

**Clinical trial results:****A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome****Summary**

EudraCT number	2011-005698-21
Trial protocol	GB SE BE NO EE LT HU ES CZ LV DE IT BG FI AT PT DK NL PL
Global end of trial date	SK SI HR GB 23 January 2018

Results information

Result version number	v1 (current)
This version publication date	07 February 2019
First version publication date	07 February 2019

Trial information**Trial identification**

Sponsor protocol code	EFC11570
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01663402
WHO universal trial number (UTN)	U1111-1127-4323

Notes:

Sponsors

Sponsor organisation name	Sanofi aventis recherche & développement
Sponsor organisation address	1 avenue Pierre Brossolette, Chilly-Mazarin, France, 91380
Public contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.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	13 February 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	23 January 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the effect of alirocumab with placebo on the occurrence of cardiovascular (CV) events (composite endpoint of coronary heart disease (CHD) death, non-fatal myocardial infarction (MI), fatal and non-fatal ischemic stroke, unstable angina (UA) requiring hospitalization) in subjects who have experienced an acute coronary syndrome (ACS) event 4 to 52 weeks prior to randomization and were treated with evidence-based medical and dietary management of dyslipidemia.

Protection of trial subjects:

Subjects were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the subject and considering the local culture. During the course of the trial, subjects were provided with individual subject cards indicating the nature of the trial the subject is participating, contact details and any information needed in the event of a medical emergency. Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy:

Statins (atorvastatin or rosuvastatin) at stable maximal tolerated dose of statin with or without other Lipid-Modifying Therapy (LMT) as clinically indicated.

Evidence for comparator: -

Actual start date of recruitment	11 October 2012
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	Georgia: 131
Country: Number of subjects enrolled	Guatemala: 25
Country: Number of subjects enrolled	Hong Kong: 17
Country: Number of subjects enrolled	Argentina: 592
Country: Number of subjects enrolled	Australia: 216
Country: Number of subjects enrolled	Bosnia and Herzegovina: 155
Country: Number of subjects enrolled	Brazil: 928
Country: Number of subjects enrolled	Canada: 361
Country: Number of subjects enrolled	Chile: 132
Country: Number of subjects enrolled	China: 614
Country: Number of subjects enrolled	Colombia: 354
Country: Number of subjects enrolled	India: 521
Country: Number of subjects enrolled	Israel: 582

Country: Number of subjects enrolled	Japan: 204
Country: Number of subjects enrolled	Korea, Republic of: 94
Country: Number of subjects enrolled	Macedonia, the former Yugoslav Republic of: 132
Country: Number of subjects enrolled	Malaysia: 110
Country: Number of subjects enrolled	Mexico: 349
Country: Number of subjects enrolled	New Zealand: 257
Country: Number of subjects enrolled	Peru: 208
Country: Number of subjects enrolled	Philippines: 116
Country: Number of subjects enrolled	Russian Federation: 1109
Country: Number of subjects enrolled	Serbia: 255
Country: Number of subjects enrolled	Singapore: 49
Country: Number of subjects enrolled	South Africa: 505
Country: Number of subjects enrolled	Sri Lanka: 314
Country: Number of subjects enrolled	Switzerland: 88
Country: Number of subjects enrolled	Taiwan: 93
Country: Number of subjects enrolled	Thailand: 161
Country: Number of subjects enrolled	Turkey: 78
Country: Number of subjects enrolled	Ukraine: 639
Country: Number of subjects enrolled	United States: 2510
Country: Number of subjects enrolled	Netherlands: 686
Country: Number of subjects enrolled	Norway: 97
Country: Number of subjects enrolled	Poland: 926
Country: Number of subjects enrolled	Portugal: 174
Country: Number of subjects enrolled	Romania: 145
Country: Number of subjects enrolled	Slovakia: 340
Country: Number of subjects enrolled	Slovenia: 36
Country: Number of subjects enrolled	Spain: 826
Country: Number of subjects enrolled	Sweden: 250
Country: Number of subjects enrolled	United Kingdom: 292
Country: Number of subjects enrolled	Croatia: 69
Country: Number of subjects enrolled	Austria: 58
Country: Number of subjects enrolled	Belgium: 197
Country: Number of subjects enrolled	Bulgaria: 333
Country: Number of subjects enrolled	Czech Republic: 381
Country: Number of subjects enrolled	Denmark: 352
Country: Number of subjects enrolled	Estonia: 216
Country: Number of subjects enrolled	Finland: 116
Country: Number of subjects enrolled	France: 185
Country: Number of subjects enrolled	Germany: 509
Country: Number of subjects enrolled	Greece: 70
Country: Number of subjects enrolled	Hungary: 224
Country: Number of subjects enrolled	Italy: 275
Country: Number of subjects enrolled	Latvia: 80
Country: Number of subjects enrolled	Lithuania: 188
Worldwide total number of subjects	18924
EEA total number of subjects	7025

Notes:

Subjects enrolled per age group

In utero	0
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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)	13840
From 65 to 84 years	5042
85 years and over	42

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 1387 sites in 57 countries. Of these, 1328 active sites randomized at least 1 subject. Overall, 35,437 subjects were screened between 11 October 2012 and 17 Jan 2017; of whom 16,513 were screen failures. Screen failures were mainly due to exclusion criteria met.

Pre-assignment

Screening details:

Randomization was stratified according to country. Assignment to treatment arms was done centrally using an Interactive Voice/Web Response System in a 1:1 ratio (alirocumab: placebo), with permuted-block randomization.

Period 1

Period 1 title	Overall Period (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	Placebo

Arm description:

Placebo (for alirocumab) subcutaneous (SC) injection every 2 weeks (Q2W) added to stable Lipid-Modifying Therapy (LMT) for up to 64 months.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo matched to alirocumab administered as a SC injection of 1 mL in the abdomen or thigh with a disposable auto-injector.

Arm title	Alirocumab 75 mg Q2W/Up to 150 mg Q2W
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Arm description:

Alirocumab 75 mg SC injection Q2W added to stable LMT for up to 64 months. Alirocumab dose up-titrated to 150 mg Q2W from Month 2 when Low-Density Lipoprotein Cholesterol (LDL-C) levels ≥ 50 mg/dL (1.29 mmol/L) at Month 1; or if up-titration was missed due to unavailability of LDL-C value, it was up-titrated at month 4 based on LDL-C value at Month 2. For subjects receiving 150 mg Q2W, alirocumab dose was down-titrated in a blinded manner to 75 mg Q2W if two consecutive values of LDL-C were < 25 mg/dL (0.65 mmol/L). For subjects receiving 75 mg Q2W, alirocumab dose was switched to placebo in a blinded manner if two consecutive values of LDL-C were < 15 mg/dL (0.39 mmol/L).

Arm type	Experimental
Investigational medicinal product name	Alirocumab
Investigational medicinal product code	SAR236553, REGN727
Other name	Praluent®
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Alirocumab administered as SC injection of 1 mL in the abdomen or thigh with a disposable auto-injector.

Number of subjects in period 1	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W
Started	9462	9462
Treated	9443	9451
Completed	7947	7378
Not completed	1515	2084
Participant moved	139	104
Other than specified above	172	147
Physician decision	77	62
Consent withdrawn by subject	118	91
Adverse Event	347	362
Randomized but not treated	19	11
Site terminated by sponsor	1	3
Poor compliance to protocol	529	454
Lost to follow-up	17	15
Related to study drug administration	96	105
Two consecutive LDL-C <15 mg/dL	-	730

Baseline characteristics

Reporting groups

Reporting group title	Placebo
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Reporting group description:

Placebo (for alirocumab) subcutaneous (SC) injection every 2 weeks (Q2W) added to stable Lipid-Modifying Therapy (LMT) for up to 64 months.

Reporting group title	Alirocumab 75 mg Q2W/Up to 150 mg Q2W
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Reporting group description:

Alirocumab 75 mg SC injection Q2W added to stable LMT for up to 64 months. Alirocumab dose up-titrated to 150 mg Q2W from Month 2 when Low-Density Lipoprotein Cholesterol (LDL-C) levels ≥ 50 mg/dL (1.29 mmol/L) at Month 1; or if up-titration was missed due to unavailability of LDL-C value, it was up-titrated at month 4 based on LDL-C value at Month 2. For subjects receiving 150 mg Q2W, alirocumab dose was down-titrated in a blinded manner to 75 mg Q2W if two consecutive values of LDL-C were < 25 mg/dL (0.65 mmol/L). For subjects receiving 75 mg Q2W, alirocumab dose was switched to placebo in a blinded manner if two consecutive values of LDL-C were < 15 mg/dL (0.39 mmol/L).

Reporting group values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W	Total
Number of subjects	9462	9462	18924
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	58.6 ± 9.4	58.5 ± 9.3	-
Gender categorical Units: Subjects			
Female	2372	2390	4762
Male	7090	7072	14162
Ethnicity Units: Subjects			
Hispanic or Latino	1555	1581	3136
Not Hispanic or Latino	7721	7700	15421
Unknown or Not Reported	186	181	367

End points

End points reporting groups

Reporting group title	Placebo
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Reporting group description:

Placebo (for alirocumab) subcutaneous (SC) injection every 2 weeks (Q2W) added to stable Lipid-Modifying Therapy (LMT) for up to 64 months.

Reporting group title	Alirocumab 75 mg Q2W/Up to 150 mg Q2W
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Reporting group description:

Alirocumab 75 mg SC injection Q2W added to stable LMT for up to 64 months. Alirocumab dose up-titrated to 150 mg Q2W from Month 2 when Low-Density Lipoprotein Cholesterol (LDL-C) levels ≥ 50 mg/dL (1.29 mmol/L) at Month 1; or if up-titration was missed due to unavailability of LDL-C value, it was up-titrated at month 4 based on LDL-C value at Month 2. For subjects receiving 150 mg Q2W, alirocumab dose was down-titrated in a blinded manner to 75 mg Q2W if two consecutive values of LDL-C were < 25 mg/dL (0.65 mmol/L). For subjects receiving 75 mg Q2W, alirocumab dose was switched to placebo in a blinded manner if two consecutive values of LDL-C were < 15 mg/dL (0.39 mmol/L).

Primary: Time to First Occurrence of Major Adverse Cardiovascular Event (MACE): Coronary Heart Disease Death, Non-Fatal Myocardial Infarction, Fatal and Non-Fatal Ischemic Stroke, or Unstable Angina Requiring Hospitalization

End point title	Time to First Occurrence of Major Adverse Cardiovascular Event (MACE): Coronary Heart Disease Death, Non-Fatal Myocardial Infarction, Fatal and Non-Fatal Ischemic Stroke, or Unstable Angina Requiring Hospitalization
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End point description:

All MACE positively adjudicated by Clinical Events Committee (CEC) in a blinded fashion, were used in the analysis of the composite CV endpoint comprised of CHD death, non-fatal MI, fatal and non-fatal ischemic stroke, or unstable angina requiring hospitalization. Percentage of observed subjects with endpoint events were reported. Analysis was performed on Intent-to-treat (ITT) population which included all randomized subjects.

