Clinical trial results:
UK Multicentre Open-label Randomised Controlled Trial Of IV Iron Therapy
In Incident Haemodialysis Patients

Summary

EudraCT number	2013-002267-25
Trial protocol	GB
Global end of trial date	06 June 2018

Results information

Result version number	v1 (current)
This version publication date	04 August 2019
First version publication date	04 August 2019
Summary attachment (see zip file)	Final Publication (NEJMoa1810742.pdf)

Trial information

Trial identification

Sponsor protocol code	PIVOTAL

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	King's College Hospital NHS Foundation Trust
Sponsor organisation address	Denmark Hill, London, United Kingdom, SE5 9RS
Public contact	Professor Iain Macdougall, King's College Hospital NHS Foundation Trust, +44 02032996233, iain.macdougall@nhs.net
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 June 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 June 2018
Global end of trial reached?	Yes
Global end of trial date	06 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the effect of a proactive high-dose, with a reactive low-dose, IV iron regimen on all-cause mortality and the incidence of non-fatal cardiovascular endpoints in haemodialysis patients.

Protection of trial subjects:

During the period between informed consent and randomisation, if there is a strong clinical indication that a patient requires iron, then iron may be administered (this is not considered to be a protocol breach).

Background therapy:

Patients established on a chronic haemodialysis programme for end-stage renal failure

Evidence for comparator:

To compare the effect of a proactive high-dose, with a reactive low-dose, IV iron regimen on all-cause mortality and the incidence of non-fatal cardiovascular endpoints in haemodialysis patients

Actual start date of recruitment	01 September 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 2141
Worldwide total number of subjects	2141
EEA total number of subjects	2141

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	865
From 65 to 84 years	1024

85 years and over	252

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from multiple clinical centres across the UK between 2013 and 2018

Pre-assignment

Screening details:

Age >18 years
- Patients established on a chronic haemodialysis programme for end-stage renal failure
- Clinically stable (Investigator’s judgement)
- 0–12 months since commencing haemodialysis

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

not applicable

Arms

Are arms mutually exclusive?	Yes
Arm title	Proactive IV iron arm

Arm description:

IV iron 400mg/month
Total study period approximately 4 years (event-driven)
– projected treatment duration per patient > 2 years

Arm type	Experimental
Investigational medicinal product name	Venofer
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

IV iron 400mg/month by Intravenous Infustion

Arm title	Reactive IV iron arm

Arm description:

IV iron sucrose 100–200mg / month if becomes “iron deficien

Arm type	Active comparator
Investigational medicinal product name	Venofer
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

IV iron sucrose 100–200mg / month if becomes “iron deficien

Number of subjects in period 1	Proactive IV iron arm	Reactive IV iron arm
Started	1093	1048
Completed	488	407
Not completed	605	641
Adverse event, serious fatal	246	269
Consent withdrawn by subject	42	44
Moved to peritoneal dialysis	13	17
Home dialysis	45	36
Lost to follow-up	62	78
Transplant	184	187
Protocol deviation	13	10

Baseline characteristics

End points

End points reporting groups

Reporting group title	Proactive IV iron arm
Reporting group description:	
IV iron 400mg/month Total study period approximately 4 years (event-driven) – projected treatment duration per patient > 2 years	
Reporting group title	Reactive IV iron arm
Reporting group description:	
IV iron sucrose 100–200mg / month if becomes "iron deficien	

Primary: Time to first event

End point title	Time to first event[1]
End point description:	
Time to first event: all-cause death or a composite of non-fatal cardiovascular events (myocardial infarction, stroke, and hospitalisation for heart failure) adjudicated by a blinded Endpoint Adjudication Committee.	
End point type	Primary
End point timeframe:	
not applicable	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Please see attached publication and appendix

End point values	Proactive IV iron arm	Reactive IV iron arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1080	1038		
Units: whole	1080	1038		

Attachments (see zip file)	Results additional data/nejmoa1810742_appendix.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary Efficacy Endpoints

End point title	Secondary Efficacy Endpoints
End point description:	
Incidence of all-cause death and a composite of myocardial infarction, stroke, and hospitalisation for heart failure as recurrent events. - Time to (and incidence of) all-cause death - Time to (and incidence of) first composite cardiovascular event - Time to (and incidence of) first myocardial infarction - Time to (and incidence of) first stroke - Time to (and incidence of) first hospitalisation for heart failure - Transfusion requirements	

- EQ-5D QOL and KDQOL
- ESA dose requirements

End point type	Secondary

End point timeframe:

0 to 18 months (event driven)

End point values	Proactive IV iron arm	Reactive IV iron arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1080	1038		
Units: whole	1080	1038		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Adverse events were recorded from baseline/randomisation until the end of study for each patient.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups	
Reporting group title	Proactive IV Iron
Reporting group description: -	
Reporting group title	Reactive IV Iron
Reporting group description: -	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Adverse events or reactions listed in the SmPC were not reported, with the exception of immediate hypersensitivity-like reactions to IV iron. Common non-life-threatening symptoms such as constipation, diarrhoea, headache, etc. do not need to be reported. Only serious adverse events and episodes of infection and vascular access thrombosis will be recorded. No other non-serious adverse events will be recorded.

Serious adverse events	Proactive IV Iron	Reactive IV Iron	
Total subjects affected by serious adverse events			
subjects affected / exposed	709 / 1093 (64.87%)	671 / 1048 (64.03%)	
number of deaths (all causes)	246	269	
number of deaths resulting from adverse events	246	269	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADRENAL NEOPLASM			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER CANCER			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
BLADDER NEOPLASM			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BREAST CANCER			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
CARDIAC MYXOMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CENTRAL NERVOUS SYSTEM LYMPHOMA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CERVIX CANCER METASTATIC			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
COLON CANCER			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
GASTRIC CANCER			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL CARCINOMA			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG ADENOCARCINOMA			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG CANCER METASTATIC			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
LUNG NEOPLASM MALIGNANT			
subjects affected / exposed	4 / 1093 (0.37%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 2	
LUNG SQUAMOUS CELL CARCINOMA STAGE UNSPECIFIED			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHOMA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
MALIGNANT MELANOMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDIASTINUM NEOPLASM			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
MESOTHELIOMA MALIGNANT			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTASES TO CENTRAL NERVOUS SYSTEM			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTASES TO PANCREAS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTASIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
METASTATIC MALIGNANT MELANOMA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
METASTATIC NEOPLASM			
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
MULTIPLE MYELOMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
NEOPLASM MALIGNANT			

subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
NEUROENDOCRINE TUMOUR			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NON-SMALL CELL LUNG CANCER			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATIC CARCINOMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
PELVIC NEOPLASM			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PITUITARY TUMOUR BENIGN			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL NEOPLASM			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
PROSTATE CANCER METASTATIC			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RECTAL CANCER			

subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CANCER RECURRENT			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CELL CARCINOMA RECURRENT			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SALIVARY GLAND CANCER			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN CANCER			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL CELL LUNG CANCER STAGE UNSPECIFIED			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
VULVAL CANCER			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
PROGRESSIVE SUPRANUCLEAR PALSY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Stroke			
subjects affected / exposed	12 / 1093 (1.10%)	13 / 1048 (1.24%)	
occurrences causally related to treatment / all	0 / 12	0 / 13	
deaths causally related to treatment / all	0 / 12	0 / 13	
AIR EMBOLISM			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANEURYSM RUPTURED			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
ANGIOPATHY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
AORTIC ANEURYSM			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
AORTIC CALCIFICATION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
AORTIC STENOSIS			
subjects affected / exposed	0 / 1093 (0.00%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
ARTERIAL DISORDER			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIOSCLEROSIS			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIOVENOUS FISTULA			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRACHIOCEPHALIC ARTERY OCCLUSION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CIRCULATORY COLLAPSE			
subjects affected / exposed	17 / 1093 (1.56%)	16 / 1048 (1.53%)	
occurrences causally related to treatment / all	0 / 22	0 / 18	
deaths causally related to treatment / all	0 / 5	0 / 4	
DEEP VEIN THROMBOSIS			
subjects affected / exposed	3 / 1093 (0.27%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
DIABETIC VASCULAR DISORDER			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EMBOLISM			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENOUS EMBOLISM			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EXTREMITY NECROSIS			

subjects affected / exposed	5 / 1093 (0.46%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
HAEMATOMA			
subjects affected / exposed	6 / 1093 (0.55%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHAGE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTENSION			
subjects affected / exposed	10 / 1093 (0.91%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
HYPERTENSIVE CRISIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOTENSION			
subjects affected / exposed	20 / 1093 (1.83%)	18 / 1048 (1.72%)	
occurrences causally related to treatment / all	0 / 22	0 / 20	
deaths causally related to treatment / all	0 / 2	0 / 3	
HYPOVOLAEMIC SHOCK			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
INTERMITTENT CLAUDICATION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT HYPERTENSION			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MICROSCOPIC POLYANGIITIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ARTERIAL OCCLUSIVE DISEASE			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ARTERY THROMBOSIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ISCHAEMIA			
subjects affected / exposed	14 / 1093 (1.28%)	22 / 1048 (2.10%)	
occurrences causally related to treatment / all	0 / 15	0 / 25	
deaths causally related to treatment / all	0 / 4	0 / 7	
PERIPHERAL VASCULAR DISORDER			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
STEAL SYNDROME			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUPERIOR VENA CAVA SYNDROME			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOSIS			
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR STENOSIS			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENOUS OCCLUSION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENOUS STENOSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENA CAVA THROMBOSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TEMPORAL ARTERITIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POOR VENOUS ACCESS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
ABSCESS DRAINAGE			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
AMPUTATION OF PENIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
ANEURYSM REPAIR			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANGIOPLASTY			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANKLE OPERATION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
AORTIC VALVE REPLACEMENT			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIOVENOUS FISTULA OPERATION			
subjects affected / exposed	29 / 1093 (2.65%)	18 / 1048 (1.72%)	
occurrences causally related to treatment / all	0 / 34	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIOVENOUS GRAFT			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER NECK OPERATION			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BUNION OPERATION			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC PACEMAKER INSERTION			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARPAL TUNNEL DECOMPRESSION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CATHETER PLACEMENT			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CATHETER REMOVAL			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CENTRAL VENOUS CATHETERISATION			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLECYSTECTOMY			
subjects affected / exposed	0 / 1093 (0.00%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORONARY ANGIOPLASTY			

subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORONARY ARTERIAL STENT INSERTION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORONARY ARTERY BYPASS			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEBRIDEMENT			
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIALYSIS			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIALYSIS DEVICE INSERTION			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRUG THERAPY			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
EMERGENCY CARE			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
EMPYEMA DRAINAGE			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
ENDOTRACHEAL INTUBATION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
FINGER AMPUTATION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FISTULA REPAIR			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
FOOT AMPUTATION			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL SURGERY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENITOURINARY OPERATION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERNIA REPAIR			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
HIP ARTHROPLASTY			

subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
HOSPITALISATION			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYSTERECTOMY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ILEOSTOMY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCISIONAL DRAINAGE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCISIONAL HERNIA REPAIR			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
INTRAVENOUS CATHETER MANAGEMENT			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
KNEE ARTHROPLASTY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LEG AMPUTATION			

subjects affected / exposed	7 / 1093 (0.64%)	7 / 1048 (0.67%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
LESION EXCISION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIMB AMPUTATION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT TUMOUR EXCISION			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MASTECTOMY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENISCUS OPERATION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEPHRECTOMY			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
OPEN REDUCTION OF FRACTURE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OVARIOCENTESIS			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATICODUODENECTOMY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARATHYROIDECTOMY			
subjects affected / exposed	9 / 1093 (0.82%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARTIAL LUNG RESECTION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERCUTANEOUS CORONARY INTERVENTION			
subjects affected / exposed	5 / 1093 (0.46%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ARTERY ANGIOPLASTY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ARTERY BYPASS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PREOPERATIVE CARE			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROLAPSE REPAIR			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROPHYLAXIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL TRANSPLANT			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SALPINGO-OOPHORECTOMY UNILATERAL			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SALVAGE THERAPY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN GRAFT			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN NEOPLASM EXCISION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SURGERY			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THERAPY CESSATION			

subjects affected / exposed	7 / 1093 (0.64%)	8 / 1048 (0.76%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 7	0 / 8	
THORACIC CAVITY DRAINAGE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBECTOMY			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOEMBOLECTOMY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOLYSIS			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOSIS PROPHYLAXIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOE AMPUTATION			
subjects affected / exposed	6 / 1093 (0.55%)	7 / 1048 (0.67%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSFUSION			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETERAL STENT INSERTION			

subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT OPERATION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UROSTOMY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR OPERATION			
subjects affected / exposed	15 / 1093 (1.37%)	8 / 1048 (0.76%)	
occurrences causally related to treatment / all	0 / 15	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	6 / 1093 (0.55%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Cardiac death			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Catheter site haemorrhage			
subjects affected / exposed	1 / 1093 (0.09%)	12 / 1048 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site pain			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	52 / 1093 (4.76%)	51 / 1048 (4.87%)	
occurrences causally related to treatment / all	0 / 72	0 / 67	
deaths causally related to treatment / all	0 / 3	0 / 2	
Chills			
subjects affected / exposed	2 / 1093 (0.18%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication of device removal			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	34 / 1093 (3.11%)	28 / 1048 (2.67%)	
occurrences causally related to treatment / all	0 / 34	0 / 28	
deaths causally related to treatment / all	0 / 34	0 / 28	
Device dislocation			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	7 / 1093 (0.64%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug resistance			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue management			
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	5 / 1093 (0.46%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 2	
Hernia			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Injury associated with device			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic ulcer			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
local swelling			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	18 / 1093 (1.65%)	10 / 1048 (0.95%)	
occurrences causally related to treatment / all	0 / 19	0 / 12	
deaths causally related to treatment / all	0 / 3	0 / 1	
medical device complication			
subjects affected / exposed	10 / 1093 (0.91%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 11	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ failure			
subjects affected / exposed	5 / 1093 (0.46%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 5	0 / 1	
Necrosis			
subjects affected / exposed	6 / 1093 (0.55%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 1093 (0.00%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	2 / 1093 (0.18%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pain			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic mass			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	17 / 1093 (1.56%)	11 / 1048 (1.05%)	
occurrences causally related to treatment / all	0 / 18	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sudden cardiac death			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Sudden unexplained death in epilepsy			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Swelling			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suprapubic pain			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Treatment failure			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	13 / 1093 (1.19%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEART TRANSPLANT REJECTION			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
SOCIAL PROBLEM			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SOCIAL STAY HOSPITALISATION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TREATMENT NONCOMPLIANCE			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
EPIDIDYMITIS			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PELVIC HAEMATOMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

PENILE NECROSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL EFFUSION			
subjects affected / exposed	22 / 1093 (2.01%)	19 / 1048 (1.81%)	
occurrences causally related to treatment / all	0 / 25	0 / 27	
deaths causally related to treatment / all	0 / 2	0 / 4	
Respiratory, thoracic and mediastinal disorders			
ACUTE PULMONARY OEDEMA			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ALVEOLITIS ALLERGIC			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASPIRATION			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
ASTHMA			
subjects affected / exposed	1 / 1093 (0.09%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	

BRONCHIECTASIS			
subjects affected / exposed	0 / 1093 (0.00%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
CHOKING			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	8 / 1093 (0.73%)	14 / 1048 (1.34%)	
occurrences causally related to treatment / all	0 / 10	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 3	
CHRONIC RESPIRATORY FAILURE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
COUGH			
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPNOEA			
subjects affected / exposed	42 / 1093 (3.84%)	43 / 1048 (4.10%)	
occurrences causally related to treatment / all	0 / 53	0 / 50	
deaths causally related to treatment / all	0 / 2	0 / 6	
EMPHYSEMA			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
EPISTAXIS			
subjects affected / exposed	5 / 1093 (0.46%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOPTYSIS			

subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOTHORAX			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
LARYNGEAL DYSPNOEA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
LARYNGEAL STENOSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NON-CARDIOGENIC PULMONARY OEDEMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG DISORDER			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG CONSOLIDATION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOXIA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
DYSPNOEA EXERTIONAL			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURISY			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURITIC PAIN			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA ASPIRATION			
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
PNEUMOTHORAX			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
PRODUCTIVE COUGH			
subjects affected / exposed	3 / 1093 (0.27%)	7 / 1048 (0.67%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY ARTERY ANEURYSM			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY CONGESTION			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			

subjects affected / exposed	6 / 1093 (0.55%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
PULMONARY FIBROSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
PULMONARY OEDEMA			
subjects affected / exposed	25 / 1093 (2.29%)	27 / 1048 (2.58%)	
occurrences causally related to treatment / all	0 / 25	0 / 35	
deaths causally related to treatment / all	0 / 1	0 / 3	
RESPIRATORY ARREST			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
RESPIRATORY DISORDER			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
RESPIRATORY DISTRESS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY FAILURE			
subjects affected / exposed	2 / 1093 (0.18%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 2	
WHEEZING			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Psychiatric disorders			
AFFECT LABILITY			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
AGITATION			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANXIETY			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONFUSIONAL STATE			
subjects affected / exposed	18 / 1093 (1.65%)	18 / 1048 (1.72%)	
occurrences causally related to treatment / all	0 / 23	0 / 19	
deaths causally related to treatment / all	0 / 3	0 / 4	
DELIRIUM			
subjects affected / exposed	3 / 1093 (0.27%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEPRESSED MOOD			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
IMPAIRED SELF-CARE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PSYCHOTIC DISORDER			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct obstruction			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	8 / 1093 (0.73%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	3 / 1093 (0.27%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder perforation			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			

subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatitis acute			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic failure			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Jaundice			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Jaundice cholestatic			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
ANTICOAGULATION DRUG LEVEL ABOVE THERAPEUTIC			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORONARY ARTERIOGRAM			
subjects affected / exposed	0 / 1093 (0.00%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
BIOPSY LYMPH GLAND			

subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD CULTURE POSITIVE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD GLUCOSE ABNORMAL			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD GLUCOSE FLUCTUATION			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD PHOSPHORUS DECREASED			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD POTASSIUM INCREASED			
subjects affected / exposed	4 / 1093 (0.37%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC OUTPUT DECREASED			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC PACEMAKER EVALUATION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM TEST POSITIVE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLONOSCOPY			
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
COMA SCALE ABNORMAL			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-REACTIVE PROTEIN ABNORMAL			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRUG LEVEL ABOVE THERAPEUTIC			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ECHOCARDIOGRAM ABNORMAL			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ELECTROCARDIOGRAM ABNORMAL			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FISTULOGRAM			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DECREASED HAEMOGLOBIN			
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEART RATE IRREGULAR			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFLAMMATORY MARKER INCREASED			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERNATIONAL NORMALISED RATIO ABNORMAL			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERNATIONAL NORMALISED			

RATIO INCREASED			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
LISTERIA TEST POSITIVE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDIASTINOSCOPY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY FUNCTION TEST DECREASED			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SIGMOIDOSCOPY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TROPONIN INCREASED			
subjects affected / exposed	1 / 1093 (0.09%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCREASED T TROPONIN			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINE OUTPUT DECREASED			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WEIGHT DECREASED			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Injury, poisoning and procedural complications			
ACCIDENTAL OVERDOSE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANKLE FRACTURE			
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANEURYSM ARTERIOVENOUS FISTULA			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIOVENOUS FISTULA OCCLUSION			
subjects affected / exposed	34 / 1093 (3.11%)	33 / 1048 (3.15%)	
occurrences causally related to treatment / all	0 / 38	0 / 36	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACCIDENT			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
ARTERIOVENOUS FISTULA SITE COMPLICATION			
subjects affected / exposed	24 / 1093 (2.20%)	20 / 1048 (1.91%)	
occurrences causally related to treatment / all	0 / 24	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 1	

ARTERIOVENOUS FISTULA SITE HAEMORRHAGE			
subjects affected / exposed	12 / 1093 (1.10%)	12 / 1048 (1.15%)	
occurrences causally related to treatment / all	0 / 13	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
ARTERIOVENOUS FISTULA THROMBOSIS			
subjects affected / exposed	43 / 1093 (3.93%)	27 / 1048 (2.58%)	
occurrences causally related to treatment / all	0 / 52	0 / 28	
deaths causally related to treatment / all	0 / 1	0 / 0	
ARTERIOVENOUS GRAFT SITE HAEMATOMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CERVICAL VERTEBRAL FRACTURE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLAVICLE FRACTURE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COMPLICATIONS OF TRANSPLANT SURGERY			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONTUSION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIALYSIS RELATED COMPLICATION			
subjects affected / exposed	7 / 1093 (0.64%)	7 / 1048 (0.67%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 2	

FACE INJURY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FALL			
subjects affected / exposed	33 / 1093 (3.02%)	55 / 1048 (5.25%)	
occurrences causally related to treatment / all	0 / 39	0 / 59	
deaths causally related to treatment / all	0 / 1	0 / 13	
FEMORAL NECK FRACTURE			
subjects affected / exposed	13 / 1093 (1.19%)	23 / 1048 (2.19%)	
occurrences causally related to treatment / all	0 / 14	0 / 24	
deaths causally related to treatment / all	0 / 2	0 / 2	
FEMUR FRACTURE			
subjects affected / exposed	2 / 1093 (0.18%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
FIBULA FRACTURE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FOOT FRACTURE			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
FOREIGN BODY			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
FRACTURE			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
GASTROINTESTINAL STOMA COMPLICATION			

subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GRAFT COMPLICATION			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GRAFT HAEMORRHAGE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GRAFT THROMBOSIS			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATURIA TRAUMATIC			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMODIALYSIS COMPLICATION			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
HAEMODIALYSIS-INDUCED SYMPTOM			
subjects affected / exposed	4 / 1093 (0.37%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAND FRACTURE			
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEAD INJURY			

subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC HAEMATOMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIP FRACTURE			
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
HUMERUS FRACTURE			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
IATROGENIC INJURY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCISIONAL HERNIA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCISIONAL HERNIA, OBSTRUCTIVE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INJURY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
JOINT DISLOCATION			

subjects affected / exposed	0 / 1093 (0.00%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
JOINT INJURY			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
LACERATION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIMB INJURY			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER LIMB FRACTURE			
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTIPLE FRACTURES			
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCLE INJURY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OVERDOSE			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PATELLA FRACTURE			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PELVIC FRACTURE			
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPROSTHETIC FRACTURE			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERITONEAL DIALYSIS COMPLICATION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST GASTRIC SURGERY SYNDROME			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL COMPLICATION			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL DIARRHOEA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL HAEMATOMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL MYOCARDIAL INFARCTION			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
POST PROCEDURAL SWELLING			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POSTOPERATIVE ILEUS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
POSTOPERATIVE WOUND COMPLICATION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROCEDURAL COMPLICATION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROCEDURAL HYPERTENSION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROCEDURAL HYPOTENSION			
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
PROCEDURAL PAIN			

subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROCEDURAL VOMITING			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PUBIS FRACTURE			
subjects affected / exposed	2 / 1093 (0.18%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
RADIUS FRACTURE			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL GRAFT LOSS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RIB FRACTURE			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
SHUNT OCCLUSION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SOFT TISSUE INJURY			

subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL FRACTURE			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
SUBDURAL HAEMATOMA			
subjects affected / exposed	4 / 1093 (0.37%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
SUBDURAL HAEMORRHAGE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
TIBIA FRACTURE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRAUMATIC HAEMATOMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER LIMB FRACTURE			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR ACCESS COMPLICATION			

subjects affected / exposed	20 / 1093 (1.83%)	13 / 1048 (1.24%)	
occurrences causally related to treatment / all	0 / 24	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 1	
VASCULAR GRAFT COMPLICATION			
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR GRAFT OCCLUSION			
subjects affected / exposed	8 / 1093 (0.73%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 11	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR GRAFT THROMBOSIS			
subjects affected / exposed	14 / 1093 (1.28%)	13 / 1048 (1.24%)	
occurrences causally related to treatment / all	0 / 16	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR PSEUDOANEURYSM			
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND HAEMATOMA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WRIST FRACTURE			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENOUS INJURY			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Tracheo-oesophageal fistula			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	16 / 1093 (1.46%)	9 / 1048 (0.86%)	
occurrences causally related to treatment / all	0 / 16	0 / 9	
deaths causally related to treatment / all	0 / 16	0 / 9	
Acute coronary syndrome			
subjects affected / exposed	5 / 1093 (0.46%)	13 / 1048 (1.24%)	
occurrences causally related to treatment / all	0 / 5	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	42 / 1093 (3.84%)	50 / 1048 (4.77%)	
occurrences causally related to treatment / all	0 / 46	0 / 59	
deaths causally related to treatment / all	0 / 6	0 / 5	
Angina pectoris			
subjects affected / exposed	9 / 1093 (0.82%)	12 / 1048 (1.15%)	
occurrences causally related to treatment / all	0 / 11	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unstable Angina			
subjects affected / exposed	3 / 1093 (0.27%)	9 / 1048 (0.86%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	

Atrial fibrillation			
subjects affected / exposed	13 / 1093 (1.19%)	21 / 1048 (2.00%)	
occurrences causally related to treatment / all	0 / 19	0 / 26	
deaths causally related to treatment / all	0 / 2	0 / 3	
Bradycardia			
subjects affected / exposed	8 / 1093 (0.73%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiac arrest			
subjects affected / exposed	21 / 1093 (1.92%)	26 / 1048 (2.48%)	
occurrences causally related to treatment / all	0 / 22	0 / 26	
deaths causally related to treatment / all	0 / 17	0 / 19	
Cardiac disorder			
subjects affected / exposed	6 / 1093 (0.55%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure			
subjects affected / exposed	7 / 1093 (0.64%)	9 / 1048 (0.86%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 4	
Acute Cardiac failure			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Congestive Cardiac failure			
subjects affected / exposed	6 / 1093 (0.55%)	7 / 1048 (0.67%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 5	
Cardio-respiratory arrest			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Coronary artery disease			

subjects affected / exposed	4 / 1093 (0.37%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Atrial flutter			
subjects affected / exposed	2 / 1093 (0.18%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complete Atrioventricular block			
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure chronic			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cardiac tamponade			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	6 / 1093 (0.55%)	7 / 1048 (0.67%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 5	
Cardiogenic shock			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiomegaly			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertensive heart disease			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intracardiac mass			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Left ventricular failure			
subjects affected / exposed	0 / 1093 (0.00%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
Left ventricular hypertrophy			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mitral valve disease			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	5 / 1093 (0.46%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 3	
Myocarditis			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	5 / 1093 (0.46%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal arrhythmia			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial haemorrhage			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pericarditis			

subjects affected / exposed	4 / 1093 (0.37%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Supraventricular tachycardia			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tachycardia			
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trifascicular block			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
AMNESIA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
APHASIA			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BALANCE DISORDER			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BALLISMUS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BASAL GANGLIA STROKE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRAIN INJURY			
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 3	
CAROTID ARTERY STENOSIS			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CENTRAL NERVOUS SYSTEM LESION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	1 / 1093 (0.09%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 2	
CEREBRAL INFARCTION			

subjects affected / exposed	4 / 1093 (0.37%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
CEREBRAL ISCHAEMIA			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	12 / 1093 (1.10%)	16 / 1048 (1.53%)	
occurrences causally related to treatment / all	0 / 45	0 / 18	
deaths causally related to treatment / all	0 / 8	0 / 5	
CEREBROVASCULAR DISORDER			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COMA URAEMIC			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
CONSCIOUSNESS FLUCTUATING			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
CONVULSION			
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEPRESSED LEVEL OF CONSCIOUSNESS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIZZINESS			

subjects affected / exposed	8 / 1093 (0.73%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSARTHRIA			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSKINESIA			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EMBOLIC CEREBRAL INFARCTION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENCEPHALITIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENCEPHALITIS AUTOIMMUNE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENCEPHALOPATHY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPILEPSY			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GRAND MAL CONVULSION			

subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GUILLAIN-BARRE SYNDROME			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHAGE INTRACRANIAL			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
HAEMORRHAGIC CEREBRAL INFARCTION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
HAEMORRHAGIC STROKE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
HEADACHE			
subjects affected / exposed	6 / 1093 (0.55%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEMIPARESIS			
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
HEPATIC ENCEPHALOPATHY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERGLYCAEMIC SEIZURE			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTENSIVE ENCEPHALOPATHY			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOAESTHESIA			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOGLYCAEMIC SEIZURE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTRAVENTRICULAR HAEMORRHAGE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ISCHAEMIC STROKE			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LACUNAR INFARCTION			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
LETHARGY			
subjects affected / exposed	5 / 1093 (0.46%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
LOSS OF CONSCIOUSNESS			

subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MERALGIA PARAESTHETICA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MIGRAINE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MOVEMENT DISORDER			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
MYOCLONUS			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYXOEDEMA COMA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
NEUROLOGICAL SYMPTOM			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERONEAL NERVE PALSY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PRESYNCOPE			
subjects affected / exposed	7 / 1093 (0.64%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEIZURE LIKE PHENOMENA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
SENSORY LOSS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SOMNOLENCE			
subjects affected / exposed	0 / 1093 (0.00%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPEECH DISORDER			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL CORD COMPRESSION			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNCOPE			
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	11 / 1093 (1.01%)	11 / 1048 (1.05%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
TREMOR			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
UNRESPONSIVE TO STIMULI			
subjects affected / exposed	7 / 1093 (0.64%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
VASCULAR DEMENTIA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIITH NERVE PARALYSIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 1093 (0.73%)	13 / 1048 (1.24%)	
occurrences causally related to treatment / all	0 / 8	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lymphadenectomy			

subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrogenic anaemia			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye pain			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyphaema			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vascular occlusion			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	1 / 1093 (0.09%)	11 / 1048 (1.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal pain			
subjects affected / exposed	23 / 1093 (2.10%)	14 / 1048 (1.34%)	
occurrences causally related to treatment / all	0 / 28	0 / 15	
deaths causally related to treatment / all	0 / 4	0 / 1	
Abdominal distension			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	0 / 1093 (0.00%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal strangulated hernia			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bowel movement irregularity			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coeliac disease			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colitis			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
colonic stenosis			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	6 / 1093 (0.55%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastroparesis			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			

subjects affected / exposed	11 / 1093 (1.01%)	13 / 1048 (1.24%)	
occurrences causally related to treatment / all	0 / 12	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea haemorrhagic			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer perforation			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faeces discoloured			

subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
faecal incontinence			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric disorder			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric perforation			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	3 / 1093 (0.27%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			

subjects affected / exposed	3 / 1093 (0.27%)	9 / 1048 (0.86%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 1	
Gastrointestinal motility disorder			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal pain			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrooesophagitis			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	5 / 1093 (0.46%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemorrhoidal haemorrhage			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ileitis			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	6 / 1093 (0.55%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal fistula			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Inguinal hernia			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	7 / 1093 (0.64%)	8 / 1048 (0.76%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 4	0 / 5	
Intestinal obstruction			
subjects affected / exposed	3 / 1093 (0.27%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 3	
Irritable bowel syndrome			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Large intestine perforation			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malabsorption			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	7 / 1093 (0.64%)	7 / 1048 (0.67%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Megacolon			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth ulceration			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal rupture			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic cyst			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatic mass			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pancreatitis chronic			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Proctitis			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	7 / 1093 (0.64%)	11 / 1048 (1.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 2	
Retching			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal fibrosis			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Small intestinal obstruction			
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Steatorrhoea			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 1093 (0.27%)	10 / 1048 (0.95%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Umbilical hernia, obstructive			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	26 / 1093 (2.38%)	18 / 1048 (1.72%)	
occurrences causally related to treatment / all	0 / 30	0 / 20	
deaths causally related to treatment / all	0 / 3	0 / 0	
Skin and subcutaneous tissue disorders			
COLD SWEAT			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DECUBITUS ULCER			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETIC FOOT			
subjects affected / exposed	7 / 1093 (0.64%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
DIABETIC ULCER			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRY GANGRENE			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERHIDROSIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH MACULO-PAPULAR			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN NECROSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN REACTION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN SWELLING			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN ULCER			
subjects affected / exposed	11 / 1093 (1.01%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
AZOTAEMIA			

subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER OUTLET OBSTRUCTION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSURIA			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATURIA			
subjects affected / exposed	10 / 1093 (0.91%)	10 / 1048 (0.95%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
MICTURITION URGENCY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEPHROLITHIASIS			
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEPHROTIC SYNDROME			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
OBSTRUCTIVE UROPATHY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL COLIC			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CYST HAEMORRHAGE			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
ACUTE RENAL FAILURE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC RENAL FAILURE			
subjects affected / exposed	8 / 1093 (0.73%)	27 / 1048 (2.58%)	
occurrences causally related to treatment / all	0 / 8	0 / 27	
deaths causally related to treatment / all	0 / 7	0 / 21	
RENAL IMPAIRMENT			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
RENAL MASS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL PAIN			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY RETENTION			

subjects affected / exposed	4 / 1093 (0.37%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT DISORDER			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PRIAPISM			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TESTICULAR PAIN			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperparathyroidism tertiary			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 1093 (0.09%)	7 / 1048 (0.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTHRITIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

ARTHROPATHY			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACK PAIN			
subjects affected / exposed	3 / 1093 (0.27%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BURSITIS			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
COCCYDYNIA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COSTOCHONDRITIS			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FLANK PAIN			
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
FRACTURE NONUNION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GROIN PAIN			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMARTHROSIS			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
JOINT SWELLING			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MOBILITY DECREASED			
subjects affected / exposed	4 / 1093 (0.37%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
MUSCLE TWITCHING			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 1093 (0.00%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	6 / 1093 (0.55%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULOSKELETAL PAIN			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOPATHY			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NECK PAIN			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUROPATHIC ARTHROPATHY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEOARTHRITIS			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEONECROSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN IN EXTREMITY			
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
POLYMYALGIA RHEUMATICA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RHEUMATOID ARTHRITIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
SPINAL OSTEOARTHRITIS			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYSTEMIC LUPUS ERYTHEMATOSUS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (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			
ABDOMINAL SEPSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABSCESS			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABSCESS LIMB			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANAL ABSCESS			
subjects affected / exposed	0 / 1093 (0.00%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
APPENDICITIS			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
APPENDICITIS PERFORATED			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIOVENOUS FISTULA SITE INFECTION			

subjects affected / exposed	8 / 1093 (0.73%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 8	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIOVENOUS GRAFT SITE INFECTION			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTHRITIS BACTERIAL			
subjects affected / exposed	4 / 1093 (0.37%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTHRITIS INFECTIVE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERAEMIA			
subjects affected / exposed	4 / 1093 (0.37%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERIAL INFECTION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERIAL SEPSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
BILIARY SEPSIS			
subjects affected / exposed	1 / 1093 (0.09%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHIOLITIS			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHITIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHOPNEUMONIA			
subjects affected / exposed	2 / 1093 (0.18%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 2	
CAMPYLOBACTER GASTROENTERITIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CAMPYLOBACTER INFECTION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CAMPYLOBACTER SEPSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC VALVE VEGETATION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
CATHETER SITE INFECTION			
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS			

subjects affected / exposed	18 / 1093 (1.65%)	24 / 1048 (2.29%)	
occurrences causally related to treatment / all	0 / 18	0 / 32	
deaths causally related to treatment / all	0 / 0	0 / 2	
CELLULITIS GANGRENOUS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CENTRAL NERVOUS SYSTEM INFECTION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIAL INFECTION			
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYSTITIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED INFECTION			
subjects affected / exposed	23 / 1093 (2.10%)	20 / 1048 (1.91%)	
occurrences causally related to treatment / all	0 / 25	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED SEPSIS			
subjects affected / exposed	25 / 1093 (2.29%)	15 / 1048 (1.43%)	
occurrences causally related to treatment / all	0 / 27	0 / 18	
deaths causally related to treatment / all	0 / 1	0 / 2	
DIABETIC FOOT INFECTION			

subjects affected / exposed	0 / 1093 (0.00%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULITIS			
subjects affected / exposed	3 / 1093 (0.27%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIARRHOEA INFECTIOUS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EMPHYSEMATOUS PYELONEPHRITIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EMPYEMA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENCEPHALITIS VIRAL			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
ENDOCARDITIS1			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
ENTEROBACTER SEPSIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOCCAL INFECTION			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOCCAL SEPSIS			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	6 / 1093 (0.55%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA INFECTION			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GALLBLADDER ABSCESS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GANGRENE			
subjects affected / exposed	10 / 1093 (0.91%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 11	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 0	
GASTROENTERITIS			
subjects affected / exposed	11 / 1093 (1.01%)	11 / 1048 (1.05%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS VIRAL			

subjects affected / exposed	4 / 1093 (0.37%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
GRAFT INFECTION			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GROIN ABSCESS			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
H1N1 INFLUENZA			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATOMA INFECTION			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTED SKIN ULCER			
subjects affected / exposed	6 / 1093 (0.55%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTION			
subjects affected / exposed	11 / 1093 (1.01%)	8 / 1048 (0.76%)	
occurrences causally related to treatment / all	1 / 12	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 0	
INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE			
subjects affected / exposed	4 / 1093 (0.37%)	11 / 1048 (1.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 4	
INFLUENZA			

subjects affected / exposed	8 / 1093 (0.73%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 0	
INTERVERTEBRAL DISCITIS			
subjects affected / exposed	4 / 1093 (0.37%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
KLEBSIELLA SEPSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIVER ABSCESS			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOBAR PNEUMONIA			
subjects affected / exposed	1 / 1093 (0.09%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
LOCALISED INFECTION			
subjects affected / exposed	10 / 1093 (0.91%)	12 / 1048 (1.15%)	
occurrences causally related to treatment / all	0 / 10	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	77 / 1093 (7.04%)	94 / 1048 (8.97%)	
occurrences causally related to treatment / all	0 / 92	0 / 113	
deaths causally related to treatment / all	0 / 4	0 / 11	
INJECTION SITE INFECTION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTIVE EXACERBATION OF BRONCHIECTASIS			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
INFECTIVE ANEURYSM			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTIOUS PLEURAL EFFUSION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTED FISTULA			
subjects affected / exposed	4 / 1093 (0.37%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERPES ZOSTER			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG INFECTION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG INFECTION PSEUDOMONAL			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METAPNEUMOVIRUS INFECTION			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIC SEPSIS			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OESOPHAGEAL CANDIDIASIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEOMYELITIS			
subjects affected / exposed	8 / 1093 (0.73%)	17 / 1048 (1.62%)	
occurrences causally related to treatment / all	0 / 8	0 / 25	
deaths causally related to treatment / all	0 / 0	0 / 4	
OTITIS EXTERNA			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
PAROTITIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIHEPATIC ABSCESS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERITONITIS			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PILONIDAL CYST			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOCOCCAL SEPSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOCYSTIS JIROVECI PNEUMONIA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			
subjects affected / exposed	72 / 1093 (6.59%)	70 / 1048 (6.68%)	
occurrences causally related to treatment / all	0 / 83	0 / 85	
deaths causally related to treatment / all	0 / 13	0 / 9	
PNEUMONIA BACTERIAL			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA INFLUENZAL			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA KLEBSIELLA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA VIRAL			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL INFECTION			
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL PNEUMONIA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL SEPSIS			
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
PSEUDOMEMBRANOUS COLITIS			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PSOAS ABSCESS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY SEPSIS			
subjects affected / exposed	8 / 1093 (0.73%)	10 / 1048 (0.95%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 3	0 / 1	
PULMONARY TUBERCULOSIS			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PYELONEPHRITIS				
subjects affected / exposed	4 / 1093 (0.37%)	1 / 1048 (0.10%)		
occurrences causally related to treatment / all	0 / 5	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PYONEPHROSIS				
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
RENAL ABSCESS				
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
RENAL CYST INFECTION				
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)		
occurrences causally related to treatment / all	0 / 3	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
RESPIRATORY SYNCYTIAL VIRUS INFECTION				
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
RESPIRATORY TRACT INFECTION VIRAL				
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
RESPIRATORY TRACT INFECTION				
subjects affected / exposed	4 / 1093 (0.37%)	0 / 1048 (0.00%)		
occurrences causally related to treatment / all	0 / 4	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
RHINOVIRUS INFECTION				

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPSIS			
subjects affected / exposed	60 / 1093 (5.49%)	57 / 1048 (5.44%)	
occurrences causally related to treatment / all	0 / 71	0 / 61	
deaths causally related to treatment / all	0 / 16	0 / 13	
SEPTIC ARTHRITIS STAPHYLOCOCCAL			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPTIC EMBOLUS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPTIC ENCEPHALOPATHY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
SEPTIC NECROSIS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPTIC SHOCK			
subjects affected / exposed	2 / 1093 (0.18%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 3	
SOFT TISSUE INFECTION			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPLENIC ABSCESS			

subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	8 / 1093 (0.73%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 9	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL SEPSIS			
subjects affected / exposed	5 / 1093 (0.46%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	2 / 5	0 / 1	
deaths causally related to treatment / all	2 / 2	0 / 0	
STREPTOCOCCAL SEPSIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TONSILLITIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOOTH ABSCESS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUBERCULOSIS			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETHRITIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION			
subjects affected / exposed	29 / 1093 (2.65%)	18 / 1048 (1.72%)	
occurrences causally related to treatment / all	0 / 29	0 / 18	
deaths causally related to treatment / all	0 / 2	0 / 0	
UROSEPSIS			
subjects affected / exposed	18 / 1093 (1.65%)	11 / 1048 (1.05%)	
occurrences causally related to treatment / all	0 / 20	0 / 12	
deaths causally related to treatment / all	0 / 2	0 / 1	
URINARY TRACT INFECTION PSEUDOMONAL			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL INFECTION			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND INFECTION			
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			

FLUID OVERLOAD			
subjects affected / exposed	41 / 1093 (3.75%)	63 / 1048 (6.01%)	
occurrences causally related to treatment / all	0 / 51	0 / 79	
deaths causally related to treatment / all	0 / 2	0 / 4	
GOUT			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERCALCAEMIA			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERGLYCAEMIA			
subjects affected / exposed	9 / 1093 (0.82%)	9 / 1048 (0.86%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERKALAEMIA			
subjects affected / exposed	29 / 1093 (2.65%)	28 / 1048 (2.67%)	
occurrences causally related to treatment / all	0 / 35	0 / 36	
deaths causally related to treatment / all	0 / 3	0 / 1	
HYPOCALCAEMIA			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOGLYCAEMIA			
subjects affected / exposed	10 / 1093 (0.91%)	20 / 1048 (1.91%)	
occurrences causally related to treatment / all	0 / 11	0 / 25	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPONATRAEMIA			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOVOLAEMIA			

subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALNUTRITION			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
METABOLIC ACIDOSIS			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
TYPE 1 DIABETES MELLITUS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACIDOSIS			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CACHEXIA			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CALCIPHYLAXIS			
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
DECREASED APPETITE			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEHYDRATION			

subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETES MELLITUS			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 2	
INADEQUATE CONTROL DIABETES MELLITUS			
subjects affected / exposed	1 / 1093 (0.09%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETIC KETOACIDOSIS			
subjects affected / exposed	9 / 1093 (0.82%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 13	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 1	
ELECTROLYTE IMBALANCE			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Proactive IV Iron	Reactive IV Iron	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1093 (0.00%)	0 / 1048 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30641026