Clinical trial results:
An Observational Follow-Up Study for: A Phase III Randomized, Placebo-Controlled Clinical Trial to Assess the Safety and Efficacy of Odanacatib (MK-0822) to Reduce the Risk of Fracture in Osteoporotic Postmenopausal Women Treated With Vitamin D and Calcium (Protocol 018).

Summary

EudraCT number	2013-001526-26
Trial protocol	IT LT DE EE LV ES CZ PL BG DK HR
Global end of trial date	23 July 2016

Results information

Result version number	v1 (current)
This version publication date	19 May 2019
First version publication date	19 May 2019

Trial information

Trial identification

Sponsor protocol code	0822-083

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Merck Registration Number: MK-0822-083

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 July 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 July 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this observational follow-up study to MK-0822-018 was to collect follow-up safety information on participants who had discontinued from follow-up prior to reaching 5 years after randomization in study MK-0822-083.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 October 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 280
Country: Number of subjects enrolled	Belgium: 37
Country: Number of subjects enrolled	Brazil: 1611
Country: Number of subjects enrolled	Bulgaria: 220
Country: Number of subjects enrolled	Chile: 62
Country: Number of subjects enrolled	China: 610
Country: Number of subjects enrolled	Colombia: 1999
Country: Number of subjects enrolled	Croatia: 33
Country: Number of subjects enrolled	Czech Republic: 317
Country: Number of subjects enrolled	Denmark: 1048
Country: Number of subjects enrolled	Dominican Republic: 144
Country: Number of subjects enrolled	Estonia: 170
Country: Number of subjects enrolled	France: 42
Country: Number of subjects enrolled	Germany: 27
Country: Number of subjects enrolled	Guatemala: 293
Country: Number of subjects enrolled	Hong Kong: 211
Country: Number of subjects enrolled	Italy: 79
Country: Number of subjects enrolled	Japan: 454
Country: Number of subjects enrolled	Korea, Republic of: 194

Country: Number of subjects enrolled	Latvia: 53
Country: Number of subjects enrolled	Lithuania: 178
Country: Number of subjects enrolled	Mexico: 421
Country: Number of subjects enrolled	New Zealand: 86
Country: Number of subjects enrolled	Norway: 289
Country: Number of subjects enrolled	Peru: 603
Country: Number of subjects enrolled	Philippines: 116
Country: Number of subjects enrolled	Poland: 1171
Country: Number of subjects enrolled	Romania: 129
Country: Number of subjects enrolled	Russian Federation: 793
Country: Number of subjects enrolled	Serbia: 60
Country: Number of subjects enrolled	South Africa: 1129
Country: Number of subjects enrolled	Spain: 61
Country: Number of subjects enrolled	Switzerland: 27
Country: Number of subjects enrolled	Taiwan: 64
Country: Number of subjects enrolled	Ukraine: 84
Country: Number of subjects enrolled	United Kingdom: 1711
Country: Number of subjects enrolled	United States: 262
Country: Number of subjects enrolled	Australia: 3
Country: Number of subjects enrolled	India: 981
Country: Number of subjects enrolled	Lebanon: 19
Worldwide total number of subjects	16071
EEA total number of subjects	5565

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	12
From 65 to 84 years	15650
85 years and over	409

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Of 16,071 participants who received blinded study treatment during the MK-0822-018 base study and first extension, 2887 participants participated in observational follow-up study MK-0822-083. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension.

Period 1

Period 1 title	018 Base Study and First Extension
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Odanacatib (ODN) 50 mg Once Weekly

Arm description:

Participants receive 50 mg of blinded odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also receive 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.

Arm type	Experimental
Investigational medicinal product name	Vitamin D3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5600 IU (2 x 2800 IU tablets) administered orally, once weekly, open label

Investigational medicinal product name	Odanacatib (ODN)
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

50 mg tablet administered orally, once weekly

Arm title	Placebo Once Weekly

Arm description:

Participants received blinded placebo to 50 mg of odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also received 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.

Arm type	Placebo
Investigational medicinal product name	Vitamin D3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:	
5600 IU (2 x 2800 IU tablets) administered orally, once weekly, open label	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Placebo tablet to match ODN 50 mg tablet, administered orally, once weekly	

Number of subjects in period 1	Odanacatib (ODN) 50 mg Once Weekly	Placebo Once Weekly
Started	8043	8028
Completed	3640	2961
Not completed	4403	5067
Consent withdrawn by subject	1358	1254
Not Reported	46	67
Physician Decision	110	97
Adverse event, non-fatal	687	612
Completed Base Study, Did Not Enter 1st Extension	1795	2238
Final Disposition Unknown	-	1
Lost to follow-up	262	245
Protocol deviation	64	51
Lack of efficacy	81	502

Period 2

Period 2 title	-083 Observational Follow-Up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

No study medication was provided as part of this observational follow-up study. However, during this study, sponsor personnel, the study investigator, and the participant remained blinded to the study drug treatment received in MK-0822-018 (Base study and the first Extension study).

Arms

Are arms mutually exclusive?	Yes

Arm title	Formerly Received Odanacatib (ODN) 50 mg Once Weekly

Arm description:

Participants received no intervention during this study. However, participants in this arm had received 50 mg of ODN once weekly as part of the MK-0822-018 study.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Formerly Received Placebo 50 mg Once Weekly (No intervention)

Arm description:

Participants received no intervention during this study. However, participants in this arm had received placebo once weekly as part of the MK-0822-018 study.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2[1]	Formerly Received Odanacatib (ODN) 50 mg Once Weekly	Formerly Received Placebo 50 mg Once Weekly (No intervention)
Started	1181	1706
Completed	1162	1673
Not completed	19	33
Consent withdrawn by subject	2	8
Adverse event, non-fatal	7	10
Other Protocol Specified Criteria	2	2
Unknown: Disposition Record Did Not Exist	2	2
Lost to follow-up	6	11

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all participants from the 018 period were required or expected to enter the 083 period. The 083 period is an observational follow-up study for participants who did not complete 5 years of treatment in 018.

Baseline characteristics

Reporting groups	
Reporting group title	Odanacatib (ODN) 50 mg Once Weekly
Reporting group description:	
Participants receive 50 mg of blinded odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also receive 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.	
Reporting group title	Placebo Once Weekly
Reporting group description:	
Participants received blinded placebo to 50 mg of odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also received 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.	

Reporting group values	Odanacatib (ODN) 50 mg Once Weekly	Placebo Once Weekly	Total
Number of subjects	8043	8028	16071
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	6	12
From 65-84 years	7826	7824	15650
85 years and over	211	198	409
Age Continuous Units: years			
arithmetic mean	72.8	72.9	
standard deviation	± 5.4	± 5.3	-
Gender Categorical Units: Subjects			
Female	8043	8028	16071
Male	0	0	0
Race Units: Subjects			
American Indian Or Alaska Native	97	88	185
Asian	1421	1411	2832
Black Or African American	129	132	261
Multi-Racial	1867	1839	3706
Native Hawaiian Or Other Pacific Islander	1	1	2
White	4528	4557	9085

End points

End points reporting groups

Reporting group title	Odanacatib (ODN) 50 mg Once Weekly

Reporting group description:

Participants receive 50 mg of blinded odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also receive 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.

Reporting group title	Placebo Once Weekly

Reporting group description:

Participants received blinded placebo to 50 mg of odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also received 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.

Reporting group title	Formerly Received Odanacatib (ODN) 50 mg Once Weekly

Reporting group description:

Participants received no intervention during this study. However, participants in this arm had received 50 mg of ODN once weekly as part of the MK-0822-018 study.

Reporting group title	Formerly Received Placebo 50 mg Once Weekly (No intervention)

Reporting group description:

Participants received no intervention during this study. However, participants in this arm had received placebo once weekly as part of the MK-0822-018 study.

Subject analysis set title	Participants Who Had Received Odanacatib During the 018 Study
Subject analysis set type	Intention-to-treat

Subject analysis set description:

This set represents data collected on participants during the MK-0822-018 base and first extension study, combined with data collected during the MK-0822-083 observational followup study, inclusive of participants who participated in MK-0822-018 but did not later enroll in MK-0822-083. During the MK-0822-018 study, these participants received oadanacatib 50 mg once weekly.

Subject analysis set title	Participants Who Had Received Placebo During the 018 Study
Subject analysis set type	Intention-to-treat

Subject analysis set description:

This set represents data collected on participants during the MK-0822-018 base and first extension study, combined with data collected during the MK-0822-083 observational followup study, inclusive of participants who participated in MK-0822-018 but did not later enroll in MK-0822-083. During the MK-0822-018 study, these participants received placebo once weekly.

Primary: Number of Participants With Adverse Events (AEs) per 100 Patient-Years of Follow-up

End point title	Number of Participants With Adverse Events (AEs) per 100 Patient-Years of Follow-up

End point description:

The number of participants experiencing ≥1 AE per 100 patient-years of follow-up was presented. An AE was defined as any unfavorable and unintended sign, symptom, or disease (new or worsening) temporally associated with the use of study therapy, regardless of whether or not a causal relationship with the study therapy could be determined. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.

End point type	Primary

End point timeframe:

Up to approximately 90 months

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	92.11 (89.98 to 94.27)	91.42 (89.31 to 93.57)		

Statistical analyses

Statistical analysis title	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.33
upper limit	3.7

Primary: Number of Participants With Serious AEs per 100 Patient-Years of Follow-up

End point title	Number of Participants With Serious AEs per 100 Patient-Years of Follow-up
End point description:	
The number of participants with serious adverse events per 100 patient-years of follow-up was presented. An AE was defined as any unfavorable and unintended sign, symptom, or disease (new or worsening) temporally associated with the use of study therapy, regardless of whether or not a causal relationship with the study therapy could be determined. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe:	
Up to approximately 90 months	

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	9.27 (8.91 to 9.64)	9.39 (9.03 to 9.76)		

Statistical analyses

Statistical analysis title	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.63
upper limit	0.4

Primary: Number of Participants With AEs Leading to Death per 100 Patient-Years of Follow-up

End point title	Number of Participants With AEs Leading to Death per 100 Patient-Years of Follow-up
End point description:	
The number of participants with adverse events that led to death per 100 patient-years of follow-up was presented. An AE was defined as any unfavorable and unintended sign, symptom, or disease (new or worsening) temporally associated with the use of study therapy, regardless of whether or not a causal relationship with the study therapy could be determined. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe:	
Up to approximately 90 months	

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	1.19 (1.07 to 1.31)	1.04 (0.93 to 1.16)		

Statistical analyses

Statistical analysis title	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	0.31

Primary: Number of Participants With an Atypical Femoral Shaft Fracture Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With an Atypical Femoral Shaft Fracture Confirmed by Adjudication per 100 Patient-Years of Follow-up
End point description:	
The number of participants with an atypical femoral shaft fractures confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe:	
Up to 90 months	

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.03 (0.01 to 0.06)	0.00 (0.00 to 0.01)		

Statistical analyses

Statistical analysis title	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	0.06

Primary: Number of Participants With Cerebrovascular Events Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Cerebrovascular Events Confirmed by Adjudication per 100 Patient-Years of Follow-up
End point description:	
The number of participants with cerebrovascular events confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe:	
Up to approximately 90 months	

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.45 (0.38 to 0.53)	0.38 (0.31 to 0.45)		

Statistical analyses

Statistical analysis title	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.02
upper limit	0.18

Primary: Number of Participants With Cardiovascular Events Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Cardiovascular Events Confirmed by Adjudication per 100 Patient-Years of Follow-up
End point description:	
The number of participants with cardiovascular events confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe:	
Up to approximately 90 months	

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.92 (0.82 to 1.03)	0.86 (0.76 to 0.97)		

Statistical analyses

Statistical analysis title	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.08
upper limit	0.21

Primary: Number of Participants With Skin Adverse Events (AEs) reported as an Event of Clinical Interest per 100 Patient-Years of Follow-up

End point title	Number of Participants With Skin Adverse Events (AEs) reported as an Event of Clinical Interest per 100 Patient-Years of Follow-up

End point description:

The number of participants with skin AEs reported as events of clinical interest (ECI) per 100 patient-years of follow-up was presented. Protocol pre-specifed skin AEs considered ECIs included all serious skin AEs, severe skin AEs, or skin AEs with skin thickening and hardening suggestive of morphea or systemic sclerosis (scleroderma). An AE was defined as any unfavorable and unintended sign, symptom, or disease (new or worsening) temporally associated with the use of study therapy, regardless of whether or not a causal relationship with the study therapy could be determined. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.

End point type	Primary

End point timeframe:

Up to approximately 90 months

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.15 (0.11 to 0.20)	0.15 (0.11 to 0.19)		

Statistical analyses

Statistical analysis title	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.05
upper limit	0.07

Primary: Number of Participants With Serious Respiratory Infections Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Serious Respiratory Infections Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point description:

The number of participants with serious respiratory infections confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.

End point type	Primary

End point timeframe:

Up to approximately 90 months

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.41 (0.34 to 0.48)	0.48 (0.41 to 0.56)		

Statistical analyses

Statistical analysis title	Difference in Rates
Statistical analysis description: Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.03

Primary: Number of Participants With Osteonecrosis of the Jaw Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Osteonecrosis of the Jaw Confirmed by Adjudication per 100 Patient-Years of Follow-up[1]
End point description: The number of participants with osteonecrosis of the jaw confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe: Up to approximately 90 months	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis plan stipulated that if osteonecrosis of the jaw occurred in less than 4 participants in a treatment group, then only estimates within each treatment group would be presented. Therefore, per the plan, no statistical analysis is presented.

