



## Clinical trial results:

**A long-term extension trial of the Phase III lipid-lowering trials to assess the effect of long-term dosing of inclisiran given as subcutaneous injections in subjects with high cardiovascular risk and elevated LDL-C (ORION-8)**

### Summary

EudraCT number	2017-003092-55
Trial protocol	GB CZ DE SE DK HU NL
Global end of trial date	13 February 2023

### Results information

Result version number	v1 (current)
This version publication date	06 March 2024
First version publication date	06 March 2024

### Trial information

#### Trial identification

Sponsor protocol code	MDCO-PCS-17-05
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03814187
WHO universal trial number (UTN)	-
Other trial identifiers	Novartis Pharmaceuticals: CKJX839A12306B

Notes:

### Sponsors

Sponsor organisation name	NovartisPharma AG
Sponsor organisation address	Novartis Campus, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 February 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	13 February 2023
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

Primary objectives were to evaluate: -The effect of inclisiran treatment on the proportion of subjects achieving the pre-specified LDL-C targets at the end of study (EOS) -The safety and tolerability profile of long-term use of inclisiran

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 April 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 65
Country: Number of subjects enrolled	Czechia: 28
Country: Number of subjects enrolled	Denmark: 45
Country: Number of subjects enrolled	Germany: 106
Country: Number of subjects enrolled	Hungary: 88
Country: Number of subjects enrolled	Netherlands: 147
Country: Number of subjects enrolled	Poland: 588
Country: Number of subjects enrolled	South Africa: 275
Country: Number of subjects enrolled	Spain: 80
Country: Number of subjects enrolled	Sweden: 29
Country: Number of subjects enrolled	Ukraine: 101
Country: Number of subjects enrolled	United Kingdom: 380
Country: Number of subjects enrolled	United States: 1342
Worldwide total number of subjects	3274
EEA total number of subjects	1111

Notes:

<b>Subjects enrolled per age group</b>	
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)	1425
From 65 to 84 years	1830
85 years and over	19

## Subject disposition

### Recruitment

Recruitment details:

1513 patients were enrolled to "Phase III Inclisiran-Inclisiran" arm, but one patient discontinued before receiving the study drug, and therefore the number of patients starting on that arm is 1512.

### Pre-assignment

Screening details:

Participants completed a qualifying Phase II lipid lowering trial [MDCO-PCS-16-01 (ORION-3)] or Phase III lipid-lowering ORION feeder study [MDCO-PCS-17-03 (ORION-9), MDCO-PCS-17-04 (ORION-10), or MDCO-PCS-17-08 (ORION-11) ] meaning the subject received the last dose of study drug and completed the final study visit per applicable protocol.

### Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Phase III Inclisiran-Inclisiran

Arm description:

Subjects who received inclisiran (actual treatment) in studies ORION-9/ ORION-10/ORION-11

Arm type	Experimental
Investigational medicinal product name	Inclisiran
Investigational medicinal product code	KJX839
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Inclisiran sodium 300 mg (equivalent to 284 mg inclisiran) administered as a single subcutaneous (SC) dose every 180 days from the last dose in previous feeder study until the end of the study.

<b>Arm title</b>	Phase III Placebo-Inclisiran
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Arm description:

subjects who received placebo (actual treatment) in ORION-9/ORION-10/ORION-11

Arm type	Experimental
Investigational medicinal product name	Inclisiran
Investigational medicinal product code	KJX839
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Inclisiran sodium 300 mg (equivalent to 284 mg inclisiran) administered as a single subcutaneous (SC) dose every 180 days from the last dose in previous feeder study (since subjects in this arm were newly initiating inclisiran, they received the first two doses 90 days apart) until the end of the study.

<b>Arm title</b>	ORION-3 Rollover
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Arm description:

Subjects rolling over from ORION-3 Phase II study

Arm type	Experimental
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Investigational medicinal product name	Inclisiran
Investigational medicinal product code	KJX839
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Inclisiran sodium 300 mg (equivalent to 284 mg inclisiran) administered as a single subcutaneous (SC) dose every 180 days from the last dose in previous feeder study until the end of the study.

Number of subjects in period 1	Phase III Inclisiran-Inclisiran	Phase III Placebo-Inclisiran	ORION-3 Rollover
Started	1512	1478	284
Completed	1246	1200	0
Not completed	266	278	284
Adverse event, serious fatal	80	81	4
Withdrew Consent	77	78	2
Physician decision	6	4	2
Initiation Of Prohibited Approved PCSK9 Inhibitor	-	-	1
Adverse event, non-fatal	22	23	-
Other reasons	34	40	2
Lost to follow-up	47	52	1
Sponsor's Administrative Decision	-	-	272

## Baseline characteristics

### Reporting groups

Reporting group title	Phase III Inclisiran-Inclisiran
Reporting group description:	
Subjects who received inclisiran (actual treatment) in studies ORION-9/ ORION-10/ORION-11	
Reporting group title	Phase III Placebo-Inclisiran
Reporting group description:	
subjects who received placebo (actual treatment) in ORION-9/ORION-10/ORION-11	
Reporting group title	ORION-3 Rollover
Reporting group description:	
Subjects rolling over from ORION-3 Phase II study	

Reporting group values	Phase III Inclisiran-Inclisiran	Phase III Placebo-Inclisiran	ORION-3 Rollover
Number of subjects	1512	1478	284
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)	666	672	87
From 65-84 years	838	798	194
85 years and over	8	8	3
Age Continuous			
Units: years			
arithmetic mean	64.7	64.6	67.7
standard deviation	± 9.83	± 9.82	± 9.97
Sex: Female, Male			
Units: participants			
Female	482	476	100
Male	1030	1002	184
Race/Ethnicity, Customized			
Units: Subjects			
American Indian/Alaska Native	3	2	2
Asian	17	7	3
Black/African American	103	78	7
Native Hawaiian/Other Pacific Islander	6	4	0
White	1383	1387	271
Missing	0	0	1

Reporting group values	Total		
Number of subjects	3274		

Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	1425		
From 65-84 years	1830		
85 years and over	19		
Age Continuous Units: years arithmetic mean standard deviation	-		
Sex: Female, Male Units: participants			
Female	1058		
Male	2216		
Race/Ethnicity, Customized Units: Subjects			
American Indian/Alaska Native	7		
Asian	27		
Black/African American	188		
Native Hawaiian/Other Pacific Islander	10		
White	3041		
Missing	1		

## End points

### End points reporting groups

Reporting group title	Phase III Inclisiran-Inclisiran
Reporting group description:	
Subjects who received inclisiran (actual treatment) in studies ORION-9/ ORION-10/ORION-11	
Reporting group title	Phase III Placebo-Inclisiran
Reporting group description:	
subjects who received placebo (actual treatment) in ORION-9/ORION-10/ORION-11	
Reporting group title	ORION-3 Rollover
Reporting group description:	
Subjects rolling over from ORION-3 Phase II study	
Subject analysis set title	Total
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Total number of participants from the safety population with valid LDL-C measurements at Day 1080/EOS	
Subject analysis set title	Total
Subject analysis set type	Safety analysis
Subject analysis set description:	
The safety population consisted of all ORION-3 rollover subjects who signed the informed consent to Study ORION-8, and all ORION-9/ORION-10/ORION-11 rollover subjects with at least one study drug administration in Study ORION-8	

### Primary: Proportion of subjects achieving global lipid targets for their level of ASCVD risk

End point title	Proportion of subjects achieving global lipid targets for their level of ASCVD risk <sup>[1]</sup>
End point description:	
The primary objective of the study is to evaluate the effect of inclisiran treatment on the proportion of subjects achieving prespecified LDL-C targets at end of study (EOS). Target is <70 mg/dL for atherosclerotic cardiovascular disease (ASCVD) subjects and <100 mg/dL for ASCVD risk equivalent subjects. Risk equivalent subjects are defined as either type 2 diabetes, familial hypercholesterolemia or a 10-year risk of a cardiovascular event $\geq 20\%$ as assessed by the Framingham Risk Score or equivalent; without a medical history of coronary heart disease , cerebrovascular disease or peripheral artery disease.	
End point type	Primary
End point timeframe:	
From ORION-8 Day 1 to the end of study (up to 1080 days)	

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: No statistical analysis was planned for this primary outcome

End point values	Phase III Inclisiran-Inclisiran	Phase III Placebo-Inclisiran	ORION-3 Rollover	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1251	1204	276	2731
Units: Percentage of participants				
number (confidence interval 95%)				
% with Global Lipid Targets (GLT)	78.18 (75.8 to 80.4)	79.07 (76.7 to 81.3)	76.81 (71.4 to 81.6)	78.43 (76.8 to 80.0)



% of ASCVD with GLT of <70 mg/dL	79.34 (76.8 to 81.7)	79.96 (77.4 to 82.4)	76.70 (70.0 to 82.5)	79.41 (77.7 to 81.1)
% of ASCVD risk equivalent with GLT of <100 mg/dL	72.56 (66.1 to 78.3)	74.88 (68.6 to 80.5)	77.00 (67.7 to 84.7)	74.33 (70.4 to 78.0)

## Statistical analyses

No statistical analyses for this end point

### Primary: Incidence of treatment-emergent adverse events (TEAEs)

End point title	Incidence of treatment-emergent adverse events (TEAEs) <sup>[2]</sup>
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End point description:

Safety assessments include adverse events and serious adverse events until the end of study. End of study visit occurred at least 90 days following the last inclisiran dose once a decision was made to end the study (either by the subject, investigator or sponsor). For subjects prematurely and permanently discontinued from study treatment, who were not willing to return within the 90 day timeframe, the EOS visit was scheduled as soon as possible, or if decision to discontinue and not return was made at a specific visit, this visit became the EOS visit.

End point type	Primary
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End point timeframe:

From ORION-8 Day 1 to the end of study (up to 1080 days)

Notes:

[2] - 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: No statistical analysis was planned for this primary outcome

End point values	Phase III Inclisiran- Inclisiran	Phase III Placebo- Inclisiran	ORION-3 Rollover	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1512	1478	284	3274
Units: participants				
Adverse events	1197	1170	181	2548
SAEs	464	482	43	989
Fatal SAEs	80	81	4	165
Adverse events: Treatment-related	133	148	16	297
SAEs: Treatment-related	2	2	1	5
Fatal SAEs: Treatment-related	0	0	0	0

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage change in LDL-C from the initial feeder study baseline

End point title	Percentage change in LDL-C from the initial feeder study baseline
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End point description:

Percentage change from baseline in low density lipoprotein cholesterol (LDL-C) was calculated to evaluate the effect of inclisiran on LDL-C levels.

End point type	Secondary
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End point timeframe:

Feeder study baseline, ORION-8 baseline, Day 1080/EOS (ORION-8) (up to a maximum of 2340 days)

End point values	Phase III Inclisiran- Inclisiran	Phase III Placebo- Inclisiran	ORION-3 Rollover	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1512	1478	284	
Units: Percentage change in LDL-C				
arithmetic mean (confidence interval 95%)				
ORION-8 Baseline	-50.02 (-51.3 to -48.8)	3.10 (1.4 to 4.9)	-48.22 (-51.2 to -45.2)	
Day 1080 / EOS	-48.96 (-50.5 to -47.4)	-49.69 (-51.3 to -48.0)	-49.95 (-52.6 to -47.3)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Absolute change from the initial feeder study baseline in total cholesterol, triglycerides and HDL-C

End point title	Absolute change from the initial feeder study baseline in total cholesterol, triglycerides and HDL-C
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End point description:

Absolute change from baseline in total cholesterol, triglycerides and high density lipoprotein cholesterol (HDL-C) was calculated to evaluate the effect of inclisiran on other lipids and lipoproteins.

End point type	Secondary
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End point timeframe:

Feeder study baseline, ORION-8 baseline, Day 1080/EOS (ORION-8) (up to a maximum of 2340 days)

End point values	Phase III Inclisiran- Inclisiran	Phase III Placebo- Inclisiran	ORION-3 Rollover	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1512	1478	284	
Units: mg/dL				
arithmetic mean (confidence interval 95%)				
ORION-8 Baseline Total Cholesterol (TC)	-59.05 (-61.0 to -57.1)	-0.07 (-2.2 to 2.1)	-63.11 (-68.3 to -57.9)	
Day 1080 / EOS Total Cholesterol (TC)	-58.48 (-61.0 to -55.9)	-57.08 (-59.6 to -54.6)	-65.43 (-70.5 to -60.3)	
ORION-8 Baseline Triglycerides	-21.50 (-25.1 to -17.9)	-5.74 (-9.5 to -2.0)	-14.43 (-23.7 to -5.1)	
Day 1080 / EOS Triglycerides	-19.58 (-23.7 to -15.4)	-22.12 (-26.3 to -17.9)	-21.32 (-30.3 to -12.4)	

ORION-8 Baseline HDL Cholesterol	3.37 (2.9 to 3.9)	0.59 (0.1 to 1.1)	3.41 (2.2 to 4.6)	
Day 1080 / EOS HDL Cholesterol	3.60 (3.0 to 4.2)	4.39 (3.8 to 5.0)	5.27 (3.8 to 6.7)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage change from the initial feeder study baseline in total cholesterol, triglycerides and HDL-C

End point title	Percentage change from the initial feeder study baseline in total cholesterol, triglycerides and HDL-C
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End point description:

Percentage change from baseline in total cholesterol (TC), triglycerides and high density lipoprotein cholesterol (HDL-C) was calculated to evaluate the effect of inclisiran on other lipids and lipoproteins.

End point type	Secondary
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End point timeframe:

Feeder study baseline, ORION-8 baseline, Day 1080/EOS (ORION-8) (up to a maximum of 2340 days)

End point values	Phase III Inclisiran- Inclisiran	Phase III Placebo- Inclisiran	ORION-3 Rollover	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1512	1478	284	
Units: Percentage change				
arithmetic mean (confidence interval 95%)				
ORION-8 Baseline Total Cholesterol (TC)	-30.64 (-31.5 to -29.7)	1.28 (0.1 to 2.4)	-29.49 (-31.6 to -27.4)	
Day 1080 / EOS Total Cholesterol (TC)	-29.34 (-30.5 to -28.2)	-29.53 (-30.7 to -28.4)	-30.44 (-32.4 to -28.5)	
ORION-8 Baseline Triglycerides	-7.84 (-10.0 to -5.7)	3.03 (0.8 to 5.2)	-0.20 (-7.6 to 7.2)	
Day 1080 / EOS Triglycerides	-3.90 (-6.5 to -1.3)	-6.85 (-9.2 to -4.5)	-3.18 (-9.2 to 2.8)	
ORION-8 Baseline HDL Cholesterol	9.28 (8.2 to 10.4)	3.48 (2.4 to 4.6)	8.13 (5.7 to 10.5)	
Day 1080 / EOS HDL Cholesterol	9.91 (8.7 to 11.2)	11.75 (10.3 to 13.2)	12.16 (9.3 to 15.0)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Absolute change in LDL-C from the initial feeder study baseline

End point title	Absolute change in LDL-C from the initial feeder study baseline
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End point description:

Absolute change from baseline in low density lipoprotein cholesterol (LDL-C) was calculated to evaluate the effect of inclisiran on LDL-C levels.

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End point type	Secondary
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End point timeframe:

Feeder study baseline, ORION-8 baseline, Day 1080/EOS (ORION-8) (up to a maximum of 2340 days)

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End point values	Phase III Inclisiran- Inclisiran	Phase III Placebo- Inclisiran	ORION-3 Rollover	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1512	1478	284	
Units: mg/dL				
arithmetic mean (confidence interval 95%)				
ORION-8 Baseline	-55.21 (-56.9 to -53.5)	0.46 (-1.4 to 2.3)	-61.58 (-66.4 to -56.8)	
Day 1080 / EOS	-55.81 (-58.0 to -53.6)	-54.70 (-56.9 to -52.5)	-64.31 (-69.0 to -59.7)	

### Statistical analyses

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events were reported from the start of study in ORION-8 until end of study treatment plus 90 days post treatment, up to a maximum duration of 1080 days.

