



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	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
-----------------------	----------

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
----------	---

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
------------------	---------------------------------------

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
-----------------------	---------

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
-----------------------	---------------------------------------

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
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
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
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
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
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
-----------------	---

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
----------------	-----------

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
-----------------------------------	--------------------------------------

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
-------------------	---

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
-----------------	---

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
----------------	-----------

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
-----------------------------------	--

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
-------------------	---

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
-----------------	--

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
----------------	-----------

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
----------------------------	-------------------------------------

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	= 0.0003 ^[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
-----------------	---

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
----------------	-----------

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
----------------------------	-----------------------

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	= 0.0003 ^[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
-----------------	---

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
----------------	-----------

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
-----------------	--

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
----------------	-----------

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
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
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
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
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
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
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
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
-----------------	---

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
-----------------	------------

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Placebo
-----------------------	---------

Reporting group description:

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

Reporting group title	Alirocumab
-----------------------	------------

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	
Gastrooesophageal 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 Phimosis			
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 Mycoplasmal			
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 Neuronitis			
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