroenteritis		1	234	1	1	.	.
Infections and infestations	Gastrointestinal infection		1	234	1	1	.	.
Infections and infestations	Infection		1	234	1	1	.	.
Infections and infestations	Infection leg		1	234	1	1	.	.
Infections and infestations	Infection pulmonary		1	234	1	1	.	.
Infections and infestations	Infection urinarytract		1	234	1	1	.	.
Infections and infestations	Infection without focus		1	234	1	1	.	.
Infections and infestations	Lung infection		2	234	2	2	.	.
Infections and infestations	Phlebitis infective		1	234	1	.	.	.

Infections and infestations	Pneumonia	21	234	25	21	2	1
Infections and infestations	Pneumonia (lung infection)	1	234	1	1	.	.
Infections and infestations	Pneumonia / Pneumonitis	1	234	1	.	.	.
Infections and infestations	Pneumonia / bronchial infection	1	234	1	1	.	.
Infections and infestations	Pneumonia: admission	1	234	1	.	.	.
Infections and infestations	Pneumonie	1	234	1	1	.	.
Infections and infestations	Pneumosepsis	1	234	1	1	.	.
Infections and infestations	Respiratory infection	3	234	3	.	.	.
Infections and infestations	Sepsis	5	234	5	3	.	.
Infections and infestations	Septic shock	1	234	1	1	.	.
Infections and infestations	Urinary tract infection	5	234	5	2	.	.
Infections and infestations	Urosepsis	3	234	3	1	.	.
Infections and infestations	Viral infection	1	234	1	1	.	.
Infections and infestations	Yeast infection	1	234	1	1	.	.
Injury, poisoning and procedural complications	Femur fracture	1	234	1	.	.	.
Injury, poisoning and procedural complications	Fracture	1	234	1	.	.	.
Injury, poisoning and procedural complications	Fracture (threatening)	1	234	1	.	.	.
Injury, poisoning and procedural complications	Fracture Th2	1	234	1	.	.	.
Injury, poisoning and procedural complications	Hip fracture	1	234	1	.	.	.
Investigations	Increased CRP	1	234	1	.	.	.
Investigations	Weight loss	1	234	1	1	.	.
Metabolism and nutrition disorders	Dehydration	4	234	5	3	.	.
Metabolism and nutrition disorders	Hyper calcaemia	1	234	1	.	.	.
Metabolism and nutrition disorders	Hypercalcaemia	1	234	1	.	.	.
Metabolism and nutrition disorders	Hypercalcaemia	2	234	2	.	.	.
Metabolism and nutrition disorders	Hyperglyceamia	1	234	1	1	.	.
Metabolism and nutrition disorders	Hyperkalemia	1	234	1	.	.	.
Metabolism and nutrition disorders	Hyperkaliemie at pre renal impairment	1	234	1	1	.	.
Metabolism and nutrition disorders	Hyponatremia	3	234	3	1	.	.
Musculoskeletal and connective tissue disorders	Back pain	1	234	1	.	.	.
Musculoskeletal and connective tissue disorders	Backache	1	234	1	.	.	.
Musculoskeletal and connective tissue disorders	Bone pain	1	234	1	.	.	.
Musculoskeletal and connective tissue disorders	Bone pain aggravated	1	234	1	.	.	.
Musculoskeletal and connective tissue disorders	Myopathy	1	234	1	1	.	.
Musculoskeletal and connective tissue disorders	Pain back (para/end thoracic)	1	234	1	1	.	.
Musculoskeletal and connective tissue disorders	Pain due to MM	1	234	1	.	.	.
Musculoskeletal and connective tissue disorders	Pain in extremity	1	234	1	.	.	.
Musculoskeletal and connective tissue disorders	Painfull hip (right)	1	234	1	.	.	.
Musculoskeletal and connective tissue disorders	Painfull hip right	1	234	1	.	.	.
Musculoskeletal and connective tissue disorders	Referred pain right leg	1	234	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	AML	1	234	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	2	234	2	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Multiple myeloma progression	1	234	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Oesophagus carcinoma	1	234	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Rectal carcinoma	1	234	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	1	234	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Urothelcelcarcinoom	1	234	1	.	.	.
Nervous system disorders	Admission because of dizziness	1	234	1	.	.	.
Nervous system disorders	CVA	1	234	1	.	1	.
Nervous system disorders	Dizziness	2	234	2	2	.	.
Nervous system disorders	Ischialgie	1	234	1	.	.	.
Nervous system disorders	Neurological paralysis	1	234	1	.	.	.
Nervous system disorders	Polyneuropathy	2	234	2	2	.	.
Nervous system disorders	Stroke	1	234	1	.	.	.
Nervous system disorders	Syncope	1	234	1	1	.	.
Nervous system disorders	Transient ischemic attack	1	234	1	.	.	.
Psychiatric disorders	Anxiety	1	234	1	1	.	.
Psychiatric disorders	Anxiety disorder	1	234	1	.	.	.
Psychiatric disorders	Confusion	1	234	1	1	.	.
Psychiatric disorders	Delirium	3	234	3	2	.	.
Renal and urinary disorders	Acute kidney injury gr.4	1	234	1	.	.	.
Renal and urinary disorders	Kidney failure	3	234	6	1	.	.
Renal and urinary disorders	Pain right kidney area intermittent	1	234	1	.	.	.
Renal and urinary disorders	Progressive renal insufficiency	1	234	1	.	.	.
Renal and urinary disorders	Renal failure	1	234	1	1	.	.
Renal and urinary disorders	Renal failure, requiring dialysis	1	234	1	.	.	.
Renal and urinary disorders	Renal insufficiency	1	234	1	.	.	.
Renal and urinary disorders	Urinary retention	2	234	2	.	.	.
Reproductive system and breast disorders	Ovarian cyst	1	234	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Aspiration	1	234	1	.	.	.
Respiratory, thoracic and mediastinal disorders	COPD exacerbatie	1	234	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnea	5	234	5	2	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnoea	1	234	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Epistaxis	1	234	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Ex. COPD	1	234	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pleural Effusion	1	234	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pleural effusion	1	234	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pneumonitis	4	234	4	2	.	.

Respiratory, thoracic and mediastinal disorders	Relapse pleural effusion	1	234	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Respiratory failure	1	234	1	1	.	.
Skin and subcutaneous tissue disorders	Ulcer left foot	1	234	1	.	.	.
Surgical and medical procedures	Hip surgery	1	234	1	.	.	.
Surgical and medical procedures	Surgery	1	234	1	.	.	.
Vascular disorders	Cerebral Ischemia	1	234	1	1	.	.
Vascular disorders	Collapse (vasovagal episode)	1	234	1	1	.	.
Vascular disorders	Hypotension	2	234	2	.	.	.
Vascular disorders	Intermittent claudication	1	234	1	.	.	.
Vascular disorders	Orthostatic hypotension	1	234	1	.	.	.
Vascular disorders	Ruptured abdominal aneurysm	1	234	1	.	1	.
Vascular disorders	Vein thrombosis v. poplitea R	1	234	1	1	.	.
Vascular disorders	Venous Thrombosis right leg	1	234	1	.	.	.