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

Adverse Events are assessed in the safety population.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

### Reporting groups

Reporting group title	Phase III Inclisiran-Inclisiran
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Reporting group description:

Phase III Inclisiran-Inclisiran

Reporting group title	Total
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Reporting group description:

Total

Reporting group title	ORION-3 Rollover
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Reporting group description:

ORION-3 Rollover

Reporting group title	Phase III Placebo-Inclisiran
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Reporting group description:

Phase III Placebo-Inclisiran

Serious adverse events	Phase III Inclisiran-Inclisiran	Total	ORION-3 Rollover
Total subjects affected by serious adverse events			
subjects affected / exposed	464 / 1512 (30.69%)	989 / 3274 (30.21%)	43 / 284 (15.14%)
number of deaths (all causes)	80	165	4
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign lung neoplasm			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			

subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaplastic thyroid cancer			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma metastatic			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	5 / 1512 (0.33%)	8 / 3274 (0.24%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 5	0 / 16	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brenner tumour			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer metastatic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	2 / 1512 (0.13%)	8 / 3274 (0.24%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 2	0 / 16	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer recurrent			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			

subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenoma			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal carcinoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal tract adenoma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stromal tumour			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon neoplasm			



subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	2 / 1512 (0.13%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 14	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip squamous cell carcinoma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Invasive ductal breast carcinoma			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal papilloma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	3 / 1512 (0.20%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant mediastinal neoplasm			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant glioma			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Lung adenocarcinoma stage IV			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	7 / 1512 (0.46%)	11 / 3274 (0.34%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 22	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 0
Lung neoplasm			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Lung cancer metastatic			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung squamous cell carcinoma metastatic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma metastatic			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm prostate			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lymph nodes			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			

subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Mantle cell lymphoma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma stage III			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant pleural effusion			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Non-small cell lung cancer metastatic			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal neoplasm			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Oncocytoma			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma metastatic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Ovarian cancer			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer metastatic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Ovarian epithelial cancer			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 4	0 / 0
Ovarian adenoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic neoplasm			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Paraneoplastic syndrome			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid tumour benign			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	8 / 1512 (0.53%)	15 / 3274 (0.46%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 32	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Small cell lung cancer metastatic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma uterus			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Prostate cancer metastatic			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 2	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 14	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma metastatic			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Triple negative breast cancer			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric cancer			



subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aneurysm			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm			
subjects affected / exposed	5 / 1512 (0.33%)	12 / 3274 (0.37%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 26	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aortic occlusion			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Aortic stenosis			
subjects affected / exposed	3 / 1512 (0.20%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 18	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Hypertensive crisis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential hypertension			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granulomatosis with polyangiitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 3	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism venous			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	4 / 1512 (0.26%)	6 / 3274 (0.18%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 4	0 / 14	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labile hypertension			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penetrating aortic ulcer			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	5 / 1512 (0.33%)	13 / 3274 (0.40%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 38	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leriche syndrome			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			

subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	6 / 1512 (0.40%)	17 / 3274 (0.52%)	3 / 284 (1.06%)
occurrences causally related to treatment / all	0 / 7	0 / 38	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	12 / 1512 (0.79%)	33 / 3274 (1.01%)	2 / 284 (0.70%)
occurrences causally related to treatment / all	0 / 12	0 / 66	0 / 2
deaths causally related to treatment / all	0 / 12	0 / 33	0 / 2
Exercise tolerance decreased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	10 / 1512 (0.66%)	20 / 3274 (0.61%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 42	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organ failure			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyrexia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling face			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent occlusion			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent stenosis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immunisation reaction			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoidosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Perineal fistula			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign prostatic hyperplasia			
subjects affected / exposed	7 / 1512 (0.46%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 18	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast necrosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Postmenopausal haemorrhage subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure subjects affected / exposed	9 / 1512 (0.60%)	28 / 3274 (0.86%)	2 / 284 (0.70%)
occurrences causally related to treatment / all	0 / 9	0 / 62	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 5	0 / 1
Dyspnoea exertional subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	8 / 1512 (0.53%)	17 / 3274 (0.52%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 40	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Chronic respiratory failure			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	6 / 1512 (0.40%)	16 / 3274 (0.49%)	2 / 284 (0.70%)
occurrences causally related to treatment / all	0 / 6	0 / 32	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Asthma			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			

subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	8 / 1512 (0.53%)	14 / 3274 (0.43%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 30	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pulmonary hypertension			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis aspiration			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pulmonary sarcoidosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Psychiatric disorders			
Completed suicide			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Confusional state			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised anxiety disorder			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conversion disorder			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device loosening			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Troponin T increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis marker			

increased				
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Hepatic enzyme increased				
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Haemoglobin decreased				
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Blood creatinine increased				
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic				
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Troponin increased				
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Injury, poisoning and procedural complications				
Acetabulum fracture				
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Alcohol poisoning				
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	

Concussion			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back injury			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic restenosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	2 / 1512 (0.13%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	6 / 1512 (0.40%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Fractured sacrum			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture displacement			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat stroke			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural hypotension			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			



subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Spinal compression fracture			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound complication			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic fracture			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomal hernia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular access site haematoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft occlusion			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hydrocele			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	17 / 1512 (1.12%)	44 / 3274 (1.34%)	3 / 284 (1.06%)
occurrences causally related to treatment / all	0 / 18	0 / 104	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Angina pectoris			
subjects affected / exposed	21 / 1512 (1.39%)	43 / 3274 (1.31%)	2 / 284 (0.70%)
occurrences causally related to treatment / all	0 / 21	0 / 90	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Angina unstable			
subjects affected / exposed	12 / 1512 (0.79%)	32 / 3274 (0.98%)	2 / 284 (0.70%)
occurrences causally related to treatment / all	0 / 12	0 / 70	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve calcification			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			

subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Arrhythmic storm			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	3 / 1512 (0.20%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 22	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 6	0 / 0
Atrial flutter			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	2 / 1512 (0.13%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			

subjects affected / exposed	17 / 1512 (1.12%)	35 / 3274 (1.07%)	3 / 284 (1.06%)
occurrences causally related to treatment / all	0 / 21	0 / 80	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure			
subjects affected / exposed	10 / 1512 (0.66%)	26 / 3274 (0.79%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 10	0 / 74	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 5	0 / 0
Cardiac failure acute			
subjects affected / exposed	4 / 1512 (0.26%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 16	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cardiac failure chronic			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure congestive			
subjects affected / exposed	15 / 1512 (0.99%)	29 / 3274 (0.89%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 19	0 / 78	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 0
Chronic coronary syndrome			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiomyopathy			

subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiorenal syndrome			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular insufficiency			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 4	0 / 0
Chronic left ventricular failure			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	36 / 1512 (2.38%)	64 / 3274 (1.95%)	2 / 284 (0.70%)
occurrences causally related to treatment / all	0 / 38	0 / 138	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 3	0 / 0
Coronary artery occlusion			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			

subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	12 / 1512 (0.79%)	33 / 3274 (1.01%)	2 / 284 (0.70%)
occurrences causally related to treatment / all	0 / 12	0 / 66	0 / 2
deaths causally related to treatment / all	0 / 4	0 / 11	0 / 1
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diastolic dysfunction			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	7 / 1512 (0.46%)	15 / 3274 (0.46%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 32	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nodal arrhythmia			



subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prinzmetal angina			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular hypokinesia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			

subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Sinus node dysfunction			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	4 / 1512 (0.26%)	10 / 3274 (0.31%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 22	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Basal ganglia haemorrhage			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bell's palsy			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid arteriosclerosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery disease			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			

subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	8 / 1512 (0.53%)	14 / 3274 (0.43%)	2 / 284 (0.70%)
occurrences causally related to treatment / all	0 / 8	0 / 30	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Cerebellar haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cerebral infarction			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cauda equina syndrome			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cerebrovascular disorder			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical cord compression			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cortical laminar necrosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Intracranial mass			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embololic stroke			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	16 / 1512 (1.06%)	26 / 3274 (0.79%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 18	0 / 56	0 / 0
deaths causally related to treatment / all	0 / 4	0 / 4	0 / 0
Lacunar infarction			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar stroke			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	4 / 1512 (0.26%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralysis			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuritis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinson's disease			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			

subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	11 / 1512 (0.73%)	18 / 3274 (0.55%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 12	0 / 38	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Thalamus haemorrhage			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	5 / 1512 (0.33%)	13 / 3274 (0.40%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 5	0 / 26	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular encephalopathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasogenic cerebral oedema			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 14	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia macrocytic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Deficiency anaemia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Ear canal stenosis			



subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniere's disease			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otosclerosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vein thrombosis			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal haemorrhage			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	6 / 1512 (0.40%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 16	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal fat apron			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	5 / 1512 (0.33%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenogastric reflux			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			

subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric fistula			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric volvulus			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal atony			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	5 / 1512 (0.33%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 22	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Intestinal polyp			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic cyst			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive pancreatitis			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal dysplasia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal mucosal tear			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	1 / 4	2 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pancreatitis chronic			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis ulcerative			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pylorospasm			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal prolapse			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Salivary duct obstruction			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal ulcer haemorrhage			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Terminal ileitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	1 / 1512 (0.07%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			



subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic hepatitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	2 / 1512 (0.13%)	7 / 3274 (0.21%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 2	0 / 14	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	6 / 1512 (0.40%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 18	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cirrhosis alcoholic			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder rupture			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic fibrosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	3 / 1512 (0.20%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 18	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reactive perforating collagenosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ulcer			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	16 / 1512 (1.06%)	29 / 3274 (0.89%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 19	0 / 64	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis chronic			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal haemorrhage			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	4 / 1512 (0.26%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	2 / 1512 (0.13%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bladder			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	3 / 1512 (0.20%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 16	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Glomerulonephritis membranous			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal mass			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism primary			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroiditis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	2 / 1512 (0.13%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 14	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma muscle			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	5 / 1512 (0.33%)	9 / 3274 (0.27%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 6	0 / 22	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint instability			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			

subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	8 / 1512 (0.53%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 18	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	16 / 1512 (1.06%)	36 / 3274 (1.10%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 17	0 / 78	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			



subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal synovial cyst			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess limb			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	21 / 1512 (1.39%)	49 / 3274 (1.50%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 21	0 / 98	0 / 0
deaths causally related to treatment / all	0 / 5	0 / 15	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial colitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			

subjects affected / exposed	14 / 1512 (0.93%)	35 / 3274 (1.07%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 15	0 / 72	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 8	0 / 0
Cellulitis			
subjects affected / exposed	7 / 1512 (0.46%)	15 / 3274 (0.46%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 7	0 / 30	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter pneumonia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Enterobacter infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Gastroenteritis			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningoencephalitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected bite			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	16 / 1512 (1.06%)	35 / 3274 (1.07%)	2 / 284 (0.70%)
occurrences causally related to treatment / all	0 / 18	0 / 80	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 4	0 / 0
Neuroborreliosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	2 / 1512 (0.13%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 16	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	1 / 1512 (0.07%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-acute COVID-19 syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 1512 (0.07%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sepsis			
subjects affected / exposed	4 / 1512 (0.26%)	15 / 3274 (0.46%)	3 / 284 (1.06%)
occurrences causally related to treatment / all	0 / 4	0 / 30	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelitis			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal urinary tract infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound sepsis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			



subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 3	0 / 10	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	9 / 1512 (0.60%)	14 / 3274 (0.43%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 30	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viraemia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	4 / 1512 (0.26%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cachexia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			

subjects affected / exposed	0 / 1512 (0.00%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	4 / 1512 (0.26%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	1 / 4	2 / 14	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 4	0 / 10	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase III Placebo-Inclisiran		
Total subjects affected by serious adverse events			
subjects affected / exposed	482 / 1478 (32.61%)		
number of deaths (all causes)	81		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign lung neoplasm			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Anaplastic thyroid cancer			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma metastatic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Acute myeloid leukaemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of thyroid gland			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder cancer			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Chronic lymphocytic leukaemia			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchial carcinoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brenner tumour			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer metastatic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Bowen's disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder neoplasm			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder cancer recurrent			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clear cell renal cell carcinoma			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Colorectal adenoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colorectal cancer			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal carcinoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colorectal adenocarcinoma			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon neoplasm			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Gastrointestinal neoplasm			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glioblastoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cancer			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatocellular carcinoma			

subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Invasive ductal breast carcinoma				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Laryngeal papilloma				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukaemia				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lip and/or oral cavity cancer				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lip neoplasm malignant stage unspecified				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma in situ				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma				
subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Malignant mediastinal neoplasm				



subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant glioma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung neoplasm malignant			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Lung neoplasm			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung cancer metastatic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Lung squamous cell carcinoma metastatic			

subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine carcinoma metastatic				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neoplasm prostate				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic renal cell carcinoma				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastatic malignant melanoma				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to lymph nodes				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to lung				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to liver				
subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Metastases to central nervous system				

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to bone			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Mantle cell lymphoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-Hodgkin's lymphoma stage III			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant pleural effusion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-small cell lung cancer			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-small cell lung cancer metastatic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Oesophageal carcinoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal neoplasm			

subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Oncocytoma				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma metastatic				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer				
subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer metastatic				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian epithelial cancer				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Ovarian adenoma				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic neoplasm				

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraneoplastic syndrome			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parathyroid tumour benign			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Plasma cell myeloma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 1		
Small cell lung cancer metastatic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal cancer			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sarcoma uterus			

subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small cell lung cancer				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostate cancer metastatic				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma				
subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of lung				
subjects affected / exposed	3 / 1478 (0.20%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Squamous cell carcinoma of skin				
subjects affected / exposed	3 / 1478 (0.20%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the oral cavity				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transitional cell carcinoma metastatic				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Triple negative breast cancer				

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Ureteric cancer			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transitional cell carcinoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aneurysm			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic aneurysm			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Aortic dissection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Aortic occlusion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic stenosis			

subjects affected / exposed	6 / 1478 (0.41%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Arterial stenosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Circulatory collapse			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Essential hypertension			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extremity necrosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Granulomatosis with polyangiitis			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Embolism venous			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive emergency			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive urgency			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intermittent claudication			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Labile hypertension			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral artery stenosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Penetrating aortic ulcer			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial occlusive disease			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Peripheral artery aneurysm			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral artery occlusion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Leriche syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral embolism			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varicose vein			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral vascular disorder			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest discomfort			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	19 / 1478 (1.29%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 19		
Exercise tolerance decreased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Face oedema			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Non-cardiac chest pain			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Organ failure			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pyrexia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Swelling face			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular stent occlusion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular stent stenosis			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Sudden cardiac death			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immunisation reaction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sarcoidosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Perineal fistula			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Breast necrosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Cystocele			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostatitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine prolapse			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	17 / 1478 (1.15%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 3		
Dyspnoea exertional			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchiectasis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Chronic obstructive pulmonary disease				
subjects affected / exposed	9 / 1478 (0.61%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Chronic respiratory failure				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	8 / 1478 (0.54%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 1			
Asthma				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Laryngeal oedema				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nasal disorder				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstructive sleep apnoea syndrome				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumothorax spontaneous			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Pulmonary hypertension			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonitis aspiration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pulmonary sarcoidosis			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Confusional state			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Psychotic disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Generalised anxiety disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Major depression			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Conversion disorder			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Product issues			
Device dislocation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device loosening			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device malfunction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device occlusion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Troponin T increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostatic specific antigen increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oxygen saturation decreased			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial necrosis marker increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic enzyme increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoglobin decreased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Troponin increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Alcohol poisoning				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Back injury				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aortic restenosis				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankle fracture				
subjects affected / exposed	4 / 1478 (0.27%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Animal bite				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fractured sacrum				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fracture displacement				

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fibula fracture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Femoral neck fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Heat stroke			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Patella fracture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbar vertebral fracture			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb injury			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Ligament rupture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint injury			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Procedural hypotension			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Procedural haemorrhage			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound complication			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haematoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periprosthetic fracture			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin laceration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Traumatic fracture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Traumatic haemothorax			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sternal fracture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stomal hernia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haemorrhage			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular access site haematoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular graft occlusion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Acute left ventricular failure			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction			
subjects affected / exposed	24 / 1478 (1.62%)		
occurrences causally related to treatment / all	0 / 29		
deaths causally related to treatment / all	0 / 2		
Angina pectoris			
subjects affected / exposed	20 / 1478 (1.35%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	18 / 1478 (1.22%)		
occurrences causally related to treatment / all	0 / 21		
deaths causally related to treatment / all	0 / 0		
Aortic valve calcification			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Aortic valve stenosis				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	3 / 1478 (0.20%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Arrhythmic storm				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis coronary artery				
subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	6 / 1478 (0.41%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 3			
Atrial flutter				
subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	3 / 1478 (0.20%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block second degree				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bradycardia				

subjects affected / exposed	4 / 1478 (0.27%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	15 / 1478 (1.01%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Cardiac disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiac failure			
subjects affected / exposed	15 / 1478 (1.01%)		
occurrences causally related to treatment / all	0 / 26		
deaths causally related to treatment / all	0 / 3		
Cardiac failure acute			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cardiac failure chronic			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Cardiac failure congestive			
subjects affected / exposed	13 / 1478 (0.88%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 1		
Chronic coronary syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiogenic shock			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiomyopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiorenal syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiovascular insufficiency			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Chronic left ventricular failure			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congestive cardiomyopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	26 / 1478 (1.76%)		
occurrences causally related to treatment / all	0 / 29		
deaths causally related to treatment / all	0 / 0		
Coronary artery occlusion			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	19 / 1478 (1.29%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 6		
Ischaemic cardiomyopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Left ventricular dysfunction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Left ventricular failure			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mitral valve incompetence			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Diastolic dysfunction			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial ischaemia			

subjects affected / exposed	8 / 1478 (0.54%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
Nodal arrhythmia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prinzmetal angina			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus bradycardia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular hypokinesia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus tachycardia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular extrasystoles			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Sinus node dysfunction			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Basal ganglia haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aphasia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bell's palsy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carotid arteriosclerosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carotid artery disease			



subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery stenosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Carpal tunnel syndrome			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Cerebellar haemorrhage			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cauda equina syndrome			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical cord compression			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cortical laminar necrosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dementia Alzheimer's type			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ischaemic cerebral infarction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epilepsy			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage intracranial			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial mass			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolic stroke			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Lacunar infarction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lacunar stroke			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paralysis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Migraine			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Nervous system disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Optic neuritis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolic encephalopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parkinson's disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polyneuropathy			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sciatica			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Thalamus haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Vascular encephalopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vasogenic cerebral oedema			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Anaemia macrocytic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iron deficiency anaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Microcytic anaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deficiency anaemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood loss anaemia			

subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Ear canal stenosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meniere's disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vestibular disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otosclerosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diplopia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal vein thrombosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Anal haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Abdominal fat apron			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Faecaloma			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis ischaemic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulum			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulum intestinal			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenogastric reflux			

subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dyspepsia				
subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	3 / 1478 (0.20%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Gastric fistula				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Gastric ulcer				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric volvulus				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal atony				

subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Incarcerated inguinal hernia				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	4 / 1478 (0.27%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Intestinal ischaemia				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal polyp			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large intestinal haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large intestinal obstruction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic cyst			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obstructive pancreatitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal dysplasia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal mucosal tear			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large intestine polyp			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pancreatitis chronic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Proctitis ulcerative			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pylorospasm			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Rectal prolapse			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retroperitoneal haematoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Salivary duct obstruction			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal ulcer haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Terminal ileitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			

subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct stenosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic hepatitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Hepatomegaly			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cirrhosis alcoholic			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gallbladder rupture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic fibrosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reactive perforating collagenosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic foot			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic ulcer			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rash			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	12 / 1478 (0.81%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
End stage renal disease			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glomerulonephritis chronic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal haemorrhage			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			

subjects affected / exposed	4 / 1478 (0.27%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Neurogenic bladder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Glomerulonephritis membranous			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal mass			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ureteric obstruction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ureterolithiasis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Urethral stenosis			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Goitre			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperparathyroidism primary			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroiditis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Arthralgia				
subjects affected / exposed	5 / 1478 (0.34%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Arthritis				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc degeneration				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematoma muscle				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mobility decreased				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	3 / 1478 (0.20%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Joint instability				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc disorder			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bursitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foot deformity			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Scoliosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotator cuff syndrome			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Rheumatoid arthritis			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rhabdomyolysis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal osteoarthritis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	20 / 1478 (1.35%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 0		
Neck pain			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal stiffness			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Systemic lupus erythematosus			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spondylolisthesis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal synovial cyst			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal stenosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal pain			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tenosynovitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis			

subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Appendicitis perforated			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	28 / 1478 (1.89%)		
occurrences causally related to treatment / all	0 / 28		
deaths causally related to treatment / all	0 / 10		
Bacteraemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial colitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Atypical pneumonia			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19 pneumonia			
subjects affected / exposed	21 / 1478 (1.42%)		
occurrences causally related to treatment / all	0 / 21		
deaths causally related to treatment / all	0 / 5		
Cellulitis			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Cholecystitis infective			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic sinusitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterobacter pneumonia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Empyema			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocarditis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Enterobacter infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic foot infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enterococcal bacteraemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epstein-Barr virus infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gangrene			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis salmonella			

subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of chronic obstructive airways disease				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes zoster meningoencephalitis				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Implant site infection				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infected bite				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected skin ulcer				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intervertebral discitis				

subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Labyrinthitis				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngitis				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	17 / 1478 (1.15%)			
occurrences causally related to treatment / all	0 / 20			
deaths causally related to treatment / all	0 / 2			
Neuroborreliosis				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	4 / 1478 (0.27%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis chronic				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				

subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	4 / 1478 (0.27%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post-acute COVID-19 syndrome				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	5 / 1478 (0.34%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 1			
Sepsis				
subjects affected / exposed	8 / 1478 (0.54%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				

subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelitis				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural infection				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal urinary tract infection				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound sepsis				
subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Viral infection				

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viraemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gout			

subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemic hyperosmolar nonketotic syndrome				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	1 / 1478 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cachexia				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus inadequate control				
subjects affected / exposed	2 / 1478 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				
subjects affected / exposed	0 / 1478 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertriglyceridaemia				



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypervolaemia			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypovolaemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iron deficiency			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Phase III Inclisiran- Inclisiran	Total	ORION-3 Rollover
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1110 / 1512 (73.41%)	2352 / 3274 (71.84%)	169 / 284 (59.51%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cholesteatoma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Acrochordon			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Adrenal adenoma			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	1	8	1
Adrenal neoplasm			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
B-cell lymphoma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Basal cell carcinoma			
subjects affected / exposed	24 / 1512 (1.59%)	30 / 3274 (0.92%)	1 / 284 (0.35%)
occurrences (all)	33	78	1
Benign bone neoplasm			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Benign laryngeal neoplasm			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Benign neoplasm of bladder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Benign neoplasm of skin			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Benign neoplasm of thyroid gland			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Bladder cancer			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Bladder papilloma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Bowen's disease			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	1	4	1
Breast cancer			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Breast cancer metastatic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Meningioma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Melanocytic naevus			
subjects affected / exposed	5 / 1512 (0.33%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	5	14	0
Colorectal adenoma			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Dysplastic naevus			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Eye naevus			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Fibroma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Fibrous histiocytoma			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal tract adenoma			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Haemangioma			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Haemangioma of liver			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Haemangioma of skin			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Juvenile melanoma benign			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Leiomyoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Lipoma			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	1	8	0
Lymphoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Mantle cell lymphoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0

Metastases to bone			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Renal cell carcinoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Metastatic malignant melanoma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Metastatic neoplasm			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Myelodysplastic syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Oesophageal papilloma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Oral papilloma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Pancreatic neoplasm			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Parathyroid tumour benign			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Phaeochromocytoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Pituitary tumour			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Pituitary tumour benign			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0

Plasma cell myeloma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Prostate cancer			
subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	3	14	0
Prostatic adenoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Renal cancer			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Metastases to liver			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Renal hamartoma			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Seborrhoeic keratosis			
subjects affected / exposed	5 / 1512 (0.33%)	12 / 3274 (0.37%)	3 / 284 (1.06%)
occurrences (all)	5	24	3
Skin cancer			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Skin papilloma			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Skin squamous cell carcinoma recurrent			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Squamous cell carcinoma of skin			

subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	4 / 3274 (0.12%) 8	1 / 284 (0.35%) 1
Thyroid adenoma subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Thyroid cancer subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Uterine leiomyoma subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Vulvovaginal warts subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Vascular disorders			
Aortic aneurysm rupture subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Aneurysm subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Angiodysplasia subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Angiopathy subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Aortic aneurysm subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	6 / 3274 (0.18%) 16	0 / 284 (0.00%) 0
Aortic arteriosclerosis subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	4 / 3274 (0.12%) 8	0 / 284 (0.00%) 0

Hot flush			
subjects affected / exposed	0 / 1512 (0.00%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	0	8	0
Aortic stenosis			
subjects affected / exposed	6 / 1512 (0.40%)	10 / 3274 (0.31%)	1 / 284 (0.35%)
occurrences (all)	6	20	1
Arterial occlusive disease			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Arterial thrombosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Arteriosclerosis			
subjects affected / exposed	8 / 1512 (0.53%)	10 / 3274 (0.31%)	0 / 284 (0.00%)
occurrences (all)	8	20	0
Arteritis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Blood pressure fluctuation			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Blood pressure inadequately controlled			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Circulatory collapse			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Cyanosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Deep vein thrombosis			
subjects affected / exposed	5 / 1512 (0.33%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	6	16	0
Diastolic hypertension			



subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Essential hypertension			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Extravasation blood			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Flushing			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Haematoma			
subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	1 / 284 (0.35%)
occurrences (all)	3	14	1
Haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Aortic dilatation			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	2	10	0
Peripheral artery stenosis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Peripheral artery occlusion			
subjects affected / exposed	2 / 1512 (0.13%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	2	14	0
Peripheral ischaemia			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Peripheral vascular disorder			
subjects affected / exposed	5 / 1512 (0.33%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	5	14	0
Peripheral venous disease			
subjects affected / exposed	6 / 1512 (0.40%)	14 / 3274 (0.43%)	0 / 284 (0.00%)
occurrences (all)	8	34	0
Hypertension			

subjects affected / exposed	106 / 1512 (7.01%)	225 / 3274 (6.87%)	9 / 284 (3.17%)
occurrences (all)	112	484	9
Hypertensive crisis			
subjects affected / exposed	3 / 1512 (0.20%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	3	10	0
Hypertensive urgency			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Hypotension			
subjects affected / exposed	21 / 1512 (1.39%)	43 / 3274 (1.31%)	1 / 284 (0.35%)
occurrences (all)	23	100	2
Iliac artery arteriosclerosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Iliac artery stenosis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Intermittent claudication			
subjects affected / exposed	0 / 1512 (0.00%)	8 / 3274 (0.24%)	3 / 284 (1.06%)
occurrences (all)	0	16	3
Jugular vein thrombosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Lymphoedema			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	3	8	1
Microangiopathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Orthostatic hypertension			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Orthostatic hypotension			
subjects affected / exposed	3 / 1512 (0.20%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	3	16	0
Peripheral arterial occlusive disease			

subjects affected / exposed	11 / 1512 (0.73%)	22 / 3274 (0.67%)	1 / 284 (0.35%)
occurrences (all)	11	46	1
Peripheral coldness			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Phlebitis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
White coat hypertension			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Phlebitis superficial			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Post thrombotic syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Raynaud's phenomenon			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Superficial vein prominence			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Systolic hypertension			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Thrombophlebitis			
subjects affected / exposed	3 / 1512 (0.20%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	3	10	0
Thrombosed varicose vein			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Thrombosis			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Varicose vein			
subjects affected / exposed	6 / 1512 (0.40%)	15 / 3274 (0.46%)	0 / 284 (0.00%)
occurrences (all)	6	30	0
Vasculitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Venous hypertension			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Phlebitis deep			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 1512 (0.07%)	5 / 3274 (0.15%)	1 / 284 (0.35%)
occurrences (all)	1	10	1
Application site rash			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Asthenia			
subjects affected / exposed	12 / 1512 (0.79%)	20 / 3274 (0.61%)	0 / 284 (0.00%)
occurrences (all)	12	40	0
Calcinosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Chest discomfort			
subjects affected / exposed	8 / 1512 (0.53%)	16 / 3274 (0.49%)	3 / 284 (1.06%)
occurrences (all)	8	32	3
Chest pain			
subjects affected / exposed	16 / 1512 (1.06%)	36 / 3274 (1.10%)	5 / 284 (1.76%)
occurrences (all)	21	82	5
Chills			

subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	10	0
Crepitations			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Injection site oedema			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	8	0
Drug intolerance			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Exercise tolerance decreased			
subjects affected / exposed	6 / 1512 (0.40%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	6	16	0
Eye complication associated with device			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Facial pain			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Fatigue			
subjects affected / exposed	27 / 1512 (1.79%)	53 / 3274 (1.62%)	4 / 284 (1.41%)
occurrences (all)	30	114	4
Feeling abnormal			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Gait disturbance			
subjects affected / exposed	2 / 1512 (0.13%)	7 / 3274 (0.21%)	1 / 284 (0.35%)
occurrences (all)	2	14	1
Generalised oedema			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Hernia			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0

Inflammation			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Influenza like illness			
subjects affected / exposed	10 / 1512 (0.66%)	17 / 3274 (0.52%)	2 / 284 (0.70%)
occurrences (all)	12	40	2
Injection site bruising			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	3	12	0
Injection site eczema			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Injection site erythema			
subjects affected / exposed	10 / 1512 (0.66%)	24 / 3274 (0.73%)	2 / 284 (0.70%)
occurrences (all)	22	92	5
Injection site hypersensitivity			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Injection site induration			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Cyst			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Injection site pain			
subjects affected / exposed	22 / 1512 (1.46%)	39 / 3274 (1.19%)	0 / 284 (0.00%)
occurrences (all)	28	100	0
Polyp			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	1	4	1
Injection site pruritus			
subjects affected / exposed	2 / 1512 (0.13%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	2	12	0
Injection site rash			
subjects affected / exposed	9 / 1512 (0.60%)	16 / 3274 (0.49%)	0 / 284 (0.00%)
occurrences (all)	12	42	0

Injection site reaction			
subjects affected / exposed	42 / 1512 (2.78%)	93 / 3274 (2.84%)	2 / 284 (0.70%)
occurrences (all)	94	402	4
Injection site vesicles			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Injury associated with device			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Malaise			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Mass			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	1	4	1
Mucosal inflammation			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Nodule			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Non-cardiac chest pain			
subjects affected / exposed	10 / 1512 (0.66%)	22 / 3274 (0.67%)	1 / 284 (0.35%)
occurrences (all)	11	46	1
Oedema			
subjects affected / exposed	3 / 1512 (0.20%)	9 / 3274 (0.27%)	3 / 284 (1.06%)
occurrences (all)	3	18	3
Oedema peripheral			
subjects affected / exposed	29 / 1512 (1.92%)	51 / 3274 (1.56%)	2 / 284 (0.70%)
occurrences (all)	30	108	2
Pain			
subjects affected / exposed	7 / 1512 (0.46%)	13 / 3274 (0.40%)	1 / 284 (0.35%)
occurrences (all)	7	26	1
Peripheral swelling			
subjects affected / exposed	13 / 1512 (0.86%)	27 / 3274 (0.82%)	0 / 284 (0.00%)
occurrences (all)	15	58	0

Physical deconditioning subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Injection site paraesthesia subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	7 / 3274 (0.21%) 14	0 / 284 (0.00%) 0
Vessel puncture site bruise subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Swelling face subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	8 / 1512 (0.53%) 11	21 / 3274 (0.64%) 52	0 / 284 (0.00%) 0
Sensation of foreign body subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Vessel puncture site haemorrhage subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Immune system disorders			
Allergy to arthropod bite subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Allergy to arthropod sting subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Contrast media allergy subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Drug hypersensitivity subjects affected / exposed occurrences (all)	3 / 1512 (0.20%) 3	7 / 3274 (0.21%) 20	1 / 284 (0.35%) 4
Dust allergy			



subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Food allergy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Hypersensitivity			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	0	8	0
Immunisation reaction			
subjects affected / exposed	5 / 1512 (0.33%)	13 / 3274 (0.40%)	1 / 284 (0.35%)
occurrences (all)	6	30	2
Sarcoidosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Seasonal allergy			
subjects affected / exposed	9 / 1512 (0.60%)	26 / 3274 (0.79%)	1 / 284 (0.35%)
occurrences (all)	9	52	1
Social circumstances			
Family stress			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 1512 (0.00%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	0	8	1
Acquired phimosis			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Atrophic vulvovaginitis			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Benign prostatic hyperplasia			
subjects affected / exposed	26 / 1512 (1.72%)	48 / 3274 (1.47%)	2 / 284 (0.70%)
occurrences (all)	26	96	2
Breast disorder			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Breast mass			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Breast necrosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Endometrial hyperplasia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Erectile dysfunction			
subjects affected / exposed	11 / 1512 (0.73%)	21 / 3274 (0.64%)	2 / 284 (0.70%)
occurrences (all)	11	42	2
Genital prolapse			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Prostatic mass			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	0	4	1
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Prostatitis			
subjects affected / exposed	2 / 1512 (0.13%)	9 / 3274 (0.27%)	1 / 284 (0.35%)
occurrences (all)	2	18	1
Prostatomegaly			
subjects affected / exposed	6 / 1512 (0.40%)	11 / 3274 (0.34%)	0 / 284 (0.00%)
occurrences (all)	6	24	0
Rectocele			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Scrotal oedema			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Scrotal pain			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Sexual dysfunction			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Spermatocele			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Heavy menstrual bleeding			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Menopausal symptoms			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Nipple exudate bloody			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Ovarian calcification			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Ovarian mass			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Pelvic pain			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Penile discharge			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Peyronie's disease			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Prostatism			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Testicular hypertrophy			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Testicular pain			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Uterine prolapse			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Vaginal discharge			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Vaginal haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Vaginal prolapse			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Vulva cyst			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	1 / 284 (0.35%)
occurrences (all)	2	6	1
Vulvovaginal dryness			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Vulvovaginal inflammation			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Vulvovaginal pruritus			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Testicular mass			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			

subjects affected / exposed	1 / 1512 (0.07%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	1	10	0
Acquired diaphragmatic eventration			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Acute pulmonary oedema			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Acute respiratory failure			
subjects affected / exposed	1 / 1512 (0.07%)	6 / 3274 (0.18%)	1 / 284 (0.35%)
occurrences (all)	1	12	1
Allergic sinusitis			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Aspiration			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Asthma			
subjects affected / exposed	10 / 1512 (0.66%)	17 / 3274 (0.52%)	2 / 284 (0.70%)
occurrences (all)	14	48	4
Asthma exercise induced			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bronchial hyperreactivity			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bronchiectasis			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Bronchospasm			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Chronic obstructive pulmonary			

disease			
subjects affected / exposed	13 / 1512 (0.86%)	39 / 3274 (1.19%)	2 / 284 (0.70%)
occurrences (all)	16	92	2
Cough			
subjects affected / exposed	36 / 1512 (2.38%)	71 / 3274 (2.17%)	3 / 284 (1.06%)
occurrences (all)	39	148	3
Diaphragmatic disorder			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Dry throat			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Dysphonia			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Dyspnoea			
subjects affected / exposed	39 / 1512 (2.58%)	76 / 3274 (2.32%)	6 / 284 (2.11%)
occurrences (all)	40	160	6
Dyspnoea exertional			
subjects affected / exposed	11 / 1512 (0.73%)	23 / 3274 (0.70%)	3 / 284 (1.06%)
occurrences (all)	12	48	3
Emphysema			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Epiglottic oedema			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Epistaxis			
subjects affected / exposed	10 / 1512 (0.66%)	16 / 3274 (0.49%)	0 / 284 (0.00%)
occurrences (all)	10	32	0
Haemoptysis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Hiccups			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0

Hypoxia			
subjects affected / exposed	4 / 1512 (0.26%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	4	8	0
Bronchial secretion retention			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Pneumothorax			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Pleuritic pain			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Laryngeal ulceration			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Lung infiltration			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Lung opacity			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Nasal congestion			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Nasal mucosal blistering			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Nasal polyps			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Nasal septum deviation			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Obstructive airways disorder			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0

Obstructive sleep apnoea syndrome subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	3 / 3274 (0.09%) 6	0 / 284 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	6 / 1512 (0.40%) 7	13 / 3274 (0.40%) 28	1 / 284 (0.35%) 1
Paranasal cyst subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Paranasal sinus discomfort subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Paranasal sinus inflammation subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Pleural effusion subjects affected / exposed occurrences (all)	5 / 1512 (0.33%) 5	18 / 3274 (0.55%) 36	1 / 284 (0.35%) 1
Pleural thickening subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	3 / 3274 (0.09%) 6	0 / 284 (0.00%) 0
Pleurisy subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Interstitial lung disease subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Productive cough subjects affected / exposed occurrences (all)	3 / 1512 (0.20%) 3	7 / 3274 (0.21%) 14	0 / 284 (0.00%) 0
Pulmonary calcification subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Pulmonary congestion subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	3 / 3274 (0.09%) 6	0 / 284 (0.00%) 0



Pulmonary embolism			
subjects affected / exposed	5 / 1512 (0.33%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	5	12	0
Pulmonary fibrosis			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Pulmonary hypertension			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Pulmonary mass			
subjects affected / exposed	7 / 1512 (0.46%)	13 / 3274 (0.40%)	0 / 284 (0.00%)
occurrences (all)	7	26	0
Pulmonary oedema			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	10	0
Rales			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Reflux laryngitis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Respiratory acidosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Respiratory disorder			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Respiratory failure			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Rhinitis allergic			
subjects affected / exposed	5 / 1512 (0.33%)	11 / 3274 (0.34%)	0 / 284 (0.00%)
occurrences (all)	5	22	0
Rhinorrhoea			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	2	10	0

Sinus congestion subjects affected / exposed occurrences (all)	3 / 1512 (0.20%) 3	6 / 3274 (0.18%) 14	0 / 284 (0.00%) 0
Sinus disorder subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Sinus polyp subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Sleep apnoea syndrome subjects affected / exposed occurrences (all)	3 / 1512 (0.20%) 3	8 / 3274 (0.24%) 16	0 / 284 (0.00%) 0
Sneezing subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Throat tightness subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	1 / 284 (0.35%) 1
Upper respiratory tract congestion subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Upper-airway cough syndrome subjects affected / exposed occurrences (all)	3 / 1512 (0.20%) 3	8 / 3274 (0.24%) 16	1 / 284 (0.35%) 1
Vocal cord cyst subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Wheezing subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Throat irritation subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Psychiatric disorders Bipolar II disorder			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Abnormal behaviour			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Abnormal dreams			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Acute stress disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Agitation			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Alcohol abuse			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Alcoholism			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Anxiety			
subjects affected / exposed	16 / 1512 (1.06%)	38 / 3274 (1.16%)	1 / 284 (0.35%)
occurrences (all)	16	76	1
Anxiety disorder			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Bipolar disorder			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Delirium			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Delusion			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Depressed mood			
subjects affected / exposed	5 / 1512 (0.33%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences (all)	5	18	0
Depression			
subjects affected / exposed	29 / 1512 (1.92%)	51 / 3274 (1.56%)	3 / 284 (1.06%)
occurrences (all)	30	104	3
Grief reaction			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Habit cough			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Hallucination			
subjects affected / exposed	4 / 1512 (0.26%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	5	10	0
Hallucination, visual			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Initial insomnia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Insomnia			
subjects affected / exposed	13 / 1512 (0.86%)	28 / 3274 (0.86%)	0 / 284 (0.00%)
occurrences (all)	13	56	0
Irritability			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Libido decreased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Loss of libido			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Mental status changes			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Nightmare			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Confusional state			
subjects affected / exposed	6 / 1512 (0.40%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	7	16	0
Panic attack			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	0	4	1
Post-traumatic stress disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Restlessness			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Schizoaffective disorder bipolar type			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Sleep disorder			
subjects affected / exposed	3 / 1512 (0.20%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	3	16	0
Stress			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	1	8	0
Suicidal ideation			

subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Poor quality sleep subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Product issues			
Device dislocation subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Device malfunction subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Device physical property issue subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Hepatobiliary disorders			
Alcoholic liver disease subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Biliary colic subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Biliary dilatation subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Cholecystitis subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	4 / 3274 (0.12%) 8	0 / 284 (0.00%) 0
Cholecystitis acute subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Cholecystitis chronic subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Cholelithiasis			

subjects affected / exposed	11 / 1512 (0.73%)	28 / 3274 (0.86%)	1 / 284 (0.35%)
occurrences (all)	11	56	1
Gallbladder polyp			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Hepatic calcification			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Hepatic cirrhosis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Hepatic cyst			
subjects affected / exposed	0 / 1512 (0.00%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	0	12	0
Hepatic fibrosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Hepatic function abnormal			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Hepatic haematoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Hepatic lesion			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Hepatomegaly			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Hyperbilirubinaemia			
subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	3	14	0
Hypertransaminaemia			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Liver injury			

subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	3 / 3274 (0.09%) 6	0 / 284 (0.00%) 0
Non-alcoholic fatty liver subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	4 / 3274 (0.12%) 8	1 / 284 (0.35%) 1
Hepatic steatosis subjects affected / exposed occurrences (all)	17 / 1512 (1.12%) 17	38 / 3274 (1.16%) 76	4 / 284 (1.41%) 4
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	6 / 1512 (0.40%) 6	11 / 3274 (0.34%) 24	1 / 284 (0.35%) 1
Aortic bruit subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Arteriogram coronary normal subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	1 / 284 (0.35%) 1
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	3 / 1512 (0.20%) 4	9 / 3274 (0.27%) 24	1 / 284 (0.35%) 1
Bilirubin conjugated increased subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	7 / 1512 (0.46%) 7	12 / 3274 (0.37%) 24	0 / 284 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	6 / 1512 (0.40%) 7	14 / 3274 (0.43%) 30	1 / 284 (0.35%) 1
Blood bilirubin unconjugated increased subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Blood calcium decreased			



subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Blood calcium increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Antiphospholipid antibodies			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Blood cholesterol increased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Blood sodium decreased			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Blood creatine phosphokinase increased			
subjects affected / exposed	27 / 1512 (1.79%)	58 / 3274 (1.77%)	0 / 284 (0.00%)
occurrences (all)	29	124	0
Blood creatinine increased			
subjects affected / exposed	8 / 1512 (0.53%)	15 / 3274 (0.46%)	0 / 284 (0.00%)
occurrences (all)	8	30	0
Blood folate decreased			
subjects affected / exposed	2 / 1512 (0.13%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	2	12	0
Blood glucose abnormal			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Blood glucose increased			
subjects affected / exposed	1 / 1512 (0.07%)	5 / 3274 (0.15%)	3 / 284 (1.06%)
occurrences (all)	1	10	3
Blood homocysteine increased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Blood iron decreased			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0

Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Blood lactic acid increased			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Blood potassium decreased			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Blood potassium increased			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	2	8	1
Blood pressure ambulatory increased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Blood pressure decreased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Blood pressure diastolic decreased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Blood pressure increased			
subjects affected / exposed	13 / 1512 (0.86%)	27 / 3274 (0.82%)	0 / 284 (0.00%)
occurrences (all)	13	58	0
Blood pressure systolic increased			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Blood creatine abnormal			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Blood sodium increased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Electrocardiogram QT prolonged			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Blood triglycerides increased			
subjects affected / exposed	4 / 1512 (0.26%)	13 / 3274 (0.40%)	1 / 284 (0.35%)
occurrences (all)	4	28	1
Blood urea increased			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Blood urine present			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Body temperature abnormal			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Borrelia test positive			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Brain natriuretic peptide increased			
subjects affected / exposed	3 / 1512 (0.20%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	3	10	0
C-reactive protein increased			
subjects affected / exposed	8 / 1512 (0.53%)	17 / 3274 (0.52%)	2 / 284 (0.70%)
occurrences (all)	8	34	2
Carbohydrate antigen 15-3 increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Cardiac murmur			

subjects affected / exposed	5 / 1512 (0.33%)	10 / 3274 (0.31%)	0 / 284 (0.00%)
occurrences (all)	5	20	0
Cardiac stress test abnormal			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Carotid bruit			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Coronavirus test positive			
subjects affected / exposed	1 / 1512 (0.07%)	8 / 3274 (0.24%)	3 / 284 (1.06%)
occurrences (all)	1	16	3
Ejection fraction decreased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Blood testosterone decreased			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Hepatic enzyme abnormal			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Helicobacter test positive			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Electrocardiogram ST-T change			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Electrocardiogram T wave inversion			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Electrocardiogram abnormal			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	4	10	0
Electrocardiogram repolarisation abnormality			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0

Fibrin D dimer increased			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	16 / 1512 (1.06%)	39 / 3274 (1.19%)	0 / 284 (0.00%)
occurrences (all)	20	88	0
Glomerular filtration rate decreased			
subjects affected / exposed	9 / 1512 (0.60%)	18 / 3274 (0.55%)	1 / 284 (0.35%)
occurrences (all)	9	36	1
Glucose urine present			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Glycosylated haemoglobin increased			
subjects affected / exposed	13 / 1512 (0.86%)	29 / 3274 (0.89%)	1 / 284 (0.35%)
occurrences (all)	13	58	1
Haematology test abnormal			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Haemoglobin decreased			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	1 / 284 (0.35%)
occurrences (all)	3	12	1
Haemoglobin increased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Heart rate decreased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Heart rate irregular			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	2	10	0
Hepatic enzyme increased			

subjects affected / exposed	9 / 1512 (0.60%)	17 / 3274 (0.52%)	1 / 284 (0.35%)
occurrences (all)	9	34	1
Immunoglobulins decreased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Immunoglobulins increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
International normalised ratio increased			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Intraocular pressure increased			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Laboratory test abnormal			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Lipase increased			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Lipids increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Lipoprotein (a) increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Lipoprotein increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Liver function test abnormal			
subjects affected / exposed	0 / 1512 (0.00%)	7 / 3274 (0.21%)	1 / 284 (0.35%)
occurrences (all)	0	14	1
Liver function test increased			
subjects affected / exposed	2 / 1512 (0.13%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences (all)	2	18	0

Low density lipoprotein increased subjects affected / exposed occurrences (all)	5 / 1512 (0.33%) 5	8 / 3274 (0.24%) 16	0 / 284 (0.00%) 0
Mean cell volume increased subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Monofilament pressure perception test abnormal subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
N-terminal prohormone brain natriuretic peptide increased subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Nitrite urine subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Occult blood positive subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Oxygen saturation decreased subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Thyroxine increased subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Vitamin D decreased subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Serum ferritin decreased subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Scan myocardial perfusion abnormal			

subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	1	8	1
Romberg test positive			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Respiratory rate increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Protein urine present			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Prostatic specific antigen increased			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Transaminases increased			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Troponin increased			
subjects affected / exposed	3 / 1512 (0.20%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	3	16	0
Tryptase increased			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Ultrasound Doppler abnormal			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Ultrasound scan abnormal			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Urinary system x-ray abnormal			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Urine analysis abnormal			



subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Urine output decreased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Serum ferritin increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
White blood cells urine positive			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
White blood cell count increased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Weight increased			
subjects affected / exposed	4 / 1512 (0.26%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	4	12	0
Weight decreased			
subjects affected / exposed	12 / 1512 (0.79%)	19 / 3274 (0.58%)	0 / 284 (0.00%)
occurrences (all)	12	38	0
Injury, poisoning and procedural complications			
Back injury			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Accident			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Administration related reaction			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Alcohol poisoning			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Anaemia postoperative			

subjects affected / exposed	3 / 1512 (0.20%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	3	12	0
Animal bite			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	3	12	0
Animal scratch			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Ankle fracture			
subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	3	14	0
Arterial injury			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Arthropod bite			
subjects affected / exposed	5 / 1512 (0.33%)	14 / 3274 (0.43%)	1 / 284 (0.35%)
occurrences (all)	5	28	1
Arthropod sting			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Avulsion fracture			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bone contusion			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Facial bones fracture			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	2	10	0
Burns first degree			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Cartilage injury			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Chest injury			

subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Clavicle fracture			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	1 / 284 (0.35%)
occurrences (all)	2	10	1
Comminuted fracture			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Complications of transplanted lung			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Concussion			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Contusion			
subjects affected / exposed	15 / 1512 (0.99%)	38 / 3274 (1.16%)	2 / 284 (0.70%)
occurrences (all)	17	84	3
Corneal abrasion			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Costochondral separation			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Ear injury			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Electric shock			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Epicondylitis			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	3	10	1
Eye contusion			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Eye injury			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	1	4	1
Face injury			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Brain contusion			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Fall			
subjects affected / exposed	33 / 1512 (2.18%)	81 / 3274 (2.47%)	6 / 284 (2.11%)
occurrences (all)	45	204	6
Jaw fracture			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Fibula fracture			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Foot fracture			
subjects affected / exposed	3 / 1512 (0.20%)	8 / 3274 (0.24%)	1 / 284 (0.35%)
occurrences (all)	3	16	1
Forearm fracture			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Foreign body			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Foreign body in ear			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Foreign body in eye			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Fractured sacrum			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Hand fracture			

