Clinical trial results:
The ARRIVE Study (Aspirin to Reduce Risk of Initial Vascular Events) - A Randomized, Double-Blind, Placebo Controlled, Multicenter, Parallel Group Study to Assess the Efficacy (Reduction of Cardiovascular Disease Events) and Safety of 100 mg Enteric-Coated Acetylsalicylic Acid in Patients at Moderate Risk of Cardiovascular Disease

Summary

EudraCT number	2006-003622-29
Trial protocol	GB ES DE IE IT
Global end of trial date	15 November 2016

Results information

Result version number	v2 (current)
This version publication date	13 October 2018
First version publication date	26 November 2017
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	BAYE4465/12198

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00501059
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser-Wilhelm-Allee, D-51368 Leverkusen, Germany,
Public contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.com
Scientific contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.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	24 January 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 November 2016
Global end of trial reached?	Yes
Global end of trial date	15 November 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the clinical effect of a 100 mg/day enteric coated aspirin vs placebo in the reduction of CVD events in patients at moderate risk of CHD events (approx 10 - 20% 10 year-risk). This corresponds to a patient population mean 10-year CVD risk of approx 30% based on the underlying assumption at study start.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and the International Conference on Harmonization guideline E6: Good Clinical Practice. Before entering the study, the informed consent form was read by and explained to all subjects. Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 July 2007
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	Germany: 3050
Country: Number of subjects enrolled	Ireland: 112
Country: Number of subjects enrolled	Italy: 335
Country: Number of subjects enrolled	Poland: 3095
Country: Number of subjects enrolled	Spain: 412
Country: Number of subjects enrolled	United Kingdom: 5028
Country: Number of subjects enrolled	United States: 514
Worldwide total number of subjects	12546
EEA total number of subjects	12032

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	7029
From 65 to 84 years	5467
85 years and over	50

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 501 centers in 7 countries between 05 Jul 2007 (first subject first visit) and 15 Nov 2016 (last subject last visit).

Pre-assignment

Screening details:

Overall, 15823 subjects were screened. Of these, 3277 subjects were screening failures. The remaining 12546 subjects were randomized to treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Acetylsalicylic acid (Aspirin, BAYE4465)

Arm description:

Subjects received 1 tablet of enteric-coated acetylsalicylic acid [100 milligram (mg)] orally once daily.

Arm type	Experimental
Investigational medicinal product name	Enteric coated acetylsalicylic acid 100 mg tablets
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were instructed to take 1 tablet daily before meals with a large glass of water.

Arm title	Placebo

Arm description:

Subjects received 1 tablets of matching placebo orally once daily.

Arm type	Placebo
Investigational medicinal product name	Matching placebo tablets
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were instructed to take 1 tablet daily before meals with a large glass of water.

Number of subjects in period 1	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo
Started	6270	6276
Completed	4402	4384
Not completed	1868	1892
Consent withdrawn by subject	817	873
Reason not given	3	1
Non-compliant with study treatment	23	16
Insufficient therapeutic effect	4	5
Adverse Event	129	122
Clinical endpoint reached	110	123
Other	236	239
Death	140	137
Lost to follow-up	210	198
Missing end-of-study page	91	92
Not treated	25	17
Protocol deviation	80	69

Baseline characteristics

Reporting groups	
Reporting group title	Acetylsalicylic acid (Aspirin, BAYE4465)
Reporting group description:	
Subjects received 1 tablet of enteric-coated acetylsalicylic acid [100 milligram (mg)] orally once daily.	
Reporting group title	Placebo
Reporting group description:	
Subjects received 1 tablets of matching placebo orally once daily.	

Reporting group values	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo	Total
Number of subjects	6270	6276	12546
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	63.9	63.9	
standard deviation	± 7.1	± 7.05	-
Gender Categorical Units: Subjects			
Female	1851	1857	3708
Male	4419	4419	8838

End points

End points reporting groups

Reporting group title	Acetylsalicylic acid (Aspirin, BAYE4465)
Reporting group description:	
Subjects received 1 tablet of enteric-coated acetylsalicylic acid [100 milligram (mg)] orally once daily.	
Reporting group title	Placebo
Reporting group description:	
Subjects received 1 tablets of matching placebo orally once daily.	
Subject analysis set title	Intent-to-treat
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
The intent-to-treat (ITT) group (N=12546) consists of all patients who were randomized to the assigned study drug.	
Subject analysis set title	Per-protocol
Subject analysis set type	Per protocol
Subject analysis set description:	
Per-protocol (PP) group (N=7702) consists of all patients who had no protocol violation.	

Primary: Time to the first occurrence of the composite outcome of MI (myocardial infarction), stroke, cardiovascular death, UA (unstable angina) or TIA (transient ischemic attack)

End point title	Time to the first occurrence of the composite outcome of MI (myocardial infarction), stroke, cardiovascular death, UA (unstable angina) or TIA (transient ischemic attack)
End point description:	
The primary efficacy endpoint was a composite outcome consisting of the first occurrence of confirmed MI, stroke, cardiovascular death, UA, TIA. The time to event was defined as the number of days from the date of randomization to the date of the event confirmed by adjudication. The numbers of days for milestones when 1%, 2%, 3% and 4% of the subjects have reached endpoint events were estimated from Kaplan-Meier-Analyses.	
End point type	Primary
End point timeframe:	
Until follow-up (approximate 6 years)	

End point values	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6270[1]	6276[2]		
Units: days				
number (not applicable)				
Days until 1% subjects had an efficacy event	528	381		
Days until 2% subjects had an efficacy event	889	796		
Days until 3% subjects had an efficacy event	1225	1134		
Days until 4% subjects had an efficacy event	1630	1582		

Notes:
[1] - ITT
[2] - ITT

Statistical analyses

Statistical analysis title	Statistics for primary composite outcome

Statistical analysis description:

Primary efficacy analysis of time to the composite endpoint was conducted via a 2-sided log-rank test stratified for treatment, country, and sex. Results would be considered statistically significant and the primary objective of the study will have been met if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.597
Method	Logrank

Secondary: Time to the first occurrence of the composite outcome of cardiovascular death, MI, or stroke (ischemic, hemorrhagic, or unknown)

End point title	Time to the first occurrence of the composite outcome of cardiovascular death, MI, or stroke (ischemic, hemorrhagic, or unknown)

End point description:

The time to Composite outcome consisting of the first occurrence of cardiovascular death, MI, or stroke (ischemic, hemorrhagic, or unknown) was defined as the number of days from the date of randomization to the date of the event confirmed by adjudication. The numbers of days for milestones when 1%, 2%, 3% and 4% of the subjects have reached endpoint events were estimated from Kaplan-Meier-Analyses.

End point type	Secondary

End point timeframe:

Until follow-up (approximate 6 years)

End point values	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6270[3]	6276[4]		
Units: Days				
number (not applicable)				
Days until 1% subjects had an efficacy event	678	522		
Days until 2% subjects had an efficacy event	1167	1053		
Days until 3% subjects had an efficacy event	1599	1501		
Days until 4% subjects had an efficacy event	1949	1930		

Notes:
[3] - ITT
[4] - ITT

Statistical analyses

Statistical analysis title	Statistics for secondary composite outcome

Statistical analysis description:

Statistics for time to the composite endpoint was conducted via a 2-sided log-rank test stratified for treatment, country, and sex. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAYE4465)
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.6125
Method	Logrank

Secondary: Time to the first occurrence of the individual components of the primary: non-fatal MI, total MI, non-fatal stroke, total stroke, cardiovascular death, UA and TIA

End point title	Time to the first occurrence of the individual components of the primary: non-fatal MI, total MI, non-fatal stroke, total stroke, cardiovascular death, UA and TIA

End point description:

The time to event was defined as the number of days from the date of randomization to the date of the event confirmed by adjudication. The numbers of days for milestones when 1%, 2%, 3% and 4% of the subjects have reached endpoint events were estimated from Kaplan-Meier-Analyses. "99999" indicates not applicable (NA) because these milestones did not occur before completion of the study.

End point type	Secondary

End point timeframe:

Until follow-up (approximately 6 years)

End point values	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6270[5]	6276[6]		
Units: Days				
number (not applicable)				
Days until 1% subjects had non-fatal MI	1309	1085		
Days until 2% subjects had non-fatal MI	99999	2121		
Days until 1% subjects had total MI	1216	1014		
Days until 2% subjects had total MI	2128	1906		
Days until 1% subjects had non-fatal stroke	1576	1650		

Days until 2% subjects had non-fatal stroke	99999	99999		
Days until 1% subjects had total stroke	1543	1627		
Days until 2% subjects had total stroke	99999	99999		
Days until 1% subjects had cardiovascular death	99999	99999		
Days until 2% subjects had cardiovascular death	99999	99999		
Days until 1% subjects had UA	99999	99999		
Days until 2% subjects had UA	99999	99999		
Days until 1% subjects had TIA	99999	99999		
Days until 2% subjects had TIA	99999	99999		

Notes:

[5] - ITT

[6] - ITT

Statistical analyses

Statistical analysis title	Statistics for time to non-fatal MI

Statistical analysis description:

Statistics for time to non-fatal MI was conducted via a 2-sided log-rank test stratified for treatment, country, and sex. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4505
Method	Logrank

Statistical analysis title	Statistics for time to total MI

Statistical analysis description:

Statistics for time to total MI was conducted via a 2-sided log-rank test stratified for treatment, country, and sex. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.229
Method	Logrank

Statistical analysis title	Statistics for time to non-fatal stroke

Statistical analysis description:

Statistics for time to non-fatal stroke was conducted via a 2-sided log-rank test stratified for treatment, country, and sex. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAYE4465)

Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3947
Method	Logrank

Statistical analysis title	Statistics for time to total stroke

Statistical analysis description:

Statistics for time to total stroke was conducted via a 2-sided log-rank test stratified for treatment, country, and sex. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.5125
Method	Logrank

Secondary: Time to all-cause mortality, the first occurrence of all cancers excluding non-melanoma skin cancer (NMSC) and the first occurrence of colon cancer

End point title	Time to all-cause mortality, the first occurrence of all cancers excluding non-melanoma skin cancer (NMSC) and the first occurrence of colon cancer

End point description:

The time to event was defined as the number of days from the date of randomization to the date of the event confirmed by adjudication. The numbers of days for milestones when 1%, 2%, 3% and 4% of the subjects have reached endpoint events were estimated from Kaplan-Meier-Analyses. "99999" indicates not applicable (NA) because these milestones did not occur before completion of the study..

End point type	Secondary

End point timeframe:

Until follow-up (approximately 6 years)

End point values	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6270[7]	6276[8]		
Units: Days				
number (not applicable)				
Days until 1% subjects had all-cause mortality	838	938		
Days until 2% subjects had all-cause mortality	1493	1460		
Days until 3% subjects had all-cause mortality	1970	1963		
Days until 4% subjects had all-cause mortality	99999	99999		
Days until 1% subjects had all cancer excl. NMSC	374	420		

Days until 2% subjects had all cancer excl. NMSC	849	805		
Days until 3% subjects had all cancer excl. NMSC	1164	1276		
Days until 4% subjects had all cancer excl. NMSC	1542	1751		
Days until 1% subjects had colon cancer	99999	99999		
Days until 2% subjects had colon cancer	99999	99999		
Days until 3% subjects had colon cancer	99999	99999		
Days until 4% subjects had colon cancer	99999	99999		

Notes:

[7] - ITT

[8] - ITT

Statistical analyses

Statistical analysis title	Statistics for time to all-cause mortality

Statistical analysis description:

Analysis of time to all-cause mortality was conducted via a 2-sided log-rank test stratified for treatment, country, and sex. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.9544
Method	Logrank

Statistical analysis title	Statistics for time to 1st occurance colon cancer

Statistical analysis description:

Analysis of time to the first occurance colon cancer was conducted via a 2-sided log-rank test stratified for treatment, country, and sex. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.611
Method	Logrank

Statistical analysis title	Statistics for the first occurrence of all cancers

Statistical analysis description:

Analysis of time to the first occurrence of all cancers excluding non-melanoma skin cancer was conducted via a 2-sided log-rank test stratified for treatment, country, and sex. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo

Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4422
Method	Logrank

Secondary: Incidence of all-cause mortality, all cancers excluding non-melanoma skin cancer and colon cancer

End point title	Incidence of all-cause mortality, all cancers excluding non-melanoma skin cancer and colon cancer

End point description:

End point type	Secondary

End point timeframe:

Until follow-up (approximately 6 years)

End point values	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6270[9]	6276[10]		
Units: Percentage of subjects				
number (not applicable)				
all-cause mortality	2.55	2.57		
all cancers excluding non-melanoma skin cancer	4.02	3.76		
colon cancer	0.48	0.41		

Notes:

[9] - ITT

[10] - ITT

Statistical analyses

Statistical analysis title	Statistics for all-cause mortality

Statistical analysis description:

Analysis of incidence of all-cause mortality was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.9459
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.99

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.24

Secondary: Incidence of confirmed MI, stroke, cardiovascular death, UA and TIA separately

End point title	Incidence of confirmed MI, stroke, cardiovascular death, UA and TIA separately

End point description:

The percentages of subjects with the efficacy endpoints of confirmed MI, stroke, cardiovascular death, UA and TIA are reported separately. *all other CV death without fatal MI and fatal stroke

End point type	Secondary

End point timeframe:

Until follow-up (approximately 6 years)

End point values	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6270[11]	6276[12]		
Units: Percentage of subjects				
number (not applicable)				
MI	1.52	1.78		
stroke	1.20	1.07		
CV death*	0.61	0.62		
UA	0.32	0.32		
TIA	0.67	0.72		

Notes:

[11] - ITT

[12] - ITT

Statistical analyses

Statistical analysis title	Statistics for MI

Statistical analysis description:

Analysis of incidence of MI was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.2325
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.85

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.11

Statistical analysis title	Statistics for stroke

Statistical analysis description:

Analysis of incidence of stroke was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.5072
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.55

Statistical analysis title	Statistics for cardiovascular death

Statistical analysis description:

Analysis of incidence of cardiovascular death was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other[13]
P-value	= 0.901
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.52

Notes:

[13] - Analysis of incidence of cardiovascular death was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Statistical analysis title	Statistics for UA

Statistical analysis description:

Analysis of incidence of UA was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.9979
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.86

Statistical analysis title	Statistics for TIA

Statistical analysis description:

Analysis of incidence of TIA was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.7455
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.42

Other pre-specified: Number of subjects with adjudicated GI bleeding by severity

End point title	Number of subjects with adjudicated GI bleeding by severity

End point description:

End point type	Other pre-specified

End point timeframe:

Until follow-up (approximate 6 years)

End point values	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6270[14]	6276[15]		
Units: Subjects				
Total	61	29		
Mild	42	22		
Moderate	15	5		
Severe	4	2		

Notes:

[14] - ITT

[15] - ITT

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Incidence of Composite outcomes and non-fatal MI

End point title	Incidence of Composite outcomes and non-fatal MI

End point description:

End point type	Other pre-specified

End point timeframe:

Until follow-up (approximate 6 years)

End point values	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6270[16]	6276[17]		
Units: Percentage of subjects				
number (not applicable)				
MI, stroke, CV death, UA or TIA	4.29	4.48		
MI, stroke or CV death	3.32	3.47		
non-fatal MI	1.40	1.56		

Notes:

[16] - ITT

[17] - ITT

Statistical analyses

Statistical analysis title	Statistics for composite outcome

Statistical analysis description:

Analysis of incidence of composite outcome of MI, stroke, CV death, UA or TIA was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo

Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.6038
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.13

Statistical analysis title	Statistics for composite outcome
Statistical analysis description:	
Analysis of incidence of composite outcome of MI, stroke or CV death was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.	
Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.619
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.15

Statistical analysis title	Statistics for non-fatal MI
Statistical analysis description:	
Analysis of incidence of non-fatal MI was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.	
Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	12546
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4562
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.2

Other pre-specified: Incidence of Composite outcomes and individual outcomes in per-protocol population

End point title	Incidence of Composite outcomes and individual outcomes in per-protocol population

End point description:

*all other CV death without fatal MI and fatal stroke

End point type	Other pre-specified

End point timeframe:

Until follow-up (approximate 6 years)

End point values	Acetylsalicylic acid (Aspirin, BAYE4465)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3790[18]	3912[19]		
Units: Percentage of subjects				
number (not applicable)				
MI, stroke, CV death, UA or TIA	3.40	4.19		
MI, stroke or CV death	2.72	3.45		
MI	0.98	1.84		
Non-fatal MI	0.84	1.53		
Stroke	1.06	0.95		
CV death*	0.69	0.66		
UA	0.21	0.28		
TIA	0.50	0.49		
All-cause mortality	2.85	2.58		

Notes:

[18] - PP

[19] - PP

Statistical analyses

Statistical analysis title	Statistics for composite outcome

Statistical analysis description:

Analysis of incidence of composite outcome of MI, stroke, CV death, UA or TIA was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo

Number of subjects included in analysis	7702
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0756
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.02

Statistical analysis title	Statistics for composite outcome
Statistical analysis description:	
Analysis of incidence of composite outcome of MI, stroke or CV death was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.	
Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	7702
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0661
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.02

Statistical analysis title	Statistics for MI
Statistical analysis description:	
Analysis of incidence of MI was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.	
Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	7702
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0014
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.53

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	0.79

Statistical analysis title	Statistics for non-fatal MI

Statistical analysis description:

Analysis of incidence of non-fatal MI was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	7702
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0056
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	0.84

Statistical analysis title	Statistics for stroke

Statistical analysis description:

Analysis of incidence of stroke was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	7702
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.6291
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.75

Statistical analysis title	Statistics for CV death

Statistical analysis description:

Analysis of incidence of CV death was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	7702
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.9161
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1.77

Statistical analysis title	Statistics for UA

Statistical analysis description:

Analysis of incidence of UA was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	7702
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.538
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	1.87

Statistical analysis title	Statistics for TIA

Statistical analysis description:

Analysis of incidence of TIA was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	7702
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.9181
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	1.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	1.95

Statistical analysis title	Statistics for all-cause mortality

Statistical analysis description:

Analysis of incidence of all-cause mortality was conducted via a 2-sided log-rank test. Results would be considered statistically significant if the 2-sided P value is ≤0.05.

Comparison groups	Acetylsalicylic acid (Aspirin, BAYE4465) v Placebo
Number of subjects included in analysis	7702
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4796
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.45

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Until follow-up (approximately 6 years)	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	19
Reporting groups	
Reporting group title	Acetylsalicylic Acid
Reporting group description: Subjects received 1 tablet of enteric-coated acetylsalicylic acid [100 milligram (mg)] orally one daily.	
Reporting group title	Placebo
Reporting group description: Subjects received 1 tablet of matching placebo orally one daily.	

Serious adverse events	Acetylsalicylic Acid	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1266 / 6270 (20.19%)	1311 / 6276 (20.89%)	
number of deaths (all causes)	160	161	
number of deaths resulting from adverse events	81	78	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma of colon			

subjects affected / exposed	6 / 6270 (0.10%)	6 / 6276 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Adenolymphoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenoma benign			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal adenoma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal gland cancer metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adrenocortical carcinoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ameloblastoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical fibroxanthoma			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma stage IV			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
B-cell unclassifiable lymphoma high grade			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	2 / 6270 (0.03%)	7 / 6276 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basosquamous carcinoma of skin			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign anorectal neoplasm			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign lung neoplasm			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign mediastinal neoplasm			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of testis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of thyroid gland			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign ovarian tumour			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign salivary gland neoplasm			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (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	6 / 6270 (0.10%)	7 / 6276 (0.11%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder neoplasm			
subjects affected / exposed	4 / 6270 (0.06%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder papilloma			

subjects affected / exposed	3 / 6270 (0.05%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	9 / 6270 (0.14%)	10 / 6276 (0.16%)	
occurrences causally related to treatment / all	0 / 10	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma metastatic			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma stage I			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain cancer metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Brain neoplasm			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Brain neoplasm malignant			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Breast cancer			
subjects affected / exposed	10 / 6270 (0.16%)	7 / 6276 (0.11%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	4 / 6270 (0.06%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast neoplasm			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial carcinoma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid tumour of the caecum			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system lymphoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chondroma			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choroid melanoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			
subjects affected / exposed	4 / 6270 (0.06%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	2 / 6270 (0.03%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	14 / 6270 (0.22%)	6 / 6276 (0.10%)	
occurrences causally related to treatment / all	0 / 14	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 1	
Colon cancer metastatic			
subjects affected / exposed	4 / 6270 (0.06%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			

subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colorectal cancer metastatic			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Diffuse large B-cell lymphoma stage III			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extraskeletal myxoid chondrosarcoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibroma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal cancer metastatic			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal carcinoma			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stromal cancer			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal stromal tumour			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glottis carcinoma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic cancer metastatic			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hodgkin's disease			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insulinoma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial haemangioma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular melanoma			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	5 / 6270 (0.08%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			

subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leiomyoma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lentigo maligna			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lentigo maligna recurrent			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liposarcoma			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 0	
Lung adenocarcinoma metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Lung adenocarcinoma stage I			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	4 / 6270 (0.06%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Lung carcinoma cell type unspecified recurrent			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	10 / 6270 (0.16%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 10	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Lung squamous cell carcinoma metastatic			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangiosis carcinomatosa			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	9 / 6270 (0.14%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of ampulla of Vater			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of pleura metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of unknown primary site			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant nipple neoplasm			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant pleural effusion			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mantle cell lymphoma			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melanoma recurrent			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Meningioma			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma malignant			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to bone			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to liver			
subjects affected / exposed	4 / 6270 (0.06%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metastases to lung			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lymph nodes			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to pleura			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic bronchial carcinoma			
subjects affected / exposed	3 / 6270 (0.05%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Metastatic gastric cancer			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic malignant melanoma			
subjects affected / exposed	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic neoplasm			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic renal cell carcinoma			

subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mixed hepatocellular cholangiocarcinoma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myelodysplastic syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myxofibrosarcoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neoplasm malignant			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neoplasm prostate			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma of the skin			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurofibroma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 stage II			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	3 / 6270 (0.05%)	6 / 6276 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 2	
Non-small cell lung cancer stage IIIB			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer stage IV			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal adenocarcinoma			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal cancer metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			

subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal squamous cell carcinoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteosarcoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ovarian adenoma			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian epithelial cancer metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pancreatic carcinoma			
subjects affected / exposed	1 / 6270 (0.02%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 3	
Pancreatic carcinoma metastatic			

subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraproteinaemia			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
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	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary tumour benign			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pleural mesothelioma malignant			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Prostate cancer			

subjects affected / exposed	59 / 6270 (0.94%)	44 / 6276 (0.70%)	
occurrences causally related to treatment / all	0 / 59	0 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	4 / 6270 (0.06%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Prostate cancer recurrent			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage 0			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage I			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage III			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma			
subjects affected / exposed	5 / 6270 (0.08%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	2 / 6270 (0.03%)	6 / 6276 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			

subjects affected / exposed	2 / 6270 (0.03%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectosigmoid cancer			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	1 / 6270 (0.02%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal neoplasm			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			
subjects affected / exposed	1 / 6270 (0.02%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Small cell lung cancer metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue neoplasm			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			

subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
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 oral cavity			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Throat cancer			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thymoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid adenoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer metastatic			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Tongue cancer metastatic			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder adenoma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	2 / 6270 (0.03%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine neoplasm			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	10 / 6270 (0.16%)	6 / 6276 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 0	
Aortic dilatation			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic stenosis			
subjects affected / exposed	0 / 6270 (0.00%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial rupture			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bleeding varicose vein			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			
subjects affected / exposed	4 / 6270 (0.06%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 4	1 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	5 / 6270 (0.08%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granulomatosis with polyangiitis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	3 / 6270 (0.05%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	8 / 6270 (0.13%)	11 / 6276 (0.18%)	
occurrences causally related to treatment / all	0 / 10	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			

subjects affected / exposed	3 / 6270 (0.05%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labile hypertension			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leriche syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoedema			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant hypertension			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	5 / 6270 (0.08%)	12 / 6276 (0.19%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal arteritis			

subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosed varicose vein			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	5 / 6270 (0.08%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Arthrodesis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker insertion			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental operation			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Elbow operation			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			
subjects affected / exposed	3 / 6270 (0.05%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip surgery			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia repair			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation reduction			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty			
subjects affected / exposed	0 / 6270 (0.00%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee operation			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrectomy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotidectomy			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic operation			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Removal of internal fixation			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fusion surgery			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroidectomy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral prostatectomy			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanoplasty			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse repair			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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			
Chest discomfort			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	23 / 6270 (0.37%)	19 / 6276 (0.30%)	
occurrences causally related to treatment / all	0 / 24	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	3 / 6270 (0.05%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 3	
Feeling abnormal			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection site injury			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device pain			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	2 / 6270 (0.03%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 2	
Non-cardiac chest pain			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organ failure			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Performance status decreased			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Sudden death			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unevaluable event			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	10 / 6270 (0.16%)	20 / 6276 (0.32%)	
occurrences causally related to treatment / all	0 / 10	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast enlargement			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colpocele			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymal cyst			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Erectile dysfunction			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gynaecomastia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	0 / 6270 (0.00%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic cyst			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic disorder			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic obstruction			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatism			
subjects affected / exposed	4 / 6270 (0.06%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			

subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	4 / 6270 (0.06%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular disorder			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testis discomfort			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterovaginal prolapse			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haematoma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			

subjects affected / exposed	5 / 6270 (0.08%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asphyxia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Asthma			
subjects affected / exposed	2 / 6270 (0.03%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	8 / 6270 (0.13%)	9 / 6276 (0.14%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphonia			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	6 / 6270 (0.10%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	10 / 6270 (0.16%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	9 / 11	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	3 / 6270 (0.05%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Interstitial lung disease			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal oedema			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			

subjects affected / exposed	0 / 6270 (0.00%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinal cyst			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum deviation			
subjects affected / exposed	0 / 6270 (0.00%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal turbinate hypertrophy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal hypertrophy			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal oedema			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural calcification			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	4 / 6270 (0.06%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	3 / 6270 (0.05%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	4 / 6270 (0.06%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary cavitation			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	12 / 6270 (0.19%)	16 / 6276 (0.25%)	
occurrences causally related to treatment / all	1 / 12	0 / 16	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary fibrosis			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary haemorrhage			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary hypertension			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	4 / 6270 (0.06%)	6 / 6276 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord disorder			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord leukoplakia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 depressed mood			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agitated depression			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Alcohol withdrawal syndrome			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	3 / 6270 (0.05%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Confusional state			

subjects affected / exposed	6 / 6270 (0.10%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	3 / 6270 (0.05%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phobia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Withdrawal syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			

subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	2 / 6270 (0.03%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patient-device incompatibility			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Bile duct stone			
subjects affected / exposed	4 / 6270 (0.06%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary cirrhosis primary			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary cyst			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary fistula			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	13 / 6270 (0.21%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 13	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	7 / 6270 (0.11%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	24 / 6270 (0.38%)	17 / 6276 (0.27%)	
occurrences causally related to treatment / all	0 / 24	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder enlargement			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder perforation			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder polyp			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic pain			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatotoxicity			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Arteriogram coronary			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy prostate			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram abnormal			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic specific antigen increased			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Serum ferritin increased			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell count increased			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accident at work			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			

subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Anaemia postoperative			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	13 / 6270 (0.21%)	9 / 6276 (0.14%)	
occurrences causally related to treatment / all	0 / 13	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial bypass occlusion			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbon monoxide poisoning			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epicondylitis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid injury			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	0 / 6270 (0.00%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			

subjects affected / exposed	4 / 6270 (0.06%)	7 / 6276 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	3 / 6270 (0.05%)	9 / 6276 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	4 / 6270 (0.06%)	6 / 6276 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured ischium			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gas poisoning			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal anastomotic leak			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	5 / 6270 (0.08%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	2 / 6270 (0.03%)	11 / 6276 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ilium fracture			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site ulcer			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			

subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intentional overdose			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney contusion			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			
subjects affected / exposed	2 / 6270 (0.03%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			

subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	3 / 6270 (0.05%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	10 / 6270 (0.16%)	11 / 6276 (0.18%)	
occurrences causally related to treatment / all	0 / 10	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Muscle rupture			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post concussion syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural discharge			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural inflammation			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural myocardial infarction			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			

subjects affected / exposed	0 / 6270 (0.00%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	2 / 6270 (0.03%)	7 / 6276 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 6270 (0.00%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Scapula fracture			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fractured base			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			

subjects affected / exposed	0 / 6270 (0.00%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stab wound			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sternal fracture			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	6 / 6270 (0.10%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	2 / 6	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous haematoma			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	2 / 6270 (0.03%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	2 / 2	0 / 3	
deaths causally related to treatment / all	1 / 1	0 / 0	
Subdural haemorrhage			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Synovial rupture			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon injury			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	4 / 6270 (0.06%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	4 / 6270 (0.06%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
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 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uveitis-glaucoma-hyphaema syndrome			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft occlusion			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound complication			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			

Congenital cystic kidney disease			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital urinary tract obstruction			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Familial tremor			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial bridging			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Odontogenic cyst			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type IIa hyperlipidaemia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			

Acute coronary syndrome			
subjects affected / exposed	10 / 6270 (0.16%)	12 / 6276 (0.19%)	
occurrences causally related to treatment / all	0 / 10	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	43 / 6270 (0.69%)	58 / 6276 (0.92%)	
occurrences causally related to treatment / all	0 / 44	0 / 58	
deaths causally related to treatment / all	0 / 4	0 / 5	
Angina pectoris			
subjects affected / exposed	20 / 6270 (0.32%)	14 / 6276 (0.22%)	
occurrences causally related to treatment / all	0 / 20	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	15 / 6270 (0.24%)	19 / 6276 (0.30%)	
occurrences causally related to treatment / all	0 / 17	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve calcification			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease mixed			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			

subjects affected / exposed	1 / 6270 (0.02%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	3 / 6270 (0.05%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriospasm coronary			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	37 / 6270 (0.59%)	40 / 6276 (0.64%)	
occurrences causally related to treatment / all	0 / 39	0 / 41	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrial flutter			
subjects affected / exposed	2 / 6270 (0.03%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial thrombosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			

subjects affected / exposed	2 / 6270 (0.03%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	0 / 6270 (0.00%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	0 / 6270 (0.00%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block right			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	4 / 6270 (0.06%)	9 / 6276 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 5	
Cardiac disorder			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	7 / 6270 (0.11%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure acute			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure chronic			
subjects affected / exposed	0 / 6270 (0.00%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock			
subjects affected / exposed	3 / 6270 (0.05%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 1	
Cardiopulmonary failure			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Congestive cardiomyopathy			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	46 / 6270 (0.73%)	61 / 6276 (0.97%)	
occurrences causally related to treatment / all	0 / 46	0 / 63	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery thrombosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary ostial stenosis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dressler's syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrasystoles			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Left ventricular hypertrophy			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	1 / 6270 (0.02%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve prolapse			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial fibrosis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	29 / 6270 (0.46%)	38 / 6276 (0.61%)	
occurrences causally related to treatment / all	0 / 29	0 / 38	
deaths causally related to treatment / all	0 / 2	0 / 8	
Myocardial ischaemia			
subjects affected / exposed	7 / 6270 (0.11%)	10 / 6276 (0.16%)	
occurrences causally related to treatment / all	1 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Palpitations			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pleuropericarditis			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prinzmetal angina			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Silent myocardial infarction			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinoatrial block			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			

subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tachycardia paroxysmal			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade de pointes			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	2 / 6270 (0.03%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ventricular tachycardia			

subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia haemorrhage			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basilar artery aneurysm			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem infarction			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem stroke			

subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid arteriosclerosis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	5 / 6270 (0.08%)	9 / 6276 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery occlusion			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral circulatory failure			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	3 / 3	1 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cerebral infarction			
subjects affected / exposed	8 / 6270 (0.13%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	2 / 6270 (0.03%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	10 / 6270 (0.16%)	9 / 6276 (0.14%)	
occurrences causally related to treatment / all	0 / 10	1 / 9	
deaths causally related to treatment / all	0 / 2	0 / 1	
Cerebrovascular insufficiency			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical cord compression			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical myelopathy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complex partial seizures			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's type			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Demyelinating polyneuropathy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	1 / 6270 (0.02%)	6 / 6276 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic cerebral infarction			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Facial paresis			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			

subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	2 / 6270 (0.03%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	1 / 2	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Headache			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemianaesthesia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hypoaesthesia			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intercostal neuralgia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ischaemic stroke			
subjects affected / exposed	22 / 6270 (0.35%)	19 / 6276 (0.30%)	
occurrences causally related to treatment / all	0 / 22	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lacunar infarction			
subjects affected / exposed	6 / 6270 (0.10%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar stroke			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	4 / 6270 (0.06%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Morton's neuralgia			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Motor neurone disease			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myasthenia gravis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgic amyotrophy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurodegenerative disorder			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Orthostatic intolerance			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	1 / 6270 (0.02%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Quadriparesis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reversible ischaemic neurological deficit			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ruptured cerebral aneurysm			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	2 / 6270 (0.03%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal vascular disorder			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	7 / 6270 (0.11%)	12 / 6276 (0.19%)	
occurrences causally related to treatment / all	1 / 7	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic infarction			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			

subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	26 / 6270 (0.41%)	30 / 6276 (0.48%)	
occurrences causally related to treatment / all	0 / 27	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIIIth nerve lesion			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis cerebral			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual field defect			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wernicke's encephalopathy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Abdominal lymphadenopathy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	6 / 6270 (0.10%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	2 / 6	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic anaemia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			

subjects affected / exposed	3 / 6270 (0.05%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	3 / 3	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inner ear disorder			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	8 / 6270 (0.13%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chalazion			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal disorder			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine ophthalmopathy			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorder			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye haemorrhage			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid dermatochalasis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid ptosis			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	4 / 6270 (0.06%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacrimation increased			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular fibrosis			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular hole			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polypoidal choroidal vasculopathy			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			

subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	3 / 6270 (0.05%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal tear			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein thrombosis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strabismus			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	11 / 6270 (0.18%)	10 / 6276 (0.16%)	
occurrences causally related to treatment / all	1 / 11	4 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal haemorrhage			

subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's oesophagus			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Change of bowel habit			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon dysplasia			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	4 / 6270 (0.06%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal stenosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	1 / 1	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer perforation			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecaloma			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faeces discoloured			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral hernia			
subjects affected / exposed	0 / 6270 (0.00%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			

subjects affected / exposed	0 / 6270 (0.00%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Gastric polyps			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	4 / 6270 (0.06%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	3 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer perforation			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	2 / 6270 (0.03%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	1 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	13 / 6270 (0.21%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	11 / 13	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal obstruction			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	2 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic erosive gastritis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			

subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	4 / 6270 (0.06%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 6270 (0.00%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory bowel disease			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			

subjects affected / exposed	35 / 6270 (0.56%)	31 / 6276 (0.49%)	
occurrences causally related to treatment / all	0 / 35	0 / 32	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia strangulated			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal fibrosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal polyp			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal haemorrhage			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	3 / 6270 (0.05%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	4 / 6270 (0.06%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukoplakia oral			
subjects affected / exposed	3 / 6270 (0.05%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	3 / 6270 (0.05%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	2 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mechanical ileus			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	2 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric vein thrombosis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal achalasia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal obstruction			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer haemorrhage			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophagitis ulcerative			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral mucosal hypertrophy			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	5 / 6270 (0.08%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal fissure			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			

subjects affected / exposed	6 / 6270 (0.10%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	5 / 6	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	2 / 6270 (0.03%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	3 / 6270 (0.05%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis mesenteric vessel			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	5 / 6270 (0.08%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 6270 (0.02%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurodermatitis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parapsoriasis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Photosensitivity reaction			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prurigo			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinophyma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sebaceous hyperplasia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin discolouration			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swelling face			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	8 / 6270 (0.13%)	7 / 6276 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 1	
Bladder diverticulum			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck sclerosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder outlet obstruction			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder sphincter atony			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			
subjects affected / exposed	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	7 / 6270 (0.11%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	1 / 7	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incontinence			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower urinary tract symptoms			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			

subjects affected / exposed	6 / 6270 (0.10%)	7 / 6276 (0.11%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurogenic bladder			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pollakiuria			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prerenal failure			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	8 / 6270 (0.13%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst haemorrhage			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal haematoma			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral pain			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder haemorrhage			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	6 / 6270 (0.10%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urine flow decreased			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	6 / 6270 (0.10%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cyst			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 6270 (0.05%)	10 / 6276 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	6 / 6270 (0.10%)	6 / 6276 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	6 / 6270 (0.10%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	4 / 6270 (0.06%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's contracture			

subjects affected / exposed	3 / 6270 (0.05%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facet joint syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	3 / 6270 (0.05%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture nonunion			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin pain			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc compression			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			

subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	6 / 6270 (0.10%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	3 / 6270 (0.05%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscal degeneration			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mixed connective tissue disease			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle haemorrhage			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			

subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	104 / 6270 (1.66%)	103 / 6276 (1.64%)	
occurrences causally related to treatment / all	0 / 114	0 / 109	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondritis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporotic fracture			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patellofemoral pain syndrome			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arthritis			
subjects affected / exposed	2 / 6270 (0.03%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	4 / 6270 (0.06%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudarthrosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			

subjects affected / exposed	6 / 6270 (0.10%)	13 / 6276 (0.21%)	
occurrences causally related to treatment / all	0 / 6	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scoliosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	4 / 6270 (0.06%)	7 / 6276 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal deformity			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal disorder			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	2 / 6270 (0.03%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.00%)	2 / 6276 (0.03%)	
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 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal sepsis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula infection			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	9 / 6270 (0.14%)	9 / 6276 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	1 / 6270 (0.02%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone tuberculosis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			

subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	6 / 6270 (0.10%)	8 / 6276 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis orbital			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chlamydial infection			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic abscess			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			

subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (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	5 / 6270 (0.08%)	7 / 6276 (0.11%)	
occurrences causally related to treatment / all	1 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dural abscess			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis bacterial			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural abscess			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	6 / 6270 (0.10%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 6	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis norovirus			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			

subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter gastritis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster infection neurological			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster meningoencephalitis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
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 / 6270 (0.11%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 11	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labyrinthitis			

subjects affected / exposed	3 / 6270 (0.05%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	3 / 6270 (0.05%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis meningococcal			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis viral			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle abscess			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	0 / 6270 (0.00%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media chronic			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (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	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perihepatic abscess			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal abscess			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			

subjects affected / exposed	4 / 6270 (0.06%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar abscess			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillitis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pilonidal cyst			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural infection			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	26 / 6270 (0.41%)	19 / 6276 (0.30%)	
occurrences causally related to treatment / all	0 / 28	0 / 19	
deaths causally related to treatment / all	0 / 5	0 / 4	
Pneumonia bacterial			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia legionella			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomembranous colitis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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 / 6270 (0.00%)	1 / 6276 (0.02%)	
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 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelocystitis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			

subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal abscess			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	4 / 6270 (0.06%)	6 / 6276 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 0	
Septic shock			
subjects affected / exposed	0 / 6270 (0.00%)	3 / 6276 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sinusitis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			

subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdiaphragmatic abscess			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (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	0 / 6270 (0.00%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	9 / 6270 (0.14%)	7 / 6276 (0.11%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	2 / 6270 (0.03%)	4 / 6276 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	1 / 6270 (0.02%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Yersinia infection			

subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
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	4 / 6270 (0.06%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetes mellitus			
subjects affected / exposed	2 / 6270 (0.03%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid retention			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	2 / 6270 (0.03%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			

subjects affected / exposed	1 / 6270 (0.02%)	2 / 6276 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	1 / 6270 (0.02%)	0 / 6276 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	0 / 6270 (0.00%)	1 / 6276 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	8 / 6270 (0.13%)	5 / 6276 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Acetylsalicylic Acid	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5059 / 6270 (80.69%)	5053 / 6276 (80.51%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	478 / 6270 (7.62%)	514 / 6276 (8.19%)	
occurrences (all)	526	578	
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	374 / 6270 (5.96%)	362 / 6276 (5.77%)	
occurrences (all)	446	419	
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	442 / 6270 (7.05%)	497 / 6276 (7.92%)	
occurrences (all)	556	601	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	636 / 6270 (10.14%)	653 / 6276 (10.40%)	
occurrences (all)	816	803	
Back pain			
subjects affected / exposed	695 / 6270 (11.08%)	688 / 6276 (10.96%)	
occurrences (all)	897	908	
Osteoarthritis			
subjects affected / exposed	468 / 6270 (7.46%)	423 / 6276 (6.74%)	
occurrences (all)	548	517	
Pain in extremity			
subjects affected / exposed	354 / 6270 (5.65%)	359 / 6276 (5.72%)	
occurrences (all)	406	406	
Infections and infestations			
Bronchitis			
subjects affected / exposed	514 / 6270 (8.20%)	482 / 6276 (7.68%)	
occurrences (all)	741	680	
Lower respiratory tract infection			
subjects affected / exposed	377 / 6270 (6.01%)	420 / 6276 (6.69%)	
occurrences (all)	650	703	
Nasopharyngitis			
subjects affected / exposed	421 / 6270 (6.71%)	407 / 6276 (6.49%)	
occurrences (all)	550	524	
Upper respiratory tract infection			
subjects affected / exposed	348 / 6270 (5.55%)	371 / 6276 (5.91%)	
occurrences (all)	443	491	
Urinary tract infection			
subjects affected / exposed	363 / 6270 (5.79%)	321 / 6276 (5.11%)	
occurrences (all)	549	474	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 April 2008	Amendment #2: • Systolic blood pressure (SBP) limit of 170 mmHg has been added to the exclusion criteria • Exclusion of patients currently taking anticoagulant medication • A longer interval between the daily dose of study drug and ibuprofen • Revised wording in moderate risk definitions for coronary heart disease (CHD) and cerebrovascular disease (CVD): "To evaluate the clinical effects of a 100 mg/day enteric-coated acetylsalicylic acid versus placebo in the reduction of CVD events in patients at moderate risk of major CHD events (approximately 10 to 20% 10-year CHD risk; approximately 20 to 30% 10-year risk of CVD). This corresponds to a patient population mean 10-year CVD risk of approximately 30%."
02 January 2009	Amendment #3: • Increase in the number of allowed risk factors for males, age is no longer a risk factor
02 October 2013	Amendment #4: • The primary endpoint is changed to include confirmed UA and TIA. • The estimated event rate is changed to 1.5% per year due to new information. • Effect size (risk reduction) changed from 14.9% to 17 to 18%. • Achieving 60,000 person-years instead of 1488 primary endpoint events • Additional treatment and follow-up for a maximum of another 12 months. • Change to reduced adverse event and concomitant therapy reporting

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The reported analyses are limited to endpoint events that met strict criteria. Further blinded review of events is ongoing to identify endpoints based on pragmatic criteria. Interpretations for clinical decision making should await future reporting.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30158069