End point type	Primary
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End point timeframe:

From randomization up to 64 months

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	11.1	9.5		

Statistical analyses

Statistical analysis title	MACE: Placebo vs Alirocumab
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Statistical analysis description:

Analysis was performed using Cox proportional hazard model and log rank test stratified on geographical region (North America, South America, Western Europe, Eastern Europe, Asia, Rest of the world).

Comparison groups	Placebo v Alirocumab 75 mg Q2W/Up to 150 mg Q2W
Number of subjects included in analysis	18924
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003 ^[1]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	0.93

Notes:

[1] - Threshold for statistical significance at 0.0498 level.

Secondary: Time to First Occurrence of Any Coronary Heart Disease (CHD) Event: Any CHD Death, Non-Fatal Myocardial Infarction, Unstable Angina Requiring Hospitalization, Ischemia-Driven Coronary Revascularization Procedure

End point title	Time to First Occurrence of Any Coronary Heart Disease (CHD) Event: Any CHD Death, Non-Fatal Myocardial Infarction, Unstable Angina Requiring Hospitalization, Ischemia-Driven Coronary Revascularization Procedure
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End point description:

All CHD events positively adjudicated by CEC in a blinded fashion, were used in the analysis of the composite CHD endpoint comprised of any CHD death, non-fatal MI, unstable angina requiring hospitalization, or ischemia-driven coronary revascularization procedure. Percentage of observed subjects with endpoint events were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

From randomization up to 64 months

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	14.3	12.7		

Statistical analyses

Statistical analysis title	Any CHD Event: Placebo vs Alirocumab
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Statistical analysis description:

Analysis was performed using Cox proportional hazard model and log rank test stratified on geographical region(North America,South America,Western Europe,Eastern Europe,Asia, Rest of the world).A hierarchical testing approach was used to control the overall type-I error at 0.0249 one-sided alpha level(0.0498 two-sided).Testing was then performed sequentially in the order endpoints were reported.Hierarchical testing sequence continued only if the previous endpoint was statistically

Comparison groups	Placebo v Alirocumab 75 mg Q2W/Up to 150 mg Q2W
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Number of subjects included in analysis	18924
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0013 [2]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	0.95

Notes:

[2] - Threshold for statistical significance at 0.0498 level.

Secondary: Time to First Occurrence of Any Major Coronary Heart Disease (CHD) Event: Any CHD Death and Non-Fatal Myocardial Infarction

End point title	Time to First Occurrence of Any Major Coronary Heart Disease (CHD) Event: Any CHD Death and Non-Fatal Myocardial Infarction
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End point description:

All CHD events positively adjudicated by CEC in a blinded fashion, were used in the analysis of the composite CHD endpoint comprised of any CHD death and non-fatal MI. Percentage of observed subjects with endpoint events were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

From randomization up to 64 months

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	9.5	8.4		

Statistical analyses

Statistical analysis title	Any Major CHD Event: Placebo vs Alirocumab
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Statistical analysis description:

Analysis was performed using Cox proportional hazard model and log rank test stratified on geographical region (North America, South America, Western Europe, Eastern Europe, Asia, Rest of the world). Testing was performed according to the hierarchical testing procedure (continued only if the previous endpoint was statistically significant).

Comparison groups	Placebo v Alirocumab 75 mg Q2W/Up to 150 mg Q2W
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Number of subjects included in analysis	18924
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [3]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	0.96

Notes:

[3] - Threshold for statistical significance at 0.0498 level.

Secondary: Time to First Occurrence of any Cardiovascular (CV) Event: Any Non-Fatal Coronary Heart Disease Event, Any CV Death, and Non-Fatal Ischemic Stroke

End point title	Time to First Occurrence of any Cardiovascular (CV) Event: Any Non-Fatal Coronary Heart Disease Event, Any CV Death, and Non-Fatal Ischemic Stroke
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End point description:

All CV events positively adjudicated by CEC in a blinded fashion, were used in the analysis of the composite CV endpoint comprised of any non-fatal CHD event, any CV death and non-fatal ischemic stroke. Percentage of observed subjects with endpoint events were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

From randomization up to 64 months

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	15.6	13.7		

Statistical analyses

Statistical analysis title	Any CV Event: Placebo vs Alirocumab
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Statistical analysis description:

Analysis was performed using Cox proportional hazard model and log rank test stratified on geographical region (North America, South America, Western Europe, Eastern Europe, Asia, Rest of the world). Testing according to the hierarchical testing procedure (continued only if the previous endpoint was statistically significant).

Comparison groups	Placebo v Alirocumab 75 mg Q2W/Up to 150 mg Q2W
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Number of subjects included in analysis	18924
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003 [4]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	0.94

Notes:

[4] - Threshold for statistical significance at 0.0498 level.

Secondary: Time to First Occurrence of All-Cause Mortality, Non-Fatal Myocardial Infarction, Non-Fatal Ischemic Stroke

End point title	Time to First Occurrence of All-Cause Mortality, Non-Fatal Myocardial Infarction, Non-Fatal Ischemic Stroke
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End point description:

All-cause mortality, non-fatal MI and non-fatal ischemic stroke positively adjudicated by CEC in a blinded fashion, were used in the analysis of this endpoint. Percentage of observed subjects with endpoint events were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

From randomization up to 64 months

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	11.9	10.3		

Statistical analyses

Statistical analysis title	Placebo vs Alirocumab
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Statistical analysis description:

Analysis was performed using Cox proportional hazard model and log rank test stratified on geographical region (North America, South America, Western Europe, Eastern Europe, Asia, Rest of the world). Testing according to the hierarchical testing procedure (continued only if the previous endpoint was statistically significant).

Comparison groups	Placebo v Alirocumab 75 mg Q2W/Up to 150 mg Q2W
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Number of subjects included in analysis	18924
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003 ^[5]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	0.93

Notes:

[5] - Threshold for statistical significance at 0.0498 level.

Secondary: Time to Coronary Heart Disease Death

End point title	Time to Coronary Heart Disease Death
End point description: Percentage of observed subjects with CHD death (positively adjudicated by CEC in a blinded fashion) were reported. Analysis was performed on ITT population.	
End point type	Secondary
End point timeframe: From randomization up to 64 months	

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	2.3	2.2		

Statistical analyses

Statistical analysis title	CHD Death: Placebo vs Alirocumab
Statistical analysis description: Analysis was performed using Cox proportional hazard model and log rank test stratified on geographical region (North America, South America, Western Europe, Eastern Europe, Asia, Rest of the world). Testing according to the hierarchical testing procedure (continued only if the previous endpoint was statistically significant).	
Comparison groups	Placebo v Alirocumab 75 mg Q2W/Up to 150 mg Q2W
Number of subjects included in analysis	18924
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3824 ^[6]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.92

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.11

Notes:

[6] - Threshold for statistical significance at 0.0498 level.

Secondary: Time to Cardiovascular Death

End point title	Time to Cardiovascular Death
End point description: Percentage of observed subjects with CV death (positively adjudicated by CEC in a blinded fashion) were reported. Analysis was performed on ITT population.	
End point type	Secondary
End point timeframe: From randomization up to 64 months	

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	2.9	2.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to All-Cause Death

End point title	Time to All-Cause Death
End point description: Percentage of observed subjects with all-cause death (positively adjudicated by CEC in a blinded fashion) were reported. Analysis was performed on ITT population.	
End point type	Secondary
End point timeframe: From randomization up to 64 months	

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	4.1	3.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Occurrence of Any Non-Fatal Myocardial Infarction

End point title	Time to First Occurrence of Any Non-Fatal Myocardial Infarction
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End point description:

Percentage of observed subjects with any non-fatal MI (positively adjudicated by CEC in a blinded fashion) were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

From randomization up to 64 months

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	7.6	6.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Occurrence of Fatal or Any Non-Fatal Ischemic Stroke

End point title	Time to First Occurrence of Fatal or Any Non-Fatal Ischemic Stroke
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End point description:

Percentage of observed subjects with any non-fatal ischemic stroke (positively adjudicated by CEC in a blinded fashion) were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

From randomization up to 64 months

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	1.6	1.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Occurrence of any Unstable Angina Requiring Hospitalization

End point title	Time to First Occurrence of any Unstable Angina Requiring Hospitalization
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End point description:

Percentage of observed subjects with any UA requiring hospitalization (positively adjudicated by CEC in a blinded fashion) were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

From randomization up to 64 months

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	0.6	0.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Occurrence of Any Ischemia-Driven Coronary Revascularization Procedure

End point title	Time to First Occurrence of Any Ischemia-Driven Coronary Revascularization Procedure
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End point description:

Percentage of observed subjects with any ischemia-driven coronary revascularization procedure (positively adjudicated by CEC in a blinded fashion) were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

From randomization up to 64 months

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	8.8	7.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Occurrence of Any Congestive Heart Failure (CHF) Requiring Hospitalization

End point title	Time to First Occurrence of Any Congestive Heart Failure (CHF) Requiring Hospitalization
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End point description:

Percentage of observed subjects with any CHF requiring hospitalization (positively adjudicated by CEC in a blinded fashion) were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

From randomization up to 64 months

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: percentage of subjects				
number (not applicable)	1.9	1.9		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percent Change From Baseline in Calculated LDL-C at Months 4, 12, and 48: ITT Analysis

End point title	Percent Change From Baseline in Calculated LDL-C at Months 4, 12, and 48: ITT Analysis
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End point description:

Adjusted means and standard errors at Month 4, 12 and 48 from multiple imputation approach (to account for missing data) followed by analyses of covariance (ANCOVA) model with the fixed categorical effect of treatment group and the continuous fixed covariate of baseline LDL-C value, including all

available post-baseline data from Month 1 up to Month 48 regardless of status on- or off-treatment. Analysis was performed on ITT population. Here, 'n' signifies number of subjects with the parameter measured and baseline measure available for each time-point, for each arm respectively. A multiple approach was used to account for subjects with missing data.

End point type	Other pre-specified
End point timeframe:	
Baseline, Months 4, 12 and 48	

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9462	9462		
Units: Percent change				
least squares mean (standard error)				
Month 4 (n= 8750, 8602)	4.4 (± 0.3)	-55.8 (± 0.3)		
Month 12 (n= 8397, 8336)	8.0 (± 0.4)	-45.7 (± 0.4)		
Month 48 (n= 790, 812)	16.4 (± 1.8)	-23.5 (± 1.6)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percent Change From Baseline in Calculated LDL-C at Months 4, 12, and 48: On-Treatment Analysis

End point title	Percent Change From Baseline in Calculated LDL-C at Months 4, 12, and 48: On-Treatment Analysis
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End point description:

Adjusted Least-squares (LS) means and standard errors at Month 4, 12 and 48 were obtained from a mixed-effect model with repeated measures (MMRM) including available post-baseline on-treatment data from Month 1 up to Month 48 (i.e. up to 21 days after last injection). Analysis was performed on randomized and treated population. Here, 'n' signifies number of subjects evaluable for this endpoint at specified time points, for each arm respectively.