subjects affected / exposed	8 / 1512 (0.53%)	12 / 3274 (0.37%)	1 / 284 (0.35%)
occurrences (all)	8	24	1
Head injury			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	4	10	0
Heat exhaustion			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Humerus fracture			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Incisional hernia			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Injection related reaction			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	4	10	0
Injury			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Intra-ocular injection complication			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Femur fracture			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Joint dislocation			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Pelvic fracture			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Ligament rupture			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	1 / 284 (0.35%)
occurrences (all)	0	6	1
Ligament sprain			

subjects affected / exposed	8 / 1512 (0.53%)	15 / 3274 (0.46%)	0 / 284 (0.00%)
occurrences (all)	8	32	0
Limb crushing injury			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Limb fracture			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Limb injury			
subjects affected / exposed	10 / 1512 (0.66%)	26 / 3274 (0.79%)	1 / 284 (0.35%)
occurrences (all)	10	58	1
Limb traumatic amputation			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Lower limb fracture			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Meniscus injury			
subjects affected / exposed	5 / 1512 (0.33%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	5	14	0
Multiple injuries			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Muscle injury			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Muscle rupture			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	1 / 284 (0.35%)
occurrences (all)	1	6	1
Muscle strain			
subjects affected / exposed	7 / 1512 (0.46%)	11 / 3274 (0.34%)	0 / 284 (0.00%)
occurrences (all)	7	22	0
Musculoskeletal foreign body			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Neck injury			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Patella fracture			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Joint injury			
subjects affected / exposed	4 / 1512 (0.26%)	12 / 3274 (0.37%)	1 / 284 (0.35%)
occurrences (all)	4	24	1
Peripancreatic fluid collection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Rib fracture			
subjects affected / exposed	8 / 1512 (0.53%)	17 / 3274 (0.52%)	1 / 284 (0.35%)
occurrences (all)	8	34	1
Post procedural constipation			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Post procedural hypothyroidism			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Post procedural inflammation			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Post vaccination syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Post-traumatic pain			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Postoperative thoracic procedure			

complication			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Postoperative wound complication			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Procedural complication			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Procedural headache			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Procedural nausea			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Procedural pain			
subjects affected / exposed	4 / 1512 (0.26%)	17 / 3274 (0.52%)	3 / 284 (1.06%)
occurrences (all)	5	38	3
Radiation injury			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Radiation proctitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Radius fracture			
subjects affected / exposed	0 / 1512 (0.00%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	0	8	0
Post procedural complication			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Road traffic accident			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	1 / 284 (0.35%)
occurrences (all)	2	10	1
Traumatic arthrosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0



Skin injury			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Skin laceration			
subjects affected / exposed	18 / 1512 (1.19%)	31 / 3274 (0.95%)	2 / 284 (0.70%)
occurrences (all)	19	64	2
Skull fracture			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Soft tissue injury			
subjects affected / exposed	6 / 1512 (0.40%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences (all)	6	18	0
Spinal compression fracture			
subjects affected / exposed	3 / 1512 (0.20%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	3	16	0
Spinal fracture			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Splinter			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Subdural haematoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Synovial rupture			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Tendon injury			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Tendon rupture			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	1 / 284 (0.35%)
occurrences (all)	2	12	2
Thermal burn			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	1 / 284 (0.35%)
occurrences (all)	4	10	1

Thoracic vertebral fracture subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	4 / 3274 (0.12%) 8	0 / 284 (0.00%) 0
Tibia fracture subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	3 / 3274 (0.09%) 6	1 / 284 (0.35%) 1
Tobacco poisoning subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Tooth fracture subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	6 / 3274 (0.18%) 12	1 / 284 (0.35%) 1
Skin abrasion subjects affected / exposed occurrences (all)	7 / 1512 (0.46%) 7	12 / 3274 (0.37%) 24	0 / 284 (0.00%) 0
Wrist fracture subjects affected / exposed occurrences (all)	4 / 1512 (0.26%) 4	5 / 3274 (0.15%) 10	0 / 284 (0.00%) 0
Ulna fracture subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	3 / 3274 (0.09%) 6	0 / 284 (0.00%) 0
Upper limb fracture subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	3 / 3274 (0.09%) 6	0 / 284 (0.00%) 0
Vaccination complication subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	5 / 1512 (0.33%) 5	7 / 3274 (0.21%) 14	0 / 284 (0.00%) 0
Wound dehiscence subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Wound haemorrhage subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0

Wound necrosis subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Congenital, familial and genetic disorders			
Genetic polymorphism subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Adenomatous polyposis coli subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Apolipoprotein E e4 gene carrier subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Atrial septal defect subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Congenital cystic kidney disease subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Developmental hip dysplasia subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Hydrocele subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Phimosis subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 4	1 / 284 (0.35%) 1
SF3B1 gene mutation subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Cardiac disorders			
Atrioventricular block complete subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Atrial thrombosis			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Atrial tachycardia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Atrial flutter			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Atrial fibrillation			
subjects affected / exposed	40 / 1512 (2.65%)	80 / 3274 (2.44%)	4 / 284 (1.41%)
occurrences (all)	43	168	4
Atrial enlargement			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Arrhythmia supraventricular			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Arrhythmia			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	3	12	0
Aortic valve stenosis			
subjects affected / exposed	2 / 1512 (0.13%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	2	14	0
Aortic valve sclerosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Aortic valve incompetence			
subjects affected / exposed	4 / 1512 (0.26%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	4	16	0
Angina unstable			
subjects affected / exposed	4 / 1512 (0.26%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	4	14	0
Angina pectoris			

subjects affected / exposed	24 / 1512 (1.59%)	58 / 3274 (1.77%)	2 / 284 (0.70%)
occurrences (all)	26	120	2
Acute myocardial infarction			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Atrioventricular block			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Cardiac amyloidosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Cardiac aneurysm			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Cardiac disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Cardiac failure			
subjects affected / exposed	15 / 1512 (0.99%)	34 / 3274 (1.04%)	0 / 284 (0.00%)
occurrences (all)	16	76	0
Cardiac failure acute			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Cardiac failure chronic			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Cardiac failure congestive			
subjects affected / exposed	15 / 1512 (0.99%)	26 / 3274 (0.79%)	0 / 284 (0.00%)
occurrences (all)	16	54	0
Cardiac flutter			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Cardiac hypertrophy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Cardiac perfusion defect			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Cardiac sarcoidosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Cardiac valve disease			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Atrioventricular block first degree			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	3	12	0
Atrioventricular block second degree			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Bradycardia			
subjects affected / exposed	12 / 1512 (0.79%)	26 / 3274 (0.79%)	1 / 284 (0.35%)
occurrences (all)	12	52	1
Bundle branch block			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bundle branch block left			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Bundle branch block right			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Cardiac ventricular thrombosis			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Hypertensive heart disease			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Cardiomegaly			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Cardiomyopathy			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Cardiorenal syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Cardiovascular disorder			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Chronic left ventricular failure			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Chronotropic incompetence			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Conduction disorder			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Congestive cardiomyopathy			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Coronary artery disease			
subjects affected / exposed	17 / 1512 (1.12%)	41 / 3274 (1.25%)	0 / 284 (0.00%)
occurrences (all)	18	84	0
Coronary artery occlusion			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Coronary artery stenosis			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	12	0
Diastolic dysfunction			
subjects affected / exposed	1 / 1512 (0.07%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	1	10	0
Dressler's syndrome			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Extrasystoles			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Heart valve incompetence			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Hypertensive cardiomyopathy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Cardiogenic shock			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Ischaemic cardiomyopathy			
subjects affected / exposed	1 / 1512 (0.07%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	1	10	0
Left atrial enlargement			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Left ventricular dysfunction			
subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	3	14	0
Left ventricular enlargement			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Left ventricular failure			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	1	8	1
Left ventricular hypertrophy			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	4	10	0
Mitral valve calcification			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Mitral valve incompetence			
subjects affected / exposed	11 / 1512 (0.73%)	19 / 3274 (0.58%)	1 / 284 (0.35%)
occurrences (all)	11	38	1
Mitral valve prolapse			



subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Mitral valve stenosis			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Myocardial ischaemia			
subjects affected / exposed	4 / 1512 (0.26%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences (all)	4	18	0
Palpitations			
subjects affected / exposed	21 / 1512 (1.39%)	30 / 3274 (0.92%)	1 / 284 (0.35%)
occurrences (all)	24	70	1
Pericardial effusion			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	4	8	0
Pericarditis			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Prinzmetal angina			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Pulmonary valve incompetence			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Right atrial dilatation			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Sinus arrhythmia			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	1 / 284 (0.35%)
occurrences (all)	0	6	1
Sinus bradycardia			
subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	4	16	0
Sinus node dysfunction			
subjects affected / exposed	4 / 1512 (0.26%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	4	16	0
Supraventricular extrasystoles			

subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	4	10	0
Supraventricular tachycardia			
subjects affected / exposed	2 / 1512 (0.13%)	10 / 3274 (0.31%)	0 / 284 (0.00%)
occurrences (all)	2	22	0
Systolic dysfunction			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Tachycardia			
subjects affected / exposed	7 / 1512 (0.46%)	14 / 3274 (0.43%)	1 / 284 (0.35%)
occurrences (all)	7	28	1
Tachycardia paroxysmal			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Tricuspid valve incompetence			
subjects affected / exposed	6 / 1512 (0.40%)	11 / 3274 (0.34%)	1 / 284 (0.35%)
occurrences (all)	7	24	1
Ventricular arrhythmia			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Ventricular dysfunction			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Ventricular extrasystoles			
subjects affected / exposed	9 / 1512 (0.60%)	13 / 3274 (0.40%)	1 / 284 (0.35%)
occurrences (all)	9	26	1
Ventricular tachycardia			
subjects affected / exposed	5 / 1512 (0.33%)	14 / 3274 (0.43%)	0 / 284 (0.00%)
occurrences (all)	6	42	0
Sinus tachycardia			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	3	12	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0

Akinesia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Altered state of consciousness			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Amnesia			
subjects affected / exposed	6 / 1512 (0.40%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences (all)	6	18	0
Aphasia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Arachnoid cyst			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Balance disorder			
subjects affected / exposed	8 / 1512 (0.53%)	11 / 3274 (0.34%)	1 / 284 (0.35%)
occurrences (all)	8	22	1
Bell's palsy			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	2	8	1
Cervicogenic headache			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Carotid arteriosclerosis			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	1 / 284 (0.35%)
occurrences (all)	3	12	1
Carotid artery disease			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Carotid artery occlusion			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Carotid artery stenosis			
subjects affected / exposed	6 / 1512 (0.40%)	10 / 3274 (0.31%)	0 / 284 (0.00%)
occurrences (all)	6	20	0

Carpal tunnel syndrome			
subjects affected / exposed	13 / 1512 (0.86%)	22 / 3274 (0.67%)	1 / 284 (0.35%)
occurrences (all)	14	48	1
Cerebellar atrophy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Cerebral arteriosclerosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Cerebral atrophy			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	2	8	1
Cerebral ischaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Cerebral microangiopathy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Cerebral small vessel ischaemic disease			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Cerebrovascular accident			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Cerebrovascular disorder			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Cervical radiculopathy			
subjects affected / exposed	6 / 1512 (0.40%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	6	16	0
Cervicobrachial syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Burning sensation			

subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Dysgeusia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Dysarthria			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Epilepsy			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Essential tremor			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Facial paralysis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Facial paresis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Head discomfort			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	1	4	1
Headache			
subjects affected / exposed	41 / 1512 (2.71%)	83 / 3274 (2.54%)	5 / 284 (1.76%)
occurrences (all)	44	174	5
Hemiparesis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Cognitive disorder			
subjects affected / exposed	4 / 1512 (0.26%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	4	12	0
Cortical laminar necrosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Cubital tunnel syndrome			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Dementia			
subjects affected / exposed	3 / 1512 (0.20%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	3	10	0
Dementia Alzheimer's type			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Diabetic neuropathy			
subjects affected / exposed	6 / 1512 (0.40%)	11 / 3274 (0.34%)	1 / 284 (0.35%)
occurrences (all)	6	22	1
Disturbance in attention			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Dizziness			
subjects affected / exposed	40 / 1512 (2.65%)	88 / 3274 (2.69%)	6 / 284 (2.11%)
occurrences (all)	46	192	6
Encephalopathy			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Hepatic encephalopathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Myelopathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Hypoaesthesia			
subjects affected / exposed	5 / 1512 (0.33%)	12 / 3274 (0.37%)	0 / 284 (0.00%)
occurrences (all)	5	26	0
Hyporeflexia			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Hyposmia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Intercostal neuralgia			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Intracranial aneurysm			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Intracranial mass			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Ischaemic stroke			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Lethargy			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Loss of consciousness			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	0	4	1
Lumbosacral radiculopathy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Memory impairment			
subjects affected / exposed	5 / 1512 (0.33%)	8 / 3274 (0.24%)	1 / 284 (0.35%)
occurrences (all)	5	16	1
Migraine			
subjects affected / exposed	5 / 1512 (0.33%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	5	12	0
Morton's neuralgia			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Hyperaesthesia			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Nerve compression			
subjects affected / exposed	3 / 1512 (0.20%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	3	16	0
Restless legs syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Neuropathy peripheral			
subjects affected / exposed	18 / 1512 (1.19%)	33 / 3274 (1.01%)	4 / 284 (1.41%)
occurrences (all)	18	70	6
Pachymeningitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Paraesthesia			
subjects affected / exposed	6 / 1512 (0.40%)	12 / 3274 (0.37%)	2 / 284 (0.70%)
occurrences (all)	6	28	3
Paralysis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Parkinson's disease			
subjects affected / exposed	5 / 1512 (0.33%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	5	16	0
Partial seizures			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Periodic limb movement disorder			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Peroneal nerve palsy			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Polyneuropathy			



subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Post herpetic neuralgia			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Post polio syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Presyncope			
subjects affected / exposed	6 / 1512 (0.40%)	11 / 3274 (0.34%)	1 / 284 (0.35%)
occurrences (all)	6	22	1
Quadrantanopia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Radiculopathy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Neuralgia			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	3	12	0
Sciatica			
subjects affected / exposed	15 / 1512 (0.99%)	38 / 3274 (1.16%)	1 / 284 (0.35%)
occurrences (all)	18	84	1
Vlth nerve paralysis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Senile dementia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Sensory disturbance			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Sensory loss			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Somnolence			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Speech disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Spinal claudication			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Syncope			
subjects affected / exposed	16 / 1512 (1.06%)	31 / 3274 (0.95%)	0 / 284 (0.00%)
occurrences (all)	19	78	0
Taste disorder			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Tension headache			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Thoracic radiculopathy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Thunderclap headache			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Transient global amnesia			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	1	4	1
Transient ischaemic attack			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Tremor			
subjects affected / exposed	7 / 1512 (0.46%)	12 / 3274 (0.37%)	1 / 284 (0.35%)
occurrences (all)	7	24	1
Trigeminal neuralgia			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Ulnar neuritis			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Seizure			
subjects affected / exposed	4 / 1512 (0.26%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	5	14	0
Vascular dementia			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Vascular parkinsonism			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Vocal cord paralysis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Vascular encephalopathy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	45 / 1512 (2.98%)	80 / 3274 (2.44%)	2 / 284 (0.70%)
occurrences (all)	46	170	2
Anaemia macrocytic			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	1	8	0
Anaemia megaloblastic			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Cytopenia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0

Blood loss anaemia			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Bone marrow oedema			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Coagulopathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Bicytopenia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Eosinophilia			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	0	4	1
Haemolytic anaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Polycythaemia			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Pancytopenia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Normocytic anaemia			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Neutropenia			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Nephrogenic anaemia			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0

Monoclonal B-cell lymphocytosis subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Microcytic anaemia subjects affected / exposed occurrences (all)	3 / 1512 (0.20%) 3	9 / 3274 (0.27%) 18	1 / 284 (0.35%) 1
Macrocytosis subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	6 / 3274 (0.18%) 12	1 / 284 (0.35%) 1
Lymph node fibrosis subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Leukopenia subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	8 / 1512 (0.53%) 15	12 / 3274 (0.37%) 38	0 / 284 (0.00%) 0
Iron deficiency anaemia subjects affected / exposed occurrences (all)	10 / 1512 (0.66%) 11	14 / 3274 (0.43%) 30	0 / 284 (0.00%) 0
Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Hypochromic anaemia subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Hilar lymphadenopathy subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Splenomegaly subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	3 / 3274 (0.09%) 6	0 / 284 (0.00%) 0

