

**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
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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
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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
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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
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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 standard deviation	63.6 ± 9.7	63.6 ± 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 \geq 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)
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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 \geq 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
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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
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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)
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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
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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)
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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
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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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.0
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Reporting groups

Reporting group title	Ezetimibe/Simvastatin
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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
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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 Lentiginos 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
Enterocoele		
subjects affected / exposed	1 / 9067 (0.01%)	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
Echinococcosis		

subjects affected / exposed	1 / 9067 (0.01%)	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 occurrences (all)	540 / 9067 (5.96%) 540	552 / 9077 (6.08%) 552	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	702 / 9067 (7.74%) 702	740 / 9077 (8.15%) 740	
Dyspnoea subjects affected / exposed occurrences (all)	787 / 9067 (8.68%) 787	815 / 9077 (8.98%) 815	
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	1001 / 9067 (11.04%) 1001	914 / 9077 (10.07%) 914	
Muscle Spasms subjects affected / exposed occurrences (all)	616 / 9067 (6.79%) 616	576 / 9077 (6.35%) 576	
Musculoskeletal Pain subjects affected / exposed occurrences (all)	581 / 9067 (6.41%) 581	535 / 9077 (5.89%) 535	
Back Pain subjects affected / exposed occurrences (all)	866 / 9067 (9.55%) 866	825 / 9077 (9.09%) 825	
Pain In Extremity subjects affected / exposed occurrences (all)	955 / 9067 (10.53%) 955	899 / 9077 (9.90%) 899	
Myalgia subjects affected / exposed occurrences (all)	954 / 9067 (10.52%) 954	908 / 9077 (10.00%) 908	
Infections and infestations			
Influenza subjects affected / exposed occurrences (all)	461 / 9067 (5.08%) 461	483 / 9077 (5.32%) 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