End point type	Other pre-specified
End point timeframe:	
Baseline, Months 4, 12 and 48	

End point values	Placebo	Alirocumab 75 mg Q2W/Up to 150 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9443	9451		
Units: Percent change				
least squares mean (standard error)				
Month 4 (n= 8647, 8486)	4.4 (± 0.3)	-58.3 (± 0.3)		
Month 12 (n= 8183, 7727)	8.2 (± 0.4)	-52.8 (± 0.4)		
Month 48 (n= 726, 647)	14.6 (± 1.0)	-40.1 (± 1.0)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All Adverse Events (AEs) were collected from signature of the informed consent form until the end of study (Month 64) regardless of seriousness or relationship to Investigational Medicinal Product (IMP).

Adverse event reporting additional description:

Reported AEs are treatment-emergent AEs that is AEs that developed/worsened during the 'treatment-emergent period' (the time from the first dose of study drug up to the last dose of study drug +70 days). Safety population included randomized subjects who actually received at least 1 dose or part of a dose of the double-blind IMP injection.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Placebo
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Reporting group description:

Placebo (for alirocumab) SC injection Q2W added to stable LMT for up to 64 months.

Reporting group title	Alirocumab
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Reporting group description:

Alirocumab 75 mg SC injection Q2W added to stable LMT for up to 64 months. Alirocumab dose up-titrated to 150 mg Q2W from Month 2 when LDL-C levels ≥ 50 mg/dL (1.29 mmol/L) at Month 1; or if up-titration was missed due to unavailability of LDL-C value, it was up-titrated at month 4 based on LDL-C value at Month 2. For subjects receiving 150 mg Q2W, alirocumab dose was down-titrated in a blinded manner to 75 mg Q2W if two consecutive values of LDL-C were < 25 mg/dL (0.65 mmol/L). For subjects receiving 75 mg Q2W, alirocumab dose was switched to placebo in a blinded manner if two consecutive values of LDL-C were < 15 mg/dL (0.39 mmol/L).

Serious adverse events	Placebo	Alirocumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	2350 / 9443 (24.89%)	2202 / 9451 (23.30%)	
number of deaths (all causes)	278	238	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Lymphocytic Leukaemia			
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Myeloid Leukaemia			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

Adenocarcinoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma Gastric		
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Adenocarcinoma Of Colon		
subjects affected / exposed	14 / 9443 (0.15%)	10 / 9451 (0.11%)
occurrences causally related to treatment / all	1 / 14	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 0
Adrenal Adenoma		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal Neoplasm		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal Cancer Stage Iii		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal Squamous Cell Carcinoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anaplastic Large Cell Lymphoma T- And Null-Cell Types		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
B-Cell Small Lymphocytic Lymphoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basal Cell Carcinoma		
subjects affected / exposed	14 / 9443 (0.15%)	11 / 9451 (0.12%)
occurrences causally related to treatment / all	0 / 18	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Benign Ovarian Tumour		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Cancer		
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Cancer Stage Iv		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Bladder Neoplasm		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Papilloma		

subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Transitional Cell Carcinoma		
subjects affected / exposed	9 / 9443 (0.10%)	8 / 9451 (0.08%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Transitional Cell Carcinoma Stage Ii		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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 Iii		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bowen's Disease		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain Neoplasm		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Brain Neoplasm Benign		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast Cancer Metastatic		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Breast Cancer Stage I		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast Cancer Stage Ii		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Breast Cancer Stage Iii		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial Carcinoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid Tumour Of The Appendix		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid Tumour Pulmonary		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac Myxoma		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac Valve Fibroelastoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar Tumour		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix Carcinoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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 Ii		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholesteatoma		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic Lymphocytic Leukaemia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic Myeloid Leukaemia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic Myelomonocytic Leukaemia		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clear Cell Renal Cell Carcinoma		
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colon Adenoma		
subjects affected / exposed	6 / 9443 (0.06%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Colon Cancer		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (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	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 1
Colon Cancer Stage Iii		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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 Iv		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Colorectal Adenocarcinoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal Cancer Metastatic		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Colorectal Cancer Stage Iii		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Craniopharyngioma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Diffuse Large B-Cell Lymphoma		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ductal Adenocarcinoma Of Pancreas		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Endometrial Adenocarcinoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Cancer Stage Ii		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Stromal Tumour		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Tract Adenoma		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroesophageal Cancer		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma		
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Glioblastoma Multiforme		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Haemangioma Of Bone		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hair Follicle Tumour Benign		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Hepatic Neoplasm		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular Carcinoma		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Hodgkin's Disease		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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 Stage Iv		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypopharyngeal Cancer		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal Proliferative Breast Lesion		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	3 / 9443 (0.03%)	8 / 9451 (0.08%)
occurrences causally related to treatment / all	1 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive Lobular Breast Carcinoma		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large Cell Lung Cancer		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Large Cell Lung Cancer Metastatic		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Laryngeal Cancer Stage I		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal Squamous Cell Carcinoma		
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Lentigo Maligna		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lip Squamous Cell Carcinoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Adenocarcinoma		
subjects affected / exposed	4 / 9443 (0.04%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 3
Lung Adenocarcinoma Stage I		

subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Adenocarcinoma Stage Ii			
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Adenocarcinoma Stage Iii			
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Adenocarcinoma Stage Iv			
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Lung Cancer Metastatic			
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Lung Carcinoma Cell Type Unspecified Stage I			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Carcinoma Cell Type Unspecified Stage Iii			
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung Carcinoma Cell Type Unspecified Stage Iv			
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
Lung Neoplasm			

subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Neoplasm Malignant		
subjects affected / exposed	2 / 9443 (0.02%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0
Lung Squamous Cell Carcinoma Metastatic		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Lung Squamous Cell Carcinoma Stage I		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Squamous Cell Carcinoma Stage Ii		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung Squamous Cell Carcinoma Stage Iii		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Lung Squamous Cell Carcinoma Stage Iv		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Lymphoma		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

Malignant Anorectal Neoplasm			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Ascites			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Glioma			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	2 / 9443 (0.02%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Melanoma In Situ			
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Melanoma Stage I			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Melanoma Stage Ii			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Melanoma Stage Iv			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Palate Neoplasm			

subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Malignant Pleural Effusion		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant Sweat Gland Neoplasm		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases To Bone		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases To Central Nervous System		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases To Liver		
subjects affected / exposed	3 / 9443 (0.03%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2
Metastases To Lung		
subjects affected / exposed	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases To Lymph Nodes		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases To Peritoneum		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases To Spine		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic Bronchial Carcinoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic Carcinoma Of The Bladder		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic Gastric Cancer		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic Malignant Melanoma		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic Neoplasm		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic Renal Cell Carcinoma		

subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic Squamous Cell Carcinoma		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Monoclonal Gammopathy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mucinous Cystadenocarcinoma Ovary		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Myeloproliferative Neoplasm		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Nasal Cavity Cancer		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine Carcinoma Metastatic		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Neuroendocrine Tumour		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine Tumour Of The Lung		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Neuroendocrine Tumour Of The Lung Metastatic		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Non-Hodgkin's Lymphoma		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Non-Hodgkin's Lymphoma Metastatic		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's Lymphoma Recurrent		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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 Metastatic		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Small Cell Lung Cancer Stage Ii		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Non-Small Cell Lung Cancer Stage Iv		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Oesophageal Adenocarcinoma		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal Adenocarcinoma Stage Iii		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal Carcinoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal Cancer Stage Iv		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal Squamous Cell Carcinoma		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian Adenoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic Carcinoma		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic Carcinoma Metastatic		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Pancreatic Carcinoma Stage Ii		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatic Carcinoma Stage Iv		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Pancreatic Neuroendocrine Tumour		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary Thyroid Cancer		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid Tumour Benign		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Penile Cancer		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal Mesothelioma Malignant		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Phaeochromocytoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary Tumour Benign		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma Cell Leukaemia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma Cell Myeloma		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Plasmacytoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural Mesothelioma		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Polycythaemia Vera		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate Cancer		

subjects affected / exposed	17 / 9443 (0.18%)	18 / 9451 (0.19%)
occurrences causally related to treatment / all	0 / 17	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate Cancer Metastatic		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Prostate Cancer Stage I		
subjects affected / exposed	4 / 9443 (0.04%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate Cancer Stage Ii		
subjects affected / exposed	4 / 9443 (0.04%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate Cancer Stage Iii		
subjects affected / exposed	6 / 9443 (0.06%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate Cancer Stage Iv		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic Adenoma		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal Adenoma		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal Adenocarcinoma		

subjects affected / exposed	6 / 9443 (0.06%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	1 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal Cancer		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal Cancer Stage Iii		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal Neoplasm		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid Cancer Stage Ii		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Cancer		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Cancer Metastatic		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Renal Cancer Stage Ii		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Cell Carcinoma Stage Ii		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Cell Carcinoma Stage I		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Cell Carcinoma Stage Iii		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Oncocytoma		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary Gland Cancer Stage Iv		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Schwannoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seborrhoeic Keratosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinonasal Papilloma		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus Cancer Metastatic		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Skin Cancer			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Papilloma			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Cell Lung Cancer			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Cell Lung Cancer Limited Stage			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	3 / 9443 (0.03%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Squamous Cell Carcinoma Of Lung			
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Squamous Cell Carcinoma Of Skin			
subjects affected / exposed	6 / 9443 (0.06%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma Of The Cervix			

subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous Cell Carcinoma Of The Hypopharynx		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Squamous Cell Carcinoma Of The Tongue		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Squamous Cell Carcinoma Of The Vulva		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial Sarcoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue Carcinoma Stage Iv		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsil Cancer		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional Cell Cancer Of Renal Pelvis And Ureter Metastatic		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1

Transitional Cell Carcinoma			
subjects affected / exposed	5 / 9443 (0.05%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour Haemorrhage			
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Bladder Sarcoma			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Cancer			
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Leiomyoma			
subjects affected / exposed	4 / 9443 (0.04%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal Cord Neoplasm			
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval Cancer			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval Cancer Metastatic			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Accelerated Hypertension			
subjects affected / exposed	4 / 9443 (0.04%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Aneurysm			
subjects affected / exposed	12 / 9443 (0.13%)	10 / 9451 (0.11%)	
occurrences causally related to treatment / all	0 / 12	0 / 10	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic Aneurysm Rupture			
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Aortic Dissection			
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Intramural Haematoma			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Thrombosis			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aorto-Duodenal Fistula			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arterial Insufficiency			