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8038		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.00 (0.00 to 0.01)	0.00 (0.00 to 0.01)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Morphea or Systemic Scleroses Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Morphea or Systemic Scleroses Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point description:

The number of participants with morphea or systemic sclerosis confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.

End point type	Primary

End point timeframe:

Up to approximately 90 months

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.05 (0.03 to 0.08)	0.01 (0.00 to 0.03)		

Statistical analyses

Statistical analysis title	Difference in Rates
Statistical analysis description: Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.01
upper limit	0.06

Primary: Number of Participants With Delayed Fracture Unions Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Delayed Fracture Unions Confirmed by Adjudication per 100 Patient-Years of Follow-up
End point description: The number of participants with delayed fracture unions confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. Participants who received ≥1 dose of study treatment during the MK-0822-018 base study, and who had a fracture confirmed by adjudication during the MK-0822-018 base or first extension study, were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe: Up to approximately 90 months	

End point values	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.73 (0.44 to 1.13)	0.56 (0.34 to 0.88)		

Statistical analyses

Statistical analysis title	Difference in Rates
Statistical analysis description: Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0.62

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 90 months

Adverse event reporting additional description:

AEs reported on follow-up arms of this study were pooled and analyzed with AEs from the respective treatment arms of the MK-0822-018 base study and first extension.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Participants Who Had Received Placebo During the 018 Study

Reporting group description:

This set represents data collected on participants during the MK-0822-018 base and first extension study, combined with data collected during the MK-0822-083 observational followup study, inclusive of participants who participated in MK-0822-018 but did not later enroll in MK-0822-083. During the MK-0822-018 study, these participants received placebo once weekly.

Reporting group title	Participants Who Had Received Odanacatib During the 018 Study

Reporting group description:

This set represents data collected on participants during the MK-0822-018 base and first extension study, combined with data collected during the MK-0822-083 observational followup study, inclusive of participants who participated in MK-0822-018 but did not later enroll in MK-0822-083. During the MK-0822-018 study, these participants received oadanacatib 50 mg once weekly.

Serious adverse events	Participants Who Had Received Placebo During the 018 Study	Participants Who Had Received Odanacatib During the 018 Study	
Total subjects affected by serious adverse events			
subjects affected / exposed	2566 / 8028 (31.96%)	2528 / 8043 (31.43%)	
number of deaths (all causes)	341	388	
number of deaths resulting from adverse events	1	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	7 / 8028 (0.09%)	11 / 8043 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 2	
Angiosarcoma metastatic			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	76 / 8028 (0.95%)	83 / 8043 (1.03%)	
occurrences causally related to treatment / all	0 / 92	0 / 98	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	33 / 8028 (0.41%)	35 / 8043 (0.44%)	
occurrences causally related to treatment / all	0 / 33	0 / 35	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colon cancer			
subjects affected / exposed	17 / 8028 (0.21%)	24 / 8043 (0.30%)	
occurrences causally related to treatment / all	0 / 17	0 / 24	
deaths causally related to treatment / all	0 / 3	0 / 2	
Colorectal cancer			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal carcinoma			

subjects affected / exposed	5 / 8028 (0.06%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	8 / 8028 (0.10%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratoacanthoma			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	4 / 8028 (0.05%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lung			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to lymph nodes			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine tumour			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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			

subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ovarian cancer			
subjects affected / exposed	4 / 8028 (0.05%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 4	1 / 8	
deaths causally related to treatment / all	0 / 2	0 / 2	
Ovarian epithelial cancer			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pancreatic carcinoma			
subjects affected / exposed	9 / 8028 (0.11%)	14 / 8043 (0.17%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 6	0 / 8	
Plasma cell myeloma			
subjects affected / exposed	6 / 8028 (0.07%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenoma			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland cancer			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin cancer			
subjects affected / exposed	7 / 8028 (0.09%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			

subjects affected / exposed	13 / 8028 (0.16%)	14 / 8043 (0.17%)	
occurrences causally related to treatment / all	0 / 13	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 1	
Squamous cell carcinoma of skin			
subjects affected / exposed	11 / 8028 (0.14%)	18 / 8043 (0.22%)	
occurrences causally related to treatment / all	0 / 11	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	5 / 8028 (0.06%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid neoplasm			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute leukaemia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Adenocarcinoma gastric			
subjects affected / exposed	5 / 8028 (0.06%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 2	
Adenocarcinoma of the cervix			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal cancer			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiosarcoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Benign breast neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign gastric neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign lung neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign muscle neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 bladder			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign salivary gland neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign vulval neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct cancer			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Bladder neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone cancer			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone neoplasm			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Borderline mucinous tumour of ovary			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	6 / 8028 (0.07%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain cancer metastatic			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cancer in situ			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Breast cancer recurrent			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage III			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial carcinoma			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchioloalveolar carcinoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid tumour of the stomach			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoma in situ of skin			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar tumour			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellopontine angle tumour			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix cancer metastatic			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cervix carcinoma			
subjects affected / exposed	3 / 8028 (0.04%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix carcinoma stage II			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Choroid melanoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell endometrial carcinoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer metastatic			
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Colon neoplasm			
subjects affected / exposed	4 / 8028 (0.05%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colorectal cancer recurrent			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysplastic naevus			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer			
subjects affected / exposed	0 / 8028 (0.00%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential thrombocythaemia			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fallopian tube cancer			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female reproductive neoplasm			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Fibroadenoma of breast			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibromatosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicle centre lymphoma, follicular grade I, II, III stage II			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder adenocarcinoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gallbladder cancer			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	1 / 2	0 / 3	
deaths causally related to treatment / all	1 / 1	0 / 2	
Gastric cancer			
subjects affected / exposed	6 / 8028 (0.07%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 3	0 / 2	
Gastric cancer stage IV			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastric neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stromal tumour			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingival cancer			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Glioblastoma multiforme			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomus tumour			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma of bone			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	4 / 8028 (0.05%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 4	
Hepatic neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Inflammatory carcinoma of the breast			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intraductal papilloma of breast			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular melanoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive lobular breast carcinoma			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kaposi's sarcoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leiomyoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leiomyosarcoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lentigo maligna			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lip and/or oral cavity cancer			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liposarcoma			
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lobular breast carcinoma in situ			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	1 / 8028 (0.01%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 4	
Lung adenocarcinoma stage I			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma stage IV			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung cancer metastatic			
subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	23 / 8028 (0.29%)	13 / 8043 (0.16%)	
occurrences causally related to treatment / all	0 / 24	0 / 13	
deaths causally related to treatment / all	0 / 5	0 / 6	
Lymphangioma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoma			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lymphoproliferative disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma in situ			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of ampulla of Vater			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 eyelid			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of renal pelvis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant neoplasm of unknown primary site			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Malignant neoplasm progression			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mantle cell lymphoma			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medullary thyroid cancer			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melanocytic naevus			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melanoma recurrent			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Mesothelioma malignant			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metaplastic breast carcinoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to central nervous system			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metastases to peritoneum			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to pleura			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to skin			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastasis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic bronchial carcinoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic gastric cancer			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic neoplasm			

subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 3	
Metastatic salivary gland cancer			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic uterine cancer			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucinous breast carcinoma			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycosis fungoides			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome transformation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myeloproliferative disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal cavity cancer			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nasal neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngeal cancer			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Neuroendocrine carcinoma			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neuroendocrine carcinoma metastatic			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer metastatic			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-small cell lung cancer stage IV			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal adenocarcinoma			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Oesophageal carcinoma			
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 3	2 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Oesophageal squamous cell carcinoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oligodendroglioma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal cancer			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Osteoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteosarcoma			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ovarian adenoma			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer metastatic			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ovarian epithelial cancer stage I			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma metastatic			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Pancreatic carcinoma stage IV			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic neoplasm			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Papillary serous endometrial carcinoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			

subjects affected / exposed	5 / 8028 (0.06%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papilloma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid tumour benign			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic neoplasm			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal mesothelioma malignant			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal cancer			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmacytoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Rectal cancer			

subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal neoplasm			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Refractory anaemia with an excess of blasts			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Refractory cytopenia with unilineage dysplasia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	5 / 8028 (0.06%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma stage II			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal oncocytoma			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal cancer			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Schwannoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seborrhoeic keratosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			
subjects affected / exposed	1 / 8028 (0.01%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 4	
Small cell lung cancer limited stage			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue neoplasm			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord neoplasm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Splenic marginal zone lymphoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 lung			
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the cervix			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

T-cell lymphoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Thymoma malignant			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer metastatic			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ureteric cancer			

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral cancer			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	2 / 8028 (0.02%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine neoplasm			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer stage 0			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	10 / 8028 (0.12%)	17 / 8043 (0.21%)	
occurrences causally related to treatment / all	0 / 10	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypertension			

subjects affected / exposed	41 / 8028 (0.51%)	32 / 8043 (0.40%)	
occurrences causally related to treatment / all	0 / 43	1 / 36	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertensive emergency			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	3 / 8028 (0.04%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accelerated hypertension			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	4 / 8028 (0.05%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic aneurysm rupture			

subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Aortic arteriosclerosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arterial disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stenosis			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	2 / 8028 (0.02%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 1	
Bleeding varicose vein			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure fluctuation			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.05%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Distributive shock			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Essential hypertension			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Femoral artery occlusion			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	0 / 8028 (0.00%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hot flush			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			

subjects affected / exposed	20 / 8028 (0.25%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 21	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypotension			
subjects affected / exposed	3 / 8028 (0.04%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypovolaemic shock			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Iliac artery occlusion			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infarction			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant hypertension			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	4 / 8028 (0.05%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			

subjects affected / exposed	5 / 8028 (0.06%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral circulatory failure			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Subgaleal haematoma			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal arteritis			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	4 / 8028 (0.05%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose ulceration			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adverse event			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	26 / 8028 (0.32%)	22 / 8043 (0.27%)	
occurrences causally related to treatment / all	0 / 27	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	67 / 8028 (0.83%)	67 / 8043 (0.83%)	
occurrences causally related to treatment / all	0 / 67	0 / 67	
deaths causally related to treatment / all	0 / 67	0 / 67	
Device battery issue			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	5 / 8028 (0.06%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	7 / 8028 (0.09%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental death			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 2	
Asthenia			
subjects affected / exposed	3 / 8028 (0.04%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 3	
Capsular contracture associated with breast implant			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device adhesion issue			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device breakage			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device damage			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device material issue			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug intolerance			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug withdrawal syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial pain			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General symptom			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ill-defined disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Impaired healing			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site reaction			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device complication			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Multi-organ failure			
subjects affected / exposed	6 / 8028 (0.07%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 6	0 / 9	
Nodule			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			

subjects affected / exposed	0 / 8028 (0.00%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral administration complication			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	7 / 8028 (0.09%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue inflammation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated hernia			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	2 / 8028 (0.02%)	15 / 8043 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 15	
deaths causally related to treatment / all	0 / 2	0 / 15	
Systemic inflammatory response syndrome			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Immobile			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
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			
Endometrial atrophy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ovarian cyst			
subjects affected / exposed	6 / 8028 (0.07%)	12 / 8043 (0.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic floor muscle weakness			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	15 / 8028 (0.19%)	15 / 8043 (0.19%)	
occurrences causally related to treatment / all	0 / 16	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexa uteri mass			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexal torsion			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anisomastia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast mass			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical leukoplakia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical polyp			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	2 / 8028 (0.02%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysfunctional uterine bleeding			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital prolapse			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metrorrhagia			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic pain			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic prolapse			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal fistula			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	10 / 8028 (0.12%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval leukoplakia			

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvar dysplasia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal pruritus			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	19 / 8028 (0.24%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 24	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	38 / 8028 (0.47%)	36 / 8043 (0.45%)	
occurrences causally related to treatment / all	0 / 49	0 / 47	
deaths causally related to treatment / all	0 / 4	0 / 5	
Nasal polyps			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal cyst			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	10 / 8028 (0.12%)	13 / 8043 (0.16%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 2	0 / 2	
Pulmonary embolism			

subjects affected / exposed	28 / 8028 (0.35%)	31 / 8043 (0.39%)	
occurrences causally related to treatment / all	0 / 31	0 / 32	
deaths causally related to treatment / all	0 / 9	0 / 7	
Pulmonary hypertension			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	7 / 8028 (0.09%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Respiratory distress			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory failure			
subjects affected / exposed	10 / 8028 (0.12%)	14 / 8043 (0.17%)	
occurrences causally related to treatment / all	0 / 10	0 / 15	
deaths causally related to treatment / all	0 / 6	0 / 8	
Acute pulmonary oedema			
subjects affected / exposed	9 / 8028 (0.11%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 4	0 / 1	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute respiratory failure			

subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 3	0 / 3	
Aspiration			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthmatic crisis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	5 / 8028 (0.06%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Bronchitis chronic			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.07%)	6 / 8043 (0.07%)	
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 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophilic pneumonia chronic			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottic cyst			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	2 / 8028 (0.02%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Laryngeal granuloma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal polyp			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung consolidation			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Mediastinal cyst			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum deviation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophagobronchial fistula			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal pouch			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pickwickian syndrome			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	5 / 8028 (0.06%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 3	
Pneumonitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumothorax			

subjects affected / exposed	3 / 8028 (0.04%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 1	
Pulmonary arteriopathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary fibrosis			
subjects affected / exposed	4 / 8028 (0.05%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 4	
Pulmonary ossification			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary thrombosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Respiratory disorder			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract inflammation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus polyp degeneration			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Throat irritation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal stenosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder due to a general medical condition			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	3 / 8028 (0.04%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	10 / 8028 (0.12%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	1 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysthymic disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphemia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			

subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mood disorder due to a general medical condition			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic attack			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychogenic pain disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood pressure increased			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram abnormal			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Grip strength decreased			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate irregular			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	21 / 8028 (0.26%)	13 / 8043 (0.16%)	
occurrences causally related to treatment / all	0 / 25	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	8 / 8028 (0.10%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Contusion			

subjects affected / exposed	16 / 8028 (0.20%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 19	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Femoral neck fracture			
subjects affected / exposed	66 / 8028 (0.82%)	36 / 8043 (0.45%)	
occurrences causally related to treatment / all	0 / 70	0 / 36	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	42 / 8028 (0.52%)	46 / 8043 (0.57%)	
occurrences causally related to treatment / all	0 / 43	1 / 51	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	12 / 8028 (0.15%)	11 / 8043 (0.14%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	11 / 8028 (0.14%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 11	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	5 / 8028 (0.06%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured sacrum			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	13 / 8028 (0.16%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	0 / 13	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Heat stroke			

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	114 / 8028 (1.42%)	61 / 8043 (0.76%)	
occurrences causally related to treatment / all	0 / 115	0 / 62	
deaths causally related to treatment / all	0 / 1	0 / 0	
Humerus fracture			
subjects affected / exposed	51 / 8028 (0.64%)	30 / 8043 (0.37%)	
occurrences causally related to treatment / all	0 / 51	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliotibial band syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	7 / 8028 (0.09%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			
subjects affected / exposed	4 / 8028 (0.05%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			

subjects affected / exposed	27 / 8028 (0.34%)	16 / 8043 (0.20%)	
occurrences causally related to treatment / all	0 / 29	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 1	
Meniscus injury			
subjects affected / exposed	3 / 8028 (0.04%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic fracture			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pubis fracture			
subjects affected / exposed	10 / 8028 (0.12%)	11 / 8043 (0.14%)	
occurrences causally related to treatment / all	0 / 10	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	81 / 8028 (1.01%)	71 / 8043 (0.88%)	
occurrences causally related to treatment / all	0 / 83	0 / 73	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	6 / 8028 (0.07%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	28 / 8028 (0.35%)	13 / 8043 (0.16%)	
occurrences causally related to treatment / all	0 / 33	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			

subjects affected / exposed	23 / 8028 (0.29%)	13 / 8043 (0.16%)	
occurrences causally related to treatment / all	0 / 23	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	28 / 8028 (0.35%)	17 / 8043 (0.21%)	
occurrences causally related to treatment / all	0 / 28	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	7 / 8028 (0.09%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract stoma complication			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	4 / 8028 (0.05%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wound dehiscence			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal bite			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic injury			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arterial injury			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial restenosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod bite			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back injury			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder injury			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone fissure			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve rupture			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chillblains			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Comminuted fracture			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compression fracture			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	8 / 8028 (0.10%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug dispensing error			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural haematoma			

subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Face injury			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	2 / 8028 (0.02%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture displacement			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun shot wound			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hand fracture			
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heat exhaustion			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heat illness			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Jaw fracture			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb crushing injury			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb traumatic amputation			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth injury			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Muscle injury			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle strain			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	11 / 8028 (0.14%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal injury			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Post procedural discomfort			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural fistula			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural inflammation			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural oedema			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative adhesion			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative hernia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative respiratory failure			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural nausea			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary contusion			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	10 / 8028 (0.12%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 10	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Road traffic accident			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Scapula fracture			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scar			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin abrasion			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fractured base			
subjects affected / exposed	0 / 8028 (0.00%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue injury			

subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column injury			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Spinal compression fracture			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury cervical			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Splenic rupture			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sternal injury			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous haematoma			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			

subjects affected / exposed	5 / 8028 (0.06%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial rupture			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.01%)	0 / 8043 (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	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic shock			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulnar nerve injury			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular injury			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 8028 (0.00%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			

subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital bronchiectasis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital cystic kidney disease			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exomphalos			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	59 / 8028 (0.73%)	56 / 8043 (0.70%)	
occurrences causally related to treatment / all	0 / 64	2 / 58	
deaths causally related to treatment / all	0 / 14	0 / 16	
Angina pectoris			
subjects affected / exposed	44 / 8028 (0.55%)	40 / 8043 (0.50%)	
occurrences causally related to treatment / all	0 / 47	0 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	8 / 8028 (0.10%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Arrhythmia supraventricular			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	85 / 8028 (1.06%)	76 / 8043 (0.94%)	
occurrences causally related to treatment / all	0 / 104	0 / 89	
deaths causally related to treatment / all	0 / 3	0 / 2	
Atrial flutter			
subjects affected / exposed	7 / 8028 (0.09%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	1 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	6 / 8028 (0.07%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bradycardia			
subjects affected / exposed	7 / 8028 (0.09%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	13 / 8028 (0.16%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 13	0 / 11	
deaths causally related to treatment / all	0 / 12	0 / 7	
Cardiac disorder			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure			

subjects affected / exposed	44 / 8028 (0.55%)	37 / 8043 (0.46%)	
occurrences causally related to treatment / all	0 / 47	0 / 40	
deaths causally related to treatment / all	0 / 9	0 / 9	
Cardiac failure chronic			
subjects affected / exposed	3 / 8028 (0.04%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure congestive			
subjects affected / exposed	36 / 8028 (0.45%)	39 / 8043 (0.48%)	
occurrences causally related to treatment / all	2 / 38	0 / 40	
deaths causally related to treatment / all	0 / 5	0 / 8	
Cardio-respiratory arrest			
subjects affected / exposed	17 / 8028 (0.21%)	11 / 8043 (0.14%)	
occurrences causally related to treatment / all	0 / 17	0 / 11	
deaths causally related to treatment / all	0 / 14	0 / 11	
Coronary artery disease			
subjects affected / exposed	32 / 8028 (0.40%)	32 / 8043 (0.40%)	
occurrences causally related to treatment / all	1 / 35	0 / 35	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypertensive heart disease			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	49 / 8028 (0.61%)	47 / 8043 (0.58%)	
occurrences causally related to treatment / all	0 / 52	0 / 50	
deaths causally related to treatment / all	0 / 19	0 / 16	
Myocardial ischaemia			
subjects affected / exposed	15 / 8028 (0.19%)	19 / 8043 (0.24%)	
occurrences causally related to treatment / all	0 / 15	0 / 21	
deaths causally related to treatment / all	0 / 2	0 / 2	
Sinus node dysfunction			

subjects affected / exposed	10 / 8028 (0.12%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	9 / 8028 (0.11%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adams-Stokes syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	34 / 8028 (0.42%)	34 / 8043 (0.42%)	
occurrences causally related to treatment / all	1 / 37	0 / 43	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular dissociation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	1 / 8028 (0.01%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block bilateral			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block left			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block right			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiac tamponade			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac valve disease			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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 / 8028 (0.04%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 3	0 / 5	
Cardiopulmonary failure			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Cardiovascular disorder			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiovascular insufficiency			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cor pulmonale acute			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery insufficiency			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery perforation			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytotoxic cardiomyopathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrasystoles			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve incompetence			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive cardiomyopathy			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Left ventricular failure			
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	1 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Microvascular coronary artery disease			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve disease			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mitral valve stenosis			

