

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

-> group == Arm A

	ssoccd	aeterm	affected	exposed	occurrences	occurrel	fatality	fatalrel
Blood and lymphatic disorders	Autoimmune thrombopenia	1	184	1	1	.	.	
Blood and lymphatic disorders	Febrile neutropenia	1	184	1	.	.	.	
Blood and lymphatic disorders	Fever neutropenic	1	184	1	1	.	.	
Blood and lymphatic disorders	Neutropenic fever	2	184	2	1	.	.	
Blood and lymphatic disorders	Pancytopenia	1	184	1	1	.	.	
Cardiac disorders	Astma cardiale	1	184	1	.	.	.	
Cardiac disorders	Cardiac ischemia/infarction	1	184	1	.	.	.	
Cardiac disorders	Cardio pulmonary arrest	1	184	1	.	1	.	
Cardiac disorders	Cardiomyopathy	1	184	1	.	.	.	
Gastrointestinal disorders	Bloody diarrhea	1	184	1	.	.	.	
Gastrointestinal disorders	Diarrhea	4	184	5	2	.	.	
Gastrointestinal disorders	Fever	1	184	1	1	.	.	
Gastrointestinal disorders	GVHD (gastrointestinal-vomiting)	1	184	1	1	.	.	
Gastrointestinal disorders	Ileus	1	184	1	.	.	.	
Gastrointestinal disorders	Nausea	1	184	1	1	.	.	
Gastrointestinal disorders	Nausea, vomiting	1	184	1	1	.	.	
Gastrointestinal disorders	Naussea	1	184	1	1	.	.	
Gastrointestinal disorders	Naussea/vomitting	1	184	1	1	.	.	
Gastrointestinal disorders	Obstipation	1	184	1	1	.	.	
Gastrointestinal disorders	Recurrence ileus	1	184	1	.	.	.	
Gastrointestinal disorders	Vomiting	5	184	5	5	.	.	
General disorders and administration site conditions	Detoriatng condition (const sympt) with disease prog	1	184	1	.	1	.	
General disorders and administration site conditions	Fatigue	1	184	1	.	.	.	
General disorders and administration site conditions	Fever	3	184	3	2	.	.	
General disorders and administration site conditions	Fever (with malaise)	1	184	1	.	.	.	
Hepatobiliary disorders	Cholecystitis	1	184	1	.	.	.	
Hepatobiliary disorders	Obstruction Bile duct	1	184	1	.	.	.	
Immune system disorders	A GvHD gr. III	1	184	1	.	.	.	
Immune system disorders	A GvHD grade III gut	1	184	1	.	.	.	
Immune system disorders	A GvHD gut (stage 2, grade 3)	1	184	1	.	.	.	
Immune system disorders	A GvHD gut gr. III	1	184	1	.	.	.	
Immune system disorders	AGVHD gut, gr. 2	1	184	1	.	.	.	
Immune system disorders	Acute GVHD, grade IV	1	184	1	.	1	.	
Immune system disorders	Acute GvHD intestine	1	184	1	.	.	.	
Immune system disorders	Acute GvHD skin	1	184	1	.	.	.	
Immune system disorders	Allergic reaction medication	1	184	1	.	.	.	
Immune system disorders	Fever eci	1	184	1	.	.	.	
Immune system disorders	Graft versus host grade IV	1	184	1	.	1	.	
Immune system disorders	GvHD	2	184	2	2	.	.	
Immune system disorders	Pulmonary GVHD	1	184	1	.	.	.	
Immune system disorders	Recurrence AGVHD	1	184	1	1	1	1	
Infections and infestations	Abdominal sepsis	1	184	1	.	1	.	
Infections and infestations	CMV disease	1	184	1	.	.	.	
Infections and infestations	CMV reactivatie	1	184	1	.	.	.	
Infections and infestations	CMV reactivation	1	184	1	1	.	.	
Infections and infestations	Candida sepsis	1	184	1	.	1	.	
Infections and infestations	Infection upper airway	1	184	1	.	.	.	
Infections and infestations	Infection with normal ANC-upper airway NOS	1	184	1	.	.	.	
Infections and infestations	Periodontitis	1	184	1	.	.	.	
Infections and infestations	Pneumonia	2	184	2	.	.	.	
Infections and infestations	Upper respiratory infection	1	184	1	.	.	.	
Infections and infestations	Urinary tract infection	1	184	1	.	.	.	
Injury, poisoning and procedural complications	Graft failure	2	184	2	1	.	.	
Investigations	Creatinine increase	1	184	1	1	.	.	
Investigations	Increased creatinine	9	184	10	10	.	.	
Investigations	Increased liverenzymes	1	184	1	1	.	.	
Metabolism and nutrition disorders	Electrolyte imbalance	1	184	1	.	.	.	
Metabolism and nutrition disorders	Hyperglycemia	1	184	1	.	.	.	
Metabolism and nutrition disorders	Hyperkalemia	1	184	1	.	.	.	
Metabolism and nutrition disorders	Hyponatremia	2	184	2	2	.	.	
Neoplasms benign, malignant and unspecified	Recurrence MM	1	184	1	.	.	.	
Nervous system disorders	Headache	1	184	1	1	.	.	

Nervous system disorders	Pain- headache	1	184	1	1	.	.
Nervous system disorders	Seizure	1	184	1	1	.	.
Nervous system disorders	Syncope	1	184	1	.	.	.
Renal and urinary disorders	Renal Insufficiency	1	184	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnea	1	184	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Respiratory insufficiency	1	184	1	.	1	.
Skin and subcutaneous tissue disorders	Skin rash	1	184	1	.	.	.
Vascular disorders	Orthostatic hypotension	1	184	3	1	.	.
Vascular disorders	Veno occlusive disease	1	184	1	.	1	.

-> group == Arm B

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 disorders	A I HA		1	185	1	.	.	.
Blood and lymphatic disorders	Cyclkosporine associated post transplant TTP		1	185	1	1	.	.
Blood and lymphatic disorders	Febrile neutropenia		3	185	3	1	.	.
Blood and lymphatic disorders	Neutropenic fever		4	185	4	3	.	.
Cardiac disorders	Angina pectoris		1	185	1	.	.	.
Gastrointestinal disorders	Diarrhea		7	185	7	3	.	.
Gastrointestinal disorders	Melena		1	185	1	.	.	.
Gastrointestinal disorders	Nausea		1	185	1	1	.	.
Gastrointestinal disorders	Vomiting		7	185	7	6	.	.
General disorders and administration site conditions	Fever		3	185	3	1	.	.
General disorders and administration site conditions	Fever e.c.i.		1	185	1	.	.	.
General disorders and administration site conditions	Fever eci		2	185	2	.	.	.
Hepatobiliary disorders	Cholecystitis		1	185	1	.	.	.
Hepatobiliary disorders	Vanishing bile duct syndrome		1	185	1	1	1	1
Immune system disorders	A GVHD gut, stage 3		1	185	1	.	1	.
Immune system disorders	A GvHD gut		1	185	1	.	.	.
Immune system disorders	A GvHD gut gr. III		1	185	1	.	1	.
Immune system disorders	AGvHD intestinal		1	185	1	1	.	.
Immune system disorders	Acute GVHD		1	185	1	.	.	.
Immune system disorders	Engraftment syndrome		1	185	1	.	.	.
Immune system disorders	GVHD		4	185	4	1	.	.
Immune system disorders	GVHD st3		1	185	1	.	.	.
Immune system disorders	GvHD of the skin		1	185	1	.	.	.
Immune system disorders	Suspect for a GvHD intestinal		1	185	1	1	.	.
Immune system disorders	Suspected graft vs host disease		1	185	1	.	.	.
Infections and infestations	(abdominal) sepsis		1	185	1	1	1	1
Infections and infestations	CNS		1	185	1	.	.	.
Infections and infestations	Clostridium infection		1	185	1	.	.	.
Infections and infestations	Gastro-intestinal-infection		1	185	1	.	.	.
Infections and infestations	Infection		1	185	1	.	.	.
Infections and infestations	Infection (doc. cl.) - skin		1	185	1	.	.	.
Infections and infestations	Infection viral		1	185	1	.	.	.
Infections and infestations	Lung infection		1	185	1	.	.	.
Infections and infestations	Pneumosepsis		2	185	2	.	1	.
Infections and infestations	Pustular skin rash		1	185	1	.	.	.
Infections and infestations	Rhinovirus infection		1	185	1	.	.	.
Infections and infestations	Sepsis		1	185	1	1	1	1
Infections and infestations	Viral Pneumonia		1	185	1	.	.	.
Injury, poisoning and procedural complications	Subdural Hematoma		1	185	1	.	1	.
Investigations	Creatinine		2	185	2	2	.	.
Investigations	Increased creatinin		1	185	1	1	.	.
Investigations	Increased creatinine		4	185	4	4	.	.
Investigations	Oligo arthritis		1	185	1	.	.	.
Metabolism and nutrition disorders	Dehydration		1	185	1	.	.	.
Metabolism and nutrition disorders	Hyperglycemia		1	185	1	.	.	.
Metabolism and nutrition disorders	Steroid induced diabetes mellitus		1	185	1	.	.	.
Neoplasms benign, malignant and unspecified	AML progression		1	185	1	.	1	.
Neoplasms benign, malignant and unspecified	Secondary malignancy		1	185	1	.	1	.
Nervous system disorders	Depressed level of consciousness		1	185	1	1	.	.
Nervous system disorders	Epileptic insult		2	185	2	2	.	.
Nervous system disorders	Headache		3	185	3	1	.	.
Nervous system disorders	Idiopathic intra cranial hypertension		1	185	1	1	.	.
Nervous system disorders	PRES (Posterior reversible encephalopathy syndrome)		1	185	1	1	1	1
Nervous system disorders	Seizure		1	185	1	1	.	.
Nervous system disorders	TIA		1	185	1	1	.	.
Renal and urinary disorders	Renal insufficiency		1	185	1	.	.	.

Renal and urinary disorders	Renal insufficiency	1	185	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnea	1	185	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Respiratory failure	1	185	1	1	1	1
Vascular disorders	Clinically VOD	1	185	1	1	1	1
Vascular disorders	VOD	1	185	1	.	1	.
Vascular disorders	Veno-occlusive disease	1	185	1	.	.	.

-> group == Arm C

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fatality	Fatalities number
fatalrel	Fatalities causally related to treatment number

	ssoccd	aeterm	affected	exposed	occurrences	occurrel	fatality	fatalrel
Blood and lymphatic disorders	Febrile neutropenia		1	99	1	1	.	.
Blood and lymphatic disorders	Neutropenic fever		1	99	1	1	.	.
Blood and lymphatic disorders	TTP		1	99	1	1	1	1
Cardiac disorders	Myocard infarction		1	99	1	1	.	.
Cardiac disorders	Pericardial effusion		1	99	1	1	.	.
Cardiac disorders	Supraventricular tachycardia		1	99	1	.	.	.
Gastrointestinal disorders	Diarrhea		1	99	1	1	.	.
Gastrointestinal disorders	Small intestinal sterosis		1	99	1	.	.	.
Gastrointestinal disorders	Stomach pain		1	99	1	.	.	.
Gastrointestinal disorders	Vomiting		1	99	1	.	.	.
General disorders and administration site conditions	Asthenia (weakness)		1	99	1	1	.	.
General disorders and administration site conditions	Fever		1	99	1	.	.	.
General disorders and administration site conditions	Fever eci		1	99	1	.	.	.
General disorders and administration site conditions	Multi organ failure		1	99	1	.	1	.
Immune system disorders	A GVHD gut gr.III		1	99	1	.	.	.
Immune system disorders	A GvHD gut grade 2		2	99	2	.	.	.
Immune system disorders	AGVHD st 2 grade 3		1	99	1	.	.	.
Immune system disorders	AGvHD gwt grade III		1	99	1	.	1	.
Immune system disorders	Engraftment syndrome		1	99	1	.	.	.
Infections and infestations	Chronic rhinosinusitis		1	99	1	.	.	.
Investigations	Increased creatinine		1	99	1	1	.	.
Metabolism and nutrition disorders	Diabetic keto-acidosis		1	99	1	.	.	.
Psychiatric disorders	Suicide		1	99	1	.	1	.
Renal and urinary disorders	Hematuria		1	99	1	1	.	.
Renal and urinary disorders	Renal failure		1	99	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Aspiration pneumonia		1	99	1	.	1	.
Respiratory, thoracic and mediastinal disorders	Respiratory insufficiency		3	99	3	.	2	.
Vascular disorders	Hypertension		1	99	1	.	.	.