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Arteriovenous Fistula		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Blood Pressure Inadequately Controlled		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory Collapse		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Deep Vein Thrombosis		
subjects affected / exposed	8 / 9443 (0.08%)	11 / 9451 (0.12%)
occurrences causally related to treatment / all	1 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Dry Gangrene		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Embolism Venous		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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 / 9443 (0.01%)	0 / 9451 (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	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hot Flush		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	36 / 9443 (0.38%)	34 / 9451 (0.36%)
occurrences causally related to treatment / all	0 / 41	0 / 35
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive Crisis		
subjects affected / exposed	17 / 9443 (0.18%)	21 / 9451 (0.22%)
occurrences causally related to treatment / all	0 / 19	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive Emergency		
subjects affected / exposed	4 / 9443 (0.04%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		

subjects affected / exposed	17 / 9443 (0.18%)	16 / 9451 (0.17%)
occurrences causally related to treatment / all	0 / 17	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic Shock		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Iliac Artery Embolism		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac Artery Occlusion		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent Claudication		
subjects affected / exposed	6 / 9443 (0.06%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic Limb Pain		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Leriche Syndrome		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphatic Fistula		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphorrhoea		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant Hypertension		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic Hypotension		
subjects affected / exposed	3 / 9443 (0.03%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Penetrating Aortic Ulcer		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Arterial Occlusive Disease		
subjects affected / exposed	47 / 9443 (0.50%)	27 / 9451 (0.29%)
occurrences causally related to treatment / all	1 / 49	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Aneurysm		
subjects affected / exposed	2 / 9443 (0.02%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Dissection		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Occlusion		

subjects affected / exposed	13 / 9443 (0.14%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 15	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Stenosis		
subjects affected / exposed	8 / 9443 (0.08%)	8 / 9451 (0.08%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Thrombosis		
subjects affected / exposed	4 / 9443 (0.04%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Peripheral Ischaemia		
subjects affected / exposed	20 / 9443 (0.21%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 23	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Peripheral Embolism		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Vascular Disorder		
subjects affected / exposed	6 / 9443 (0.06%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Venous Disease		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis Superficial		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Raynaud's Phenomenon		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renovascular Hypertension		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Shock Haemorrhagic		
subjects affected / exposed	4 / 9443 (0.04%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Subclavian Artery Occlusion		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian Artery Stenosis		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Superior Vena Cava Occlusion		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Temporal Arteritis		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	3 / 9443 (0.03%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	3 / 9443 (0.03%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous Thrombosis			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous Thrombosis Limb			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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			
Asthenia			
subjects affected / exposed	3 / 9443 (0.03%)	6 / 9451 (0.06%)	
occurrences causally related to treatment / all	0 / 3	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Discomfort			

subjects affected / exposed	5 / 9443 (0.05%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Chest Pain		
subjects affected / exposed	29 / 9443 (0.31%)	25 / 9451 (0.26%)
occurrences causally related to treatment / all	0 / 32	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 1
Death		
subjects affected / exposed	33 / 9443 (0.35%)	25 / 9451 (0.26%)
occurrences causally related to treatment / all	0 / 33	0 / 25
deaths causally related to treatment / all	0 / 33	0 / 25
Device Related Thrombosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise Tolerance Decreased		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial Pain		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	4 / 9443 (0.04%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gait Disturbance		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
General Physical Health Deterioration		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (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 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired Healing		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant Site Haematoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Implant Site Pain		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated Hernia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza Like Illness		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Injection Site Reaction		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical Device Pain		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical Device Site Dermatitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical Device Site Joint Pain		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical Device Site Pain		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	222 / 9443 (2.35%)	219 / 9451 (2.32%)
occurrences causally related to treatment / all	1 / 256	1 / 264
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple Organ Dysfunction Syndrome		
subjects affected / exposed	8 / 9443 (0.08%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 6	0 / 4
Oedema Peripheral		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pacemaker Generated Arrhythmia		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic Mass		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Swelling		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	6 / 9443 (0.06%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Soft Tissue Inflammation		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden Cardiac Death		
subjects affected / exposed	42 / 9443 (0.44%)	36 / 9451 (0.38%)
occurrences causally related to treatment / all	0 / 42	0 / 36
deaths causally related to treatment / all	0 / 42	0 / 36
Strangulated Hernia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden Death		

subjects affected / exposed	9 / 9443 (0.10%)	14 / 9451 (0.15%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 9	0 / 14	
Systemic Inflammatory Response Syndrome			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Stent Restenosis			
subjects affected / exposed	1 / 9443 (0.01%)	9 / 9451 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Stent Thrombosis			
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vessel Puncture Site Haematoma			
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vessel Puncture Site Haemorrhage			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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 Bite			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergy To Arthropod Sting			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic Reaction			

subjects affected / exposed	2 / 9443 (0.02%)	4 / 9451 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic Shock			
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contrast Media Allergy			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iodine Allergy			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Physical Assault			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired Hydrocele			
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Acquired Phimosi		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign Prostatic Hyperplasia		
subjects affected / exposed	13 / 9443 (0.14%)	16 / 9451 (0.17%)
occurrences causally related to treatment / all	0 / 13	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Breast Mass		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast Pain		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysfunctional Uterine Bleeding		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial Hyperplasia		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erectile Dysfunction		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Menorrhagia		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metrorrhagia		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian Cyst		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peyronie's Disease		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rectocele		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal Ulcer		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spermatocele		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Testicular Cyst		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine Haemorrhage		

subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine Polyp		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine Prolapse		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (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	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vaginal Dysplasia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vaginal Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vaginal Prolapse		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varicocele		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vulva Cyst		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acquired Diaphragmatic Eventration			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Pulmonary Oedema			
subjects affected / exposed	10 / 9443 (0.11%)	6 / 9451 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 3	0 / 1	
Acute Respiratory Distress Syndrome			
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Respiratory Failure			
subjects affected / exposed	24 / 9443 (0.25%)	19 / 9451 (0.20%)	
occurrences causally related to treatment / all	0 / 35	0 / 21	
deaths causally related to treatment / all	0 / 3	0 / 5	
Adenoidal Hypertrophy			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Asthma			
subjects affected / exposed	6 / 9443 (0.06%)	10 / 9451 (0.11%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atelectasis			

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial Hyperreactivity		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis Chronic		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Choking		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Chronic Obstructive Pulmonary Disease		
subjects affected / exposed	51 / 9443 (0.54%)	38 / 9451 (0.40%)
occurrences causally related to treatment / all	0 / 76	0 / 47
deaths causally related to treatment / all	0 / 4	0 / 1
Chronic Respiratory Failure		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cough		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	12 / 9443 (0.13%)	20 / 9451 (0.21%)
occurrences causally related to treatment / all	0 / 12	0 / 21
deaths causally related to treatment / all	0 / 1	0 / 0
Dyspnoea Exertional		
subjects affected / exposed	4 / 9443 (0.04%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	12 / 9443 (0.13%)	10 / 9451 (0.11%)
occurrences causally related to treatment / all	0 / 12	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	4 / 9443 (0.04%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Haemothorax		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperventilation		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoventilation		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic Pulmonary Fibrosis		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial Lung Disease		
subjects affected / exposed	4 / 9443 (0.04%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal Haemorrhage		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Laryngeal Oedema		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngospasm		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Infiltration		

subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal Mucosal Ulcer		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal Obstruction		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal Polyps		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal Septum Deviation		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal Turbinate Hypertrophy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	8 / 9443 (0.08%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	5 / 9443 (0.05%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic Pain		

subjects affected / exposed	0 / 9443 (0.00%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Aspiration		
subjects affected / exposed	8 / 9443 (0.08%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 3	0 / 2
Pneumothorax		
subjects affected / exposed	5 / 9443 (0.05%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Alveolar Haemorrhage		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary Calcification		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Congestion		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Embolism		
subjects affected / exposed	19 / 9443 (0.20%)	16 / 9451 (0.17%)
occurrences causally related to treatment / all	2 / 19	0 / 16
deaths causally related to treatment / all	0 / 1	0 / 3
Pulmonary Fibrosis		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Infarction		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Hypertension		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Mass		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Oedema		
subjects affected / exposed	5 / 9443 (0.05%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Respiratory Acidosis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory Arrest		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory Disorder		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory Distress		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory Failure		

subjects affected / exposed	15 / 9443 (0.16%)	8 / 9451 (0.08%)	
occurrences causally related to treatment / all	0 / 16	0 / 11	
deaths causally related to treatment / all	0 / 5	0 / 2	
Respiratory Tract Oedema			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis Allergic			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	4 / 9443 (0.04%)	4 / 9451 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillolith			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal Cord Disorder			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wheezing			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal Cord Polyp			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Adjustment Disorder With Mixed Disturbance Of Emotion And Conduct			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute Psychosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Affective Disorder		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Agoraphobia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol Abuse		
subjects affected / exposed	2 / 9443 (0.02%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholic Psychosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholism		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anger		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety		

subjects affected / exposed	5 / 9443 (0.05%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety Disorder		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar I Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Borderline Personality Disorder		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyphrenia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Catatonia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Completed Suicide		
subjects affected / exposed	6 / 9443 (0.06%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 6	0 / 3
Confusional State		

subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Conversion Disorder		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium Tremens		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Delusional Disorder, Unspecified Type		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	25 / 9443 (0.26%)	13 / 9451 (0.14%)
occurrences causally related to treatment / all	2 / 26	1 / 18
deaths causally related to treatment / all	0 / 2	0 / 0
Depression Suicidal		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug Abuse		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Factitious Disorder		

subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Homicidal Ideation		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Insomnia		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Major Depression		
subjects affected / exposed	2 / 9443 (0.02%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	1 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Mental Status Changes		
subjects affected / exposed	4 / 9443 (0.04%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Mood Disorder Due To A General Medical Condition		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Panic Attack		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-Traumatic Stress Disorder		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (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 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal Behaviour			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal Ideation			
subjects affected / exposed	8 / 9443 (0.08%)	7 / 9451 (0.07%)	
occurrences causally related to treatment / all	2 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide Attempt			
subjects affected / exposed	14 / 9443 (0.15%)	5 / 9451 (0.05%)	
occurrences causally related to treatment / all	1 / 15	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient Psychosis			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	11 / 9443 (0.12%)	10 / 9451 (0.11%)	
occurrences causally related to treatment / all	0 / 11	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation Drug Level Above Therapeutic			
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Calcium Increased			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood Creatine Phosphokinase Mb Increased		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood Creatine Phosphokinase Increased		
subjects affected / exposed	4 / 9443 (0.04%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	2 / 4	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Blood Creatinine Increased		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood Potassium Increased		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood Pressure Increased		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain Natriuretic Peptide Increased		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
C-Reactive Protein Increased		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac Stress Test Abnormal		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection Fraction Decreased		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram Qt Prolonged		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise Electrocardiogram Abnormal		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerular Filtration Rate Decreased		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hiv Test Positive		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematocrit Decreased		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematocrit Increased		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoglobin Decreased		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Enzyme Abnormal		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Enzyme Increased		
subjects affected / exposed	3 / 9443 (0.03%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C Virus Test Positive		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Human Papilloma Virus Test Positive		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza A Virus Test Positive		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
International Normalised Ratio Increased		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver Function Test Increased		

subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycobacterium Tuberculosis Complex Test Positive			
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scan Myocardial Perfusion			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases Increased			
subjects affected / exposed	3 / 9443 (0.03%)	5 / 9451 (0.05%)	
occurrences causally related to treatment / all	0 / 3	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin Increased			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour Marker Increased			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight Decreased			
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
White Blood Cell Count Increased			
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			

Abdominal Injury			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Wound Dehiscence			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental Overdose			
subjects affected / exposed	9 / 9443 (0.10%)	8 / 9451 (0.08%)	
occurrences causally related to treatment / all	5 / 14	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum Fracture			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol Poisoning			
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergic Transfusion Reaction			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Postoperative			
subjects affected / exposed	3 / 9443 (0.03%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaesthetic Complication			
Neurological			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic Haemorrhage			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ankle Fracture		
subjects affected / exposed	8 / 9443 (0.08%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic Injury		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Arterial Bypass Thrombosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial Injury		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropod Bite		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropod Sting		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Auricular Haematoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blast Injury		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone Contusion		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brachial Plexus Injury		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain Contusion		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Brain Herniation		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carbon Monoxide Poisoning		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiac Contusion		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac Valve Replacement Complication		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cervical Vertebral Fracture		

subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (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 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Chemical Burn Of Gastrointestinal Tract		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle Fracture		
subjects affected / exposed	5 / 9443 (0.05%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	8 / 9443 (0.08%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Confusion Postoperative		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	4 / 9443 (0.04%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary Artery Restenosis		
subjects affected / exposed	8 / 9443 (0.08%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral Injury		

subjects affected / exposed	3 / 9443 (0.03%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Delayed Recovery From Anaesthesia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electric Shock		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Extra-Axial Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural Haematoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye Injury		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial Bones Fracture		
subjects affected / exposed	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		

subjects affected / exposed	32 / 9443 (0.34%)	26 / 9451 (0.28%)
occurrences causally related to treatment / all	0 / 34	0 / 26
deaths causally related to treatment / all	0 / 1	0 / 0
Femoral Neck Fracture		
subjects affected / exposed	6 / 9443 (0.06%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Femur Fracture		
subjects affected / exposed	9 / 9443 (0.10%)	13 / 9451 (0.14%)
occurrences causally related to treatment / all	0 / 9	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula Fracture		
subjects affected / exposed	4 / 9443 (0.04%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foot Fracture		
subjects affected / exposed	4 / 9443 (0.04%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm Fracture		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign Body In Urogenital Tract		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture Displacement		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fractured Skull Depressed		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal Stoma Necrosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gun Shot Wound		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hand Fracture		
subjects affected / exposed	3 / 9443 (0.03%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Head Injury		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Heat Stroke		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hip Fracture		
subjects affected / exposed	2 / 9443 (0.02%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus Fracture		
subjects affected / exposed	4 / 9443 (0.04%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hyphaema		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incision Site Pain		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional Hernia		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional Overdose		
subjects affected / exposed	8 / 9443 (0.08%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 18	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Jaw Fracture		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint Dislocation		
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Joint Injury		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		

subjects affected / exposed	4 / 9443 (0.04%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament Injury		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament Rupture		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament Sprain		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb Crushing Injury		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb Injury		
subjects affected / exposed	6 / 9443 (0.06%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Limb Traumatic Amputation		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lip Injury		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower Limb Fracture		

subjects affected / exposed	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar Vertebral Fracture		
subjects affected / exposed	5 / 9443 (0.05%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Mallet Finger		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus Injury		
subjects affected / exposed	3 / 9443 (0.03%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple Fractures		
subjects affected / exposed	0 / 9443 (0.00%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple Injuries		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Muscle Injury		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle Strain		

subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve Root Injury Lumbar		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal Injury		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic Fracture		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Penetrating Abdominal Trauma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital Haematoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Restenosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perirenal Haematoma		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax Traumatic		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Post Concussion Syndrome		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Bile Leak		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Fistula		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Haematoma		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Haematuria		
subjects affected / exposed	3 / 9443 (0.03%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Haemorrhage		

subjects affected / exposed	8 / 9443 (0.08%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Inflammation		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Pulmonary Embolism		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Swelling		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post-Traumatic Pain		
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative Ileus		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative Renal Failure		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative Respiratory Failure		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative Thoracic Procedure Complication		

subjects affected / exposed	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative Thrombosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural Haemorrhage		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Procedural Hypertension		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural Hypotension		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural Intestinal Perforation		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural Pain		
subjects affected / exposed	5 / 9443 (0.05%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural Pneumothorax		

subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis Fracture		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Contusion		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation Associated Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation Skin Injury		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	1 / 9443 (0.01%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Rib Fracture		
subjects affected / exposed	7 / 9443 (0.07%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Road Traffic Accident		
subjects affected / exposed	19 / 9443 (0.20%)	14 / 9451 (0.15%)
occurrences causally related to treatment / all	0 / 19	0 / 14
deaths causally related to treatment / all	0 / 5	0 / 3
Scapula Fracture		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal Haematoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seroma		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Silicosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Skin Injury		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull Fracture		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Soft Tissue Injury		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	4 / 9443 (0.04%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal Cord Injury		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal Fracture		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic Rupture		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stab Wound		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal Fracture		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stoma Site Discharge		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stomal Hernia		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid Haemorrhage		
subjects affected / exposed	8 / 9443 (0.08%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Subdural Haematoma		

subjects affected / exposed	5 / 9443 (0.05%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Tendon Injury		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon Rupture		
subjects affected / exposed	7 / 9443 (0.07%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal Burn		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic Vertebral Fracture		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (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	5 / 9443 (0.05%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth Fracture		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity To Various Agents		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Tracheostomy Malfunction		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic Haematoma		
subjects affected / exposed	3 / 9443 (0.03%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic Haemothorax		
subjects affected / exposed	3 / 9443 (0.03%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic Intracranial Haemorrhage		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic Liver Injury		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic Renal Injury		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic Ulcer		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna Fracture		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper Limb Fracture		

subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary Retention Postoperative		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular Access Site Haemorrhage		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular Access Site Pseudoaneurysm		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular Graft Occlusion		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular Pseudoaneurysm		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular Pseudoaneurysm Ruptured		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound Dehiscence		

subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist Fracture			
subjects affected / exposed	4 / 9443 (0.04%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial Septal Defect			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bicuspid Aortic Valve			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchogenic Cyst			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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 / 9443 (0.01%)	0 / 9451 (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	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic Arteriovenous Malformation			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hereditary Optic Atrophy			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinocerebellar Ataxia			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroglossal Cyst			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Von Hippel-Lindau Disease			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute Left Ventricular Failure			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Myocardial Infarction			
subjects affected / exposed	3 / 9443 (0.03%)	6 / 9451 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adams-Stokes Syndrome			
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina Pectoris			

subjects affected / exposed	133 / 9443 (1.41%)	113 / 9451 (1.20%)
occurrences causally related to treatment / all	0 / 148	0 / 136
deaths causally related to treatment / all	0 / 0	0 / 0
Angina Unstable		
subjects affected / exposed	8 / 9443 (0.08%)	10 / 9451 (0.11%)
occurrences causally related to treatment / all	1 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic Valve Disease Mixed		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic Valve Incompetence		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic Valve Sclerosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic Valve Stenosis		
subjects affected / exposed	17 / 9443 (0.18%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 17	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia		
subjects affected / exposed	1 / 9443 (0.01%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2
Arrhythmia Supraventricular		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis Coronary Artery		

subjects affected / exposed	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriospasm Coronary		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial Fibrillation		
subjects affected / exposed	98 / 9443 (1.04%)	82 / 9451 (0.87%)
occurrences causally related to treatment / all	0 / 110	0 / 103
deaths causally related to treatment / all	0 / 0	0 / 1
Atrial Flutter		
subjects affected / exposed	10 / 9443 (0.11%)	14 / 9451 (0.15%)
occurrences causally related to treatment / all	0 / 14	1 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial Tachycardia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular Block		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular Block Complete		
subjects affected / exposed	6 / 9443 (0.06%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular Block First Degree		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular Block Second Degree		

subjects affected / exposed	5 / 9443 (0.05%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	9 / 9443 (0.10%)	8 / 9451 (0.08%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle Branch Block Left		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle Branch Block Right		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac Aneurysm		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac Arrest		
subjects affected / exposed	9 / 9443 (0.10%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac Discomfort		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac Failure		
subjects affected / exposed	4 / 9443 (0.04%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Cardiac Failure Acute		

subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiac Failure Chronic		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac Failure Congestive		
subjects affected / exposed	5 / 9443 (0.05%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac Flutter		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac Perforation		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac Tamponade		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Cardio-Respiratory Arrest		
subjects affected / exposed	3 / 9443 (0.03%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 3
Cardiogenic Shock		
subjects affected / exposed	6 / 9443 (0.06%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 1
Cardiomyopathy		

subjects affected / exposed	6 / 9443 (0.06%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Chordae Tendinae Rupture		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Conduction Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive Cardiomyopathy		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary Artery Disease		
subjects affected / exposed	20 / 9443 (0.21%)	25 / 9451 (0.26%)
occurrences causally related to treatment / all	0 / 20	1 / 26
deaths causally related to treatment / all	0 / 0	0 / 1
Coronary Artery Dissection		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary Artery Occlusion		
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary Artery Stenosis		
subjects affected / exposed	3 / 9443 (0.03%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diastolic Dysfunction		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracardiac Mass		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracardiac Thrombus		
subjects affected / exposed	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic Cardiomyopathy		
subjects affected / exposed	9 / 9443 (0.10%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic Mitral Regurgitation		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Left Ventricular Dysfunction		
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Low Cardiac Output Syndrome		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microvascular Coronary Artery Disease		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral Valve Incompetence		
subjects affected / exposed	7 / 9443 (0.07%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral Valve Prolapse		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial Infarction		
subjects affected / exposed	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Myocardial Ischaemia		
subjects affected / exposed	13 / 9443 (0.14%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 13	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Myocardial Rupture		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Myocarditis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nodal Arrhythmia		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nodal Rhythm		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	5 / 9443 (0.05%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary Muscle Rupture		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial Effusion		
subjects affected / exposed	5 / 9443 (0.05%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	3 / 9443 (0.03%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuropericarditis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal Angina		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless Electrical Activity		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhythm Idioventricular		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Sinus Arrest		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus Bradycardia		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus Node Dysfunction		
subjects affected / exposed	9 / 9443 (0.10%)	13 / 9451 (0.14%)
occurrences causally related to treatment / all	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus Tachycardia		
subjects affected / exposed	3 / 9443 (0.03%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Stress Cardiomyopathy		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular Extrasystoles		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular Tachycardia		
subjects affected / exposed	12 / 9443 (0.13%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 16	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Systolic Dysfunction		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tachyarrhythmia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid Valve Disease		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ventricular Arrhythmia		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular Extrasystoles		

subjects affected / exposed	5 / 9443 (0.05%)	7 / 9451 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Fibrillation			
subjects affected / exposed	17 / 9443 (0.18%)	8 / 9451 (0.08%)	
occurrences causally related to treatment / all	0 / 17	0 / 8	
deaths causally related to treatment / all	0 / 4	0 / 0	
Ventricular Hypokinesia			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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 / 9443 (0.31%)	24 / 9451 (0.25%)	
occurrences causally related to treatment / all	0 / 33	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 2	
Nervous system disorders			
Alcoholic Seizure			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amnesia			
subjects affected / exposed	3 / 9443 (0.03%)	4 / 9451 (0.04%)	
occurrences causally related to treatment / all	1 / 3	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic Lateral Sclerosis			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Autonomic Nervous System Imbalance		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Axonal Neuropathy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Balance Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Brain Injury		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Brain Oedema		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Carotid Arteriosclerosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid Artery Disease		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (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	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid Artery Stenosis		
subjects affected / exposed	19 / 9443 (0.20%)	14 / 9451 (0.15%)
occurrences causally related to treatment / all	0 / 19	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid Artery Thrombosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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 / 9443 (0.00%)	1 / 9451 (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	6 / 9443 (0.06%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cauda Equina Syndrome		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral Atrophy		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral Haemorrhage		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral Ischaemia		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrospinal Fistula		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular Accident		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Cervical Radiculopathy		
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic Inflammatory Demyelinating Polyradiculoneuropathy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Coordination Abnormal		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cubital Tunnel Syndrome		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	0 / 9443 (0.00%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's Type		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Demyelinating Polyneuropathy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depressed Level Of Consciousness		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Encephalopathy		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Neuropathy		
subjects affected / exposed	3 / 9443 (0.03%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		

subjects affected / exposed	8 / 9443 (0.08%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness Exertional		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	3 / 9443 (0.03%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	6 / 9443 (0.06%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Epileptic Encephalopathy		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Essential Tremor		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extrapyramidal Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial Paralysis		

subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Focal Dyscognitive Seizures		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised Tonic-Clonic Seizure		
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage Intracranial		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic Stroke		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Headache		
subjects affected / exposed	7 / 9443 (0.07%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hemianopia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiplegia		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperaesthesia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic Seizure		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic Seizure		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemic Seizure		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-Ischaemic Encephalopathy		
subjects affected / exposed	4 / 9443 (0.04%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Intercostal Neuralgia		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial Aneurysm		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial Mass		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial Venous Sinus Thrombosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraventricular Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic Stroke		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Limbic Encephalitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Loss Of Consciousness		
subjects affected / exposed	8 / 9443 (0.08%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar Radiculopathy		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbosacral Radiculopathy		

subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Memory Impairment		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic Encephalopathy		
subjects affected / exposed	2 / 9443 (0.02%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine With Aura		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mixed Dementia		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Monoparesis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple Sclerosis Relapse		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myoclonus		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve Compression		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuromuscular Pain		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy Peripheral		
subjects affected / exposed	4 / 9443 (0.04%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Occipital Neuralgia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	8 / 9443 (0.08%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	2 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paralysis		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's Disease		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonism		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Partial Seizures With Secondary Generalisation		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Nerve Lesion		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Sensory Neuropathy		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Petit Mal Epilepsy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Posterior Reversible Encephalopathy Syndrome		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postictal Paralysis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	2 / 9443 (0.02%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Pyramidal Tract Syndrome		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radial Nerve Palsy		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular Pain		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ruptured Cerebral Aneurysm		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Sciatica		

subjects affected / exposed	1 / 9443 (0.01%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	7 / 9443 (0.07%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Sensory Loss		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal Cord Compression		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitic Myelopathy		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Status Epilepticus		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	73 / 9443 (0.77%)	67 / 9451 (0.71%)
occurrences causally related to treatment / all	0 / 82	1 / 73
deaths causally related to treatment / all	0 / 0	0 / 1
Toxic Encephalopathy		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient Global Amnesia		

subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Transient Ischaemic Attack		
subjects affected / exposed	2 / 9443 (0.02%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Trigeminal Neuralgia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulnar Neuritis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulnar Tunnel Syndrome		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vith Nerve Paralysis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vith Nerve Paresis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular Encephalopathy		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral Artery Occlusion			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar Insufficiency			
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo Cns Origin			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	15 / 9443 (0.16%)	11 / 9451 (0.12%)	
occurrences causally related to treatment / all	0 / 15	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Of Chronic Disease			
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Of Malignant Disease			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Vitamin B12 Deficiency			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune Haemolytic Anaemia			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coagulopathy		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated Intravascular Coagulation		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile Neutropenia		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemolytic Anaemia		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic Anaemia		
subjects affected / exposed	17 / 9443 (0.18%)	14 / 9451 (0.15%)
occurrences causally related to treatment / all	0 / 18	0 / 15
deaths causally related to treatment / all	0 / 3	0 / 0
Haemorrhagic Diathesis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	5 / 9443 (0.05%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Iron Deficiency Anaemia		

subjects affected / exposed	8 / 9443 (0.08%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leukopenia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenitis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic Anaemia		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrogenic Anaemia		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic Normocytic Anaemia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normocytic Anaemia		

subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	6 / 9443 (0.06%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	1 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic Thrombocytopenic Purpura			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Acute Vestibular Syndrome			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness Neurosensory			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden Hearing Loss			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic Membrane Disorder			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic Membrane Perforation			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	12 / 9443 (0.13%)	9 / 9451 (0.10%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo Labyrinthine			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo Positional			
subjects affected / exposed	3 / 9443 (0.03%)	4 / 9451 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis Fugax			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blepharochalasis			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	13 / 9443 (0.14%)	11 / 9451 (0.12%)	
occurrences causally related to treatment / all	0 / 13	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract Diabetic			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract Subcapsular		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Conjunctival Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Corneal Degeneration		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Retinopathy		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye Muscle Entrapment		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	0 / 9443 (0.00%)	2 / 9451 (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	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ocular Myasthenia		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Optic Ischaemic Neuropathy		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Posterior Capsule Opacification		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal Artery Embolism		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	0 / 9443 (0.00%)	1 / 9451 (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	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal Vein Occlusion		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ulcerative Keratitis		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual Acuity Reduced			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous Detachment			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous Haemorrhage			
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Adhesions			
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Discomfort			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Distension			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Hernia			
subjects affected / exposed	5 / 9443 (0.05%)	4 / 9451 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Incarcerated Hernia			

subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal Pain		
subjects affected / exposed	12 / 9443 (0.13%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 12	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal Pain Upper		
subjects affected / exposed	6 / 9443 (0.06%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal Strangulated Hernia		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Abdominal Wall Haematoma		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholic Pancreatitis		
subjects affected / exposed	3 / 9443 (0.03%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	1 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Anal Fissure		
subjects affected / exposed	4 / 9443 (0.04%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal Fistula		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal Incontinence		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal Polyp		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aphthous Ulcer		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Appendix Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's Oesophagus		
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bile Acid Malabsorption		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breath Odour		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic Gastritis		

subjects affected / exposed	5 / 9443 (0.05%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	7 / 9443 (0.07%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis Ischaemic		
subjects affected / exposed	6 / 9443 (0.06%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Colitis Microscopic		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis Ulcerative		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	4 / 9443 (0.04%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 4	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's Disease		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Gastroparesis		

subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	7 / 9443 (0.07%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 7	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea Haemorrhagic		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dieulafoy's Vascular Malformation		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular Perforation		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum Intestinal		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum Intestinal Haemorrhagic		
subjects affected / exposed	4 / 9443 (0.04%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal Obstruction		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal Ulcer		
subjects affected / exposed	5 / 9443 (0.05%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal Ulcer Haemorrhage		
subjects affected / exposed	9 / 9443 (0.10%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 10	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal Vascular Ectasia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis Haemorrhagic		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	6 / 9443 (0.06%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis Haemorrhagic		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive Duodenitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive Oesophagitis		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral Hernia, Obstructive		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fistula Of Small Intestine		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Food Poisoning		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Functional Gastrointestinal Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Haemorrhage		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Polyps		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Ulcer		
subjects affected / exposed	3 / 9443 (0.03%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Ulcer Haemorrhage		
subjects affected / exposed	11 / 9443 (0.12%)	14 / 9451 (0.15%)
occurrences causally related to treatment / all	0 / 12	0 / 14
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric Ulcer, Obstructive		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	17 / 9443 (0.18%)	11 / 9451 (0.12%)
occurrences causally related to treatment / all	0 / 19	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis Erosive		

subjects affected / exposed	3 / 9443 (0.03%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis Haemorrhagic		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis Haemorrhagic		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Angiectasia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Angiodysplasia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Angiodysplasia Haemorrhagic		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Disorder		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Haemorrhage		

subjects affected / exposed	13 / 9443 (0.14%)	11 / 9451 (0.12%)
occurrences causally related to treatment / all	0 / 13	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 3
Gastrointestinal Inflammation		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Mucosal Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Pain		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Polyp Haemorrhage		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Ulcer		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Ulcer Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrooesophageal Reflux Disease		
subjects affected / exposed	19 / 9443 (0.20%)	21 / 9451 (0.22%)
occurrences causally related to treatment / all	0 / 20	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Gingival Bleeding		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	2 / 9443 (0.02%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic Erosive Gastritis		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal Haemorrhage		
subjects affected / exposed	4 / 9443 (0.04%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	4 / 9443 (0.04%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus Hernia		
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus Hernia Strangulated		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileal Perforation		

subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus Paralytic		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated Hiatus Hernia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated Inguinal Hernia		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated Umbilical Hernia		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal Hernia		
subjects affected / exposed	15 / 9443 (0.16%)	29 / 9451 (0.31%)
occurrences causally related to treatment / all	0 / 15	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal Infarction		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Intestinal Ischaemia		
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Intestinal Obstruction		
subjects affected / exposed	6 / 9443 (0.06%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0
Intestinal Perforation		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Irritable Bowel Syndrome		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large Intestinal Obstruction		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large Intestinal Ulcer		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large Intestine Perforation		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Large Intestine Polyp		

subjects affected / exposed	2 / 9443 (0.02%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage		
subjects affected / exposed	4 / 9443 (0.04%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar Hernia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss Syndrome		
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Megacolon		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric Artery Thrombosis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Mesenteric Panniculitis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		

subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Obstruction Gastric		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive Pancreatitis		
subjects affected / exposed	2 / 9443 (0.02%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Odynophagia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oedematous Pancreatitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal Achalasia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal Spasm		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal Stenosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal Ulcer Haemorrhage		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal Varices Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis Haemorrhagic		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic Failure		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic Haemorrhage		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic Pseudocyst		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	6 / 9443 (0.06%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis Acute		
subjects affected / exposed	16 / 9443 (0.17%)	15 / 9451 (0.16%)
occurrences causally related to treatment / all	0 / 16	3 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis Chronic		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis Necrotising		
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic Ulcer		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic Ulcer Haemorrhage		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontal Disease		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal Cyst		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal Haemorrhage		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal Haemorrhage		
subjects affected / exposed	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal Prolapse		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal Ulcer Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal Haemorrhage		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary Duct Obstruction		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	1 / 9443 (0.01%)	0 / 9451 (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	4 / 9443 (0.04%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Small Intestinal Perforation		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small Intestinal Ulcer Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Swollen Tongue		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue Haematoma		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toothache		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical Hernia		
subjects affected / exposed	7 / 9443 (0.07%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical Hernia, Obstructive		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage		

subjects affected / exposed	7 / 9443 (0.07%)	6 / 9451 (0.06%)	
occurrences causally related to treatment / all	0 / 8	1 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Varices Oesophageal			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	6 / 9443 (0.06%)	5 / 9451 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute Hepatic Failure			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ampulla Of Vater Stenosis			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile Duct Stenosis			
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile Duct Stone			
subjects affected / exposed	7 / 9443 (0.07%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	1 / 7	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary Colic			
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary Dyskinesia			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary Tract Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	3 / 9443 (0.03%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis Acute		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis Sclerosing		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis		
subjects affected / exposed	14 / 9443 (0.15%)	8 / 9451 (0.08%)
occurrences causally related to treatment / all	0 / 14	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis Acute		
subjects affected / exposed	14 / 9443 (0.15%)	11 / 9451 (0.12%)
occurrences causally related to treatment / all	0 / 14	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 0
Cholecystitis Chronic		
subjects affected / exposed	6 / 9443 (0.06%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		

subjects affected / exposed	35 / 9443 (0.37%)	25 / 9451 (0.26%)
occurrences causally related to treatment / all	0 / 35	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic Hepatitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cirrhosis Alcoholic		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Drug-Induced Liver Injury		
subjects affected / exposed	6 / 9443 (0.06%)	15 / 9451 (0.16%)
occurrences causally related to treatment / all	0 / 6	5 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder Necrosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Cirrhosis		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Congestion		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Failure		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatic Function Abnormal		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Haemorrhage		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Lesion		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Necrosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Vein Dilatation		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis Acute		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis Alcoholic		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis Chronic Active		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis Toxic		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular Injury		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperplastic Cholecystopathy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	3 / 9443 (0.03%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice Cholestatic		

subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Liver Disorder			
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver Injury			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Steatohepatitis			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	7 / 9443 (0.07%)	4 / 9451 (0.04%)	
occurrences causally related to treatment / all	2 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus Ulcer			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	2 / 9443 (0.02%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis Allergic			

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis Atopic		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis Bullous		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis Contact		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis Exfoliative Generalised		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatomyositis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Foot		
subjects affected / exposed	11 / 9443 (0.12%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 11	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Diabetic Neuropathic Ulcer		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Ulcer		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug Eruption		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug Reaction With Eosinophilia And Systemic Symptoms		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema Nummular		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erythema		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erythema Multiforme		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erythrodermic Psoriasis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperhidrosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intertrigo		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Photosensitivity Reaction		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pruritus Allergic		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rash Erythematous		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash Pruritic		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scar Pain		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin Lesion		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Ulcer			
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swelling Face			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria Chronic			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Purpura			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	62 / 9443 (0.66%)	57 / 9451 (0.60%)	
occurrences causally related to treatment / all	0 / 74	1 / 59	
deaths causally related to treatment / all	0 / 5	0 / 6	
Acute Prerenal Failure			
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Dilatation			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Outlet Obstruction		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Perforation		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Tamponade		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus Urinary		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic Kidney Disease		
subjects affected / exposed	15 / 9443 (0.16%)	13 / 9451 (0.14%)
occurrences causally related to treatment / all	1 / 16	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis Glandularis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis Interstitial		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Cystopathy		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Nephropathy		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
End Stage Renal Disease		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Glomerulonephritis Proliferative		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephropathy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	13 / 9443 (0.14%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 15	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0
Hydronephrosis		

subjects affected / exposed	6 / 9443 (0.06%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive Nephropathy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iga Nephropathy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	21 / 9443 (0.22%)	15 / 9451 (0.16%)
occurrences causally related to treatment / all	0 / 21	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy Toxic		
subjects affected / exposed	6 / 9443 (0.06%)	10 / 9451 (0.11%)
occurrences causally related to treatment / all	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrosclerosis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic Syndrome		

subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvi-Ureteric Obstruction		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postrenal Failure		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Artery Occlusion		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Artery Stenosis		
subjects affected / exposed	4 / 9443 (0.04%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Colic		
subjects affected / exposed	6 / 9443 (0.06%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Cyst		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Cyst Haemorrhage		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Disorder		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	6 / 9443 (0.06%)	8 / 9451 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Renal Haematoma		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Infarct		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Mass		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Pain		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Tubular Disorder		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Renal Tubular Necrosis		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Vein Thrombosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stress Urinary Incontinence		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteral Disorder		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric Stenosis		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral Stenosis		
subjects affected / exposed	0 / 9443 (0.00%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	15 / 9443 (0.16%)	12 / 9451 (0.13%)
occurrences causally related to treatment / all	0 / 15	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary Bladder Haemorrhage		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Incontinence			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Retention			
subjects affected / exposed	3 / 9443 (0.03%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	0 / 3	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Obstruction			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinoma			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urogenital Fistula			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenocortical Insufficiency Acute			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenocorticotrophic Hormone Deficiency		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Autoimmune Hypothyroidism		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basedow's Disease		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Goitre		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperthyroidism		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypothyroidism		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inappropriate Antidiuretic Hormone Secretion		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary Cyst		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Mass			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic Goitre			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic Nodular Goitre			
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Ankylosing Spondylitis			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	7 / 9443 (0.07%)	5 / 9451 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthrofibrosis			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	10 / 9443 (0.11%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Bone Cyst		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical Spinal Stenosis		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chondropathy		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Compartment Syndrome		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		
subjects affected / exposed	6 / 9443 (0.06%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's Contracture		
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Enthesopathy		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoroacetabular Impingement		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot Deformity		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty Arthritis		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral Disc Degeneration		
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral Disc Disorder		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral Disc Protrusion		
subjects affected / exposed	21 / 9443 (0.22%)	21 / 9451 (0.22%)
occurrences causally related to treatment / all	0 / 22	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Joint Effusion		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint Instability		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint Range Of Motion Decreased		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar Spinal Stenosis		
subjects affected / exposed	9 / 9443 (0.10%)	10 / 9451 (0.11%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscal Degeneration		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mobility Decreased		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle Necrosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle Spasms		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle Tightness		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular Weakness		

subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal Chest Pain		
subjects affected / exposed	35 / 9443 (0.37%)	24 / 9451 (0.25%)
occurrences causally related to treatment / all	1 / 44	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal Pain		
subjects affected / exposed	4 / 9443 (0.04%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	5 / 9443 (0.05%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 5	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Myopathy		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myositis		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck Pain		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathic Arthropathy		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteitis		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	46 / 9443 (0.49%)	50 / 9451 (0.53%)
occurrences causally related to treatment / all	0 / 51	0 / 54
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		
subjects affected / exposed	4 / 9443 (0.04%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteopenia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporotic Fracture		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pain In Extremity		
subjects affected / exposed	6 / 9443 (0.06%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological Fracture		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia Rheumatica		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudarthrosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic Arthropathy		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	7 / 9443 (0.07%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	4 / 7	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatic Fever		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	4 / 9443 (0.04%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator Cuff Syndrome		
subjects affected / exposed	8 / 9443 (0.08%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal Column Stenosis		
subjects affected / exposed	5 / 9443 (0.05%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal Disorder		

subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Ligament Ossification			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Osteoarthritis			
subjects affected / exposed	8 / 9443 (0.08%)	9 / 9451 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Pain			
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sympathetic Posterior Cervical Syndrome			
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial Cyst			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic Lupus Erythematosus			

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral Foraminal Stenosis			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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			
Abdominal Abscess			
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal Infection			
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Abdominal Sepsis			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Wall Abscess			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Limb			

subjects affected / exposed	4 / 9443 (0.04%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Acute Endocarditis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute Hepatitis C		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal Abscess		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Appendiceal Abscess		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	10 / 9443 (0.11%)	13 / 9451 (0.14%)
occurrences causally related to treatment / all	0 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis Perforated		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical Pneumonia		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial Infection		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial Prostatitis		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial Sepsis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary Sepsis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Bone Tuberculosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Borrelia Infection		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast Cellulitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiolitis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	17 / 9443 (0.18%)	16 / 9451 (0.17%)
occurrences causally related to treatment / all	1 / 21	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis Bacterial		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis Viral		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Brucellosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis Infective		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter Gastroenteritis		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Candida Sepsis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cellulitis		
subjects affected / exposed	37 / 9443 (0.39%)	32 / 9451 (0.34%)
occurrences causally related to treatment / all	1 / 40	0 / 35
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis Of Male External Genital Organ		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis Staphylococcal		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis Infective		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis Infective		
subjects affected / exposed	2 / 9443 (0.02%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	1 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Chronic Sinusitis		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Citrobacter Sepsis		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	3 / 9443 (0.03%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cutaneous Tuberculosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus Infection		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue Fever		
subjects affected / exposed	8 / 9443 (0.08%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dermo-Hypodermatitis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device Related Infection		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (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	5 / 9443 (0.05%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Gangrene		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	10 / 9443 (0.11%)	9 / 9451 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis Intestinal Haemorrhagic		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Endocarditis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Enterobacter Bacteraemia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal Bacteraemia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal Sepsis		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis Bacterial		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis Infectious		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (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	8 / 9443 (0.08%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	1 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia Pyelonephritis		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia Sepsis		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia Urinary Tract Infection		
subjects affected / exposed	3 / 9443 (0.03%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
External Ear Cellulitis		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder Empyema		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	6 / 9443 (0.06%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric Ulcer Helicobacter		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis Viral		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	25 / 9443 (0.26%)	26 / 9451 (0.28%)
occurrences causally related to treatment / all	0 / 25	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis Bacterial		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis Viral		
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Graft Infection		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Groin Abscess		
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemophilus Sepsis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hantaviral Infection		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter Gastritis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Amoebiasis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic Infection Bacterial		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes Virus Infection		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (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	0 / 9443 (0.00%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Iatrogenic Infection		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant Site Infection		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected Bite		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected Cyst		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected Skin Ulcer		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious Colitis		
subjects affected / exposed	4 / 9443 (0.04%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious Pleural Effusion		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective Exacerbation Of Chronic Obstructive Airways Disease		
subjects affected / exposed	7 / 9443 (0.07%)	11 / 9451 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 1
Influenza		
subjects affected / exposed	5 / 9443 (0.05%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Injection Site Cellulitis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella Bacteraemia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Labyrinthitis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Latent Tuberculosis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver Abscess		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Localised Infection		
subjects affected / exposed	5 / 9443 (0.05%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower Respiratory Tract Infection		
subjects affected / exposed	10 / 9443 (0.11%)	11 / 9451 (0.12%)
occurrences causally related to treatment / all	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Ludwig Angina		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Abscess		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Infection		

subjects affected / exposed	2 / 9443 (0.02%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lyme Disease		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mastitis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mastoiditis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical Device Site Infection		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis Aseptic		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningoencephalitis Bacterial		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic Sepsis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic Herpes Zoster		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oral Herpes		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	8 / 9443 (0.08%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 13	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis Acute		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis Chronic		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis Externa		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis Media		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis Media Acute		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreas Infection		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic Abscess		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic Inflammatory Disease		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perichondritis		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perihepatic Abscess		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal Abscess		

subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontitis		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital Cellulitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perirectal Abscess		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal Abscess		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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 / 9443 (0.02%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar Abscess		
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngolaryngeal Abscess		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pilonidal Cyst		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy Viral		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	108 / 9443 (1.14%)	96 / 9451 (1.02%)
occurrences causally related to treatment / all	1 / 123	0 / 98
deaths causally related to treatment / all	0 / 7	0 / 4
Pneumonia Bacterial		
subjects affected / exposed	3 / 9443 (0.03%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Chlamydial		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Escherichia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Haemophilus		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Influenzal		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Klebsiella		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Legionella		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Mycoplasma		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Pneumococcal		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Staphylococcal		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonia Streptococcal		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Viral		
subjects affected / exposed	3 / 9443 (0.03%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Cellulitis		

subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Infection		
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Pneumonia		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Sepsis		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post Viral Fatigue Syndrome		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	13 / 9443 (0.14%)	13 / 9451 (0.14%)
occurrences causally related to treatment / all	0 / 14	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 0
Proctitis Bacterial		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous Colitis		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonal Bacteraemia		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonal Sepsis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoas Abscess		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Sepsis		
subjects affected / exposed	1 / 9443 (0.01%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary Tuberculosis		
subjects affected / exposed	4 / 9443 (0.04%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Pyelonephritis		
subjects affected / exposed	9 / 9443 (0.10%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis Acute		
subjects affected / exposed	5 / 9443 (0.05%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis Chronic		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Abscess		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory Syncytial Virus Infection		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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		
subjects affected / exposed	4 / 9443 (0.04%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal Abscess		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scrub Typhus		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	35 / 9443 (0.37%)	20 / 9451 (0.21%)
occurrences causally related to treatment / all	0 / 38	0 / 20
deaths causally related to treatment / all	0 / 5	0 / 3
Septic Shock		
subjects affected / exposed	12 / 9443 (0.13%)	11 / 9451 (0.12%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 5	0 / 3
Sinusitis		
subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis Bacterial		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal Abscess		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal Bacteraemia		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal Osteomyelitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal Sepsis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal Bacteraemia		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal Endocarditis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal Sepsis		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous Abscess		

subjects affected / exposed	5 / 9443 (0.05%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic Infection		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth Abscess		
subjects affected / exposed	5 / 9443 (0.05%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic Shock Syndrome		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (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	9 / 9443 (0.10%)	7 / 9451 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Tuberculous Pleurisy		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethritis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary Tract Infection		
subjects affected / exposed	33 / 9443 (0.35%)	27 / 9451 (0.29%)
occurrences causally related to treatment / all	0 / 35	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary Tract Infection Bacterial		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary Tract Infection Enterococcal		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary Tract Infection Staphylococcal		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	10 / 9443 (0.11%)	16 / 9451 (0.17%)
occurrences causally related to treatment / all	0 / 11	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 1
Viral Cardiomyopathy		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular Neuritis		
subjects affected / exposed	3 / 9443 (0.03%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Viral Infection		
subjects affected / exposed	6 / 9443 (0.06%)	8 / 9451 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Viral Labyrinthitis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viral Myocarditis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viral Pericarditis		
subjects affected / exposed	1 / 9443 (0.01%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Viral Upper Respiratory Tract Infection		
subjects affected / exposed	2 / 9443 (0.02%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Visceral Leishmaniasis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vulval Abscess		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal Candidiasis			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Infection			
subjects affected / exposed	4 / 9443 (0.04%)	0 / 9451 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Infection Staphylococcal			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	13 / 9443 (0.14%)	13 / 9451 (0.14%)	
occurrences causally related to treatment / all	0 / 13	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus			
subjects affected / exposed	3 / 9443 (0.03%)	4 / 9451 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	16 / 9443 (0.17%)	20 / 9451 (0.21%)	
occurrences causally related to treatment / all	0 / 21	1 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Complication			
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Ketoacidosis			

subjects affected / exposed	9 / 9443 (0.10%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 13	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Ketosis		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Metabolic Decompensation		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte Imbalance		
subjects affected / exposed	0 / 9443 (0.00%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid Overload		
subjects affected / exposed	3 / 9443 (0.03%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid Retention		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	2 / 9443 (0.02%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperammonaemia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		

subjects affected / exposed	2 / 9443 (0.02%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	9 / 9443 (0.10%)	10 / 9451 (0.11%)
occurrences causally related to treatment / all	0 / 9	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic Hyperosmolar Nonketotic Syndrome		
subjects affected / exposed	4 / 9443 (0.04%)	2 / 9451 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperinsulinaemic Hypoglycaemia		
subjects affected / exposed	0 / 9443 (0.00%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	7 / 9443 (0.07%)	4 / 9451 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Hypernatraemia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertriglyceridaemia		
subjects affected / exposed	1 / 9443 (0.01%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperuricaemia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypervolaemia		

subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoalbuminaemia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (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	7 / 9443 (0.07%)	6 / 9451 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	10 / 9443 (0.11%)	8 / 9451 (0.08%)
occurrences causally related to treatment / all	0 / 12	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	1 / 9443 (0.01%)	2 / 9451 (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	8 / 9443 (0.08%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	2 / 9443 (0.02%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic Acidosis		

subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic Acidosis		
subjects affected / exposed	4 / 9443 (0.04%)	5 / 9451 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Metabolic Disorder		
subjects affected / exposed	1 / 9443 (0.01%)	0 / 9451 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic Syndrome		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		
subjects affected / exposed	6 / 9443 (0.06%)	3 / 9451 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Type 1 Diabetes Mellitus		
subjects affected / exposed	0 / 9443 (0.00%)	1 / 9451 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 Diabetes Mellitus		
subjects affected / exposed	36 / 9443 (0.38%)	37 / 9451 (0.39%)
occurrences causally related to treatment / all	0 / 36	1 / 37
deaths causally related to treatment / all	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo	Alirocumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2181 / 9443 (23.10%)	2203 / 9451 (23.31%)	
Investigations			
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	488 / 9443 (5.17%)	457 / 9451 (4.84%)	
occurrences (all)	560	521	
Vascular disorders			
Hypertension			
subjects affected / exposed	574 / 9443 (6.08%)	542 / 9451 (5.73%)	
occurrences (all)	678	600	
General disorders and administration site conditions			
Non-Cardiac Chest Pain			
subjects affected / exposed	462 / 9443 (4.89%)	481 / 9451 (5.09%)	
occurrences (all)	556	591	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	496 / 9443 (5.25%)	522 / 9451 (5.52%)	
occurrences (all)	563	591	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	532 / 9443 (5.63%)	567 / 9451 (6.00%)	
occurrences (all)	697	713	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 September 2012	<ul style="list-style-type: none">- Change in the wording of the exclusion criteria E07 and E23 for clarification purpose.- The waived CV efficacy endpoints (primary and secondary efficacy endpoints) were to be reported only in the specific outcome event screens of the electronic Case Report Form (e-CRF) and no longer required to also be reported in the AE screen, to avoid duplication of data.
05 December 2013	<ul style="list-style-type: none">- Update/clarifications in the definition of the efficacy endpoints.- Adjustment of some inclusion/exclusion criteria.- Run-in period: clarifications and simplifications provided.- Lipid monitoring and LMT post-randomization: adjustment/clarifications.- Clarification in safety (Serious Adverse Event) section and addition of analysis of CV events of interest related to peripheral artery disease (PAD) and venous thromboembolic events.
16 April 2015	<p>Based on the need to randomize at least 600 subjects in China for local regulatory purposes and since the Clinical Trial Application approval in China was delayed resulting in a late start of randomization, the closing of randomization was to be performed in 2 sequential steps.</p> <ul style="list-style-type: none">- First step was to close randomization in all countries except China shortly after a total of 18,000 subjects had been randomized globally.- Second step was to close randomization in China shortly after a total of 600 subjects had been randomized to China or at common study end date (CSED), whichever came first. <p>Neurologic and neurocognitive events were considered as adverse event of special interests (AESIs), and those events leading to additional examinations/procedures and/or referral to a specialist were considered as AESI with immediate notification and subject to expedited reporting (within 24 hours) to the Sponsor.</p>
25 February 2016	<p>To streamline the requirements for the end of the study: only one final visit, called the CSED visit, was to be performed for all randomized subjects, at the end of the study and within 30 days of the CSED. The additional follow-up contact that was initially planned to be performed 8 weeks after that visit for subjects still on study treatment at the time of the CSED was no longer required.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported