

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 April 2008	Amendment #2: <ul style="list-style-type: none">• 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: <ul style="list-style-type: none">• Increase in the number of allowed risk factors for males, age is no longer a risk factor
02 October 2013	Amendment #4: <ul style="list-style-type: none">• 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>