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pericardial haemorrhage			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Postinfarction angina			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.01%)	0 / 8043 (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	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sinoatrial block			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular extrasystoles			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 4	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia paroxysmal			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ventricular dysfunction			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Carotid artery occlusion			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
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	4 / 8028 (0.05%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral arteriosclerosis			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			

subjects affected / exposed	10 / 8028 (0.12%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 10	0 / 3	
deaths causally related to treatment / all	0 / 5	0 / 2	
Cerebral infarction			
subjects affected / exposed	19 / 8028 (0.24%)	32 / 8043 (0.40%)	
occurrences causally related to treatment / all	0 / 19	2 / 33	
deaths causally related to treatment / all	0 / 1	0 / 2	
Cerebral ischaemia			
subjects affected / exposed	9 / 8028 (0.11%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	46 / 8028 (0.57%)	72 / 8043 (0.90%)	
occurrences causally related to treatment / all	1 / 47	2 / 72	
deaths causally related to treatment / all	0 / 8	0 / 10	
Cerebrovascular disorder			
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular insufficiency			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dizziness			
subjects affected / exposed	8 / 8028 (0.10%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 8	3 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			

subjects affected / exposed	3 / 8028 (0.04%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential tremor			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegia			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	41 / 8028 (0.51%)	40 / 8043 (0.50%)	
occurrences causally related to treatment / all	0 / 42	0 / 42	
deaths causally related to treatment / all	0 / 4	0 / 4	
Lacunar infarction			
subjects affected / exposed	9 / 8028 (0.11%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelitis transverse			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Radicular syndrome			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatic nerve palsy			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	20 / 8028 (0.25%)	32 / 8043 (0.40%)	
occurrences causally related to treatment / all	0 / 20	0 / 35	
deaths causally related to treatment / all	0 / 0	0 / 1	
Transient ischaemic attack			
subjects affected / exposed	35 / 8028 (0.44%)	34 / 8043 (0.42%)	
occurrences causally related to treatment / all	0 / 38	2 / 37	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Altered state of consciousness			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apallic syndrome			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia haemorrhage			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Basal ganglia infarction			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Brain oedema			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem infarction			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem stroke			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid arteriosclerosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery aneurysm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery thrombosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid sinus syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	5 / 8028 (0.06%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	0 / 5	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery embolism			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral circulatory failure			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral thrombosis			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral venous thrombosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coma			
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Complex partial seizures			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cranial nerve disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	4 / 8028 (0.05%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Depressed level of consciousness			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyslalia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic cerebral infarction			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			

subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Frontotemporal dementia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemorrhage intracranial			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemorrhagic stroke			
subjects affected / exposed	6 / 8028 (0.07%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 2	0 / 8	
Headache			
subjects affected / exposed	4 / 8028 (0.05%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	1 / 4	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			

subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertonia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic unconsciousness			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotonia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
IIIrd nerve paralysis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intracranial haematoma			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial venous sinus thrombosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic neuropathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	8 / 8028 (0.10%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Memory impairment			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningorrhagia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Morton's neuralgia			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myasthenia gravis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve compression			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuritis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinsonism			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve lesion			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post herpetic neuralgia			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ruptured cerebral aneurysm			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sciatica			
subjects affected / exposed	6 / 8028 (0.07%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sedation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	5 / 8028 (0.06%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sensory disturbance			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Senile dementia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Slow speech			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
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	5 / 8028 (0.06%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Thrombotic stroke			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Thalamus haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIIth nerve paralysis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery stenosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			

subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
White matter lesion			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	22 / 8028 (0.27%)	16 / 8043 (0.20%)	
occurrences causally related to treatment / all	0 / 23	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	5 / 8028 (0.06%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia megaloblastic			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aplastic anaemia			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic diathesis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenic purpura			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lymphadenopathy mediastinal			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pernicious anaemia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	5 / 8028 (0.06%)	16 / 8043 (0.20%)	
occurrences causally related to treatment / all	0 / 5	1 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	2 / 8028 (0.02%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute vestibular syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
External ear disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inner ear disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurosensory hypoacusis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otosclerosis			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic membrane perforation			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	84 / 8028 (1.05%)	99 / 8043 (1.23%)	
occurrences causally related to treatment / all	0 / 114	0 / 133	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract nuclear			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract subcapsular			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal tear			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein thrombosis			

subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Age-related macular degeneration			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amaurosis fugax			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angle closure glaucoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chalazion			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choroiditis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ciliary body disorder			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctival haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal opacity			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystoid macular oedema			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryostenosis acquired			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Entropion			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Excessive eye blinking			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	3 / 8028 (0.04%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iritis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratitis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratitis interstitial			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratopathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacrimal disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lens disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular degeneration			

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular fibrosis			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular hole			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Maculopathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neovascular age-related macular degeneration			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic atrophy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior capsule opacification			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery embolism			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal degeneration			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal dystrophy			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trichiasis			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative keratitis			
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual acuity reduced			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	11 / 8028 (0.14%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 11	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal prolapse			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			

subjects affected / exposed	7 / 8028 (0.09%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	10 / 8028 (0.12%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	0 / 10	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	3 / 8028 (0.04%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecaloma			
subjects affected / exposed	6 / 8028 (0.07%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	9 / 8028 (0.11%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
Gastroduodenitis			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	10 / 8028 (0.12%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 10	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	8 / 8028 (0.10%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Inguinal hernia			
subjects affected / exposed	12 / 8028 (0.15%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	11 / 8028 (0.14%)	11 / 8043 (0.14%)	
occurrences causally related to treatment / all	0 / 12	0 / 13	
deaths causally related to treatment / all	0 / 2	0 / 2	
Irritable bowel syndrome			
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			

subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	6 / 8028 (0.07%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pancreatitis chronic			
subjects affected / exposed	7 / 8028 (0.09%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	12 / 8028 (0.15%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 12	0 / 4	
deaths causally related to treatment / all	0 / 4	0 / 1	
Abdominal adhesions			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.01%)	0 / 8043 (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	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia obstructive			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal pain lower			

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
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	2 / 8028 (0.02%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 2	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Anal fissure			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal inflammation			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal stenosis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's oesophagus			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Change of bowel habit			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	5 / 8028 (0.06%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	6 / 8028 (0.07%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 6	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis microscopic			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	10 / 8028 (0.12%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	1 / 10	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Crohn's disease			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental caries			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			

subjects affected / exposed	8 / 8028 (0.10%)	12 / 8043 (0.15%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum oesophageal			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dolichocolon acquired			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal perforation			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Duodenal ulcer			
subjects affected / exposed	3 / 8028 (0.04%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer perforation			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Duodenitis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysbacteriosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocele			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocutaneous fistula			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive oesophagitis			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecal incontinence			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral hernia			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral hernia incarcerated			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Functional gastrointestinal disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric polyps			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 4	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer perforation			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastritis			
subjects affected / exposed	10 / 8028 (0.12%)	19 / 8043 (0.24%)	
occurrences causally related to treatment / all	1 / 11	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	7 / 8028 (0.09%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 1	
Gastrointestinal inflammation			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal motility disorder			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal necrosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal obstruction			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	10 / 8028 (0.12%)	11 / 8043 (0.14%)	
occurrences causally related to treatment / all	0 / 10	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernial eventration			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal mass			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intestinal polyp			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal prolapse			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischiorectal hernia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Large intestine polyp			
subjects affected / exposed	10 / 8028 (0.12%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	1 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar hernia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mechanical ileus			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			

subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery embolism			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth cyst			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth ulceration			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal achalasia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal fistula			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal hypomotility			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal pain			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis ulcerative			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral pain			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic cyst			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic pseudocyst			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	6 / 8028 (0.07%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pancreatitis necrotising			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Peptic ulcer			
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer perforation			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngo-oesophageal diverticulum			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal polyp			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal prolapse			
subjects affected / exposed	3 / 8028 (0.04%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland calculus			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	5 / 8028 (0.06%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic artery aneurysm			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomach mass			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis mesenteric vessel			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Toothache			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	6 / 8028 (0.07%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	5 / 8028 (0.06%)	11 / 8043 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	15 / 8028 (0.19%)	21 / 8043 (0.26%)	
occurrences causally related to treatment / all	0 / 15	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			

subjects affected / exposed	39 / 8028 (0.49%)	34 / 8043 (0.42%)	
occurrences causally related to treatment / all	0 / 43	0 / 34	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	5 / 8028 (0.06%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bile duct obstruction			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary fistula			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	1 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			

subjects affected / exposed	15 / 8028 (0.19%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 15	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic hepatitis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder disorder			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder polyp			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cyst			
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic steatosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis cholestatic			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal failure			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Jaundice			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic steatohepatitis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Post cholecystectomy syndrome			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Decubitus ulcer			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Skin necrosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subacute cutaneous lupus erythematosus			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Actinic keratosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute generalised exanthematous pustulosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	4 / 8028 (0.05%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis atopic			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis contact			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatomyositis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema multiforme			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema nodosum			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand dermatitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Henoch-Schonlein purpura			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkeratosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity vasculitis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lentigo			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lichen sclerosus			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurodermatitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus generalised			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyoderma gangrenosum			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash erythematous			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash generalised			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	6 / 8028 (0.07%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin wrinkling			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			

subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	7 / 8028 (0.09%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 2	
Bladder prolapse			
subjects affected / exposed	7 / 8028 (0.09%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	11 / 8028 (0.14%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 11	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal artery stenosis			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute prerenal failure			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder cyst			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder diverticulum			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder irritation			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder perforation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus ureteric			
subjects affected / exposed	5 / 8028 (0.06%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urethral			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	1 / 8028 (0.01%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 1	1 / 5	
deaths causally related to treatment / all	0 / 0	1 / 3	
Cystitis haemorrhagic			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Glomerulonephritis membranous			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis rapidly progressive			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	5 / 8028 (0.06%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertonic bladder			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oliguria			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	4 / 8028 (0.05%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 1	
Renal impairment			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal mass			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scleroderma renal crisis			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral caruncle			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral polyp			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			

subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	7 / 8028 (0.09%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic nodular goitre			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal insufficiency			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune thyroiditis			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperadrenalism			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary hypothyroidism			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Secondary hyperthyroidism			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cyst			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis subacute			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	8 / 8028 (0.10%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	10 / 8028 (0.12%)	14 / 8043 (0.17%)	
occurrences causally related to treatment / all	0 / 11	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture delayed union			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	11 / 8028 (0.14%)	14 / 8043 (0.17%)	
occurrences causally related to treatment / all	0 / 11	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	8 / 8028 (0.10%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 8028 (0.01%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			

subjects affected / exposed	123 / 8028 (1.53%)	147 / 8043 (1.83%)	
occurrences causally related to treatment / all	0 / 141	0 / 167	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	12 / 8028 (0.15%)	18 / 8043 (0.22%)	
occurrences causally related to treatment / all	0 / 13	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	8 / 8028 (0.10%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	3 / 8028 (0.04%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	8 / 8028 (0.10%)	12 / 8043 (0.15%)	
occurrences causally related to treatment / all	0 / 10	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atlantoaxial instability			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Axillary mass			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	22 / 8028 (0.27%)	20 / 8043 (0.25%)	
occurrences causally related to treatment / all	0 / 22	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone loss			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondropathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Connective tissue disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's contracture			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophilic fasciitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facet joint syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture malunion			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture pain			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc space narrowing			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw cyst			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint adhesion			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint contracture			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint range of motion decreased			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint stiffness			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint swelling			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee deformity			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mobility decreased			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monarthritis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Morphoea			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal osteoarthritis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondritis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteosclerosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	1 / 8028 (0.01%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	0 / 1	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periarthritis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periostitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plantar fasciitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	5 / 8028 (0.06%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			

subjects affected / exposed	7 / 8028 (0.09%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scleroderma			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scoliosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sjogren's syndrome			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue necrosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	17 / 8028 (0.21%)	15 / 8043 (0.19%)	
occurrences causally related to treatment / all	0 / 17	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondyloarthropathy			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	1 / 8028 (0.01%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis stenosans			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigger finger			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulnocarpal abutment syndrome			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendiceal abscess			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			