Thrombocytosis subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	8 / 3274 (0.24%) 16	0 / 284 (0.00%) 0
Ear and labyrinth disorders			
Deafness neurosensory subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	3 / 3274 (0.09%) 6	0 / 284 (0.00%) 0
Deafness bilateral subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Ear canal stenosis subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Ear haemorrhage subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	9 / 1512 (0.60%) 9	12 / 3274 (0.37%) 24	0 / 284 (0.00%) 0
Ear pruritus subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Eustachian tube dysfunction subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Excessive cerumen production subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Haematotympanum subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Hypoacusis			

subjects affected / exposed	0 / 1512 (0.00%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	0	8	1
Mastoid disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Meniere's disease			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Cerumen impaction			
subjects affected / exposed	3 / 1512 (0.20%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	3	16	0
Conductive deafness			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Deafness			
subjects affected / exposed	4 / 1512 (0.26%)	6 / 3274 (0.18%)	1 / 284 (0.35%)
occurrences (all)	4	12	1
Deafness unilateral			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Otolithiasis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Sudden hearing loss			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Tinnitus			
subjects affected / exposed	3 / 1512 (0.20%)	13 / 3274 (0.40%)	0 / 284 (0.00%)
occurrences (all)	3	26	0
Vertigo			
subjects affected / exposed	15 / 1512 (0.99%)	33 / 3274 (1.01%)	4 / 284 (1.41%)
occurrences (all)	15	66	4
Vertigo positional			
subjects affected / exposed	4 / 1512 (0.26%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	4	8	0
Otorrhoea			

subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Eye disorders			
Age-related macular degeneration subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 6	0 / 284 (0.00%) 0
Amaurosis fugax subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Exfoliation syndrome subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Blepharospasm subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Blindness subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	1 / 284 (0.35%) 1
Cataract subjects affected / exposed occurrences (all)	40 / 1512 (2.65%) 45	68 / 3274 (2.08%) 168	5 / 284 (1.76%) 8
Chalazion subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Choroidal neovascularisation subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	4 / 3274 (0.12%) 8	0 / 284 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	3 / 3274 (0.09%) 6	0 / 284 (0.00%) 0
Corneal degeneration subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0



Corneal erosion			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Dermatochalasis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Diabetic retinopathy			
subjects affected / exposed	1 / 1512 (0.07%)	8 / 3274 (0.24%)	4 / 284 (1.41%)
occurrences (all)	1	16	4
Diplopia			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Dry eye			
subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	3	14	0
Ectropion			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	0	4	1
Epiretinal membrane			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Blepharitis			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Neovascular age-related macular degeneration			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Macular oedema			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Ocular hypertension			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Periorbital swelling			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Eye discharge			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Eye haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Eye irritation			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Eye pain			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Eye pruritus			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Eye swelling			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Eyelid cyst			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Eyelid ptosis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Glaucoma			
subjects affected / exposed	5 / 1512 (0.33%)	13 / 3274 (0.40%)	1 / 284 (0.35%)
occurrences (all)	5	26	1
Iridocyclitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Iritis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Keratitis			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Lacrimation increased			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	1	4	1
Macular degeneration			
subjects affected / exposed	7 / 1512 (0.46%)	9 / 3274 (0.27%)	1 / 284 (0.35%)
occurrences (all)	7	18	1
Non-proliferative retinopathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Posterior capsule opacification			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Retinal artery embolism			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Retinal artery occlusion			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Retinal detachment			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	2	8	1
Retinal haemorrhage			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Retinal ischaemia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Retinal vascular thrombosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Retinal vein occlusion			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Retinopathy			

subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	0	4	1
Retinopathy hypertensive			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Swelling of eyelid			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Ulcerative keratitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Vision blurred			
subjects affected / exposed	3 / 1512 (0.20%)	8 / 3274 (0.24%)	1 / 284 (0.35%)
occurrences (all)	3	16	1
Visual acuity reduced			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Visual impairment			
subjects affected / exposed	5 / 1512 (0.33%)	10 / 3274 (0.31%)	1 / 284 (0.35%)
occurrences (all)	5	20	1
Vitreous detachment			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	1 / 284 (0.35%)
occurrences (all)	1	6	1
Vitreous floaters			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Vitreous haemorrhage			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Vitreous opacities			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Gastrointestinal disorders			
Change of bowel habit			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0

Abdominal distension			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Abdominal hernia			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	2	8	1
Abdominal mass			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Abdominal pain			
subjects affected / exposed	15 / 1512 (0.99%)	34 / 3274 (1.04%)	3 / 284 (1.06%)
occurrences (all)	17	76	3
Abdominal pain lower			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	1 / 284 (0.35%)
occurrences (all)	3	12	1
Abdominal pain upper			
subjects affected / exposed	6 / 1512 (0.40%)	20 / 3274 (0.61%)	3 / 284 (1.06%)
occurrences (all)	7	44	4
Abdominal wall haematoma			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Acquired oesophageal web			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Anal fissure			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Anal incontinence			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	2 / 284 (0.70%)
occurrences (all)	0	4	2
Anal prolapse			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Anal skin tags			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0

Anorectal discomfort			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Ascites			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Barrett's oesophagus			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	1	8	1
Abdominal discomfort			
subjects affected / exposed	0 / 1512 (0.00%)	8 / 3274 (0.24%)	1 / 284 (0.35%)
occurrences (all)	0	16	1
Defaecation disorder			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Crohn's disease			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Diarrhoea			
subjects affected / exposed	41 / 1512 (2.71%)	76 / 3274 (2.32%)	4 / 284 (1.41%)
occurrences (all)	47	170	4
Diarrhoea haemorrhagic			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Diverticulitis oesophageal			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Diverticulum			
subjects affected / exposed	5 / 1512 (0.33%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences (all)	5	18	0
Diverticulum intestinal			
subjects affected / exposed	6 / 1512 (0.40%)	16 / 3274 (0.49%)	0 / 284 (0.00%)
occurrences (all)	6	32	0
Dry mouth			
subjects affected / exposed	4 / 1512 (0.26%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	4	8	0

Duodenal polyp			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Duodenal ulcer			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Duodenitis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Duodenogastric reflux			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Dyspepsia			
subjects affected / exposed	8 / 1512 (0.53%)	18 / 3274 (0.55%)	1 / 284 (0.35%)
occurrences (all)	8	36	1
Chronic gastritis			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	2	10	0
Colitis			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Colitis microscopic			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Colitis ulcerative			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Constipation			
subjects affected / exposed	22 / 1512 (1.46%)	49 / 3274 (1.50%)	2 / 284 (0.70%)
occurrences (all)	23	100	2
Dental caries			
subjects affected / exposed	5 / 1512 (0.33%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences (all)	5	18	0
Dysphagia			
subjects affected / exposed	11 / 1512 (0.73%)	17 / 3274 (0.52%)	1 / 284 (0.35%)
occurrences (all)	12	36	1

Gastrointestinal pain			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Eosinophilic oesophagitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Epigastric discomfort			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Erosive duodenitis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Eructation			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	1	8	0
Faeces discoloured			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Faeces soft			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Flatulence			
subjects affected / exposed	4 / 1512 (0.26%)	11 / 3274 (0.34%)	0 / 284 (0.00%)
occurrences (all)	4	22	0
Food poisoning			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Frequent bowel movements			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Gastric antral vascular ectasia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Gastric disorder			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	1	8	1



Gastric mucosa erythema subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Gastric ulcer subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	12 / 1512 (0.79%) 12	28 / 3274 (0.86%) 58	3 / 284 (1.06%) 4
Gastritis erosive subjects affected / exposed occurrences (all)	3 / 1512 (0.20%) 3	6 / 3274 (0.18%) 12	0 / 284 (0.00%) 0
Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Enteritis subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	16 / 1512 (1.06%) 17	44 / 3274 (1.34%) 90	5 / 284 (1.76%) 5
Odynophagia subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Haematochezia subjects affected / exposed occurrences (all)	4 / 1512 (0.26%) 4	7 / 3274 (0.21%) 14	0 / 284 (0.00%) 0
Haemorrhoids subjects affected / exposed occurrences (all)	9 / 1512 (0.60%) 9	19 / 3274 (0.58%) 38	0 / 284 (0.00%) 0
Hiatus hernia subjects affected / exposed occurrences (all)	7 / 1512 (0.46%) 7	19 / 3274 (0.58%) 38	2 / 284 (0.70%) 2
Ileus subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0

Ileus paralytic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Inflammatory bowel disease			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Inguinal hernia			
subjects affected / exposed	5 / 1512 (0.33%)	13 / 3274 (0.40%)	1 / 284 (0.35%)
occurrences (all)	5	26	1
Intestinal ischaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Intestinal polyp			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Irritable bowel syndrome			
subjects affected / exposed	2 / 1512 (0.13%)	5 / 3274 (0.15%)	1 / 284 (0.35%)
occurrences (all)	3	12	1
Large intestine polyp			
subjects affected / exposed	10 / 1512 (0.66%)	17 / 3274 (0.52%)	0 / 284 (0.00%)
occurrences (all)	10	34	0
Lip swelling			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Melaena			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Mouth ulceration			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	23 / 1512 (1.52%)	41 / 3274 (1.25%)	1 / 284 (0.35%)
occurrences (all)	25	90	1
Haematemesis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0

Proctalgia			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Pneumoperitoneum			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Rectal discharge			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Rectal haemorrhage			
subjects affected / exposed	2 / 1512 (0.13%)	7 / 3274 (0.21%)	2 / 284 (0.70%)
occurrences (all)	2	14	2
Rectal polyp			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Rectal prolapse			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Oesophageal stenosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Oesophagitis			
subjects affected / exposed	5 / 1512 (0.33%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	5	16	0
Pancreatic cyst			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Pancreatic duct dilatation			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Pancreatic failure			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Pancreatic steatosis			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	3	12	0

Pancreatitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Pancreatitis acute			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Pancreatitis chronic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Peptic ulcer			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Peritoneal adhesions			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Proctitis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Regurgitation			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Retroperitoneal haematoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Salivary gland enlargement			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Salivary gland mass			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Stomatitis			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Tongue cyst			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0

Tongue ulceration subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Tooth impacted subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	5 / 3274 (0.15%) 10	0 / 284 (0.00%) 0
Umbilical hernia subjects affected / exposed occurrences (all)	5 / 1512 (0.33%) 5	10 / 3274 (0.31%) 20	0 / 284 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	16 / 1512 (1.06%) 17	28 / 3274 (0.86%) 60	3 / 284 (1.06%) 3
Skin and subcutaneous tissue disorders			
Dermatitis allergic subjects affected / exposed occurrences (all)	3 / 1512 (0.20%) 3	6 / 3274 (0.18%) 20	0 / 284 (0.00%) 0
Acne subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Actinic keratosis subjects affected / exposed occurrences (all)	5 / 1512 (0.33%) 5	11 / 3274 (0.34%) 22	2 / 284 (0.70%) 2
Alopecia subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 2	5 / 3274 (0.15%) 12	1 / 284 (0.35%) 1
Alopecia areata subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	3 / 3274 (0.09%) 6	0 / 284 (0.00%) 0
Angioedema subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Blister			

subjects affected / exposed	4 / 1512 (0.26%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	4	14	0
Cutaneous calcification			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Decubitus ulcer			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Dermal cyst			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Dermatitis			
subjects affected / exposed	2 / 1512 (0.13%)	6 / 3274 (0.18%)	1 / 284 (0.35%)
occurrences (all)	2	14	1
Dermatitis acneiform			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Dermatitis contact			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	8	0
Lichen planus			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Diabetic foot			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Diabetic ulcer			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Dry skin			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	4	10	0
Dyshidrotic eczema			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Ecchymosis			

subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Eczema			
subjects affected / exposed	6 / 1512 (0.40%)	14 / 3274 (0.43%)	1 / 284 (0.35%)
occurrences (all)	6	28	1
Eczema asteatotic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Erythema			
subjects affected / exposed	3 / 1512 (0.20%)	10 / 3274 (0.31%)	5 / 284 (1.76%)
occurrences (all)	3	22	5
Hand dermatitis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Hidradenitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Hyperhidrosis			
subjects affected / exposed	5 / 1512 (0.33%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	5	16	0
Hyperkeratosis			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Hypertrophic scar			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Ingrowing nail			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	4	8	0
Intertrigo			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Lentigo			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Dermatitis diaper			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Pityriasis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Pemphigus			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Polymorphic light eruption			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Pruritus			
subjects affected / exposed	8 / 1512 (0.53%)	16 / 3274 (0.49%)	1 / 284 (0.35%)
occurrences (all)	10	40	1
Pruritus allergic			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Psoriasis			
subjects affected / exposed	6 / 1512 (0.40%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	6	22	0
Purpura senile			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Rash			
subjects affected / exposed	13 / 1512 (0.86%)	23 / 3274 (0.70%)	1 / 284 (0.35%)
occurrences (all)	14	48	1
Rash erythematous			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Rash pruritic			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	1 / 284 (0.35%)
occurrences (all)	2	10	3
Reactive perforating collagenosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Rosacea			



subjects affected / exposed	3 / 1512 (0.20%)	5 / 3274 (0.15%)	1 / 284 (0.35%)
occurrences (all)	3	10	1
Lipohypertrophy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Milia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Nail dystrophy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Night sweats			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Panniculitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Pityriasis rosea			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Sebaceous hyperplasia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Skin discolouration			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Skin fibrosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Skin indentation			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Skin lesion			
subjects affected / exposed	6 / 1512 (0.40%)	14 / 3274 (0.43%)	1 / 284 (0.35%)
occurrences (all)	9	34	1
Skin reaction			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Skin texture abnormal			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Skin ulcer			
subjects affected / exposed	6 / 1512 (0.40%)	13 / 3274 (0.40%)	1 / 284 (0.35%)
occurrences (all)	9	34	1
Stasis dermatitis			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	2 / 284 (0.70%)
occurrences (all)	2	8	2
Subcutaneous emphysema			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Urticaria			
subjects affected / exposed	4 / 1512 (0.26%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	4	10	0
Xanthoma			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Sensitive skin			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Renal and urinary disorders			
Cystitis haemorrhagic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Acute kidney injury			
subjects affected / exposed	11 / 1512 (0.73%)	29 / 3274 (0.89%)	0 / 284 (0.00%)
occurrences (all)	11	60	0
Albuminuria			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Azotaemia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0

Bladder disorder			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bladder diverticulum			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Bladder irritation			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bladder outlet obstruction			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Bladder prolapse			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bladder stenosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Chronic kidney disease			
subjects affected / exposed	23 / 1512 (1.52%)	44 / 3274 (1.34%)	1 / 284 (0.35%)
occurrences (all)	23	88	1
Cystitis noninfective			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Neurogenic bladder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Dysuria			
subjects affected / exposed	6 / 1512 (0.40%)	10 / 3274 (0.31%)	2 / 284 (0.70%)
occurrences (all)	6	20	2
End stage renal disease			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Genitourinary symptom			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0

Glycosuria			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Haematuria			
subjects affected / exposed	14 / 1512 (0.93%)	27 / 3274 (0.82%)	0 / 284 (0.00%)
occurrences (all)	17	60	0
Hydronephrosis			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Hypertensive nephropathy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Hypertonic bladder			
subjects affected / exposed	5 / 1512 (0.33%)	11 / 3274 (0.34%)	0 / 284 (0.00%)
occurrences (all)	5	22	0
Leukocyturia			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Lower urinary tract symptoms			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	1	10	0
Microalbuminuria			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Micturition urgency			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	1 / 284 (0.35%)
occurrences (all)	1	6	1
Nephritic syndrome			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Nephrolithiasis			
subjects affected / exposed	15 / 1512 (0.99%)	26 / 3274 (0.79%)	1 / 284 (0.35%)
occurrences (all)	18	58	1
Nephropathy			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0

Diabetic nephropathy			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Nocturia			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Polyuria			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Proteinuria			
subjects affected / exposed	4 / 1512 (0.26%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	4	12	0
Pyelocaliectasis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Renal aneurysm			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Renal artery stenosis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	0	6	1
Renal colic			
subjects affected / exposed	4 / 1512 (0.26%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	4	12	0
Renal cyst			
subjects affected / exposed	9 / 1512 (0.60%)	31 / 3274 (0.95%)	0 / 284 (0.00%)
occurrences (all)	9	64	0
Renal disorder			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Renal failure			
subjects affected / exposed	5 / 1512 (0.33%)	11 / 3274 (0.34%)	0 / 284 (0.00%)
occurrences (all)	5	22	0

Renal impairment subjects affected / exposed occurrences (all)	24 / 1512 (1.59%) 28	54 / 3274 (1.65%) 118	0 / 284 (0.00%) 0
Renal mass subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Renal necrosis subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Renal pain subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Strangury subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Stress urinary incontinence subjects affected / exposed occurrences (all)	4 / 1512 (0.26%) 4	4 / 3274 (0.12%) 8	0 / 284 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	6 / 1512 (0.40%) 6	10 / 3274 (0.31%) 20	0 / 284 (0.00%) 0
Ureterolithiasis subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Urge incontinence subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Urinary bladder haemorrhage subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	6 / 1512 (0.40%) 6	12 / 3274 (0.37%) 24	1 / 284 (0.35%) 1
Urinary retention subjects affected / exposed occurrences (all)	5 / 1512 (0.33%) 5	9 / 3274 (0.27%) 18	0 / 284 (0.00%) 0

Urinary tract disorder subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Urinary tract inflammation subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Urine odour abnormal subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Urethral stenosis subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 6	0 / 284 (0.00%) 0
Endocrine disorders			
Adrenal mass subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Autoimmune thyroiditis subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	5 / 3274 (0.15%) 10	0 / 284 (0.00%) 0
Goitre subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	6 / 3274 (0.18%) 12	0 / 284 (0.00%) 0
Hyperparathyroidism subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	4 / 3274 (0.12%) 8	0 / 284 (0.00%) 0
Hyperparathyroidism primary subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Hyperprolactinaemia subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Hyperthyroidism subjects affected / exposed occurrences (all)	6 / 1512 (0.40%) 6	11 / 3274 (0.34%) 22	0 / 284 (0.00%) 0
Hypogonadism			

subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Hypothyroidism			
subjects affected / exposed	10 / 1512 (0.66%)	22 / 3274 (0.67%)	2 / 284 (0.70%)
occurrences (all)	10	44	2
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Thyroid calcification			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Thyroid mass			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Musculoskeletal and connective tissue disorders			
Dupuytren's contracture			
subjects affected / exposed	3 / 1512 (0.20%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	3	16	0
Ankle impingement			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Arthralgia			
subjects affected / exposed	94 / 1512 (6.22%)	201 / 3274 (6.14%)	5 / 284 (1.76%)
occurrences (all)	107	456	5
Arthritis			
subjects affected / exposed	14 / 1512 (0.93%)	28 / 3274 (0.86%)	2 / 284 (0.70%)
occurrences (all)	14	56	2
Arthropathy			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Back pain			
subjects affected / exposed	67 / 1512 (4.43%)	126 / 3274 (3.85%)	8 / 284 (2.82%)
occurrences (all)	72	272	8
Bone atrophy			



subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bone cyst			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Bursitis			
subjects affected / exposed	4 / 1512 (0.26%)	13 / 3274 (0.40%)	3 / 284 (1.06%)
occurrences (all)	5	28	3
Cervical spinal stenosis			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Chondrocalcinosis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Chondropathy			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Chronic kidney disease-mineral and bone disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Coccydynia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Costochondritis			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	1	8	0
Degenerative bone disease			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Diffuse idiopathic skeletal hyperostosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Exostosis			

subjects affected / exposed	3 / 1512 (0.20%)	5 / 3274 (0.15%)	1 / 284 (0.35%)
occurrences (all)	3	10	1
Limb discomfort			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Flank pain			
subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	3	14	0
Foot deformity			
subjects affected / exposed	4 / 1512 (0.26%)	9 / 3274 (0.27%)	1 / 284 (0.35%)
occurrences (all)	6	22	1
Fracture pain			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Groin pain			
subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	3	14	0
Haemarthrosis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Haematoma muscle			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Intervertebral disc degeneration			
subjects affected / exposed	6 / 1512 (0.40%)	11 / 3274 (0.34%)	0 / 284 (0.00%)
occurrences (all)	6	22	0
Intervertebral disc disorder			
subjects affected / exposed	5 / 1512 (0.33%)	10 / 3274 (0.31%)	1 / 284 (0.35%)
occurrences (all)	5	20	1
Intervertebral disc protrusion			
subjects affected / exposed	7 / 1512 (0.46%)	17 / 3274 (0.52%)	1 / 284 (0.35%)
occurrences (all)	7	36	1
Joint effusion			

subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	3	12	0
Joint instability			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Joint stiffness			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Joint swelling			
subjects affected / exposed	6 / 1512 (0.40%)	12 / 3274 (0.37%)	1 / 284 (0.35%)
occurrences (all)	6	24	1
Ligament calcification			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Fibromyalgia			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	1	8	0
Lumbar spinal stenosis			
subjects affected / exposed	4 / 1512 (0.26%)	8 / 3274 (0.24%)	1 / 284 (0.35%)
occurrences (all)	4	16	1
Neck mass			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Mobility decreased			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Muscle atrophy			
subjects affected / exposed	0 / 1512 (0.00%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	0	8	0
Muscle contracture			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Muscle discomfort			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Muscle fatigue			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Muscle oedema			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Muscle rigidity			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Muscle spasms			
subjects affected / exposed	26 / 1512 (1.72%)	37 / 3274 (1.13%)	1 / 284 (0.35%)
occurrences (all)	26	74	1
Muscle tightness			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Muscular weakness			
subjects affected / exposed	8 / 1512 (0.53%)	13 / 3274 (0.40%)	1 / 284 (0.35%)
occurrences (all)	8	26	1
Musculoskeletal chest pain			
subjects affected / exposed	4 / 1512 (0.26%)	8 / 3274 (0.24%)	1 / 284 (0.35%)
occurrences (all)	4	16	1
Musculoskeletal discomfort			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Musculoskeletal disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal pain			
subjects affected / exposed	3 / 1512 (0.20%)	7 / 3274 (0.21%)	1 / 284 (0.35%)
occurrences (all)	3	16	2
Myalgia			
subjects affected / exposed	19 / 1512 (1.26%)	48 / 3274 (1.47%)	3 / 284 (1.06%)
occurrences (all)	20	100	3
Myopathy			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Meniscal degeneration			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Pain in jaw			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Pain in extremity			
subjects affected / exposed	43 / 1512 (2.84%)	86 / 3274 (2.63%)	5 / 284 (1.76%)
occurrences (all)	47	194	5
Periarthritis			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	1	8	0
Periostitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Plantar fasciitis			
subjects affected / exposed	9 / 1512 (0.60%)	14 / 3274 (0.43%)	1 / 284 (0.35%)
occurrences (all)	9	30	2
Polymyalgia rheumatica			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Psoriatic arthropathy			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Rheumatoid arthritis			
subjects affected / exposed	5 / 1512 (0.33%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences (all)	5	20	0
Rib deformity			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Rotator cuff syndrome			
subjects affected / exposed	14 / 1512 (0.93%)	30 / 3274 (0.92%)	2 / 284 (0.70%)
occurrences (all)	16	66	2
Neck pain			
subjects affected / exposed	16 / 1512 (1.06%)	31 / 3274 (0.95%)	1 / 284 (0.35%)
occurrences (all)	17	64	1
Osteoarthritis			

subjects affected / exposed	60 / 1512 (3.97%)	119 / 3274 (3.63%)	6 / 284 (2.11%)
occurrences (all)	68	268	7
Osteochondrosis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	0	4	1
Osteonecrosis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Osteopenia			
subjects affected / exposed	2 / 1512 (0.13%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	2	12	0
Osteoporosis			
subjects affected / exposed	3 / 1512 (0.20%)	13 / 3274 (0.40%)	2 / 284 (0.70%)
occurrences (all)	3	26	2
Osteoporosis postmenopausal			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Patellofemoral pain syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
SLE arthritis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Tenosynovitis stenosans			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Sacroiliac joint dysfunction			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Sacroiliitis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Scoliosis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Soft tissue swelling			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Spinal osteoarthritis			
subjects affected / exposed	12 / 1512 (0.79%)	29 / 3274 (0.89%)	2 / 284 (0.70%)
occurrences (all)	12	58	2
Spinal pain			
subjects affected / exposed	4 / 1512 (0.26%)	11 / 3274 (0.34%)	0 / 284 (0.00%)
occurrences (all)	4	24	0
Spinal stenosis			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Spondylitis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Spondylolisthesis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Synovial cyst			
subjects affected / exposed	7 / 1512 (0.46%)	12 / 3274 (0.37%)	0 / 284 (0.00%)
occurrences (all)	7	24	0
Systemic lupus erythematosus			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Temporomandibular joint syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Tendon disorder			
subjects affected / exposed	0 / 1512 (0.00%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	0	8	0
Tendonitis			
subjects affected / exposed	3 / 1512 (0.20%)	9 / 3274 (0.27%)	2 / 284 (0.70%)
occurrences (all)	3	18	2
Tenosynovitis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Sacral pain			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Torticollis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Trismus			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Trigger finger			
subjects affected / exposed	10 / 1512 (0.66%)	18 / 3274 (0.55%)	1 / 284 (0.35%)
occurrences (all)	10	40	1
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Abscess			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bronchitis			
subjects affected / exposed	32 / 1512 (2.12%)	60 / 3274 (1.83%)	1 / 284 (0.35%)
occurrences (all)	37	138	1
Abscess of eyelid			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Acarodermatitis			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Acute sinusitis			
subjects affected / exposed	10 / 1512 (0.66%)	17 / 3274 (0.52%)	0 / 284 (0.00%)
occurrences (all)	13	40	0
Appendicitis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Arthritis infective			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	4	0



Aspergillus infection subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Asymptomatic COVID-19 subjects affected / exposed occurrences (all)	4 / 1512 (0.26%) 4	5 / 3274 (0.15%) 10	0 / 284 (0.00%) 0
Asymptomatic bacteriuria subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Bacteraemia subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Bacterial infection subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Bacterial vaginosis subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Bartholinitis subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Blister infected subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Body tinea subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Borrelia infection subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Breast cellulitis subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Abscess limb subjects affected / exposed occurrences (all)	3 / 1512 (0.20%) 3	5 / 3274 (0.15%) 10	0 / 284 (0.00%) 0

Dacryocystitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Cystitis			
subjects affected / exposed	6 / 1512 (0.40%)	13 / 3274 (0.40%)	1 / 284 (0.35%)
occurrences (all)	7	30	1
Device related infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Diverticulitis			
subjects affected / exposed	2 / 1512 (0.13%)	11 / 3274 (0.34%)	2 / 284 (0.70%)
occurrences (all)	2	24	2
Ear infection			
subjects affected / exposed	5 / 1512 (0.33%)	16 / 3274 (0.49%)	1 / 284 (0.35%)
occurrences (all)	6	40	1
Eczema infected			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Epididymitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bronchitis viral			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
COVID-19			
subjects affected / exposed	178 / 1512 (11.77%)	406 / 3274 (12.40%)	52 / 284 (18.31%)
occurrences (all)	183	832	53
COVID-19 pneumonia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Candida infection			

subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	5	12	0
Cellulitis			
subjects affected / exposed	20 / 1512 (1.32%)	43 / 3274 (1.31%)	3 / 284 (1.06%)
occurrences (all)	26	98	3
Chronic sinusitis			
subjects affected / exposed	2 / 1512 (0.13%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	2	16	0
Conjunctivitis			
subjects affected / exposed	4 / 1512 (0.26%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	4	12	0
Conjunctivitis bacterial			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Coronavirus infection			
subjects affected / exposed	5 / 1512 (0.33%)	14 / 3274 (0.43%)	4 / 284 (1.41%)
occurrences (all)	5	28	4
Dermatophytosis of nail			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Erysipelas			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Genital herpes			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
External ear cellulitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Eye infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Eye infection viral			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Eyelid infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Folliculitis			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Fungal foot infection			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Fungal infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Fungal skin infection			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	0	4	1
Furuncle			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Gangrene			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	1 / 284 (0.35%)
occurrences (all)	1	6	1
Gastroenteritis			
subjects affected / exposed	14 / 1512 (0.93%)	27 / 3274 (0.82%)	0 / 284 (0.00%)
occurrences (all)	14	54	0
Gastroenteritis clostridial			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Gastroenteritis viral			
subjects affected / exposed	2 / 1512 (0.13%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	2	16	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Genital candidiasis			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Erythema migrans			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Gingivitis			
subjects affected / exposed	1 / 1512 (0.07%)	5 / 3274 (0.15%)	1 / 284 (0.35%)
occurrences (all)	1	10	1
Influenza			
subjects affected / exposed	18 / 1512 (1.19%)	33 / 3274 (1.01%)	0 / 284 (0.00%)
occurrences (all)	18	68	0
Gynaecological chlamydia infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Helicobacter gastritis			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Helicobacter infection			
subjects affected / exposed	0 / 1512 (0.00%)	6 / 3274 (0.18%)	1 / 284 (0.35%)
occurrences (all)	0	12	1
Herpes dermatitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Herpes simplex			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	1 / 284 (0.35%)
occurrences (all)	1	4	1
Herpes virus infection			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	5	14	0
Herpes zoster			
subjects affected / exposed	16 / 1512 (1.06%)	25 / 3274 (0.76%)	0 / 284 (0.00%)
occurrences (all)	18	60	0
Herpes zoster infection neurological			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Hordeolum			

subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Infected bite			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	1 / 284 (0.35%)
occurrences (all)	3	12	1
Infected dermal cyst			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Infected skin ulcer			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Infection			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	4	8	0
Groin abscess			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Injection site cellulitis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Oral fungal infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Klebsiella infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Labyrinthitis			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Laryngitis			
subjects affected / exposed	5 / 1512 (0.33%)	8 / 3274 (0.24%)	1 / 284 (0.35%)
occurrences (all)	5	16	1

