

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

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

ssoccd MedDRA System Organ Class [EMN]
 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	Anemia		1	61	1	.	.	.
Blood and lymphatic system disorders	Disseminated intravascular coagulation		1	61	1	1	1	1
Blood and lymphatic system disorders	Febrile neutropenia		2	61	3	2	.	.
Blood and lymphatic system disorders	No adverse event		1	61	1	.	.	.
Cardiac disorders	ATRIAL FIBRILLATION		1	61	1	1	.	.
Cardiac disorders	Acute heart failure		1	61	1	1	.	.
Cardiac disorders	Acute myocardial infarction		1	61	1	1	.	.
Cardiac disorders	DIASTOLIC HEART FAILURE		1	61	1	1	.	.
Cardiac disorders	Myocardial infarction/NSTEMI		1	61	1	1	.	.
Cardiac disorders	Sinus bradycardia		1	61	1	.	.	.
Gastrointestinal disorders	Gastritis		1	61	1	1	.	.
Gastrointestinal disorders	Inguinal hernia		1	61	1	.	.	.
Gastrointestinal disorders	Mechanical ileus: gastrointestinal disorder		1	61	1	.	.	.
Gastrointestinal disorders	Nausea		1	61	1	.	.	.
Gastrointestinal disorders	Vomiting		1	61	1	1	.	.
General disorders and administration site conditions	Chest pain		1	61	1	.	.	.
General disorders and administration site conditions	Death		1	61	1	1	1	1
General disorders and administration site conditions	Fever		8	61	8	4	.	.
General disorders and administration site conditions	Malaise		1	61	1	1	.	.
General disorders and administration site conditions	Obs Progression		1	61	1	.	1	.
General disorders and administration site conditions	PROGRESSION		1	61	1	.	1	.
General disorders and administration site conditions	Pain		1	61	1	.	.	.
General disorders and administration site conditions	Pain left arm due to disease progression		1	61	1	.	.	.
General disorders and administration site conditions	Progression Disease		1	61	1	.	.	.
General disorders and administration site conditions	Progression disease due to plasma cell leukemia		1	61	1	1	.	.
General disorders and administration site conditions	Progressive disease		2	61	2	.	1	.
Hepatobiliary disorders	Biliary colic with gallstones		1	61	1	.	.	.
Hepatobiliary disorders	Cholangitis		1	61	1	.	.	.
Hepatobiliary disorders	Hepatotoxicity		1	61	1	1	.	.
Infections and infestations	21th of July intake of salmon on buffet restaurant. 24h later, watery diarrhea over 10 times a day for 2 days. Dehydrated. Hospitalized from 24th of July 2020 to 28th of July 2020. Treated with Ciprofloxacin 500mg BID oral from 25th of July 2020 - 29th of July 2020 and Ceftriaxon 2g QD IV for E-coli infection. Dehydration treated with daily fluid therapy 1000 ml IV D.		1	61	1	.	.	.
Infections and infestations	AIRWAY INFECTION		1	61	1	1	.	.
Infections and infestations	Appendicitis		1	61	1	.	.	.
Infections and infestations	Bacterial pneumonia NOS		1	61	1	1	.	.
Infections and infestations	Bowel infection		1	61	1	1	.	.
Infections and infestations	Clostridial infection		1	61	1	1	.	.
Infections and infestations	Clostridium difficile infection		1	61	1	.	.	.
Infections and infestations	Cough, febrilia, liquid from the ear		1	61	1	.	.	.
Infections and infestations	Covid-19 pneumonitis		1	61	1	.	.	.
Infections and infestations	Death due to Covid-19		1	61	1	.	1	.
Infections and infestations	Gastro-enteritis (Salmonella)		1	61	1	1	.	.
Infections and infestations	Gastroenteritis		1	61	1	.	.	.
Infections and infestations	Infection		1	61	1	.	.	.
Infections and infestations	Infection (Influenza)		1	61	1	1	.	.
Infections and infestations	Infection (catheter related)		1	61	1	1	.	.
Infections and infestations	Infection (infusion reaction)		1	61	1	.	.	.
Infections and infestations	Infection of unknown origin		1	61	1	1	.	.
Infections and infestations	Influenza A		1	61	1	1	.	.
Infections and infestations	Influenza A virus infection		1	61	1	1	.	.
Infections and infestations	Lower respiratory infection		1	61	1	1	.	.
Infections and infestations	Lung infection		4	61	4	4	.	.
Infections and infestations	Metapneumovirus pneumonia		2	61	2	2	.	.
Infections and infestations	Pneumonia		4	61	6	2	.	.
Infections and infestations	Pneumonia (previously Lung infection)		1	61	1	1	1	1

Infections and infestations	Pneumonia due to COVID-19	1	61	1	.	.	.
Infections and infestations	Postoperative infection with cerebral abscess (pneumocystis jiroveci)	1	61	1	.	.	.
Infections and infestations	RS VIRUS	1	61	1	.	.	.
Infections and infestations	Respiratory infection	1	61	1	1	.	.
Infections and infestations	Respiratory tract infection (previously fever and cough)	1	61	1	1	.	.
Infections and infestations	Sepsis	3	61	3	1	1	.
Infections and infestations	Sepsis of pulmonary origin	1	61	1	1	.	.
Infections and infestations	Systemic aspergillus infection	1	61	1	1	1	1
Infections and infestations	Unspecified infection	1	61	1	.	.	.
Infections and infestations	Upper respiratory infection	2	61	3	2	.	.
Infections and infestations	Upper respiratory infection (Rhinovirus)	1	61	1	.	.	.
Infections and infestations	Upper respiratory tract infection	1	61	1	1	.	.
Infections and infestations	Urinary tract infection	3	61	3	2	.	.
Infections and infestations	Urinary tract infection 13.03.2020. Placed on oral antibiotics for 7 days. Symptoms reappear on 29.03.2020 and the patient is hospitalized with febrilia. CRP elevated to 160. Placed on IV antibiotics. Almost immediately afebrile, switched to oral antibiotics and discharged on 01.04.2020. 29.03.2020 leucocytes was 11,1E/L and urine culture with mixed flora. No other microbiological findings	1	61	1	1	.	.
Infections and infestations	Uroinfection	1	61	1	.	.	.
Investigations	Creatinine increased	2	61	2	1	.	.
Metabolism and nutrition disorders	Acute kidney injury due to TLS syndrome	1	61	1	1	.	.
Metabolism and nutrition disorders	Dehydration	1	61	1	.	.	.
Musculoskeletal and connective tissue disorders	Multiple bone pain	1	61	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts ...	Adenocarcinoma duodenum	1	61	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts ...	Brain tumor (extramedullary plasmacytoma)	1	61	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts ...	MDS-RS-MLD	1	61	1	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts ...	Numb chin	1	61	1	.	.	.
Nervous system disorders	DECREASED LEVEL OF CONSCIOUSNESS	1	61	1	.	.	.
Psychiatric disorders	Delirium	1	61	1	.	.	.
Psychiatric disorders	Personality change	1	61	1	.	.	.
Renal and urinary disorders	Cast nephropathy	1	61	1	1	.	.
Renal and urinary disorders	Hydronephrosis	1	61	1	.	.	.
Renal and urinary disorders	RENAL INSUFFICIENCY WORSENING	1	61	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Bilateral pulmonary embolism	1	61	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Bronchospasms	1	61	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnea	2	61	2	1	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnoe	1	61	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnoea	1	61	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Pulmonary acute oedema	1	61	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	1	61	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Pulmonary thromboembolism	1	61	1	1	.	.
Respiratory, thoracic and mediastinal disorders	RESPIRATORY INSUFFICIENCY	1	61	1	1	.	.
Skin and subcutaneous tissue disorders	Skin desquamation	1	61	1	.	.	.
Skin and subcutaneous tissue disorders	Skin xerosis	1	61	1	1	.	.
Surgical and medical procedures	Osteosynthesis subtrochanteric fracture	1	61	1	.	.	.
Vascular disorders	Hematoma	1	61	1	.	.	.
Vascular disorders	Hematoma II	1	61	1	.	.	.
Vascular disorders	Hypotension (previously ''Cardiac ischemia'')	1	61	1	1	.	.
Vascular disorders	Thromboembolic event	1	61	1	1	.	.
Vascular disorders	Thrombophlebitis	1	61	1	.	.	.