subjects affected / exposed	13 / 8028 (0.16%)	20 / 8043 (0.25%)	
occurrences causally related to treatment / all	0 / 13	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	16 / 8028 (0.20%)	16 / 8043 (0.20%)	
occurrences causally related to treatment / all	0 / 17	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
subjects affected / exposed	17 / 8028 (0.21%)	19 / 8043 (0.24%)	
occurrences causally related to treatment / all	0 / 18	0 / 20	
deaths causally related to treatment / all	0 / 5	0 / 7	
Cellulitis			
subjects affected / exposed	16 / 8028 (0.20%)	17 / 8043 (0.21%)	
occurrences causally related to treatment / all	0 / 20	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	29 / 8028 (0.36%)	35 / 8043 (0.44%)	
occurrences causally related to treatment / all	0 / 31	0 / 35	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastroenteritis Escherichia coli			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	5 / 8028 (0.06%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	8 / 8028 (0.10%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	11 / 8028 (0.14%)	15 / 8043 (0.19%)	
occurrences causally related to treatment / all	0 / 11	0 / 15	
deaths causally related to treatment / all	0 / 2	0 / 2	
Peritonitis			
subjects affected / exposed	6 / 8028 (0.07%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 4	
Pneumonia			
subjects affected / exposed	128 / 8028 (1.59%)	119 / 8043 (1.48%)	
occurrences causally related to treatment / all	0 / 133	0 / 138	
deaths causally related to treatment / all	0 / 24	0 / 23	
Pulmonary sepsis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	8 / 8028 (0.10%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	3 / 8028 (0.04%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			

subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	19 / 8028 (0.24%)	23 / 8043 (0.29%)	
occurrences causally related to treatment / all	0 / 20	0 / 24	
deaths causally related to treatment / all	0 / 10	0 / 14	
Urinary tract infection			
subjects affected / exposed	54 / 8028 (0.67%)	54 / 8043 (0.67%)	
occurrences causally related to treatment / all	1 / 64	1 / 58	
deaths causally related to treatment / all	0 / 0	0 / 2	
Wound infection			
subjects affected / exposed	8 / 8028 (0.10%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal abscess			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal wall abscess			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amoebic colitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Beta haemolytic streptococcal infection			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burn infection			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter infection			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbuncle			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site infection			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system viral infection			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
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	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cutaneous tuberculosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	8 / 8028 (0.10%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	1 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryocystitis			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	5 / 8028 (0.06%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			

subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related sepsis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	20 / 8028 (0.25%)	25 / 8043 (0.31%)	
occurrences causally related to treatment / all	0 / 22	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dysentery			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endophthalmitis			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis infectious			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter pneumonia			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Erysipelas			
subjects affected / exposed	5 / 8028 (0.06%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema migrans			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder empyema			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastritis viral			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis bacterial			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis clostridial			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Graft infection			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma infection			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter gastritis			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter infection			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis A			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis E			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes simplex encephalitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Herpes zoster infection neurological			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site infection			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected bites			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected dermal cyst			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected varicose vein			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (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	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of bronchiectasis			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Influenza			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal fistula infection			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratitis bacterial			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labyrinthitis			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lobar pneumonia			
subjects affected / exposed	12 / 8028 (0.15%)	11 / 8043 (0.14%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 3	0 / 2	
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	5 / 8028 (0.06%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaria			
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Meningitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis bacterial			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurosyphilis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic abscess			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic sepsis			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital cellulitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar abscess			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngotonsillitis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia necrotising			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pneumonia pneumococcal			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomembranous colitis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonal bacteraemia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary echinococciasis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelocystitis			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis chronic			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyometra			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyonephrosis			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal abscess			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonellosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	7 / 8028 (0.09%)	12 / 8043 (0.15%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 5	0 / 10	
Sialoadenitis			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinobronchitis			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal skin infection			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma site abscess			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			

subjects affected / exposed	4 / 8028 (0.05%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdiaphragmatic abscess			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tick-borne fever			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tooth infection			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection pseudomonal			

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Vaginal abscess			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral labyrinthitis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	7 / 8028 (0.09%)	14 / 8043 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 1	
Folate deficiency			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	7 / 8028 (0.09%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hyponatraemia			
subjects affected / exposed	16 / 8028 (0.20%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	0 / 17	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	10 / 8028 (0.12%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetes mellitus inadequate control			

subjects affected / exposed	9 / 8028 (0.11%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gout			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperosmolar state			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			

subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypophagia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ketoacidosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metabolic acidosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			

subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Participants Who Had Received Placebo During the 018 Study	Participants Who Had Received Odanacatib During the 018 Study	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5525 / 8028 (68.82%)	5577 / 8043 (69.34%)	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	424 / 8028 (5.28%)	388 / 8043 (4.82%)	
occurrences (all)	572	502	
Vascular disorders			
Hypertension			
subjects affected / exposed	1093 / 8028 (13.61%)	1110 / 8043 (13.80%)	
occurrences (all)	1288	1270	
Nervous system disorders			
Dizziness			
subjects affected / exposed	485 / 8028 (6.04%)	495 / 8043 (6.15%)	
occurrences (all)	567	577	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	502 / 8028 (6.25%)	477 / 8043 (5.93%)	
occurrences (all)	586	552	
Eye disorders			
Cataract			
subjects affected / exposed	501 / 8028 (6.24%)	494 / 8043 (6.14%)	
occurrences (all)	664	646	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	508 / 8028 (6.33%)	494 / 8043 (6.14%)	
occurrences (all)	556	549	
Diarrhoea			

subjects affected / exposed	504 / 8028 (6.28%)	591 / 8043 (7.35%)	
occurrences (all)	608	728	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	469 / 8028 (5.84%)	471 / 8043 (5.86%)	
occurrences (all)	552	553	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1155 / 8028 (14.39%)	1223 / 8043 (15.21%)	
occurrences (all)	1541	1590	
Back pain			
subjects affected / exposed	1139 / 8028 (14.19%)	1200 / 8043 (14.92%)	
occurrences (all)	1400	1480	
Musculoskeletal pain			
subjects affected / exposed	464 / 8028 (5.78%)	519 / 8043 (6.45%)	
occurrences (all)	542	590	
Osteoarthritis			
subjects affected / exposed	752 / 8028 (9.37%)	794 / 8043 (9.87%)	
occurrences (all)	926	992	
Pain in extremity			
subjects affected / exposed	675 / 8028 (8.41%)	753 / 8043 (9.36%)	
occurrences (all)	802	925	
Infections and infestations			
Bronchitis			
subjects affected / exposed	461 / 8028 (5.74%)	452 / 8043 (5.62%)	
occurrences (all)	615	600	
Influenza			
subjects affected / exposed	443 / 8028 (5.52%)	497 / 8043 (6.18%)	
occurrences (all)	565	613	
Nasopharyngitis			
subjects affected / exposed	940 / 8028 (11.71%)	957 / 8043 (11.90%)	
occurrences (all)	1368	1397	
Upper respiratory tract infection			
subjects affected / exposed	600 / 8028 (7.47%)	646 / 8043 (8.03%)	
occurrences (all)	919	968	

Urinary tract infection			
subjects affected / exposed	1702 / 8028 (21.20%)	1729 / 8043 (21.50%)	
occurrences (all)	2831	2921	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported