

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All over study

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.
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Reporting groups

Reporting group title	LAA- group
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Reporting group description: -

Reporting group title	Control-Group
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Reporting group description: -

Serious adverse events	LAA- group	Control-Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	446 / 446 (100.00%)	392 / 442 (88.69%)	
number of deaths (all causes)	155	141	
number of deaths resulting from adverse events	1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasms benign, malignant and unspecified (incl cysts and polyps), others	Additional description: various carcinomas, brain and other metastases with edema of unknown origin, primary osteomyelofibrosis, soft tissue sarcoma, urethral polyp, mycosis fungoides, liver abscess, multiple myeloma		
subjects affected / exposed	40 / 446 (8.97%)	50 / 442 (11.31%)	
occurrences causally related to treatment / all	5 / 49	9 / 59	
deaths causally related to treatment / all	0 / 5	0 / 9	
Vascular disorders			
Hematoma			
subjects affected / exposed	11 / 446 (2.47%)	8 / 442 (1.81%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	6 / 446 (1.35%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			

subjects affected / exposed	8 / 446 (1.79%)	7 / 442 (1.58%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischemia			
subjects affected / exposed	10 / 446 (2.24%)	10 / 442 (2.26%)	
occurrences causally related to treatment / all	0 / 15	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thromboembolic event			
subjects affected / exposed	18 / 446 (4.04%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	0 / 20	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arterial thromboembolism			
subjects affected / exposed	3 / 446 (0.67%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ruptured aortic aneurysm			
subjects affected / exposed	1 / 446 (0.22%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Visceral arterial ischemia			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Vascular disorders, others	Additional description: pAVK stage FROM IIb to IV; Asymptomatic aneurysm of the left common iliac artery, multiple angiodysplasias in the duodenum and jejunum, shunt dysfunction/ clos, Stenosis in the area of the shunt anastomosis , Muscle vein thrombosis on the left side,		
subjects affected / exposed	9 / 446 (2.02%)	10 / 442 (2.26%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures	Additional description: Biopsie, amputation, implantation		
Surgical and medical procedures, others			
subjects affected / exposed	109 / 446 (24.44%)	129 / 442 (29.19%)	
occurrences causally related to treatment / all	2 / 149	0 / 161	
deaths causally related to treatment / all	0 / 2	0 / 0	

General disorders and administration site conditions			
Death NOS			
subjects affected / exposed	37 / 446 (8.30%)	31 / 442 (7.01%)	
occurrences causally related to treatment / all	37 / 37	31 / 31	
deaths causally related to treatment / all	0 / 37	0 / 31	
Fever			
subjects affected / exposed	2 / 446 (0.45%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ failure			
subjects affected / exposed	7 / 446 (1.57%)	8 / 442 (1.81%)	
occurrences causally related to treatment / all	7 / 7	8 / 8	
deaths causally related to treatment / all	0 / 7	0 / 8	
Non-cardiac chest pain			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
general disorders and administration site conditions, others	Additional description: Deterioration of general condition, complex geriatric early rehabilitation, palliative care		
subjects affected / exposed	5 / 446 (1.12%)	6 / 442 (1.36%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction/ shock			
subjects affected / exposed	2 / 446 (0.45%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
immune system disorders, others	Additional description: Inhibitor hemophilia, Angioneurotic edema		

subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Reproductive system and breast disorders			
Reproductive system and breast disorders, others	Additional description: Reproductive system and breast disorders prostata hyperblasie, vaginal fistula)		
subjects affected / exposed	1 / 446 (0.22%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	9 / 446 (2.02%)	11 / 442 (2.49%)	
occurrences causally related to treatment / all	1 / 11	2 / 16	
deaths causally related to treatment / all	0 / 1	0 / 2	
Bronchopulmonary hemorrhage			
subjects affected / exposed	3 / 446 (0.67%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnea			
subjects affected / exposed	10 / 446 (2.24%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 10	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epitaxis			
subjects affected / exposed	0 / 446 (0.00%)	5 / 442 (1.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	14 / 446 (3.14%)	12 / 442 (2.71%)	
occurrences causally related to treatment / all	0 / 17	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			

subjects affected / exposed	2 / 446 (0.45%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	7 / 446 (1.57%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	1 / 8	3 / 3	
deaths causally related to treatment / all	0 / 1	0 / 3	
Pulmonary hypertension			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural hemorrhage			
subjects affected / exposed	2 / 446 (0.45%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aspiration			
subjects affected / exposed	1 / 446 (0.22%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory, thoracic and mediastinal disorders, others			
subjects affected / exposed	4 / 446 (0.90%)	4 / 442 (0.90%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Delirium			
subjects affected / exposed	6 / 446 (1.35%)	11 / 442 (2.49%)	
occurrences causally related to treatment / all	0 / 6	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	2 / 446 (0.45%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders, others			

subjects affected / exposed	3 / 446 (0.67%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
INR increased			
subjects affected / exposed	1 / 446 (0.22%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
increased CRP			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations, others			
subjects affected / exposed	2 / 446 (0.45%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fracture			
Additional description: Fracture after Fall (Hip,ankle, spinal, wrist)			
subjects affected / exposed	4 / 446 (0.90%)	38 / 442 (8.60%)	
occurrences causally related to treatment / all	0 / 36	0 / 40	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	12 / 446 (2.69%)	10 / 442 (2.26%)	
occurrences causally related to treatment / all	0 / 12	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Infusion related reaction			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative hemorrhage			
subjects affected / exposed	5 / 446 (1.12%)	4 / 442 (0.90%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Vascular access complication subjects affected / exposed	1 / 446 (0.22%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound complication subjects affected / exposed	3 / 446 (0.67%)	5 / 442 (1.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications, others subjects affected / exposed	18 / 446 (4.04%)	7 / 442 (1.58%)	
occurrences causally related to treatment / all	0 / 18	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome subjects affected / exposed	2 / 446 (0.45%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease subjects affected / exposed	6 / 446 (1.35%)	8 / 442 (1.81%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asystole subjects affected / exposed	1 / 446 (0.22%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation subjects affected / exposed	54 / 446 (12.11%)	50 / 442 (11.31%)	
occurrences causally related to treatment / all	0 / 79	0 / 62	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter subjects affected / exposed	8 / 446 (1.79%)	9 / 442 (2.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	

Atrioventricular block complete subjects affected / exposed	4 / 446 (0.90%)	5 / 442 (1.13%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block first degree subjects affected / exposed	2 / 446 (0.45%)	0 / 442 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cardiac arrest subjects affected / exposed	6 / 446 (1.35%)	4 / 442 (0.90%)
occurrences causally related to treatment / all	3 / 6	4 / 4
deaths causally related to treatment / all	0 / 3	0 / 2
Chest pain - cardiac subjects affected / exposed	22 / 446 (4.93%)	21 / 442 (4.75%)
occurrences causally related to treatment / all	0 / 30	1 / 30
deaths causally related to treatment / all	0 / 0	1 / 1
Conduction disorder subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart failure subjects affected / exposed	181 / 446 (40.58%)	62 / 442 (14.03%)
occurrences causally related to treatment / all	26 / 280	22 / 187
deaths causally related to treatment / all	0 / 26	0 / 22
Mitral valve disease subjects affected / exposed	20 / 446 (4.48%)	11 / 442 (2.49%)
occurrences causally related to treatment / all	1 / 21	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 0
Myocardial infarction subjects affected / exposed	15 / 446 (3.36%)	23 / 442 (5.20%)
occurrences causally related to treatment / all	3 / 16	1 / 27
deaths causally related to treatment / all	0 / 3	0 / 1
Myocarditis		

subjects affected / exposed	0 / 446 (0.00%)	1 / 442 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paroxysmal atrial tachycardia		
subjects affected / exposed	2 / 446 (0.45%)	1 / 442 (0.23%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		
subjects affected / exposed	3 / 446 (0.67%)	3 / 442 (0.68%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial tamponade		
subjects affected / exposed	5 / 446 (1.12%)	0 / 442 (0.00%)
occurrences causally related to treatment / all	2 / 5	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Pericarditis		
subjects affected / exposed	3 / 446 (0.67%)	0 / 442 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sick sinus syndrome		
subjects affected / exposed	3 / 446 (0.67%)	4 / 442 (0.90%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	4 / 446 (0.90%)	5 / 442 (1.13%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		
subjects affected / exposed	3 / 446 (0.67%)	5 / 442 (1.13%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve disease		

