

***** 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	Anaemia grade 2		1	130	1	1	.	.
Blood and lymphatic system disorders	Anemia		1	130	1	1	.	.
Blood and lymphatic system disorders	Thrombocytopenia		1	130	1	.	1	.
Cardiac disorders	Artrial fibrillation		1	130	1	1	.	.
Cardiac disorders	Cardiac decompensation		1	130	1	.	.	.
Cardiac disorders	Decompensatio cordis		2	130	2	2	.	.
Cardiac disorders	Heart failure		4	130	4	3	1	1
Cardiac disorders	Myocardial infarction		2	130	2	1	.	.
Cardiac disorders	Secundairy cardiac isschemia		1	130	1	.	.	.
Cardiac disorders	Sick sinus syndrome		1	130	1	1	.	.
Cardiac disorders	Ventricular arrhythmia		1	130	1	.	1	.
Gastrointestinal disorders	Constipation		5	130	5	2	.	.
Gastrointestinal disorders	Diarrhea		11	130	13	13	1	1
Gastrointestinal disorders	Diarrhea Gr III		1	130	1	1	.	.
Gastrointestinal disorders	Ileus		1	130	1	.	.	.
Gastrointestinal disorders	Nausea and vomiting		1	130	1	1	.	.
Gastrointestinal disorders	Stomach ache		1	130	1	.	.	.
Gastrointestinal disorders	Vomiting		1	130	1	.	.	.
General disorders and administration site conditions	Fatigue		1	130	1	1	.	.
General disorders and administration site conditions	Fever		4	130	5	5	.	.
General disorders and administration site conditions	Fever ECI		1	130	1	1	.	.
General disorders and administration site conditions	Fever gr II		1	130	1	.	.	.
General disorders and administration site conditions	Fever without focus		1	130	1	1	.	.
General disorders and administration site conditions	Intercurrent death		1	130	1	.	1	.
General disorders and administration site conditions	Pain uncontrolled		1	130	1	.	.	.
General disorders and administration site conditions	Persistent fever		1	130	1	1	.	.
General disorders and administration site conditions	Persistent fever (hospitalization due to)		1	130	1	1	.	.
General disorders and administration site conditions	Sudden death		1	130	1	.	1	.
General disorders and administration site conditions	Uncontrolled pain due to multiple myeloma		1	130	1	.	.	.
General disorders and administration site conditions	Uncontrolled pain due to multiple myeloma before start at study entry		1	130	1	.	.	.
General disorders and administration site conditions	Weakness		1	130	1	1	.	1
Hepatobiliary disorders	Angiocholitis (lithiasis)		1	130	1	.	.	.
Hepatobiliary disorders	Angiocholitis (lithiasis) before ERCP procedure		1	130	1	.	.	.
Hepatobiliary disorders	Angiocholitis - (ERCP procedure)		1	130	1	.	.	.
Hepatobiliary disorders	Cholecystectomy (Angiocholitis lithiasis)		1	130	1	.	.	.
Hepatobiliary disorders	Decompensated cirrhotic liver		1	130	1	1	1	1
Hepatobiliary disorders	Probable angiocholitis due to prosthesis obstruction		1	130	1	.	.	.
Immune system disorders	Cryofibrinogenemia		1	130	1	.	.	.
Infections and infestations	Bronchitis		2	130	2	.	.	.
Infections and infestations	COVID 19 infection		2	130	2	.	.	.
Infections and infestations	Covid-19 infection		1	130	1	.	.	.
Infections and infestations	Cystitis (Bladder inflammation grade II)		1	130	1	.	.	.
Infections and infestations	Enterococcus faecalis bacteremia		1	130	1	1	.	.
Infections and infestations	Eschericha Coli Urinary tract infection		1	130	1	.	.	.
Infections and infestations	Faecalis enterococcus and staphylococcus haemolyticus		1	130	1	1	.	.
Infections and infestations	septicemia	
Infections and infestations	Fever, due to Human metapneumonias		1	130	1	1	.	.
Infections and infestations	Flu		1	130	1	1	.	.
Infections and infestations	Gastro-enteritis		1	130	1	.	.	.
Infections and infestations	Herpes Zoster		1	130	1	.	.	.
Infections and infestations	Infection		1	130	1	1	.	.
Infections and infestations	Infection COVID-19		1	130	1	.	1	.
Infections and infestations	Influenza		2	130	2	.	.	.
Infections and infestations	Influenza A		1	130	1	.	.	.
Infections and infestations	Long infection		1	130	1	1	.	.
Infections and infestations	Lung infection		1	130	1	1	.	.
Infections and infestations	Melanoma		1	130	1	.	.	.
Infections and infestations	Norovirus gastroenteritis		1	130	1	.	.	.

Infections and infestations	Pneumonia	13	130	13	6	3	.
Infections and infestations	Respiratory infection viral	1	130	1	.	.	.
Infections and infestations	Sepsis	3	130	3	1	1	.
Infections and infestations	Staphylococcus epidermidis septicemia	1	130	1	1	.	.
Infections and infestations	Streptococcus pneumoniae pneumonia	1	130	1	1	.	.
Infections and infestations	Upper respiratory infection	2	130	2	.	.	.
Infections and infestations	Upper respiratory tract infection	2	130	2	2	.	.
Infections and infestations	Urinary tract infection	4	130	4	2	.	.
Infections and infestations	Urosepsis	1	130	1	1	.	.
Injury, poisoning and procedural complications	Bone fractures acetabulum left and ramus superior and inferior left	1	130	1	.	.	.
Injury, poisoning and procedural complications	Femoral fracture	1	130	1	.	.	.
Injury, poisoning and procedural complications	Fracture of Th 12	1	130	1	.	.	.
Injury, poisoning and procedural complications	Hip luxation	1	130	1	.	.	.
Injury, poisoning and procedural complications	Humerus fracture	1	130	1	.	.	.
Injury, poisoning and procedural complications	IRR: chills and low back pain	1	130	1	1	.	.
Injury, poisoning and procedural complications	Infusion reaction	1	130	1	1	.	.
Injury, poisoning and procedural complications	Infusion related reaction	3	130	3	3	.	.
Injury, poisoning and procedural complications	Medial collumfracture left	1	130	1	.	.	.
Injury, poisoning and procedural complications	Rib fracture (costa 10)	1	130	1	.	.	.
Injury, poisoning and procedural complications	Right Iliac fracture	1	130	1	.	.	.
Injury, poisoning and procedural complications	Sacrum fracture	1	130	1	.	.	.
Injury, poisoning and procedural complications	Trauma	1	130	1	.	.	.
Injury, poisoning and procedural complications	Worsening of excisting collapsed vertebra L4	1	130	1	.	.	.
Injury, poisoning and procedural complications	Worsening of existing collapsed vertebra L4	1	130	1	.	.	.
Metabolism and nutrition disorders	Dehydration	3	130	3	1	.	.
Metabolism and nutrition disorders	Hypercalcemia	2	130	2	.	.	.
Metabolism and nutrition disorders	Hypokalemia	1	130	1	1	.	.
Metabolism and nutrition disorders	Hyponatremia	1	130	2	.	.	.
Musculoskeletal and connective tissue disorders	Avascular necrosis left hip	1	130	1	1	.	.
Musculoskeletal and connective tissue disorders	Bone pain	1	130	1	.	.	.
Musculoskeletal and connective tissue disorders	Cervical arthrosis	1	130	1	.	.	.
Musculoskeletal and connective tissue disorders	Coxarthrosis	1	130	1	.	.	.
Musculoskeletal and connective tissue disorders	Myalgia	1	130	1	.	.	.
Musculoskeletal and connective tissue disorders	Myopathie (steroid)	1	130	1	1	.	.
Musculoskeletal and connective tissue disorders	Pain lumbal and sacral	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma colorectal	1	130	1	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma lung right	1	130	1	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	3	130	3	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma Face-SPM	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma SPM	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma/SPM	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basocellular carcinoma fore head	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenocarcinoma SPM	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Duodenum carcinoma	1	130	1	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal stromal tumor	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Low grade follicular lymphoma	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	MDS-EB2 (second malignancy)	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Mesothelioma	1	130	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastatic sigmoid carcinoma	1	130	1	1	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nasopharynx carcinoma	1	130	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malign lung	1	130	1	1	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nodular basal cell carcinoma	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nodular basal cell carcinoma skin	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Progressive disease	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Rectosigmo?d adenocarcinoma	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	1	130	3	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma skin SPM	1	130	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tumor invasion intraspinale	1	130	1	.	.	.
Nervous system disorders	Brain stem infarction	1	130	1	.	.	.
Nervous system disorders	Cerebral Hemorrhage	1	130	1	.	1	.
Nervous system disorders	Guillain barre syndrome	1	130	1	1	.	.
Nervous system disorders	Herpes simplex (HSV1) encephalopathy	1	130	1	1	.	.
Nervous system disorders	Intracranial hemorrhage	2	130	2	.	.	.
Nervous system disorders	Intracranial hemorrhage, recurrence	1	130	1	.	.	.
Nervous system disorders	Lacunair infarct left	1	130	1	.	.	.
Nervous system disorders	Moderate to severe axonal polyneuropathie	1	130	1	1	.	.
Nervous system disorders	Neuropathy left lower extremity	1	130	1	1	.	.
Nervous system disorders	Radicular pain due to progressive disease	1	130	1	.	.	.
Nervous system disorders	Stroke	2	130	2	.	.	.
Nervous system disorders	Syncope	1	130	1	.	.	.
Nervous system disorders	Transient ischemic attack	1	130	1	.	.	.
Nervous system disorders	Transient ischemic attack (TIA)	1	130	1	.	.	.
Product issues	Aseptic loosening of total hip prosthesis	1	130	1	.	.	.

Product issues	Dislocation of the total hip prosthesis	1	130	1	.	.	.
Psychiatric disorders	Anxiety	1	130	1	.	.	.
Psychiatric disorders	Depression	1	130	1	.	.	.
Psychiatric disorders	Mental confusion	1	130	1	.	.	.
Renal and urinary disorders	Acute kidney injury	2	130	2	.	.	.
Renal and urinary disorders	Acute renal failure	2	130	2	.	.	.
Renal and urinary disorders	Progressive chronic kidney disease	1	130	1	1	.	.
Renal and urinary disorders	Renal insufficiency	2	130	2	1	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnea	2	130	2	.	.	.
Respiratory, thoracic and mediastinal disorders	Lung embolism	1	130	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Pleural Effusion	1	130	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Pneumonitis	1	130	1	1	1	1
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	1	130	1	.	.	.
Skin and subcutaneous tissue disorders	Bedsore	1	130	1	.	.	.
Skin and subcutaneous tissue disorders	Maculopapuleus exanthema	1	130	1	1	.	.
Skin and subcutaneous tissue disorders	Toxicoderma	1	130	1	1	.	.
Vascular disorders	Bleeding	1	130	1	.	.	.
Vascular disorders	Orthostatic hypotension	1	130	1	1	.	.
Vascular disorders	Orthostetic hypotension	1	130	1	.	.	.