

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

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

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	Febrile neutropenia		3	45	4	4	.	.
Blood and lymphatic system disorders	Neutropenic fever		11	45	15	15	.	.
Blood and lymphatic system disorders	Neutropenic fever (febrile neutropenia)		1	45	1	1	.	.
Blood and lymphatic system disorders	Thrombocytopenia		1	45	1	1	.	.
Cardiac disorders	Pericarditis		1	45	1	.	.	.
Eye disorders	Pain left eye		1	45	1	.	.	.
Gastrointestinal disorders	Constipation		1	45	1	1	.	.
Gastrointestinal disorders	Diarrhea		1	45	2	2	.	.
Gastrointestinal disorders	Ileum perforation		1	45	1	1	1	1
Gastrointestinal disorders	Ileus		1	45	1	1	.	.
Gastrointestinal disorders	Melena		1	45	1	1	.	.
Gastrointestinal disorders	Vomiting		1	45	1	1	.	.
General disorders and administration site conditions	Fever		3	45	4	3	.	.
General disorders and administration site conditions	High temperature 38,7°C		1	45	1	1	.	.
General disorders and administration site conditions	Progressive disease		1	45	1	.	1	.
General disorders and administration site conditions	Temperature rise		1	45	1	1	.	.
Immune system disorders	A GVHD		1	45	1	1	1	1
Immune system disorders	Acute graft versus host disease		1	45	1	1	1	1
Immune system disorders	Allergic reaction		2	45	2	.	.	.
Immune system disorders	Diarrhea		1	45	1	.	1	.
Immune system disorders	GVHD		1	45	1	.	.	.
Immune system disorders	GvHD		2	45	2	2	.	.
Infections and infestations	CMV retinitis		1	45	1	1	.	.
Infections and infestations	Central line infection		1	45	1	1	.	.
Infections and infestations	Encephalitis infection		1	45	1	1	.	.
Infections and infestations	Gastro- enteritis		1	45	1	.	.	.
Infections and infestations	Infection urinary tract		1	45	1	1	.	.
Infections and infestations	Infection viral		1	45	1	1	.	.
Infections and infestations	Infection with grade 3 neutrophils-urinary tract		1	45	1	1	.	.
Infections and infestations	Infection, pulmonary		1	45	1	1	.	.
Infections and infestations	Intracerebral toxoplasma infection		1	45	1	1	.	.
Infections and infestations	Oral candida		1	45	1	1	.	.
Infections and infestations	Pericoronitis		1	45	1	1	.	.
Infections and infestations	Pharyngitis		1	45	1	.	.	.
Infections and infestations	Pneumonia		8	45	11	7	.	.
Infections and infestations	Pustular skin rash		1	45	1	1	.	.
Infections and infestations	RSV infection		1	45	1	.	.	.
Infections and infestations	Respiratory infection		1	45	1	.	.	.
Infections and infestations	Rhinosinusitis		1	45	1	.	.	.
Infections and infestations	Sepsis		4	45	4	2	4	2
Infections and infestations	Septic shock		1	45	1	1	.	.
Investigations	Creatinine gr. II		1	45	1	1	.	.
Metabolism and nutrition disorders	Steroid induced diabetes mellitus		1	45	1	1	.	.
Metabolism and nutrition disorders	Tumorlysis syndrome		1	45	1	1	.	.
Neoplasm benign, malignant and unspecif. (inc. cysts/polyp)	Richters Transformation		1	45	1	.	1	.
Nervous system disorder	Encephalopathy		1	45	1	1	.	.
Nervous system disorder	Encephalopathy (cognitive decline)		1	45	1	1	.	.
Nervous system disorder	Leuko encephalopathy		1	45	1	1	1	1
Nervous system disorder	Leukoencephalopathy		1	45	1	1	1	1
Nervous system disorder	Melanoma in situ right shoulder		1	45	1	.	.	.
Nervous system disorder	Seizure		1	45	2	1	.	.
Psychiatric disorders	Confusion		1	45	1	1	.	.
Renal and urinary disorders	Hydronephrosis		1	45	1	.	.	.
Renal and urinary disorders	Kidney insufficiency		1	45	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnoe		1	45	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Epistaxis		1	45	1	1	.	.
Surgical and medical procedures	Transfusion reaction		1	45	1	.	.	.
Vascular disorders	Hypotension		1	45	1	1	.	.