subjects affected / exposed	10 / 446 (2.24%)	11 / 442 (2.49%)	
occurrences causally related to treatment / all	0 / 10	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	2 / 446 (0.45%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	1 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	3 / 446 (0.67%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ventricular tachycardia			
subjects affected / exposed	6 / 446 (1.35%)	9 / 442 (2.04%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac disorders, others	Additional description: KHK, progress of KHK, NSTE-ACS, thrombus on device...		
subjects affected / exposed	40 / 446 (8.97%)	30 / 442 (6.79%)	
occurrences causally related to treatment / all	0 / 41	3 / 43	
deaths causally related to treatment / all	0 / 0	0 / 3	
Nervous system disorders			
Intracranial hemorrhage			
subjects affected / exposed	16 / 446 (3.59%)	15 / 442 (3.39%)	
occurrences causally related to treatment / all	5 / 17	6 / 16	
deaths causally related to treatment / all	0 / 5	0 / 6	
stroke			
subjects affected / exposed	20 / 446 (4.48%)	16 / 442 (3.62%)	
occurrences causally related to treatment / all	3 / 23	4 / 18	
deaths causally related to treatment / all	0 / 3	0 / 4	
Transient ischemic attacks			
subjects affected / exposed	10 / 446 (2.24%)	14 / 442 (3.17%)	
occurrences causally related to treatment / all	0 / 10	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			

subjects affected / exposed	8 / 446 (1.79%)	4 / 442 (0.90%)	
occurrences causally related to treatment / all	1 / 10	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Encephalopathy			
subjects affected / exposed	1 / 446 (0.22%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Edema cerebral			
subjects affected / exposed	1 / 446 (0.22%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Syncope			
subjects affected / exposed	13 / 446 (2.91%)	14 / 442 (3.17%)	
occurrences causally related to treatment / all	0 / 15	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	3 / 446 (0.67%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Memory/ cognitive impairment			
subjects affected / exposed	3 / 446 (0.67%)	4 / 442 (0.90%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	1 / 446 (0.22%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders, others			

subjects affected / exposed	5 / 446 (1.12%)	7 / 442 (1.58%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	34 / 446 (7.62%)	38 / 442 (8.60%)	
occurrences causally related to treatment / all	0 / 42	0 / 56	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood and lymphomatic disorders, other	Additional description: Panzytopenia, "Hemoptysis due to overlapping anticoagulation with Enoxaparin and Marcumar", Thrombozytopenia		
subjects affected / exposed	3 / 446 (0.67%)	6 / 442 (1.36%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 446 (0.45%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Eye disorders,other- Glaucoma, Cataract ...			
subjects affected / exposed	3 / 446 (0.67%)	5 / 442 (1.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 446 (0.67%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	5 / 446 (1.12%)	4 / 442 (0.90%)	
occurrences causally related to treatment / all	0 / 5	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
lower gastrointestinal hemorrhage			

subjects affected / exposed	22 / 446 (4.93%)	16 / 442 (3.62%)	
occurrences causally related to treatment / all	0 / 24	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper gastrointestinal hemorrhage			
subjects affected / exposed	23 / 446 (5.16%)	18 / 442 (4.07%)	
occurrences causally related to treatment / all	1 / 27	0 / 21	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diarrhea			
subjects affected / exposed	8 / 446 (1.79%)	5 / 442 (1.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Esophageal perforation			
subjects affected / exposed	2 / 446 (0.45%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	2 / 446 (0.45%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	1 / 446 (0.22%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders, others			
subjects affected / exposed	11 / 446 (2.47%)	16 / 442 (3.62%)	
occurrences causally related to treatment / all	0 / 12	1 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic failure			

subjects affected / exposed	3 / 446 (0.67%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	1 / 3	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cholecystitis			
subjects affected / exposed	4 / 446 (0.90%)	5 / 442 (1.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	3 / 446 (0.67%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertension			
subjects affected / exposed	1 / 446 (0.22%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cirrhosis of the liver			
subjects affected / exposed	2 / 446 (0.45%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis traumatic			
subjects affected / exposed	1 / 446 (0.22%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Skin and subcutaneous tissue disorders, others	Additional description: Pruritus, skin ulceration, Stasis dermatitis		
subjects affected / exposed	5 / 446 (1.12%)	4 / 442 (0.90%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	82 / 446 (18.39%)	68 / 442 (15.38%)	
occurrences causally related to treatment / all	8 / 93	5 / 83	
deaths causally related to treatment / all	0 / 8	0 / 5	

Chronic kidney disease			
subjects affected / exposed	5 / 446 (1.12%)	7 / 442 (1.58%)	
occurrences causally related to treatment / all	1 / 6	1 / 7	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hematuria			
subjects affected / exposed	0 / 446 (0.00%)	9 / 442 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	3 / 446 (0.67%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders, others			
subjects affected / exposed	3 / 446 (0.67%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	2 / 446 (0.45%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 446 (0.00%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	5 / 446 (1.12%)	33 / 442 (7.47%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Back pain			
subjects affected / exposed	3 / 446 (0.67%)	11 / 442 (2.49%)	
occurrences causally related to treatment / all	0 / 3	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	2 / 446 (0.45%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue necrosis lower limb			
subjects affected / exposed	1 / 446 (0.22%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders, others	Additional description: SLAC wrist, right ;Active spondylarthrosis in the C3/C4 region with movement-dependent occipital pain; herniated disc, Rupture of the supraspinatus and infraspinatus tendons, inguinal hernia....		
subjects affected / exposed	18 / 446 (4.04%)	23 / 442 (5.20%)	
occurrences causally related to treatment / all	0 / 18	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
abdominal infection and infestations - Other, specify			
subjects affected / exposed	14 / 446 (3.14%)	13 / 442 (2.94%)	
occurrences causally related to treatment / all	1 / 15	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung infection			
subjects affected / exposed	47 / 446 (10.54%)	57 / 442 (12.90%)	
occurrences causally related to treatment / all	14 / 53	11 / 66	
deaths causally related to treatment / all	0 / 14	0 / 11	
Urinary tract infection			
subjects affected / exposed	30 / 446 (6.73%)	21 / 442 (4.75%)	
occurrences causally related to treatment / all	0 / 35	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper respiratory infections			
subjects affected / exposed	3 / 446 (0.67%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Sepsis			
subjects affected / exposed	32 / 446 (7.17%)	29 / 442 (6.56%)	
occurrences causally related to treatment / all	19 / 34	18 / 32	
deaths causally related to treatment / all	0 / 19	0 / 18	
Infections and infestations - Other, COVID-19			
subjects affected / exposed	5 / 446 (1.12%)	7 / 442 (1.58%)	
occurrences causally related to treatment / all	1 / 5	1 / 9	
deaths causally related to treatment / all	0 / 1	0 / 1	
Endocarditis infective			
subjects affected / exposed	4 / 446 (0.90%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	1 / 4	1 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Wound infection			
subjects affected / exposed	7 / 446 (1.57%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viremia			
subjects affected / exposed	9 / 446 (2.02%)	10 / 442 (2.26%)	
occurrences causally related to treatment / all	1 / 9	0 / 11	
deaths causally related to treatment / all	1 / 1	0 / 0	
Soft tissue infection			
subjects affected / exposed	4 / 446 (0.90%)	6 / 442 (1.36%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	2 / 446 (0.45%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Catheter/device related infection			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis infectious			

subjects affected / exposed	10 / 446 (2.24%)	2 / 442 (0.45%)	
occurrences causally related to treatment / all	1 / 10	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Fungemia			
subjects affected / exposed	1 / 446 (0.22%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder infection			
subjects affected / exposed	2 / 446 (0.45%)	4 / 442 (0.90%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone infection			
subjects affected / exposed	0 / 446 (0.00%)	1 / 442 (0.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis infective			
subjects affected / exposed	4 / 446 (0.90%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	1 / 4	1 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Joint infection			
subjects affected / exposed	2 / 446 (0.45%)	4 / 442 (0.90%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth infection			
subjects affected / exposed	1 / 446 (0.22%)	0 / 442 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations, others			
Additional description: Infection of unknown origin, superinfected hematoma, endoprosthesis inflammation			
subjects affected / exposed	11 / 446 (2.47%)	3 / 442 (0.68%)	
occurrences causally related to treatment / all	0 / 11	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Acidosis			

subjects affected / exposed	1 / 446 (0.22%)	0 / 442 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dehydration		
subjects affected / exposed	5 / 446 (1.12%)	3 / 442 (0.68%)
occurrences causally related to treatment / all	1 / 7	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Hyperkalemia		
subjects affected / exposed	2 / 446 (0.45%)	2 / 442 (0.45%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycemia		
subjects affected / exposed	6 / 446 (1.35%)	0 / 442 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycemia		
subjects affected / exposed	5 / 446 (1.12%)	6 / 442 (1.36%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatremia		
subjects affected / exposed	0 / 446 (0.00%)	1 / 442 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcemia		
subjects affected / exposed	0 / 446 (0.00%)	1 / 442 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic derailment		
subjects affected / exposed	0 / 446 (0.00%)	2 / 442 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0