Clinical trial results:
A Multicenter, Double-Blind, Randomized Study to Establish the Clinical Benefit and Safety of Vytorin (Ezetimibe/Simvastatin Tablet) vs Simvastatin Monotherapy in High-Risk Subjects Presenting With Acute Coronary Syndrome (IMProved Reduction of Outcomes: Vytorin Efficacy International Trial – IMPROVE IT)

Due to the EudraCT – Results system being out of service between 31 July 2015 and 12 January 2016, these results have been published in compliance with revised timelines.

Summary

EudraCT number	2005-001059-39
Trial protocol	FI DK SE ES BE CZ IT DE GB AT PT SK EE
Global end of trial date	18 September 2014

Results information

Result version number	v1 (current)
This version publication date	06 March 2016
First version publication date	06 March 2016

Trial information

Trial identification

Sponsor protocol code	P04103

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00202878
WHO universal trial number (UTN)	-
Other trial identifiers	Merck Study Number: MK-0653A-080

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com

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	18 September 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 September 2014
Global end of trial reached?	Yes
Global end of trial date	18 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the clinical benefit of Ezetimibe/Simvastatin Combination (single tablet containing ezetimibe and simvastatin) compared with simvastatin in stabilized acute coronary syndrome (ACS) participants – either acute myocardial infarction (MI) or unstable angina (UA). Clinical benefit was defined as the reduction in the risk of the occurrence of the composite endpoint of cardiovascular (CV) death, major coronary events, and non-fatal stroke. CV death, major coronary events, and non-fatal stroke were designated primary endpoint events. Major coronary events included non-fatal myocardial infarction (MI), documented unstable angina that required admission into a hospital, and all coronary revascularization with either percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) that occurred at least 30 days after randomized treatment assignment.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 October 2005
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	Argentina: 332
Country: Number of subjects enrolled	Australia: 116
Country: Number of subjects enrolled	Austria: 249
Country: Number of subjects enrolled	Belgium: 249
Country: Number of subjects enrolled	Brazil: 423
Country: Number of subjects enrolled	Canada: 1107
Country: Number of subjects enrolled	Chile: 152
Country: Number of subjects enrolled	Colombia: 568
Country: Number of subjects enrolled	Czech Republic: 371
Country: Number of subjects enrolled	Denmark: 576
Country: Number of subjects enrolled	Ecuador: 45
Country: Number of subjects enrolled	Estonia: 10

Country: Number of subjects enrolled	Finland: 342
Country: Number of subjects enrolled	France: 286
Country: Number of subjects enrolled	Hong Kong: 58
Country: Number of subjects enrolled	Hungary: 116
Country: Number of subjects enrolled	India: 260
Country: Number of subjects enrolled	Israel: 655
Country: Number of subjects enrolled	Italy: 593
Country: Number of subjects enrolled	Germany: 935
Country: Number of subjects enrolled	Malaysia: 59
Country: Number of subjects enrolled	Netherlands: 1191
Country: Number of subjects enrolled	New Zealand: 164
Country: Number of subjects enrolled	Norway: 295
Country: Number of subjects enrolled	Peru: 65
Country: Number of subjects enrolled	Poland: 589
Country: Number of subjects enrolled	Portugal: 102
Country: Number of subjects enrolled	Singapore: 75
Country: Number of subjects enrolled	Slovakia: 121
Country: Number of subjects enrolled	South Africa: 186
Country: Number of subjects enrolled	Korea, Republic of: 118
Country: Number of subjects enrolled	Spain: 551
Country: Number of subjects enrolled	Sweden: 480
Country: Number of subjects enrolled	Switzerland: 265
Country: Number of subjects enrolled	Taiwan: 46
Country: Number of subjects enrolled	Turkey: 50
Country: Number of subjects enrolled	Ukraine: 159
Country: Number of subjects enrolled	United Kingdom: 319
Country: Number of subjects enrolled	United States: 5866
Worldwide total number of subjects	18144
EEA total number of subjects	7375

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)	10173
From 65 to 84 years	7706
85 years and over	265

Subject disposition

Recruitment

Recruitment details:

Adult men and women presenting with non-ST segment elevation myocardial infarction (NSTEMI) , STEMI, or hospitalized, documented unstable angina (UA) whom a percutaneous coronary intervention (PCI) was planned as management for the qualifying acute coronary syndrome (ACS) event were eligible for entry into the trial.

Pre-assignment

Screening details:

Study continued until a minimum of 5,250 participants had a primary endpoint event and each participant was followed for a minimum of 2.5 years.

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Ezetimibe/simvastatin

Arm description:

One ezetimibe 10 mg/simvastatin 40 mg combination tablet and two simvastatin 40 mg placebo tablets once per day.

Arm type	Experimental
Investigational medicinal product name	Ezetimibe 10 mg/simvastatin 40 mg
Investigational medicinal product code	
Other name	SCH 465981, MK-0653A, Vytorin
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ezetimibe/simvastatin 10/40 mg per day from randomization through the end of participation.

Investigational medicinal product name	Placebo for simvastatin 40 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One or two tablets orally daily from randomization through the end of participation.

Arm title	Simvastatin

Arm description:

One simvastatin 40 mg tablet, one ezetimibe/simvastatin combination 10/40 placebo tablet and one simvastatin 40 mg placebo tablet once per day.

Arm type	Active comparator
Investigational medicinal product name	Simvastatin
Investigational medicinal product code	
Other name	Zocor
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:	
Simvastatin 40 mg per day from randomization through the end of participation.	
Investigational medicinal product name	Placebo for simvastatin 40 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
One or two tablets orally daily from randomization through the end of participation.	
Investigational medicinal product name	Placebo for ezetimibe 10 mg/simvastatin 40 mg combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
One tablet orally daily from randomization through the end of participation.	

Number of subjects in period 1	Ezetimibe/simvastatin	Simvastatin
Started	9067	9077
Completed	6868	6860
Not completed	2199	2217
Site Closure	39	36
Adverse event, serious fatal	964	968
Consent withdrawn by subject	795	808
Only Vital Status Known	357	356
Lost to follow-up	44	49

Baseline characteristics

Reporting groups	
Reporting group title	Ezetimibe/simvastatin
Reporting group description:	
One ezetimibe 10 mg/simvastatin 40 mg combination tablet and two simvastatin 40 mg placebo tablets once per day.	
Reporting group title	Simvastatin
Reporting group description:	
One simvastatin 40 mg tablet, one ezetimibe/simvastatin combination 10/40 placebo tablet and one simvastatin 40 mg placebo tablet once per day.	

Reporting group values	Ezetimibe/simvastatin	Simvastatin	Total
Number of subjects	9067	9077	18144
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	63.6	63.6	
standard deviation	± 9.7	± 9.8	-
Gender categorical			
Units: Subjects			
Female	2225	2191	4416
Male	6842	6886	13728

End points

End points reporting groups

Reporting group title	Ezetimibe/simvastatin
Reporting group description:	
One ezetimibe 10 mg/simvastatin 40 mg combination tablet and two simvastatin 40 mg placebo tablets once per day.	
Reporting group title	Simvastatin
Reporting group description:	
One simvastatin 40 mg tablet, one ezetimibe/simvastatin combination 10/40 placebo tablet and one simvastatin 40 mg placebo tablet once per day.	

Primary: Time to First Occurrence of Cardiovascular Death, Major Coronary Event, or Non-fatal Stroke (Kaplan-Meier Estimate of Percentage of Participants Experiencing a Qualifying Event)

End point title	Time to First Occurrence of Cardiovascular Death, Major Coronary Event, or Non-fatal Stroke (Kaplan-Meier Estimate of Percentage of Participants Experiencing a Qualifying Event)
End point description:	
The time (in months) from study start to the first occurrence of any of the following clinical outcomes was recorded: cardiovascular death (CV), major coronary event (non-fatal myocardial infarction, documented unstable angina requiring hospitalization, or coronary revascularization with percutaneous coronary intervention or coronary artery bypass grafting ≥ 30 days after randomization), or non-fatal stroke. A Clinical Endpoints Committee (CEC) reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, major coronary event, or non-fatal stroke within 7 years from randomization.	
End point type	Primary
End point timeframe:	
Up to approximately 9 years	

End point values	Ezetimibe/simvastatin	Simvastatin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9067	9077		
Units: Percentage of Participants				
number (confidence interval 95%)	32.72 (31.63 to 33.85)	34.67 (33.56 to 35.81)		

Statistical analyses

Statistical analysis title	Hazard Ratio
Comparison groups	Simvastatin v Ezetimibe/simvastatin

Number of subjects included in analysis	18144
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0.016
Method	Cox proportional hazard model
Parameter estimate	Cox proportional hazard
Point estimate	0.936
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.887
upper limit	0.988

Notes:

[1] - Cox proportional hazard model with covariates of the stratification factors (EARLY ACS trial, chronic prescription lipid-lowering experience, and high-risk ACS diagnosis) and treatment. Model includes events from randomization to last study visit.

Secondary: Time to First Occurrence of Death from Any Cause, Major Coronary Event, or Non-fatal Stroke (Kaplan-Meier Estimate of Percentage of Participants Experiencing a Qualifying Event)

End point title	Time to First Occurrence of Death from Any Cause, Major Coronary Event, or Non-fatal Stroke (Kaplan-Meier Estimate of Percentage of Participants Experiencing a Qualifying Event)

End point description:

The time (in months) from study start to the first occurrence of any of the following clinical outcomes was recorded: death from any cause, major coronary event (non-fatal myocardial infarction, documented unstable angina requiring hospitalization, or coronary revascularization with percutaneous coronary intervention or coronary artery bypass grafting ≥ 30 days after randomization), or non-fatal stroke. A Clinical Endpoints Committee (CEC) reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who experienced death from any cause, major coronary event, or non-fatal stroke within 7 years from randomization.

End point type	Secondary

End point timeframe:

Up to approximately 9 years

End point values	Ezetimibe/simvastatin	Simvastatin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9067	9077		
Units: Percentage of Participants				
number (confidence interval 95%)	38.65 (37.52 to 39.81)	40.25 (39.11 to 41.41)		

Statistical analyses

Statistical analysis title	Hazard Ratio

Statistical analysis description:

Cox proportional hazard model with covariates of the stratification factors (EARLY ACS trial, chronic prescription lipid-lowering experience, and high-risk ACS diagnosis) and treatment. Model includes

events from randomization to last study visit.

Comparison groups	Ezetimibe/simvastatin v Simvastatin
Number of subjects included in analysis	18144
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.035
Method	Cox proportional hazard model
Parameter estimate	Cox proportional hazard
Point estimate	0.948
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.903
upper limit	0.996

Secondary: Time to First Occurrence of Coronary Heart Disease (CHD) Death, Non-fatal MI, or Urgent Coronary Revascularization with PCI or CABG ≥ 30 days after Randomization (Kaplan-Meier Estimate of Percentage of Participants Experiencing a Qualifying Event)

End point title	Time to First Occurrence of Coronary Heart Disease (CHD) Death, Non-fatal MI, or Urgent Coronary Revascularization with PCI or CABG ≥ 30 days after Randomization (Kaplan-Meier Estimate of Percentage of Participants Experiencing a Qualifying Event)

End point description:

The time (in months) from study start to the first occurrence of any of the following clinical outcomes was recorded: CHD death, non-fatal MI, or urgent coronary revascularization with PCI or CABG ≥ 30 days after randomization. A Clinical Endpoints Committee (CEC) reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who experienced CHD death, non-fatal MI, or urgent coronary revascularization with PCI or CABG ≥ 30 days after randomization within 7 years from randomization.

End point type	Secondary

End point timeframe:

Up to approximately 9 years

End point values	Ezetimibe/simvastatin	Simvastatin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9067	9077		
Units: Percentage of Participants				
number (confidence interval 95%)	17.52 (16.62 to 18.46)	18.88 (17.96 to 19.83)		

Statistical analyses

Statistical analysis title	Hazard Ratio

Statistical analysis description:

Cox proportional hazard model with covariates of the stratification factors (EARLY ACS trial, chronic prescription lipid-lowering experience, and high-risk ACS diagnosis) and treatment. Model includes events from randomization to last study visit.

Comparison groups	Ezetimibe/simvastatin v Simvastatin
Number of subjects included in analysis	18144
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.016
Method	Cox proportional hazard model
Parameter estimate	Cox proportional hazard
Point estimate	0.912
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.847
upper limit	0.983

Secondary: Time to First Occurrence of CV Death, Nonfatal MI, UA with Hospitalization, All Revascularization Occurring ≥30 Days After Randomization, and Non-fatal Stroke (Kaplan-Meier Estimate of Percentage of Participants Experiencing a Qualifying Event)

End point title	Time to First Occurrence of CV Death, Nonfatal MI, UA with Hospitalization, All Revascularization Occurring ≥30 Days After Randomization, and Non-fatal Stroke (Kaplan-Meier Estimate of Percentage of Participants Experiencing a Qualifying Event)

End point description:

The time (in months) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, non-fatal MI, documented UA that requires admission into a hospital, all revascularization (including non-coronary) occurring at least 30 days after randomization, and non-fatal stroke. A Clinical Endpoints Committee (CEC) reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, non-fatal MI, unstable angina with hospitalization, all revascularization occurring ≥ 30 days after randomization, and non-fatal stroke within 7 Years from randomization.

End point type	Secondary

End point timeframe:

Up to approximately 9 years

End point values	Ezetimibe/simvastatin	Simvastatin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9067	9077		
Units: Percentage of Participants				
number (confidence interval 95%)	34.49 (33.38 to 35.63)	36.2 (35.07 to 37.34)		

Statistical analyses

Statistical analysis title	Hazard Ratio

Statistical analysis description:

Cox proportional hazard model with covariates of the stratification factors (EARLY ACS trial, chronic prescription lipid-lowering experience, and high-risk ACS diagnosis) and treatment. Model includes events from randomization to last study visit.

Comparison groups	Ezetimibe/simvastatin v Simvastatin
Number of subjects included in analysis	18144
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.035
Method	Cox proportional hazard model
Parameter estimate	Cox proportional hazard
Point estimate	0.945
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.897
upper limit	0.996

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
up to 30 days after last dose of study drug (Up to approximately 9 years maximum)	
Adverse event reporting additional description:	
Safety Population included all participants randomly assigned to a treatment arm.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups	
Reporting group title	Ezetimibe/Simvastatin
Reporting group description:	
One Ezetimibe 10 mg/simvastatin 40 mg combination tablet and two simvastatin 40 mg placebo tablets once per day.	
Reporting group title	Simvastatin
Reporting group description:	
One simvastatin 40 mg tablet, one ezetimibe/simvastatin combination 10/40 placebo tablet and one simvastatin 40 mg placebo tablet once per day.	

Serious adverse events	Ezetimibe/Simvastatin	Simvastatin	
Total subjects affected by serious adverse events			
subjects affected / exposed	3640 / 9067 (40.15%)	3649 / 9077 (40.20%)	
number of deaths (all causes)	347	325	
number of deaths resulting from adverse events	10	16	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Monocytic Leukaemia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Leukaemia			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Abdominal Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Acoustic Neuroma			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			
subjects affected / exposed	12 / 9067 (0.13%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 12	1 / 10	
deaths causally related to treatment / all	0 / 4	0 / 4	
Adenocarcinoma Gastric			
subjects affected / exposed	3 / 9067 (0.03%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 3	2 / 9	
deaths causally related to treatment / all	0 / 0	1 / 3	
Adenocarcinoma Of Colon			
subjects affected / exposed	14 / 9067 (0.15%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 14	2 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma Pancreas			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Adenoma Benign			
subjects affected / exposed	5 / 9067 (0.06%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenolymphoma			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Myeloid Leukaemia			
subjects affected / exposed	7 / 9067 (0.08%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 4	
Adrenal Adenoma			

subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal Gland Cancer			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal Neoplasm			
subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Squamous Cell Carcinoma			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiomyolipoma			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiosarcoma			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Anal Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basosquamous Carcinoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal Cell Carcinoma			

subjects affected / exposed	140 / 9067 (1.54%)	157 / 9077 (1.73%)	
occurrences causally related to treatment / all	2 / 140	3 / 157	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-Cell Small Lymphocytic Lymphoma			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical Fibroxanthoma			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
B-Cell Lymphoma Stage I			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Anorectal Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Bone Neoplasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-Cell Lymphoma			
subjects affected / exposed	8 / 9067 (0.09%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Benign Neoplasm Of Bladder			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Neoplasm			

subjects affected / exposed	5 / 9067 (0.06%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Lung Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Duodenal Neoplasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Breast Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Ear Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Neoplasm Of Prostate			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Neoplasm Of Skin			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Neoplasm Of Thyroid Gland			
subjects affected / exposed	4 / 9067 (0.04%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Pancreatic Neoplasm			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Salivary Gland Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Neoplasm Of Conjunctiva			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Neoplasm			
subjects affected / exposed	17 / 9067 (0.19%)	23 / 9077 (0.25%)	
occurrences causally related to treatment / all	0 / 17	0 / 23	
deaths causally related to treatment / all	0 / 1	0 / 2	
Bladder Cancer Stage 0, With Cancer In Situ			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Cancer Recurrent			
subjects affected / exposed	5 / 9067 (0.06%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 5	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Cancer			
subjects affected / exposed	32 / 9067 (0.35%)	41 / 9077 (0.45%)	
occurrences causally related to treatment / all	2 / 32	2 / 41	
deaths causally related to treatment / all	1 / 4	0 / 1	
Biliary Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bile Duct Cancer			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Benign Small Intestinal Neoplasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Transitional Cell Carcinoma Stage Ii			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Transitional Cell Carcinoma Recurrent			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Transitional Cell Carcinoma			
subjects affected / exposed	3 / 9067 (0.03%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	1 / 3	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Papilloma			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bone Cancer Metastatic			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder Transitional Cell Carcinoma Stage Iii			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	32 / 9067 (0.35%)	22 / 9077 (0.24%)	
occurrences causally related to treatment / all	1 / 32	1 / 22	
deaths causally related to treatment / all	0 / 1	0 / 0	
Brain Neoplasm			
subjects affected / exposed	6 / 9067 (0.07%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 2	
Brain Cancer Metastatic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's Disease			
subjects affected / exposed	6 / 9067 (0.07%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Sarcoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bone Neoplasm			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Giant Cell Tumour			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burkitt's Lymphoma			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchioloalveolar Carcinoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial Carcinoma			
subjects affected / exposed	10 / 9067 (0.11%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 6	0 / 3	
Breast Neoplasm			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Cancer Recurrent			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Breast Cancer Metastatic			
subjects affected / exposed	4 / 9067 (0.04%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Breast Cancer In Situ			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid Tumour			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid Tumour Pulmonary			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoma In Situ			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix Carcinoma			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Central Nervous System Lymphoma			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Valve Fibroelastoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cancer Pain			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	1 / 3	1 / 4	
deaths causally related to treatment / all	1 / 2	0 / 3	
Cholesteatoma			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondroma			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrosarcoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix Carcinoma Stage 0			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Leukaemia			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Lymphocytic Leukaemia Stage 1			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Lymphocytic Leukaemia			
subjects affected / exposed	3 / 9067 (0.03%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 3	1 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chronic Myeloid Leukaemia			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon Cancer Metastatic			
subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Colon Cancer Recurrent			

subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon Cancer			
subjects affected / exposed	32 / 9067 (0.35%)	28 / 9077 (0.31%)	
occurrences causally related to treatment / all	3 / 32	2 / 28	
deaths causally related to treatment / all	0 / 3	0 / 3	
Chronic Myelomonocytic Leukaemia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear Cell Renal Cell Carcinoma			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon Adenoma			
subjects affected / exposed	23 / 9067 (0.25%)	29 / 9077 (0.32%)	
occurrences causally related to treatment / all	0 / 23	0 / 29	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cranial Nerve Neoplasm Benign			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal Cancer Metastatic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colorectal Adenocarcinoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal Cancer			

subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colon Cancer Stage Iv			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon Cancer Stage Iii			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon Neoplasm			
subjects affected / exposed	5 / 9067 (0.06%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysplastic Naevus			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine Neoplasm Malignant			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial Adenocarcinoma			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Enteropathy-Associated T-Cell Lymphoma			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential Thrombocythaemia			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse Large B-Cell Lymphoma			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gallbladder Adenocarcinoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrosarcoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibroma			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extramammary Paget's Disease			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye Naevus			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fallopian Tube Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal Neoplasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	1 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastric Cancer			
subjects affected / exposed	10 / 9067 (0.11%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 10	1 / 8	
deaths causally related to treatment / all	0 / 4	0 / 5	
Gallbladder Neoplasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder Cancer Metastatic			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder Cancer			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Gastric Neoplasm			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Tract Adenoma			
subjects affected / exposed	14 / 9067 (0.15%)	20 / 9077 (0.22%)	
occurrences causally related to treatment / all	0 / 14	1 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal Cancer			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
subjects affected / exposed	5 / 9067 (0.06%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Glioblastoma Multiforme			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Stromal Tumour			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Adenoma			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Cancer			
subjects affected / exposed	9 / 9067 (0.10%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	2 / 9	1 / 7	
deaths causally related to treatment / all	2 / 5	1 / 3	
Hepatic Cancer Metastatic			
subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hairy Cell Leukaemia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma Of Bone			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma Of Liver			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma Of Spleen			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypergammaglobulinaemia Benign Monoclonal			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Huerthle Cell Carcinoma			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Neoplasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hodgkin's Disease			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hepatocellular Carcinoma			
subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Hypopharyngeal Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immunoblastic Lymphoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal Papillary-Mucinous Carcinoma Of Pancreas			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal Papillary Mucinous Neoplasm			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insulinoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory Pseudotumour			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory Carcinoma Of The Breast			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Adenocarcinoma			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	1 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intraocular Melanoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive Lobular Breast Carcinoma			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large Cell Lung Cancer Stage Iii			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large Cell Lung Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratoacanthoma			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal Proliferative Breast Lesion			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Leiomyosarcoma Metastatic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leiomyoma			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leiomyosarcoma			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Laryngeal Squamous Cell Carcinoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Neoplasm			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Cancer			
subjects affected / exposed	8 / 9067 (0.09%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Large Intestine Benign Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leiomyosarcoma Recurrent			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip Neoplasm Malignant Stage Unspecified			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip And/Or Oral Cavity Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 1	1 / 3	
Lip Squamous Cell Carcinoma			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			

subjects affected / exposed	10 / 9067 (0.11%)	14 / 9077 (0.15%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liposarcoma			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lentigo Maligna			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Carcinoma Cell Type Unspecified Stage 0			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Lung Carcinoma Cell Type Unspecified Recurrent			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung Cancer Metastatic			
subjects affected / exposed	10 / 9067 (0.11%)	13 / 9077 (0.14%)	
occurrences causally related to treatment / all	0 / 10	0 / 13	
deaths causally related to treatment / all	0 / 7	0 / 11	
Lung Adenocarcinoma Recurrent			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Adenocarcinoma Metastatic			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung Adenocarcinoma			

subjects affected / exposed	11 / 9067 (0.12%)	16 / 9077 (0.18%)	
occurrences causally related to treatment / all	1 / 11	0 / 16	
deaths causally related to treatment / all	1 / 5	0 / 5	
Lobular Breast Carcinoma In Situ			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoproliferative Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	5 / 9067 (0.06%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 4	0 / 0	
Lymphocytic Leukaemia			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Neoplasm Malignant			
subjects affected / exposed	65 / 9067 (0.72%)	66 / 9077 (0.73%)	
occurrences causally related to treatment / all	4 / 65	0 / 66	
deaths causally related to treatment / all	0 / 30	0 / 41	
Lung Neoplasm			
subjects affected / exposed	9 / 9067 (0.10%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 1	
Lung Carcinoma Cell Type Unspecified Stage Iv			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 1	1 / 2	
Lung Carcinoma Cell Type Unspecified Stage I			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	28 / 9067 (0.31%)	26 / 9077 (0.29%)	
occurrences causally related to treatment / all	1 / 28	0 / 26	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Melanoma In Situ			
subjects affected / exposed	4 / 9067 (0.04%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 4	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Melanoma Stage I			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Neoplasm Of Ampulla Of Vater			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Neoplasm Of Eyelid			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Neoplasm Of Pleura			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Ascites			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mantle Cell Lymphoma Stage Iii			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medullary Thyroid Cancer			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melanocytic Naevus			
subjects affected / exposed	7 / 9067 (0.08%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mantle Cell Lymphoma			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Neoplasm Of Unknown Primary Site			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant Neoplasm Progression			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant Urinary Tract Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma Benign			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric Neoplasm			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma			
subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Mesothelioma Malignant			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases To Adrenals			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases To Bone			
subjects affected / exposed	5 / 9067 (0.06%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 3	
Meningioma			
subjects affected / exposed	8 / 9067 (0.09%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases To Pelvis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases To Pancreas			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases To Lymph Nodes			

subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases To Lung			
subjects affected / exposed	5 / 9067 (0.06%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 5	1 / 6	
deaths causally related to treatment / all	0 / 1	1 / 4	
Metastases To Liver			
subjects affected / exposed	14 / 9067 (0.15%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 14	2 / 9	
deaths causally related to treatment / all	0 / 5	2 / 4	
Metastases To Gastrointestinal Tract			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases To Central Nervous System			
subjects affected / exposed	10 / 9067 (0.11%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	1 / 10	1 / 6	
deaths causally related to treatment / all	0 / 4	1 / 2	
Metastatic Gastric Cancer			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic Choriocarcinoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic Carcinoma Of The Bladder			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Metastatic Carcinoid Tumour			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastasis			
subjects affected / exposed	2 / 9067 (0.02%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 5	
Metastases To The Mediastinum			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases To Peritoneum			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic Malignant Melanoma			
subjects affected / exposed	5 / 9067 (0.06%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 3	0 / 1	
Metastatic Neoplasm			
subjects affected / exposed	5 / 9067 (0.06%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 4	0 / 4	
Metastatic Renal Cell Carcinoma			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mucoepidermoid Carcinoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Monoclonal Gammopathy			

subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic Squamous Cell Carcinoma			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metastatic Lymphoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mycosis Fungoides Recurrent			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic Syndrome			
subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	1 / 4	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Myelofibrosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myeloid Leukaemia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myeloproliferative Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Sinus Cancer			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mycosis Fungoides			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Natural Killer-Cell Leukaemia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm			
subjects affected / exposed	5 / 9067 (0.06%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm Malignant			
subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 0	
Neoplasm Prostate			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Neoplasm Skin			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine Carcinoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nasopharyngeal Cancer			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's Lymphoma Recurrent			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Non-Hodgkin's Lymphoma			
subjects affected / exposed	8 / 9067 (0.09%)	13 / 9077 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 2	
Neuroma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurofibroma			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine Tumour			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine Carcinoma Metastatic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Secretory Adenoma Of Pituitary			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Carcinoma Recurrent			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Oesophageal Carcinoma				
subjects affected / exposed	10 / 9067 (0.11%)	8 / 9077 (0.09%)		
occurrences causally related to treatment / all	1 / 10	0 / 8		
deaths causally related to treatment / all	1 / 5	0 / 3		
Oesophageal Adenocarcinoma Metastatic				
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
Non-Small Cell Lung Cancer				
subjects affected / exposed	5 / 9067 (0.06%)	8 / 9077 (0.09%)		
occurrences causally related to treatment / all	0 / 5	2 / 8		
deaths causally related to treatment / all	0 / 3	0 / 3		
Ocular Neoplasm				
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)		
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 Stage Iiia				
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)		
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 Metastatic				
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)		
occurrences causally related to treatment / all	0 / 2	0 / 3		
deaths causally related to treatment / all	0 / 1	0 / 2		
Oesophageal Adenocarcinoma				
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	1 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Ovarian Adenoma				

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondroma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Squamous Cell Carcinoma			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Oral Neoplasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oligodendroglioma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral Neoplasm Benign			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Carcinoma Stage Iv			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pancreatic Carcinoma Metastatic			
subjects affected / exposed	2 / 9067 (0.02%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 2	2 / 6	
deaths causally related to treatment / all	0 / 2	2 / 5	
Pancreatic Carcinoma			

subjects affected / exposed	17 / 9067 (0.19%)	20 / 9077 (0.22%)	
occurrences causally related to treatment / all	0 / 17	2 / 20	
deaths causally related to treatment / all	0 / 14	1 / 15	
Ovarian Cancer			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Ovarian Epithelial Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Neoplasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Cancer Metastatic			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pharyngeal Neoplasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phaeochromocytoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Neoplasm			

subjects affected / exposed	2 / 9067 (0.02%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 2	2 / 6	
deaths causally related to treatment / all	0 / 1	1 / 2	
Paraproteinaemia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papilloma			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary Thyroid Cancer			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid Tumour Benign			
subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural Mesothelioma			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pleomorphic Liposarcoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleomorphic Adenoma			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary Tumour Benign			

subjects affected / exposed	5 / 9067 (0.06%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma Cell Myeloma			
subjects affected / exposed	6 / 9067 (0.07%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	1 / 6	0 / 10	
deaths causally related to treatment / all	0 / 3	0 / 3	
Pituitary Tumour Recurrent			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmacytoma			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate Cancer Stage Ii			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate Cancer Recurrent			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate Cancer Metastatic			
subjects affected / exposed	12 / 9067 (0.13%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	1 / 12	0 / 7	
deaths causally related to treatment / all	0 / 4	0 / 1	
Pleural Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prolactin-Producing Pituitary Tumour			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia Vera			
subjects affected / exposed	4 / 9067 (0.04%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate Cancer			
subjects affected / exposed	123 / 9067 (1.36%)	117 / 9077 (1.29%)	
occurrences causally related to treatment / all	7 / 123	3 / 117	
deaths causally related to treatment / all	0 / 11	0 / 6	
Rectal Neoplasm			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	1 / 1	
Rectal Cancer Metastatic			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Prostatic Adenoma			
subjects affected / exposed	6 / 9067 (0.07%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Adenoma			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Adenocarcinoma			
subjects affected / exposed	3 / 9067 (0.03%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	1 / 3	2 / 6	
deaths causally related to treatment / all	0 / 1	1 / 1	
Rectal Cancer			

subjects affected / exposed	14 / 9067 (0.15%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	1 / 14	0 / 11	
deaths causally related to treatment / all	1 / 4	0 / 2	
Renal Neoplasm			
subjects affected / exposed	5 / 9067 (0.06%)	19 / 9077 (0.21%)	
occurrences causally related to treatment / all	1 / 5	1 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Cell Carcinoma			
subjects affected / exposed	10 / 9067 (0.11%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 10	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal Cancer Recurrent			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid Cancer			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Cancer			
subjects affected / exposed	9 / 9067 (0.10%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 9	1 / 7	
deaths causally related to treatment / all	0 / 1	0 / 1	
Renal Adenoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Cancer Metastatic			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Schwannoma			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcomatoid Mesothelioma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sarcoma			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Oncocytoma			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary Gland Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Salivary Gland Adenoma			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary Gland Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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 Metastatic			
subjects affected / exposed	2 / 9067 (0.02%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 4	
Small Cell Lung Cancer			

subjects affected / exposed	12 / 9067 (0.13%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	1 / 12	0 / 7	
deaths causally related to treatment / all	0 / 9	0 / 5	
Small Cell Carcinoma			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 1	
Seborrhoeic Keratosis			
subjects affected / exposed	5 / 9067 (0.06%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Cancer Metastatic			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Cancer			
subjects affected / exposed	18 / 9067 (0.20%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	0 / 18	1 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seminoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Papilloma			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma Of The Oral Cavity			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma Of Skin			

subjects affected / exposed	13 / 9067 (0.14%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 13	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma Of Lung			
subjects affected / exposed	9 / 9067 (0.10%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 6	0 / 1	
Small Intestine Carcinoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma			
subjects affected / exposed	84 / 9067 (0.93%)	91 / 9077 (1.00%)	
occurrences causally related to treatment / all	1 / 84	4 / 91	
deaths causally related to treatment / all	0 / 1	0 / 1	
Spindle Cell Sarcoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma Of Head And Neck			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thymoma Malignant			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Throat Cancer			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma Of The Tongue			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
T-Cell Lymphoma			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 1	1 / 1	
Sweat Gland Tumour			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testis Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue Neoplasm Malignant Stage Unspecified			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue Cancer Metastatic			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Neoplasm			
subjects affected / exposed	5 / 9067 (0.06%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thymoma Malignant Recurrent			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Cancer			

subjects affected / exposed	5 / 9067 (0.06%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	1 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Adenoma			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Cancer Metastatic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional Cell Carcinoma			
subjects affected / exposed	15 / 9067 (0.17%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	1 / 15	3 / 8	
deaths causally related to treatment / all	0 / 3	1 / 1	
Tracheal Neoplasm			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric Cancer Recurrent			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric Cancer			
subjects affected / exposed	4 / 9067 (0.04%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal Cancer			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ureteral Neoplasm			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Leiomyoma			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Cancer			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Neoplasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Bladder Sarcoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Bladder Adenoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aneurysm			

subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accelerated Hypertension			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Dilatation			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Aneurysm Rupture			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 0	
Angiopathy			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Aneurysm			
subjects affected / exposed	29 / 9067 (0.32%)	40 / 9077 (0.44%)	
occurrences causally related to treatment / all	0 / 29	0 / 40	
deaths causally related to treatment / all	0 / 2	0 / 3	
Angiodysplasia			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial Occlusive Disease			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Stenosis			
subjects affected / exposed	9 / 9067 (0.10%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Rupture			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Dissection			
subjects affected / exposed	5 / 9067 (0.06%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Behcet's Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Pressure Fluctuation			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Pressure Inadequately Controlled			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial Thrombosis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential Hypertension			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous Fistula			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep Vein Thrombosis			
subjects affected / exposed	19 / 9067 (0.21%)	33 / 9077 (0.36%)	
occurrences causally related to treatment / all	0 / 19	0 / 33	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Emergency			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Crisis			

subjects affected / exposed	21 / 9067 (0.23%)	22 / 9077 (0.24%)	
occurrences causally related to treatment / all	0 / 21	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	25 / 9067 (0.28%)	27 / 9077 (0.30%)	
occurrences causally related to treatment / all	0 / 25	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	5 / 9067 (0.06%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	12 / 9067 (0.13%)	16 / 9077 (0.18%)	
occurrences causally related to treatment / all	0 / 12	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granulomatosis With Polyangiitis			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral Artery Occlusion			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	27 / 9067 (0.30%)	16 / 9077 (0.18%)	
occurrences causally related to treatment / all	0 / 27	0 / 16	
deaths causally related to treatment / all	0 / 2	0 / 0	
Hot Flush			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral Artery Aneurysm			

subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphatic Fistula			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leriche Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular Vein Thrombosis			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemia			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lymphoedema			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent Claudication			
subjects affected / exposed	6 / 9067 (0.07%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac Artery Occlusion			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic Shock			

subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Lymphocele			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-Abdominal Haematoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrosis Ischaemic			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurogenic Shock			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Orthostatic Hypotension			
subjects affected / exposed	10 / 9067 (0.11%)	14 / 9077 (0.15%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Artery Aneurysm			
subjects affected / exposed	4 / 9067 (0.04%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	5 / 9067 (0.06%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Artery Stenosis			

subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Artery Thrombosis			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Embolism			
subjects affected / exposed	5 / 9067 (0.06%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Ischaemia			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Vascular Disorder			
subjects affected / exposed	5 / 9067 (0.06%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Hypertension			
subjects affected / exposed	0 / 9067 (0.00%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Thrombotic Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian Artery Stenosis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior Vena Cava Occlusion			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior Vena Cava Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal Arteritis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock Haemorrhagic			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose Vein			

subjects affected / exposed	4 / 9067 (0.04%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Occlusion			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis Necrotising			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous Insufficiency			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous Stenosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous Thrombosis Limb			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Varicose Ulceration			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Appendicectomy			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthrodesis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Finger Amputation			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fascia Release			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colostomy			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract Operation			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Rehabilitation Therapy			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Catheterisation			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Pacemaker Replacement			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrectomy			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colectomy			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable Defibrillator Insertion			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immunoglobulin Therapy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip Surgery			
subjects affected / exposed	8 / 9067 (0.09%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip Arthroplasty			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Surgery			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Bypass			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hospitalisation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular Lens Implant			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Arthroplasty			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mammoplasty			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee Operation			

subjects affected / exposed	13 / 9067 (0.14%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 13	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional Hernia Repair			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Septal Operation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Polypectomy			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral Valve Repair			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile Prosthesis Insertion			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Preoperative Care			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatectomy			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rehabilitation Therapy			
subjects affected / exposed	3 / 9067 (0.03%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Percutaneous Coronary Intervention			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder Arthroplasty			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder Operation			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Decompression			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgery			
subjects affected / exposed	7 / 9067 (0.08%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator Cuff Repair			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroidectomy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suture Removal			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth Extraction			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral Bladder Resection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral Prostatectomy			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Turbinectomy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose Vein Operation			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebroplasty			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adverse Drug Reaction			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brca2 Gene Mutation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adverse Event			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adverse Reaction			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	14 / 9067 (0.15%)	18 / 9077 (0.20%)	
occurrences causally related to treatment / all	1 / 14	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter Site Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Battery Issue			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst Rupture			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst			
subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication Of Device Insertion			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Breakage			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Pain			
subjects affected / exposed	7 / 9067 (0.08%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Failure			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Issue			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Lead Damage			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Lead Issue			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Malfunction			
subjects affected / exposed	5 / 9067 (0.06%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Dislocation			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Discomfort			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Occlusion			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Feeling Cold			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			

subjects affected / exposed	9 / 9067 (0.10%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 9	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fat Necrosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Withdrawal Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait Disturbance			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrosis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised Oedema			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granuloma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Feeling Hot			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General Physical Health Deterioration			

subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant Site Extravasation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired Healing			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperplasia			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia Obstructive			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	7 / 9067 (0.08%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	8 / 9067 (0.09%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	1 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Local Swelling			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza Like Illness			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant Site Haematoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection Site Thrombosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metaplasia			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrosis			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-Organ Failure			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mucosal Inflammation			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical Device Complication			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pacemaker Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	4 / 9067 (0.04%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic Mass			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pacemaker Generated Arrhythmia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Cardiac Chest Pain			
subjects affected / exposed	14 / 9067 (0.15%)	16 / 9077 (0.18%)	
occurrences causally related to treatment / all	0 / 14	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema Peripheral			
subjects affected / exposed	4 / 9067 (0.04%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			

subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	24 / 9067 (0.26%)	14 / 9077 (0.15%)	
occurrences causally related to treatment / all	0 / 24	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 1	
Stent-Graft Endoleak			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Submandibular Mass			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic Inflammatory Response Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Puncture Site Haemorrhage			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer			
subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Xerosis			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis In Device			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergy To Arthropod Sting			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic Reaction			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic Shock			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Hypersensitivity			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	8 / 9067 (0.09%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	3 / 8	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seasonal Allergy			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Cardiac Assistance Device User			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	72 / 9067 (0.79%)	72 / 9077 (0.79%)	
occurrences causally related to treatment / all	0 / 72	0 / 72	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erectile Dysfunction			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial Hypertrophy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial Hyperplasia			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Mass			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cervical Polyp			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Dysplasia			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	5 / 9067 (0.06%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic Haematoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Mass			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Cyst			
subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female Genital Tract Fistula			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gynaecomastia			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrocystic Breast Disease			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menorrhagia			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic Prolapse			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penis Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile Vein Thrombosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peyronie's Disease			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal Haemorrhage			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic Disorder			

subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatism			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic Dysplasia			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic Obstruction			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	5 / 9067 (0.06%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	6 / 9067 (0.07%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectoprostatic Fistula			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal Haematocoele			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal Haemorrhage			

subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Prolapse			
subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Polyp			
subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterovaginal Prolapse			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spermatocele			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Inflammation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal Prolapse			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal Hyperplasia			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute Pulmonary Oedema			
subjects affected / exposed	6 / 9067 (0.07%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 0	
Acute Respiratory Distress Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute Respiratory Failure			
subjects affected / exposed	18 / 9067 (0.20%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	0 / 18	0 / 12	
deaths causally related to treatment / all	0 / 4	0 / 2	
Asphyxia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthma			
subjects affected / exposed	13 / 9067 (0.14%)	17 / 9077 (0.19%)	
occurrences causally related to treatment / all	0 / 13	0 / 17	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atelectasis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial Hyperreactivity			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial Obstruction			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumopathy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary Disease			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	109 / 9067 (1.20%)	105 / 9077 (1.16%)	
occurrences causally related to treatment / all	1 / 109	0 / 105	
deaths causally related to treatment / all	0 / 3	0 / 3	
Bronchospasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Respiratory Disease			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			

subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	47 / 9067 (0.52%)	56 / 9077 (0.62%)	
occurrences causally related to treatment / all	1 / 47	0 / 56	
deaths causally related to treatment / all	0 / 1	0 / 3	
Dyspnoea Exertional			
subjects affected / exposed	1 / 9067 (0.01%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea Paroxysmal Nocturnal			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	23 / 9067 (0.25%)	16 / 9077 (0.18%)	
occurrences causally related to treatment / all	0 / 23	1 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	10 / 9067 (0.11%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemothorax			
subjects affected / exposed	0 / 9067 (0.00%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperventilation			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	6 / 9067 (0.07%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic Pulmonary Fibrosis			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Interstitial Lung Disease			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Oedema			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Polyp			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Ulceration			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Stenosis			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngospasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	4 / 9067 (0.04%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Hernia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Infiltration			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Polyps			
subjects affected / exposed	6 / 9067 (0.07%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Turbinate Hypertrophy			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Septum Disorder			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Septum Deviation			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal Pain			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organising Pneumonia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive Airways Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthopnoea			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pickwickian Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural Effusion			
subjects affected / exposed	24 / 9067 (0.26%)	24 / 9077 (0.26%)	
occurrences causally related to treatment / all	0 / 24	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pleural Fibrosis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	1 / 9067 (0.01%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax Spontaneous			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Aspiration			
subjects affected / exposed	8 / 9067 (0.09%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 3	0 / 3	
Pulmonary Arterial Hypertension			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic Pain			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	14 / 9067 (0.15%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 14	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	4 / 9067 (0.04%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Embolism			

subjects affected / exposed	46 / 9067 (0.51%)	36 / 9077 (0.40%)	
occurrences causally related to treatment / all	0 / 46	0 / 36	
deaths causally related to treatment / all	0 / 2	0 / 3	
Pulmonary Fibrosis			
subjects affected / exposed	4 / 9067 (0.04%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 2	
Pulmonary Hypertension			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Granuloma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Haemorrhage			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory Arrest			
subjects affected / exposed	4 / 9067 (0.04%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Respiratory Acidosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	6 / 9067 (0.07%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory Disorder			

subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Oedema			
subjects affected / exposed	6 / 9067 (0.07%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pulmonary Mass			
subjects affected / exposed	19 / 9067 (0.21%)	22 / 9077 (0.24%)	
occurrences causally related to treatment / all	0 / 19	1 / 22	
deaths causally related to treatment / all	0 / 2	1 / 1	
Respiratory Failure			
subjects affected / exposed	32 / 9067 (0.35%)	22 / 9077 (0.24%)	
occurrences causally related to treatment / all	0 / 32	0 / 22	
deaths causally related to treatment / all	0 / 9	0 / 7	
Restrictive Pulmonary Disease			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep Apnoea Syndrome			
subjects affected / exposed	12 / 9067 (0.13%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 12	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal Stenosis			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Status Asthmaticus			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheomalacia			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal Cord Leukoplakia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal Cord Inflammation			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal Cord Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Respiratory Tract Inflammation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal Cord Polyp			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute Psychosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abnormal Behaviour			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar I Disorder			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar Disorder			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol Withdrawal Syndrome			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	12 / 9067 (0.13%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol Abuse			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium Tremens			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			

subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conversion Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional State			
subjects affected / exposed	9 / 9067 (0.10%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed Suicide			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Burnout Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar Ii Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomania			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insomnia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major Depression			

subjects affected / exposed	1 / 9067 (0.01%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	19 / 9067 (0.21%)	17 / 9077 (0.19%)	
occurrences causally related to treatment / all	0 / 19	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Disorientation			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Generalised Anxiety Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-Traumatic Stress Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paranoia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic Attack			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurosis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental Status Changes			
subjects affected / exposed	10 / 9067 (0.11%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mental Disorder Due To A General Medical Condition			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatisation Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatoform Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia, Paranoid Type			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Withdrawal Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide Attempt			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal Ideation			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Alcoholic Liver Disease			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile Duct Obstruction			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis Acute			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	4 / 9067 (0.04%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 4	2 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary Tract Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary Dyskinesia			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary Colic			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile Duct Stone			
subjects affected / exposed	7 / 9067 (0.08%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	1 / 7	2 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cirrhosis Alcoholic			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			

subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cholelithiasis			
subjects affected / exposed	78 / 9067 (0.86%)	71 / 9077 (0.78%)	
occurrences causally related to treatment / all	3 / 78	6 / 71	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Chronic			
subjects affected / exposed	3 / 9067 (0.03%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 3	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Acute			
subjects affected / exposed	27 / 9067 (0.30%)	26 / 9077 (0.29%)	
occurrences causally related to treatment / all	0 / 27	0 / 26	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	47 / 9067 (0.52%)	73 / 9077 (0.80%)	
occurrences causally related to treatment / all	3 / 47	10 / 73	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gallbladder Cholesterolosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder Disorder			
subjects affected / exposed	5 / 9067 (0.06%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	1 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder Pain			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder Perforation			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder Polyp			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-Induced Liver Injury			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granulomatous Liver Disease			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Steatosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Cirrhosis			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic Cyst			
subjects affected / exposed	6 / 9067 (0.07%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Failure			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Hepatic Mass			

subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	1 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hydrocholecystis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic Hepatitis			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice Cholestatic			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver Disorder			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal Hypertension			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal Vein Thrombosis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood Creatinine Increased			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	4 / 9067 (0.04%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	3 / 4	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation Drug Level Below Therapeutic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Creatine Increased			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine Aminotransferase Increased			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Glucose Abnormal			

subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Glucose Increased			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Pressure Increased			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Urine Present			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Body Temperature Increased			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood Pressure Orthostatic Decreased			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram Repolarisation Abnormality			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram Qt Prolonged			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection Fraction Decreased			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Test Positive			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endoscopy Gastrointestinal			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endoscopy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonoscopy			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Examination			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin Decreased			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart Rate Increased			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart Rate Irregular			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Enzyme Increased			
subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
International Normalised Ratio Decreased			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart Rate Decreased			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laboratory Test Abnormal			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver Function Test Abnormal			
subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	3 / 4	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Occult Blood Positive			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Precancerous Cells Present			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric Evaluation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic Specific Antigen Increased			
subjects affected / exposed	6 / 9067 (0.07%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour Marker Increased			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases Increased			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Total Lung Capacity Decreased			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight Increased			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight Decreased			

subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal Wound Dehiscence			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental Overdose			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum Fracture			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol Poisoning			
subjects affected / exposed	4 / 9067 (0.04%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Postoperative			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic Leak			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic Stenosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle Fracture			

subjects affected / exposed	8 / 9067 (0.09%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial Injury			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal Bite			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Contusion			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Vertebral Fracture			
subjects affected / exposed	1 / 9067 (0.01%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod Sting			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbon Monoxide Poisoning			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursa Injury			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns Second Degree			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	7 / 9067 (0.08%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	5 / 9067 (0.06%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle Fracture			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Injury			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemical Poisoning			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chance Fracture			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compression Fracture			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral Injury			

subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electric Injury			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epicondylitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye Penetration			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face Injury			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Restenosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula Fracture			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur Fracture			
subjects affected / exposed	19 / 9067 (0.21%)	22 / 9077 (0.24%)	
occurrences causally related to treatment / all	0 / 19	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral Neck Fracture			

subjects affected / exposed	10 / 9067 (0.11%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fat Embolism			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	11 / 9067 (0.12%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial Bones Fracture			
subjects affected / exposed	5 / 9067 (0.06%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign Body			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured Sacrum			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured Ischium			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot Fracture			

subjects affected / exposed	3 / 9067 (0.03%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm Fracture			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heat Illness			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heat Exhaustion			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head Injury			
subjects affected / exposed	11 / 9067 (0.12%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hand Fracture			
subjects affected / exposed	5 / 9067 (0.06%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun Shot Wound			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Radiation			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Anastomotic Leak			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	5 / 9067 (0.06%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision Site Haematoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus Fracture			
subjects affected / exposed	7 / 9067 (0.08%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip Fracture			
subjects affected / exposed	28 / 9067 (0.31%)	23 / 9077 (0.25%)	
occurrences causally related to treatment / all	0 / 28	1 / 23	
deaths causally related to treatment / all	0 / 0	0 / 1	
Heat Stroke			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	6 / 9067 (0.07%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional Overdose			

subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Jaw Fracture			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Dislocation			
subjects affected / exposed	8 / 9067 (0.09%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Injury			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney Contusion			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation Of Wound			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney Rupture			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament Rupture			

subjects affected / exposed	5 / 9067 (0.06%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb Injury			
subjects affected / exposed	1 / 9067 (0.01%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb Traumatic Amputation			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
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	6 / 9067 (0.07%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb Crushing Injury			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle Rupture			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus Injury			
subjects affected / exposed	8 / 9067 (0.09%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth Injury			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Fractures			

subjects affected / exposed	1 / 9067 (0.01%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Multiple Injuries			
subjects affected / exposed	2 / 9067 (0.02%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lumbar Vertebral Fracture			
subjects affected / exposed	7 / 9067 (0.08%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic Fracture			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella Fracture			
subjects affected / exposed	6 / 9067 (0.07%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	9 / 9067 (0.10%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 9	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Leak			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open Fracture			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle Strain			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Near Drowning			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Concussion Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic Osteolysis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax Traumatic			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic Fracture			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Nerve Injury			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Laminectomy Syndrome			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Procedural Haemorrhage			
subjects affected / exposed	4 / 9067 (0.04%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Post Procedural Haematuria			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmastectomy Lymphoedema Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Gastric Surgery Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Ileus			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural Pain			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postpericardiotomy Syndrome			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Thoracic Procedure Complication			
subjects affected / exposed	6 / 9067 (0.07%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural Intestinal Perforation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib Fracture			
subjects affected / exposed	18 / 9067 (0.20%)	16 / 9077 (0.18%)	
occurrences causally related to treatment / all	0 / 18	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Haematoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius Fracture			
subjects affected / exposed	4 / 9067 (0.04%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation Proctitis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Contusion			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road Traffic Accident			
subjects affected / exposed	15 / 9067 (0.17%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 15	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 0	
Scapula Fracture			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scar			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal Haematoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt Malfunction			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skeletal Injury			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Silicosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Compression Fracture			
subjects affected / exposed	7 / 9067 (0.08%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Injury			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull Fracture			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Snake Bite			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Cord Injury Cauda Equina			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Column Injury			
subjects affected / exposed	4 / 9067 (0.04%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Injury			

subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Fracture			
subjects affected / exposed	4 / 9067 (0.04%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic Rupture			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal Fracture			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous Haematoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma Site Ulcer			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal Injury			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural Haematoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suture Related Complication			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial Rupture			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon Injury			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon Rupture			
subjects affected / exposed	7 / 9067 (0.08%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	1 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal Burn			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic Vertebral Fracture			
subjects affected / exposed	1 / 9067 (0.01%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic Fracture			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia Fracture			
subjects affected / exposed	4 / 9067 (0.04%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity To Various Agents			

subjects affected / exposed	7 / 9067 (0.08%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheostomy Malfunction			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Transfusion Reaction			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic Haematoma			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Graft Occlusion			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	4 / 9067 (0.04%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna Fracture			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic Haemothorax			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Pseudoaneurysm			

subjects affected / exposed	11 / 9067 (0.12%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 11	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Retention Postoperative			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Bladder Rupture			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Haemorrhage			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Dehiscence			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Haematoma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Wound			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Pseudoaneurysm Ruptured			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist Fracture			

subjects affected / exposed	4 / 9067 (0.04%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arteriovenous Malformation			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Septal Defect			
subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bicuspid Aortic Valve			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital Spinal Cord Anomaly			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermoid Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenomatous Polyposis Coli			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foramen Magnum Stenosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Arteriovenous Malformation			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	7 / 9067 (0.08%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic Cardiomyopathy			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Lentigines Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epidermal Naevus			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Septal Defect			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sickle Cell Anaemia With Crisis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Adams-Stokes Syndrome			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina Pectoris			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Valve Incompetence			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Valve Stenosis			
subjects affected / exposed	7 / 9067 (0.08%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arrhythmia			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Block			
subjects affected / exposed	11 / 9067 (0.12%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 11	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Thrombosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Flutter			
subjects affected / exposed	24 / 9067 (0.26%)	28 / 9077 (0.31%)	
occurrences causally related to treatment / all	0 / 24	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Fibrillation			

subjects affected / exposed	140 / 9067 (1.54%)	150 / 9077 (1.65%)	
occurrences causally related to treatment / all	0 / 140	0 / 150	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arrhythmia Supraventricular			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Tachycardia			
subjects affected / exposed	4 / 9067 (0.04%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	27 / 9067 (0.30%)	30 / 9077 (0.33%)	
occurrences causally related to treatment / all	0 / 27	0 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Dissociation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Block Second Degree			
subjects affected / exposed	5 / 9067 (0.06%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Block First Degree			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Block Complete			

subjects affected / exposed	13 / 9067 (0.14%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 13	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle Branch Block Left			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Aneurysm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Arrest			
subjects affected / exposed	5 / 9067 (0.06%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Failure			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Pseudoaneurysm			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle Branch Block			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiorenal Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			

subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic Shock			
subjects affected / exposed	5 / 9067 (0.06%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardio-Respiratory Arrest			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiac Ventricular Thrombosis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Tamponade			
subjects affected / exposed	2 / 9067 (0.02%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Coronary Artery Dissection			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor Pulmonale			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Congestive Cardiomyopathy			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conduction Disorder			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronotropic Incompetence			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Thrombosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Perforation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Cardiomyopathy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart Valve Incompetence			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrasystoles			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dressler's Syndrome			

subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral Valve Incompetence			
subjects affected / exposed	4 / 9067 (0.04%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left Ventricular Dysfunction			
subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial Ischaemia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic Cardiomyopathy			
subjects affected / exposed	2 / 9067 (0.02%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracardiac Thrombus			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral Valve Stenosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis Constrictive			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			

subjects affected / exposed	14 / 9067 (0.15%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 14	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial Haemorrhage			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pericardial Effusion			
subjects affected / exposed	10 / 9067 (0.11%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	9 / 9067 (0.10%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular Extrasystoles			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus Tachycardia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus Arrhythmia			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus Arrest			

subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sick Sinus Syndrome			
subjects affected / exposed	17 / 9067 (0.19%)	19 / 9077 (0.21%)	
occurrences causally related to treatment / all	0 / 17	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular Tachycardia			
subjects affected / exposed	16 / 9067 (0.18%)	18 / 9077 (0.20%)	
occurrences causally related to treatment / all	0 / 16	0 / 18	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sinus Bradycardia			
subjects affected / exposed	7 / 9067 (0.08%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade De Pointes			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia Paroxysmal			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	2 / 9067 (0.02%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular Tachyarrhythmia			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Extrasystoles			

subjects affected / exposed	3 / 9067 (0.03%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Fibrillation			
subjects affected / exposed	10 / 9067 (0.11%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Wolff-Parkinson-White Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Tachycardia			
subjects affected / exposed	29 / 9067 (0.32%)	42 / 9077 (0.46%)	
occurrences causally related to treatment / all	0 / 29	0 / 42	
deaths causally related to treatment / all	0 / 1	0 / 0	
Trifascicular Block			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Arrhythmia			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Nervous system disorders			
Amyotrophic Lateral Sclerosis			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Amnesia			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid Artery Occlusion			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid Artery Aneurysm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain Injury			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance Disorder			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic Nervous System Imbalance			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arachnoid Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid Sinus Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal Tunnel Syndrome			

subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central Nervous System Lesion			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrospinal Fluid Leakage			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Cord Compression			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular Accident			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid Artery Stenosis			
subjects affected / exposed	9 / 9067 (0.10%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Myelopathy			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Radiculopathy			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive Disorder			

subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complex Partial Seizures			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complicated Migraine			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed	12 / 9067 (0.13%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 12	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cervicobrachial Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Demyelination			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Coma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Hyperglycaemic Coma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Neuropathy			

subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	30 / 9067 (0.33%)	30 / 9077 (0.33%)	
occurrences causally related to treatment / all	0 / 30	1 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's Type			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	5 / 9067 (0.06%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Guillain-Barre Syndrome			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Grand Mal Convulsion			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial Paresis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrapyramidal Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			

subjects affected / exposed	5 / 9067 (0.06%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotonia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Encephalopathy			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Encephalopathy			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hemiparesis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			

subjects affected / exposed	11 / 9067 (0.12%)	13 / 9077 (0.14%)	
occurrences causally related to treatment / all	1 / 11	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intercostal Neuralgia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial Aneurysm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukoencephalopathy			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss Of Consciousness			
subjects affected / exposed	6 / 9067 (0.07%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-Ischaemic Encephalopathy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Migraine			
subjects affected / exposed	2 / 9067 (0.02%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine With Aura			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic Encephalopathy			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lumbar Radiculopathy			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Sclerosis			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Motor Neurone Disease			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurological Symptom			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle Spasticity			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous System Disorder			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myasthenia Gravis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve Compression			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraplegia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Occipital Neuralgia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal Pressure Hydrocephalus			

subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy Peripheral			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paralysis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Parkinsonism			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial Seizures			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineurial Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Paralysis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocephalus			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Polyneuropathy			

subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's Disease			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	4 / 9067 (0.04%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radial Nerve Palsy			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy Chronic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Polio Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			

subjects affected / exposed	16 / 9067 (0.18%)	20 / 9077 (0.22%)	
occurrences causally related to treatment / all	0 / 16	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tarsal Tunnel Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	107 / 9067 (1.18%)	96 / 9077 (1.06%)	
occurrences causally related to treatment / all	0 / 107	0 / 96	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status Epilepticus			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitic Myelopathy			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Cord Ischaemia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Dementia			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unresponsive To Stimuli			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient Global Amnesia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic Encephalopathy			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension Headache			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal Neuralgia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar Insufficiency			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viith Nerve Paralysis			

subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vith Nerve Paralysis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vith Nerve Paresis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral Artery Stenosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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			
Agranulocytosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Of Chronic Disease			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Of Malignant Disease			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Megaloblastic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			

subjects affected / exposed	71 / 9067 (0.78%)	55 / 9077 (0.61%)	
occurrences causally related to treatment / all	1 / 71	1 / 55	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Macrocytic			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic Diathesis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic Anaemia			
subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic Anaemia			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated Intravascular Coagulation			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile Neutropenia			
subjects affected / exposed	5 / 9067 (0.06%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercoagulation			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hilar Lymphadenopathy			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heparin-Induced Thrombocytopenia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypereosinophilic Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune Thrombocytopenic Purpura			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron Deficiency Anaemia			
subjects affected / exposed	5 / 9067 (0.06%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Leukocytosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypochromic Anaemia			

subjects affected / exposed	4 / 9067 (0.04%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic Normocytic Anaemia			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic Anaemia			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoid Tissue Hyperplasia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy Mediastinal			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	5 / 9067 (0.06%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	6 / 9067 (0.07%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	1 / 6	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic Mastocytosis			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic Vein Thrombosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic Lesion			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal Lymphadenopathy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Thrombocytopenic Purpura			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness Neurosensory			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness Unilateral			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			

subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden Hearing Loss			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otorrhoea			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Middle Ear Effusion			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inner Ear Inflammation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inner Ear Disorder			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo Positional			
subjects affected / exposed	5 / 9067 (0.06%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			

subjects affected / exposed	19 / 9067 (0.21%)	25 / 9077 (0.28%)	
occurrences causally related to treatment / all	0 / 19	0 / 25	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness Transient			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	15 / 9067 (0.17%)	17 / 9077 (0.19%)	
occurrences causally related to treatment / all	0 / 15	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract Nuclear			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal Scar			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Retinopathy			
subjects affected / exposed	5 / 9067 (0.06%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye Disorder			

subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exfoliation Glaucoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lens Dislocation			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular Degeneration			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular Oedema			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyphaema			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal Haemorrhage			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal Detachment			
subjects affected / exposed	4 / 9067 (0.04%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic Ischaemic Neuropathy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal Artery Occlusion			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual Impairment			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papilloedema			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous Haemorrhage			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous Disorder			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Discomfort			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Adhesions			
subjects affected / exposed	4 / 9067 (0.04%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Mass			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain			
subjects affected / exposed	41 / 9067 (0.45%)	43 / 9077 (0.47%)	
occurrences causally related to treatment / all	3 / 41	1 / 43	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal Pain Lower			
subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Hernia			
subjects affected / exposed	15 / 9067 (0.17%)	13 / 9077 (0.14%)	
occurrences causally related to treatment / all	0 / 15	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain Upper			

subjects affected / exposed	21 / 9067 (0.23%)	14 / 9077 (0.15%)	
occurrences causally related to treatment / all	1 / 21	1 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Polyp			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Fistula			
subjects affected / exposed	4 / 9067 (0.04%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Fissure			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Wall Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's Oesophagus			
subjects affected / exposed	0 / 9067 (0.00%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ascites			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Ulcer			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Stenosis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Prolapse			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bezoar			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	14 / 9067 (0.15%)	15 / 9077 (0.17%)	
occurrences causally related to treatment / all	1 / 14	1 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis Ischaemic			
subjects affected / exposed	9 / 9067 (0.10%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	0 / 9	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis Ulcerative			
subjects affected / exposed	7 / 9067 (0.08%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			

subjects affected / exposed	8 / 9067 (0.09%)	13 / 9077 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coeliac Disease			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowel Movement Irregularity			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	23 / 9067 (0.25%)	15 / 9077 (0.17%)	
occurrences causally related to treatment / all	1 / 23	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Gastroparesis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic Hernia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental Caries			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyclic Vomiting Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's Disease			

subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum Intestinal			
subjects affected / exposed	2 / 9067 (0.02%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	1 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	11 / 9067 (0.12%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 11	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis Intestinal Haemorrhagic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular Perforation			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea Haemorrhagic			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum Oesophageal			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal Polyp			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal Ulcer			

subjects affected / exposed	7 / 9067 (0.08%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal Ulcer Perforation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	3 / 9067 (0.03%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum Intestinal Haemorrhagic			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocele			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	5 / 9067 (0.06%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	5 / 9067 (0.06%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	5 / 9067 (0.06%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 5	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenogastric Reflux			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	11 / 9067 (0.12%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	1 / 11	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive Oesophagitis			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical Fistula			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive Duodenitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis Haemorrhagic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epigastric Discomfort			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecaloma			

subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral Hernia			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Disorder			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food Poisoning			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecal Incontinence			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Polyps			
subjects affected / exposed	3 / 9067 (0.03%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Ulcer			
subjects affected / exposed	12 / 9067 (0.13%)	18 / 9077 (0.20%)	
occurrences causally related to treatment / all	0 / 12	1 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Perforation			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Ulcer Haemorrhage			
subjects affected / exposed	4 / 9067 (0.04%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Ulcer Perforation			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	29 / 9067 (0.32%)	39 / 9077 (0.43%)	
occurrences causally related to treatment / all	1 / 29	2 / 39	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Disorder			
subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Angiodysplasia			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenal Ulcer			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis Haemorrhagic			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis Erosive			

subjects affected / exposed	4 / 9067 (0.04%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Pain			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Oedema			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Obstruction			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Necrosis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Hypomotility			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Haemorrhage			
subjects affected / exposed	60 / 9067 (0.66%)	64 / 9077 (0.71%)	
occurrences causally related to treatment / all	0 / 60	0 / 64	
deaths causally related to treatment / all	0 / 1	0 / 2	
Gastrointestinal Ulcer Haemorrhage			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal Reflux Disease			
subjects affected / exposed	27 / 9067 (0.30%)	33 / 9077 (0.36%)	
occurrences causally related to treatment / all	0 / 27	2 / 33	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingival Bleeding			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	6 / 9067 (0.07%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Perforation			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic Anal Papilla			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus Hernia			
subjects affected / exposed	10 / 9067 (0.11%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernial Eventration			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids Thrombosed			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	8 / 9067 (0.09%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal Haemorrhage			
subjects affected / exposed	4 / 9067 (0.04%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal Hernia			
subjects affected / exposed	69 / 9067 (0.76%)	51 / 9077 (0.56%)	
occurrences causally related to treatment / all	0 / 69	0 / 51	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory Bowel Disease			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired Gastric Emptying			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus Paralytic			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ileus			

subjects affected / exposed	11 / 9067 (0.12%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileal Ulcer			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal Hernia, Obstructive			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Infarction			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Haematoma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Fistula			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Dilatation			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Ischaemia			

subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Intestinal Mass			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Obstruction			
subjects affected / exposed	15 / 9067 (0.17%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 15	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intestinal Perforation			
subjects affected / exposed	4 / 9067 (0.04%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Polyp			
subjects affected / exposed	2 / 9067 (0.02%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large Intestine Polyp			
subjects affected / exposed	40 / 9067 (0.44%)	58 / 9077 (0.64%)	
occurrences causally related to treatment / all	2 / 40	1 / 58	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large Intestine Perforation			
subjects affected / exposed	4 / 9067 (0.04%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Large Intestinal Ulcer			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large Intestinal Stenosis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large Intestinal Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Stenosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric Artery Stenosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric Artery Embolism			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	10 / 9067 (0.11%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	1 / 10	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss Syndrome			
subjects affected / exposed	5 / 9067 (0.06%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Gastrointestinal Haemorrhage			

subjects affected / exposed	16 / 9067 (0.18%)	13 / 9077 (0.14%)	
occurrences causally related to treatment / all	0 / 16	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lumbar Hernia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	8 / 9067 (0.09%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 8	2 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedematous Pancreatitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Achalasia			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteritis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Spasm			

subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Motility Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Obstruction			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Perforation			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	7 / 9067 (0.08%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Ulcer			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Stenosis			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Necrotising			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Chronic			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	13 / 9067 (0.14%)	17 / 9077 (0.19%)	
occurrences causally related to treatment / all	3 / 13	1 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	35 / 9067 (0.39%)	28 / 9077 (0.31%)	
occurrences causally related to treatment / all	10 / 35	6 / 28	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatic Pseudocyst			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Mass			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pharyngo-Oesophageal Diverticulum			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic Ulcer			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotid Gland Enlargement			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Relapsing			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Peritoneal Perforation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Polyp			
subjects affected / exposed	17 / 9067 (0.19%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 17	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Perforation			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	15 / 9067 (0.17%)	17 / 9077 (0.19%)	
occurrences causally related to treatment / all	0 / 15	0 / 17	
deaths causally related to treatment / all	0 / 1	0 / 0	
Proctalgia			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumoperitoneum			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumatosis Intestinalis			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Ulcer Haemorrhage			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectourethral Fistula			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reflux Gastritis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal Haematoma			

subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal Haemorrhage			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Prolapse			
subjects affected / exposed	4 / 9067 (0.04%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue Dysplasia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic Artery Aneurysm			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestinal Obstruction			
subjects affected / exposed	13 / 9067 (0.14%)	14 / 9077 (0.15%)	
occurrences causally related to treatment / all	0 / 13	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 2	
Small Intestinal Haemorrhage			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary Gland Calculus			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	8 / 9067 (0.09%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	1 / 8	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	26 / 9067 (0.29%)	25 / 9077 (0.28%)	
occurrences causally related to treatment / all	0 / 26	1 / 25	
deaths causally related to treatment / all	0 / 1	0 / 1	
Umbilical Hernia, Obstructive			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical Hernia			
subjects affected / exposed	6 / 9067 (0.07%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	1 / 3	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Actinic Keratosis			
subjects affected / exposed	12 / 9067 (0.13%)	18 / 9077 (0.20%)	
occurrences causally related to treatment / all	0 / 12	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Foot			

subjects affected / exposed	9 / 9067 (0.10%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatomyositis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis Allergic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal Cyst			
subjects affected / exposed	3 / 9067 (0.03%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus Ulcer			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campbell De Morgan Spots			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Ulcer			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ecchymosis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Eruption			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Excessive Granulation Tissue			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkeratosis			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granuloma Skin			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity Vasculitis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lichen Planus			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Night Sweats			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macule			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palmoplantar Keratoderma			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lichenoid Keratosis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Precancerous Skin Lesion			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pityriasis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Punctate Keratosis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	3 / 9067 (0.03%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	1 / 3	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash Generalised			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash Papular			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash Pruritic			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Lesion			
subjects affected / exposed	3 / 9067 (0.03%)	14 / 9077 (0.15%)	
occurrences causally related to treatment / all	0 / 3	1 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Burning Sensation			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Mass			

subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Ulcer			
subjects affected / exposed	8 / 9067 (0.09%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Solar Lentigo			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous Emphysema			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swelling Face			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic Skin Eruption			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Bladder Mass			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Diverticulum			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Prerenal Failure			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Tamponade			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Spasm			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Prolapse			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Neck Obstruction			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Obstruction			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Neck Sclerosis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Perforation			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis Noninfective			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis Haemorrhagic			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crush Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus Bladder			
subjects affected / exposed	4 / 9067 (0.04%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus Urethral			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus Ureteric			
subjects affected / exposed	16 / 9067 (0.18%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 16	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus Urinary			

subjects affected / exposed	6 / 9067 (0.07%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotonic Urinary Bladder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertonic Bladder			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	5 / 9067 (0.06%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Nephropathy			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Glomerulonephritis			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	27 / 9067 (0.30%)	20 / 9077 (0.22%)	
occurrences causally related to treatment / all	0 / 27	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Aneurysm			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelocaliectasis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive Uropathy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Urinary Tract Symptoms			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrosclerosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	31 / 9067 (0.34%)	35 / 9077 (0.39%)	
occurrences causally related to treatment / all	1 / 31	0 / 35	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic Syndrome			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Failure			

subjects affected / exposed	38 / 9067 (0.42%)	29 / 9077 (0.32%)	
occurrences causally related to treatment / all	1 / 38	1 / 29	
deaths causally related to treatment / all	0 / 7	0 / 3	
Renal Embolism			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Artery Stenosis			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Cyst			
subjects affected / exposed	19 / 9067 (0.21%)	22 / 9077 (0.24%)	
occurrences causally related to treatment / all	0 / 19	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Colic			
subjects affected / exposed	7 / 9067 (0.08%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Cyst Ruptured			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Infarct			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Impairment			

subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Failure Acute			
subjects affected / exposed	51 / 9067 (0.56%)	61 / 9077 (0.67%)	
occurrences causally related to treatment / all	0 / 51	0 / 61	
deaths causally related to treatment / all	0 / 5	0 / 4	
Renal Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Failure Chronic			
subjects affected / exposed	12 / 9067 (0.13%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 12	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Hypertension			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric Obstruction			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric Dilatation			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial Nephritis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Injury			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Tubular Necrosis			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal Mass			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress Urinary Incontinence			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Bladder Haemorrhage			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urge Incontinence			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral Stenosis			
subjects affected / exposed	9 / 9067 (0.10%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric Stenosis			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral Dilatation			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral Caruncle			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Obstruction			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Retention			
subjects affected / exposed	14 / 9067 (0.15%)	27 / 9077 (0.30%)	
occurrences causally related to treatment / all	0 / 14	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Bladder Polyp			
subjects affected / exposed	1 / 9067 (0.01%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Incontinence			
subjects affected / exposed	7 / 9067 (0.08%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal Insufficiency			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Adrenal Mass				
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)		
occurrences causally related to treatment / all	0 / 2	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Basedow's Disease				
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Goitre				
subjects affected / exposed	5 / 9067 (0.06%)	11 / 9077 (0.12%)		
occurrences causally related to treatment / all	0 / 5	0 / 11		
deaths causally related to treatment / all	0 / 0	0 / 0		
Inappropriate Antidiuretic Hormone Secretion				
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Hypothyroidism				
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Pituitary Haemorrhage				
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Hyperparathyroidism Primary				
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Hyperparathyroidism				

subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	2 / 9067 (0.02%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postpartum Hypopituitarism			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Haemorrhage			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic Nodular Goitre			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	32 / 9067 (0.35%)	23 / 9077 (0.25%)	
occurrences causally related to treatment / all	0 / 32	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			

subjects affected / exposed	25 / 9067 (0.28%)	23 / 9077 (0.25%)	
occurrences causally related to treatment / all	0 / 25	3 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	7 / 9067 (0.08%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Pain			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Lesion			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis Reactive			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	5 / 9067 (0.06%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthrofibrosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back Pain			
subjects affected / exposed	36 / 9067 (0.40%)	34 / 9077 (0.37%)	
occurrences causally related to treatment / all	0 / 36	0 / 34	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diastasis Recti Abdominis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	2 / 9067 (0.02%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment Syndrome			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Spinal Stenosis			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Wall Mass			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Wall Cyst			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondropathy			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
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 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fistula			

subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibromyalgia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's Contracture			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiphysitis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extraskeletal Ossification			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty Arthritis			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot Deformity			

subjects affected / exposed	3 / 9067 (0.03%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture Malunion			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture Nonunion			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Effusion			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Protrusion			
subjects affected / exposed	28 / 9067 (0.31%)	35 / 9077 (0.39%)	
occurrences causally related to treatment / all	0 / 28	0 / 35	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Displacement			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Degeneration			
subjects affected / exposed	10 / 9067 (0.11%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Compression			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metatarsalgia			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Disorder			
subjects affected / exposed	1 / 9067 (0.01%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar Spinal Stenosis			
subjects affected / exposed	19 / 9067 (0.21%)	18 / 9077 (0.20%)	
occurrences causally related to treatment / all	0 / 19	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Extremity Mass			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Instability			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee Deformity			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb Discomfort			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal Chest Pain			
subjects affected / exposed	34 / 9067 (0.37%)	21 / 9077 (0.23%)	
occurrences causally related to treatment / all	0 / 34	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular Weakness			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mobility Decreased			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Morphoea			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monarthritis			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle Spasms			

subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	20 / 9067 (0.22%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	15 / 20	10 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal Pain			
subjects affected / exposed	14 / 9067 (0.15%)	13 / 9077 (0.14%)	
occurrences causally related to treatment / all	0 / 14	1 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck Mass			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopathy			
subjects affected / exposed	6 / 9067 (0.07%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	4 / 6	3 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myofascial Pain Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia Intercostal			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			

subjects affected / exposed	2 / 9067 (0.02%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteolysis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	175 / 9067 (1.93%)	159 / 9077 (1.75%)	
occurrences causally related to treatment / all	0 / 175	0 / 159	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic Arthropathy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyositis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia Rheumatica			

subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periarthritis			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain In Jaw			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain In Extremity			
subjects affected / exposed	10 / 9067 (0.11%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 10	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	12 / 9067 (0.13%)	18 / 9077 (0.20%)	
occurrences causally related to treatment / all	10 / 12	17 / 18	
deaths causally related to treatment / all	1 / 1	0 / 0	
Rheumatic Fever			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
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	3 / 9067 (0.03%)	8 / 9077 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib Deformity			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator Cuff Syndrome			
subjects affected / exposed	21 / 9067 (0.23%)	16 / 9077 (0.18%)	
occurrences causally related to treatment / all	0 / 21	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scleroderma			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriatic Arthropathy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Column Stenosis			
subjects affected / exposed	22 / 9067 (0.24%)	27 / 9077 (0.30%)	
occurrences causally related to treatment / all	0 / 22	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Disorder			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Osteoarthritis			
subjects affected / exposed	12 / 9067 (0.13%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Pain			

subjects affected / exposed	6 / 9067 (0.07%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	2 / 9067 (0.02%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic Lupus Erythematosus			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial Disorder			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial Cyst			
subjects affected / exposed	4 / 9067 (0.04%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon Disorder			

subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral Foraminal Stenosis			
subjects affected / exposed	3 / 9067 (0.03%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Extremity Mass			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torticollis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess Intestinal			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Wall Infection			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Abdominal Wall Abscess				
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
Abdominal Sepsis				
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 1	0 / 0		
Abdominal Abscess				
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)		
occurrences causally related to treatment / all	0 / 2	0 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
Abscess Neck				
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Abscess Limb				
subjects affected / exposed	5 / 9067 (0.06%)	7 / 9077 (0.08%)		
occurrences causally related to treatment / all	0 / 5	0 / 7		
deaths causally related to treatment / all	0 / 0	0 / 0		
Abscess Jaw				
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Alpha Haemolytic Streptococcal Infection				
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Acute Sinusitis				

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Oral			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis Bacterial			
subjects affected / exposed	4 / 9067 (0.04%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Abscess			
subjects affected / exposed	11 / 9067 (0.12%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 11	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis Perforated			
subjects affected / exposed	7 / 9067 (0.08%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	33 / 9067 (0.36%)	18 / 9077 (0.20%)	
occurrences causally related to treatment / all	0 / 33	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis Infective			
subjects affected / exposed	4 / 9067 (0.04%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendiceal Abscess			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister Infected			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial Infection			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	5 / 9067 (0.06%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Biliary Sepsis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Abscess			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (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	49 / 9067 (0.54%)	43 / 9077 (0.47%)	
occurrences causally related to treatment / all	0 / 49	0 / 43	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis Bacterial			

subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis Viral			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter Infection			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
subjects affected / exposed	17 / 9067 (0.19%)	14 / 9077 (0.15%)	
occurrences causally related to treatment / all	0 / 17	0 / 14	
deaths causally related to treatment / all	0 / 4	0 / 2	
Campylobacter Gastroenteritis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	49 / 9067 (0.54%)	63 / 9077 (0.69%)	
occurrences causally related to treatment / all	0 / 49	0 / 63	
deaths causally related to treatment / all	0 / 2	0 / 1	
Cardiac Infection			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Sinusitis			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Infective			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis Of Male External Genital Organ			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida Infection			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	8 / 9067 (0.09%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coccidioidomycosis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Difficile Sepsis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Difficile Colitis			

subjects affected / exposed	12 / 9067 (0.13%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 12	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Clostridium Difficile Infection			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Related Infection			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Foot Infection			
subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea Infectious			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Gangrene			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	34 / 9067 (0.37%)	37 / 9077 (0.41%)	
occurrences causally related to treatment / all	0 / 34	0 / 37	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue Fever			
subjects affected / exposed	5 / 9067 (0.06%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Echinococciasis			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis Viral			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis Bacterial			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis Enterococcal			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Emphysematous Cholecystitis			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia Bacteraemia			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	18 / 9067 (0.20%)	14 / 9077 (0.15%)	
occurrences causally related to treatment / all	0 / 18	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	5 / 9067 (0.06%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epidemic Nephropathy			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endophthalmitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottitis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Folliculitis			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	3 / 9067 (0.03%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder Empyema			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	51 / 9067 (0.56%)	44 / 9077 (0.48%)	
occurrences causally related to treatment / all	0 / 51	0 / 44	
deaths causally related to treatment / all	0 / 0	0 / 1	
Fungal Skin Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fungal Infection			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Bacterial			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Rotavirus			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Salmonella			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Viral			
subjects affected / exposed	5 / 9067 (0.06%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Candidiasis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Infection			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastroenteritis Norovirus			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
H1n1 Influenza			

subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingival Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin Abscess			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter Gastritis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft Infection			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant Site Infection			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiv Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes Simplex Encephalitis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis C			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis B			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes Zoster			
subjects affected / exposed	6 / 9067 (0.07%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision Site Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected Bites			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional Hernia Gangrenous			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected Cyst			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected Dermal Cyst			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected Skin Ulcer			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision Site Cellulitis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	5 / 9067 (0.06%)	6 / 9077 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Discitis			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	12 / 9067 (0.13%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Infectious Pleural Effusion			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious Colitis			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective Exacerbation Of Chronic Obstructive Airways Disease			

subjects affected / exposed	7 / 9067 (0.08%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney Infection			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lobar Pneumonia			
subjects affected / exposed	16 / 9067 (0.18%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 16	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labyrinthitis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella Sepsis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lyme Disease			

subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Infection			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised Infection			
subjects affected / exposed	4 / 9067 (0.04%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection			
subjects affected / exposed	10 / 9067 (0.11%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	1 / 10	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Abscess			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis Viral			
subjects affected / exposed	1 / 9067 (0.01%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis Aseptic			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymph Node Tuberculosis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	1 / 9067 (0.01%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Candidiasis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myringitis			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising Fasciitis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal Abscess			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreas Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	4 / 9067 (0.04%)	10 / 9077 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis Media			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis Chronic			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis Media Chronic			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periumbilical Abscess			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	2 / 9067 (0.02%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 2	
Perirectal Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis Bacterial			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Influenzal			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Chlamydial			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Bacterial			
subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pharyngitis			
subjects affected / exposed	2 / 9067 (0.02%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal Sepsis			
subjects affected / exposed	1 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pilonidal Cyst			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	255 / 9067 (2.81%)	242 / 9077 (2.67%)	
occurrences causally related to treatment / all	0 / 255	1 / 242	
deaths causally related to treatment / all	0 / 17	0 / 12	
Post Procedural Infection			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Viral			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Legionella			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Pseudomonal			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Pneumococcal			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Streptococcal			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas Infection			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomembranous Colitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Abscess			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis Infectious			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Wound Infection			

subjects affected / exposed	8 / 9067 (0.09%)	13 / 9077 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Q Fever			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyomyositis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis Acute			
subjects affected / exposed	4 / 9067 (0.04%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoas Abscess			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Tuberculosis			
subjects affected / exposed	0 / 9067 (0.00%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary Sepsis			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pyelonephritis			

subjects affected / exposed	15 / 9067 (0.17%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 15	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Tract Infection			
subjects affected / exposed	10 / 9067 (0.11%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	0 / 10	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotavirus Infection			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt Infection			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Serratia Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	37 / 9067 (0.41%)	33 / 9077 (0.36%)	
occurrences causally related to treatment / all	0 / 37	0 / 33	
deaths causally related to treatment / all	0 / 7	0 / 8	
Septic Encephalopathy			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis Syndrome			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic Shock			
subjects affected / exposed	12 / 9067 (0.13%)	12 / 9077 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 6	0 / 6	
Staphylococcal Infection			
subjects affected / exposed	5 / 9067 (0.06%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Staphylococcal Bacteraemia			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			

subjects affected / exposed	2 / 9067 (0.02%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Infection			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal Abscess			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tick-Borne Fever			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sweat Gland Infection			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous Abscess			
subjects affected / exposed	4 / 9067 (0.04%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal Sepsis			
subjects affected / exposed	0 / 9067 (0.00%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Streptococcal Infection			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternitis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subacute Endocarditis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Respiratory Tract Infection			
subjects affected / exposed	15 / 9067 (0.17%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 15	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth Abscess			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	3 / 9067 (0.03%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			

subjects affected / exposed	77 / 9067 (0.85%)	79 / 9077 (0.87%)	
occurrences causally related to treatment / all	0 / 77	0 / 79	
deaths causally related to treatment / all	0 / 1	0 / 1	
Tuberculosis			
subjects affected / exposed	2 / 9067 (0.02%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Abscess			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular Neuronitis			
subjects affected / exposed	3 / 9067 (0.03%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	19 / 9067 (0.21%)	19 / 9077 (0.21%)	
occurrences causally related to treatment / all	0 / 19	0 / 19	
deaths causally related to treatment / all	0 / 1	0 / 1	
Urinary Tract Infection Bacterial			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Infection			
subjects affected / exposed	6 / 9067 (0.07%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Sepsis			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Infection			
subjects affected / exposed	5 / 9067 (0.06%)	4 / 9077 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	34 / 9067 (0.37%)	22 / 9077 (0.24%)	
occurrences causally related to treatment / all	0 / 34	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abnormal Loss Of Weight			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholesterosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Decreased Appetite			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid Overload			
subjects affected / exposed	2 / 9067 (0.02%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure To Thrive			

subjects affected / exposed	3 / 9067 (0.03%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic Ketoacidosis			
subjects affected / exposed	2 / 9067 (0.02%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus			
subjects affected / exposed	22 / 9067 (0.24%)	29 / 9077 (0.32%)	
occurrences causally related to treatment / all	0 / 22	0 / 29	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes With Hyperosmolarity			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	14 / 9067 (0.15%)	22 / 9077 (0.24%)	
occurrences causally related to treatment / all	0 / 14	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Complication			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hyperglycaemia			
subjects affected / exposed	15 / 9067 (0.17%)	11 / 9077 (0.12%)	
occurrences causally related to treatment / all	0 / 15	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	16 / 9067 (0.18%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 16	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			

subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glucose Tolerance Impaired			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemochromatosis			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	4 / 9067 (0.04%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 4	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperammonaemia			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
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 / 9067 (0.01%)	2 / 9077 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	10 / 9067 (0.11%)	9 / 9077 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperosmolar State			

subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	20 / 9067 (0.22%)	17 / 9077 (0.19%)	
occurrences causally related to treatment / all	0 / 20	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 9067 (0.00%)	1 / 9077 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	6 / 9067 (0.07%)	3 / 9077 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 Diabetes Mellitus			
subjects affected / exposed	11 / 9067 (0.12%)	5 / 9077 (0.06%)	
occurrences causally related to treatment / all	0 / 11	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	5 / 9067 (0.06%)	7 / 9077 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour Lysis Syndrome			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Overweight			
subjects affected / exposed	1 / 9067 (0.01%)	0 / 9077 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 Diabetes Mellitus			

subjects affected / exposed	1 / 9067 (0.01%)	1 / 9077 (0.01%)	
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: 5 %

Non-serious adverse events	Ezetimibe/Simvastatin	Simvastatin	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5486 / 9067 (60.51%)	5472 / 9077 (60.28%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	580 / 9067 (6.40%)	642 / 9077 (7.07%)	
occurrences (all)	580	642	
Nervous system disorders			
Headache			
subjects affected / exposed	467 / 9067 (5.15%)	520 / 9077 (5.73%)	
occurrences (all)	467	520	
Dizziness			
subjects affected / exposed	875 / 9067 (9.65%)	909 / 9077 (10.01%)	
occurrences (all)	875	909	
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	694 / 9067 (7.65%)	731 / 9077 (8.05%)	
occurrences (all)	694	731	
Non-Cardiac Chest Pain			
subjects affected / exposed	554 / 9067 (6.11%)	543 / 9077 (5.98%)	
occurrences (all)	554	543	
Fatigue			
subjects affected / exposed	720 / 9067 (7.94%)	756 / 9077 (8.33%)	
occurrences (all)	720	756	
Oedema Peripheral			
subjects affected / exposed	520 / 9067 (5.74%)	551 / 9077 (6.07%)	
occurrences (all)	520	551	
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	540 / 9067 (5.96%)	552 / 9077 (6.08%)	
occurrences (all)	540	552	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	702 / 9067 (7.74%)	740 / 9077 (8.15%)	
occurrences (all)	702	740	
Dyspnoea			
subjects affected / exposed	787 / 9067 (8.68%)	815 / 9077 (8.98%)	
occurrences (all)	787	815	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1001 / 9067 (11.04%)	914 / 9077 (10.07%)	
occurrences (all)	1001	914	
Muscle Spasms			
subjects affected / exposed	616 / 9067 (6.79%)	576 / 9077 (6.35%)	
occurrences (all)	616	576	
Musculoskeletal Pain			
subjects affected / exposed	581 / 9067 (6.41%)	535 / 9077 (5.89%)	
occurrences (all)	581	535	
Back Pain			
subjects affected / exposed	866 / 9067 (9.55%)	825 / 9077 (9.09%)	
occurrences (all)	866	825	
Pain In Extremity			
subjects affected / exposed	955 / 9067 (10.53%)	899 / 9077 (9.90%)	
occurrences (all)	955	899	
Myalgia			
subjects affected / exposed	954 / 9067 (10.52%)	908 / 9077 (10.00%)	
occurrences (all)	954	908	
Infections and infestations			
Influenza			
subjects affected / exposed	461 / 9067 (5.08%)	483 / 9077 (5.32%)	
occurrences (all)	461	483	
Bronchitis			

subjects affected / exposed	477 / 9067 (5.26%)	450 / 9077 (4.96%)	
occurrences (all)	477	450	
Nasopharyngitis			
subjects affected / exposed	618 / 9067 (6.82%)	577 / 9077 (6.36%)	
occurrences (all)	618	577	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 May 2007	Clarified the entry criteria, criteria for increasing the simvastatin dose, entry of participants from the EARLY ACS study into the IMPROVE-IT Study, and data capture for suspected clinical endpoint events. Clarified to investigators that suspected clinical endpoint events are not to be reported as adverse events. Added assessments for cardiovascular biomarkers, pharmacoeconomic factors, quality of life factors, and renal function.
26 October 2007	Closed enrollment of new subjects with a diagnosis of STEMI; capped the number of STEMI participants at approximately 4,000; raised the number of participants from 10,000 to 12,500; raised the number of primary endpoint event from 2,955 to 5,250; increased the estimated duration of the whole study to 66 months.
08 May 2008	Increased enrollment to a maximum of 18,000 participants from the previous number of 12,500 subjects, while the minimum number of primary endpoint events remained at 5,250.
16 November 2008	Added a second interim analysis when approximately 75% of the expected total primary events were available; allowed a participant to decline to have his/her simvastatin dose increased to 80 mg (or to return to the 40 mg dose, if already receiving 80 mg) and continue in the trial at the initial 40 mg dose.
07 July 2011	Added a second interim analysis when approximately 75% of the expected total primary events are available; described changes to the USA labeling for simvastatin that effected changes to the current IMPROVE-IT Trial; Made changes to the trial as a consequence of the USA labeling changes: Restricted the highest dose of simvastatin 80 mg to those participants who tolerated that highest dose for 12 months or more without evidence of significant muscle toxicity; Prohibited new participants from having their dose of simvastatin increased from 40 mg to 80 mg; Restricted the dose of simvastatin to 40 mg for those participants who received concomitant treatment with amlodipine or ranolazine. Provided instructions to investigators for how manage participants as necessary to comply with the restrictions on the simvastatin 80 mg dose and concomitant use of amlodipine or ranolazine.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported