

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

-> group == Standard

ssoccd	SOC code	aeterm	affected	exposed	occurrences	occurrel	fatality	fatalrel
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							
Cardiac disorders	Heart Failure		1	51	1	1	1	1
Gastrointestinal disorders	Stomach ulcer		1	51	1	.	.	.
General disorders and administration site conditions	Mucositis		1	51	1	1	.	.
Hepatobiliary disorders	Cholecystitis		1	51	1	.	.	.
Infections and infestations	Bilateral pneumonia		1	51	1	.	.	.
Infections and infestations	Infection		1	51	1	1	.	.
Infections and infestations	Klebsiella sepsis		1	51	1	1	.	.
Infections and infestations	SEPSIS		1	51	1	1	.	.
Infections and infestations	Sepsis		3	51	3	3	2	2
Infections and infestations	Septicemia with staphylococcus epidermitis		1	51	1	1	.	.
Infections and infestations	Severe sepsis		1	51	1	1	.	.
Infections and infestations	Skin infection		1	51	1	.	.	.
Infections and infestations	Streptococcal infection		1	51	1	1	.	.
Nervous system disorders	Cerebral ischemia		1	51	1	1	1	1
Nervous system disorders	Intracranial hemorrhage		2	51	2	1	2	1
Nervous system disorders	Transient ischemic attacks		1	51	1	.	.	.
Renal and urinary disorders	Acute renal failure		1	51	1	.	.	.
Renal and urinary disorders	Renal failure - creatinine increased		1	51	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Acute respiratory distress		1	51	1	.	1	.
Respiratory, thoracic and mediastinal disorders	Dyspnea G4		1	51	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Respiratory distress syndrom		1	51	1	1	.	.
Surgical and medical procedures	Cholecystectomy		1	51	1	.	.	.
Vascular disorders	Thromboembolic event		1	51	1	.	.	.

-> group == Seli

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occurrences	Occurrences all number							
occurrel	Occurrences causally related to treatment number							
fatality	Fatalities number							
fatalrel	Fatalities causally related to treatment number							
Cardiac disorders	Cardial arrest		1	51	1	.	1	.
Cardiac disorders	Cardiogenic shock		1	51	1	1	1	1
Gastrointestinal disorders	Colonic perforation		1	51	1	.	.	.
Gastrointestinal disorders	Enterocolitis		1	51	1	1	.	.
Gastrointestinal disorders	Ileus		1	51	1	.	.	.
Gastrointestinal disorders	Neutropenic Colitis		1	51	1	1	.	.
General disorders and administration site conditions	Death		1	51	1	.	1	.
General disorders and administration site conditions	Death (by resistant disease)		1	51	1	.	1	.
Hepatobiliary disorders	Hepatic cytolysis		1	51	1	1	.	.
Infections and infestations	Achromabacter pneumosepsis		1	51	1	1	1	1
Infections and infestations	Catheter related infection		1	51	1	1	.	.
Infections and infestations	Central line infection		1	51	1	1	.	.
Infections and infestations	Fever due to aspergilloses		1	51	1	.	.	.
Infections and infestations	ICU admission candida sepsis		1	51	1	1	1	1
Infections and infestations	Infection (with E.faecium+candida bacteremia)		1	51	1	1	.	.
Infections and infestations	Meningo-encephalitis		1	51	1	1	1	1
Infections and infestations	Possible infection		1	51	1	1	.	.
Infections and infestations	Pulmonary infection (aspergillus)		1	51	1	.	1	.
Infections and infestations	Sepsis		3	51	3	3	.	.
Infections and infestations	Septic shock		2	51	2	2	2	2
Infections and infestations	Septicemia		2	51	2	2	.	.
Infections and infestations	Septicemia (candida glabrata)		1	51	1	1	.	.
Infections and infestations	Unthreatable infection probable due to progression		1	51	1	1	1	1

Injury, poisoning and procedural complications	Drug toxicity	1	51	1	1	.	.
Investigations	Blood Bilirubin increased	1	51	1	.	.	.
Metabolism and nutrition disorders	Hypokalemia	1	51	1	.	.	.
Nervous system disorders	Cerebral hemorrhage	1	51	1	1	1	1
Nervous system disorders	Parkinson Disease aggravated	1	51	1	1	.	.
Nervous system disorders	Syncope	2	51	2	2	.	.
Psychiatric disorders	Confusion	1	51	1	.	.	.
Renal and urinary disorders	Acute kidney injury	1	51	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Bronchopulmonary hemorrhage	1	51	1	1	1	1
Respiratory, thoracic and mediastinal disorders	Pneumopathy	1	51	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Respiratory insufficiency	1	51	1	1	1	1
Vascular disorders	Capillary leak syndrome (CLS)	1	51	1	1	.	.