Localised infection			
subjects affected / exposed	3 / 1512 (0.20%)	13 / 3274 (0.40%)	0 / 284 (0.00%)
occurrences (all)	3	26	0
Lower respiratory tract infection			
subjects affected / exposed	29 / 1512 (1.92%)	55 / 3274 (1.68%)	7 / 284 (2.46%)
occurrences (all)	43	172	8
Lower respiratory tract infection bacterial			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Lyme disease			
subjects affected / exposed	1 / 1512 (0.07%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Lymphangitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Mastitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Nail bed infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Nail infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Nasopharyngitis			
subjects affected / exposed	61 / 1512 (4.03%)	110 / 3274 (3.36%)	5 / 284 (1.76%)
occurrences (all)	70	256	5
Onychomycosis			
subjects affected / exposed	12 / 1512 (0.79%)	14 / 3274 (0.43%)	0 / 284 (0.00%)
occurrences (all)	12	30	0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Oral candidiasis			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Kidney infection			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Oral herpes			
subjects affected / exposed	1 / 1512 (0.07%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	1	8	0
Pseudomonas infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Orchitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Osteomyelitis			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	0	12	0
Otitis externa			
subjects affected / exposed	2 / 1512 (0.13%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	2	16	0
Otitis media			
subjects affected / exposed	4 / 1512 (0.26%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	4	14	0
Otitis media acute			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Otitis media chronic			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Paronychia			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	10	0
Parotitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Penile infection			



subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Perineal infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Periodontitis			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Pharyngitis			
subjects affected / exposed	8 / 1512 (0.53%)	10 / 3274 (0.31%)	0 / 284 (0.00%)
occurrences (all)	8	20	0
Pharyngitis streptococcal			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Pneumonia			
subjects affected / exposed	28 / 1512 (1.85%)	50 / 3274 (1.53%)	2 / 284 (0.70%)
occurrences (all)	29	102	2
Post procedural infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Post-acute COVID-19 syndrome			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Oral infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Pulmonary tuberculosis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Pulpitis dental			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Pyelonephritis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Pyelonephritis chronic			

subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Rectal abscess			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	7 / 1512 (0.46%)	16 / 3274 (0.49%)	0 / 284 (0.00%)
occurrences (all)	8	34	0
Respiratory tract infection viral			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	6	0
Rhinitis			
subjects affected / exposed	7 / 1512 (0.46%)	12 / 3274 (0.37%)	3 / 284 (1.06%)
occurrences (all)	8	26	3
Root canal infection			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Rotavirus infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Sepsis			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Septic shock			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Sinobronchitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Sinusitis			
subjects affected / exposed	14 / 1512 (0.93%)	45 / 3274 (1.37%)	1 / 284 (0.35%)
occurrences (all)	15	98	1
Sinusitis bacterial			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Skin candida			

subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Skin infection			
subjects affected / exposed	2 / 1512 (0.13%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	2	8	0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Tinea infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Vestibular neuronitis			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Tonsillitis			
subjects affected / exposed	0 / 1512 (0.00%)	4 / 3274 (0.12%)	1 / 284 (0.35%)
occurrences (all)	0	12	1
Staphylococcal infection			
subjects affected / exposed	5 / 1512 (0.33%)	5 / 3274 (0.15%)	0 / 284 (0.00%)
occurrences (all)	5	10	0
Staphylococcal sepsis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Staphylococcal skin infection			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	3	6	0
Subcutaneous abscess			
subjects affected / exposed	4 / 1512 (0.26%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	4	16	0
Suspected COVID-19			
subjects affected / exposed	0 / 1512 (0.00%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	0	8	0
Tick-borne fever			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Tooth abscess			

subjects affected / exposed	8 / 1512 (0.53%)	21 / 3274 (0.64%)	1 / 284 (0.35%)
occurrences (all)	8	44	1
Tooth infection			
subjects affected / exposed	5 / 1512 (0.33%)	9 / 3274 (0.27%)	1 / 284 (0.35%)
occurrences (all)	6	20	1
Tracheitis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Tracheobronchitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Upper respiratory tract infection			
subjects affected / exposed	56 / 1512 (3.70%)	110 / 3274 (3.36%)	4 / 284 (1.41%)
occurrences (all)	63	248	4
Urinary tract infection			
subjects affected / exposed	77 / 1512 (5.09%)	147 / 3274 (4.49%)	10 / 284 (3.52%)
occurrences (all)	103	418	12
Vaginal infection			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Varicella zoster virus infection			
subjects affected / exposed	2 / 1512 (0.13%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	2	4	0
Tinea pedis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Viral infection			
subjects affected / exposed	8 / 1512 (0.53%)	12 / 3274 (0.37%)	2 / 284 (0.70%)
occurrences (all)	8	24	2
Vulvitis			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Vulvovaginal mycotic infection			

subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 4	1 / 284 (0.35%) 1
Wound infection subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	4 / 3274 (0.12%) 8	1 / 284 (0.35%) 1
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	4 / 1512 (0.26%) 5	8 / 3274 (0.24%) 18	0 / 284 (0.00%) 0
Carbohydrate intolerance subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	2 / 3274 (0.06%) 4	0 / 284 (0.00%) 0
Cachexia subjects affected / exposed occurrences (all)	0 / 1512 (0.00%) 0	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Acidosis subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Abnormal loss of weight subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	10 / 1512 (0.66%) 10	21 / 3274 (0.64%) 42	0 / 284 (0.00%) 0
Fructose intolerance subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0
Folate deficiency subjects affected / exposed occurrences (all)	2 / 1512 (0.13%) 2	5 / 3274 (0.15%) 10	0 / 284 (0.00%) 0
Fluid retention subjects affected / exposed occurrences (all)	1 / 1512 (0.07%) 1	1 / 3274 (0.03%) 2	0 / 284 (0.00%) 0

Electrolyte imbalance			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Diabetic metabolic decompensation			
subjects affected / exposed	4 / 1512 (0.26%)	8 / 3274 (0.24%)	0 / 284 (0.00%)
occurrences (all)	4	16	0
Diabetic ketoacidosis			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Diabetic complication			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Diabetes mellitus inadequate control			
subjects affected / exposed	114 / 1512 (7.54%)	226 / 3274 (6.90%)	3 / 284 (1.06%)
occurrences (all)	119	480	3
Diabetes mellitus			
subjects affected / exposed	98 / 1512 (6.48%)	205 / 3274 (6.26%)	7 / 284 (2.46%)
occurrences (all)	100	434	7
Glucose tolerance impaired			
subjects affected / exposed	15 / 1512 (0.99%)	25 / 3274 (0.76%)	0 / 284 (0.00%)
occurrences (all)	15	50	0
Hypokalaemia			
subjects affected / exposed	19 / 1512 (1.26%)	32 / 3274 (0.98%)	0 / 284 (0.00%)
occurrences (all)	22	70	0
Hypercalcaemia			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Hyperglycaemia			
subjects affected / exposed	6 / 1512 (0.40%)	16 / 3274 (0.49%)	1 / 284 (0.35%)
occurrences (all)	7	34	1
Hyperhomocysteinaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0

Hyperkalaemia			
subjects affected / exposed	8 / 1512 (0.53%)	17 / 3274 (0.52%)	1 / 284 (0.35%)
occurrences (all)	10	40	2
Hyperlipidaemia			
subjects affected / exposed	7 / 1512 (0.46%)	12 / 3274 (0.37%)	1 / 284 (0.35%)
occurrences (all)	8	26	1
Hypermagnesaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Hypoglycaemia			
subjects affected / exposed	5 / 1512 (0.33%)	10 / 3274 (0.31%)	1 / 284 (0.35%)
occurrences (all)	5	20	1
Hypocalcaemia			
subjects affected / exposed	3 / 1512 (0.20%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	3	12	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Hypervolaemia			
subjects affected / exposed	0 / 1512 (0.00%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	0	6	0
Hypervitaminosis D			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Hyperuricaemia			
subjects affected / exposed	9 / 1512 (0.60%)	16 / 3274 (0.49%)	0 / 284 (0.00%)
occurrences (all)	9	32	0
Hypertriglyceridaemia			
subjects affected / exposed	10 / 1512 (0.66%)	16 / 3274 (0.49%)	0 / 284 (0.00%)
occurrences (all)	11	34	0
Hyperphosphataemia			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Hypernatraemia			
subjects affected / exposed	3 / 1512 (0.20%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	3	6	0

Gout			
subjects affected / exposed	15 / 1512 (0.99%)	37 / 3274 (1.13%)	1 / 284 (0.35%)
occurrences (all)	19	96	1
Latent autoimmune diabetes in adults			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Magnesium deficiency			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Malnutrition			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Metabolic acidosis			
subjects affected / exposed	1 / 1512 (0.07%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	1	12	0
Metabolic disorder			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Obesity			
subjects affected / exposed	2 / 1512 (0.13%)	3 / 3274 (0.09%)	0 / 284 (0.00%)
occurrences (all)	2	6	0
Overweight			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Postprandial hypoglycaemia			
subjects affected / exposed	0 / 1512 (0.00%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Type 2 diabetes mellitus			
subjects affected / exposed	32 / 1512 (2.12%)	77 / 3274 (2.35%)	4 / 284 (1.41%)
occurrences (all)	32	154	4
Vitamin B complex deficiency			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Hypomagnesaemia			



subjects affected / exposed	8 / 1512 (0.53%)	10 / 3274 (0.31%)	0 / 284 (0.00%)
occurrences (all)	8	20	0
Hyponatraemia			
subjects affected / exposed	5 / 1512 (0.33%)	11 / 3274 (0.34%)	1 / 284 (0.35%)
occurrences (all)	7	28	1
Hypophosphataemia			
subjects affected / exposed	3 / 1512 (0.20%)	4 / 3274 (0.12%)	0 / 284 (0.00%)
occurrences (all)	3	8	0
Hypovolaemia			
subjects affected / exposed	1 / 1512 (0.07%)	1 / 3274 (0.03%)	0 / 284 (0.00%)
occurrences (all)	1	2	0
Impaired fasting glucose			
subjects affected / exposed	4 / 1512 (0.26%)	6 / 3274 (0.18%)	0 / 284 (0.00%)
occurrences (all)	4	12	0
Insulin resistance			
subjects affected / exposed	1 / 1512 (0.07%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	1	4	0
Iron deficiency			
subjects affected / exposed	5 / 1512 (0.33%)	7 / 3274 (0.21%)	0 / 284 (0.00%)
occurrences (all)	5	16	0
Lactic acidosis			
subjects affected / exposed	0 / 1512 (0.00%)	2 / 3274 (0.06%)	0 / 284 (0.00%)
occurrences (all)	0	4	0
Vitamin B12 deficiency			
subjects affected / exposed	6 / 1512 (0.40%)	9 / 3274 (0.27%)	0 / 284 (0.00%)
occurrences (all)	6	18	0
Vitamin D deficiency			
subjects affected / exposed	14 / 1512 (0.93%)	30 / 3274 (0.92%)	1 / 284 (0.35%)
occurrences (all)	14	62	1

<b>Non-serious adverse events</b>	Phase III Placebo-Inclisiran		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1073 / 1478 (72.60%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Cholesteatoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Acrochordon			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Adrenal adenoma			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Adrenal neoplasm			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
B-cell lymphoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Basal cell carcinoma			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Benign bone neoplasm			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Benign laryngeal neoplasm			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Benign neoplasm of bladder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Benign neoplasm of skin			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bladder cancer			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Bladder papilloma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Bowen's disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Breast cancer			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Breast cancer metastatic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Meningioma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Melanocytic naevus			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Colorectal adenoma			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Dysplastic naevus			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Eye naevus			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Fibroma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Fibrous histiocytoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Gastrointestinal tract adenoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Haemangioma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Haemangioma of liver			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Haemangioma of skin			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Juvenile melanoma benign			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Leiomyoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Lipoma			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Lymphoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Mantle cell lymphoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Chronic myeloid leukaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Metastases to bone			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Renal cell carcinoma			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Metastatic malignant melanoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Metastatic neoplasm			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Myelodysplastic syndrome			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Oesophageal papilloma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Oral papilloma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pancreatic neoplasm			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Parathyroid tumour benign			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Phaeochromocytoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pituitary tumour			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pituitary tumour benign			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Plasma cell myeloma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Prostate cancer			

subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Prostatic adenoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Renal cancer			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Metastases to liver			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Renal hamartoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Seborrhoeic keratosis			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Skin cancer			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Skin papilloma			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Skin squamous cell carcinoma recurrent			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Squamous cell carcinoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Squamous cell carcinoma of skin			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Thyroid adenoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Thyroid cancer subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Tumour pain subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Uterine leiomyoma subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Vulvovaginal warts subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Vascular disorders			
Aortic aneurysm rupture subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Aneurysm subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Angiodysplasia subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Angiopathy subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Aortic aneurysm subjects affected / exposed occurrences (all)	4 / 1478 (0.27%) 6		
Aortic arteriosclerosis subjects affected / exposed occurrences (all)	2 / 1478 (0.14%) 2		
Hot flush subjects affected / exposed occurrences (all)	4 / 1478 (0.27%) 4		
Aortic stenosis			

subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Arterial occlusive disease			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Arterial thrombosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Arteriosclerosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Arteritis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood pressure fluctuation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood pressure inadequately controlled			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Circulatory collapse			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	3		
Cyanosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Deep vein thrombosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Diastolic hypertension			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Essential hypertension			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		



Extravasation blood			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Flushing			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Haematoma			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Haemorrhage			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Aortic dilatation			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Peripheral artery stenosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Peripheral artery occlusion			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Peripheral ischaemia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Peripheral vascular disorder			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Peripheral venous disease			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	9		
Hypertension			
subjects affected / exposed	110 / 1478 (7.44%)		
occurrences (all)	121		
Hypertensive crisis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		

Hypertensive urgency			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Hypotension			
subjects affected / exposed	21 / 1478 (1.42%)		
occurrences (all)	25		
Iliac artery arteriosclerosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Iliac artery stenosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Intermittent claudication			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Jugular vein thrombosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Lymphoedema			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Microangiopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Orthostatic hypertension			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Orthostatic hypotension			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Peripheral arterial occlusive disease			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences (all)	11		
Peripheral coldness			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Phlebitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
White coat hypertension			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Phlebitis superficial			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Post thrombotic syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Raynaud's phenomenon			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Superficial vein prominence			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Superficial vein thrombosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Systolic hypertension			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Thrombophlebitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Thrombosed varicose vein			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Thrombosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Varicose vein			
subjects affected / exposed	9 / 1478 (0.61%)		
occurrences (all)	9		

Vasculitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Venous hypertension			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Phlebitis deep			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Application site rash			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	8		
Calcinosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Chest discomfort			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Chest pain			
subjects affected / exposed	15 / 1478 (1.01%)		
occurrences (all)	15		
Chills			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	3		
Crepitations			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Injection site oedema			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	4		
Drug intolerance			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Exercise tolerance decreased			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Eye complication associated with device			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Facial pain			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	22 / 1478 (1.49%)		
occurrences (all)	23		
Feeling abnormal			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Gait disturbance			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Generalised oedema			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hernia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Inflammation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Influenza like illness			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	6		

Injection site bruising			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Injection site eczema			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Injection site erythema			
subjects affected / exposed	12 / 1478 (0.81%)		
occurrences (all)	19		
Injection site hypersensitivity			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	3		
Injection site induration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cyst			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	17 / 1478 (1.15%)		
occurrences (all)	22		
Polyp			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Injection site pruritus			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Injection site rash			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	9		
Injection site reaction			
subjects affected / exposed	49 / 1478 (3.32%)		
occurrences (all)	103		
Injection site vesicles			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Injury associated with device subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Malaise subjects affected / exposed occurrences (all)	2 / 1478 (0.14%) 2		
Mass subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Mucosal inflammation subjects affected / exposed occurrences (all)	2 / 1478 (0.14%) 2		
Nodule subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Non-cardiac chest pain subjects affected / exposed occurrences (all)	11 / 1478 (0.74%) 11		
Oedema subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Oedema peripheral subjects affected / exposed occurrences (all)	20 / 1478 (1.35%) 22		
Pain subjects affected / exposed occurrences (all)	5 / 1478 (0.34%) 5		
Peripheral swelling subjects affected / exposed occurrences (all)	14 / 1478 (0.95%) 14		
Physical deconditioning subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Injection site paraesthesia subjects affected / exposed occurrences (all)	6 / 1478 (0.41%) 6		

Vessel puncture site bruise subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Swelling face subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Pyrexia subjects affected / exposed occurrences (all)	13 / 1478 (0.88%) 15		
Sensation of foreign body subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Vessel puncture site haemorrhage subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Immune system disorders			
Allergy to arthropod bite subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Allergy to arthropod sting subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Contrast media allergy subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Drug hypersensitivity subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Dust allergy subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Food allergy subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Hypersensitivity			



subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	4		
Immunisation reaction			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Sarcoidosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Seasonal allergy			
subjects affected / exposed	16 / 1478 (1.08%)		
occurrences (all)	16		
Social circumstances			
Family stress			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Acquired phimosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Atrophic vulvovaginitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Benign prostatic hyperplasia			
subjects affected / exposed	20 / 1478 (1.35%)		
occurrences (all)	20		
Breast disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Breast mass			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Breast necrosis			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Endometrial hyperplasia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Erectile dysfunction			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	8		
Genital prolapse			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Prostatic mass			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Prostatitis			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Prostatomegaly			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	6		
Rectocele			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Scrotal oedema			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Scrotal pain			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Sexual dysfunction			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Spermatocele			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Heavy menstrual bleeding			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Menopausal symptoms			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nipple exudate bloody			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Ovarian calcification			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Ovarian mass			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pelvic pain			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Penile discharge			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Peyronie's disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Prostatism			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Testicular hypertrophy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Testicular pain			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Uterine prolapse			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vaginal discharge			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vaginal prolapse			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Vulva cyst			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vulvovaginal dryness			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vulvovaginal inflammation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vulvovaginal pruritus			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Testicular mass			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Acquired diaphragmatic eventration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Acute pulmonary oedema			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Acute respiratory failure			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Allergic sinusitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Aspiration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Asthma			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	6		
Asthma exercise induced			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bronchial hyperreactivity			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bronchiectasis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Bronchospasm			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	24 / 1478 (1.62%)		
occurrences (all)	28		
Cough			
subjects affected / exposed	32 / 1478 (2.17%)		
occurrences (all)	32		

Diaphragmatic disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Dry throat			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Dysphonia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Dyspnoea			
subjects affected / exposed	31 / 1478 (2.10%)		
occurrences (all)	34		
Dyspnoea exertional			
subjects affected / exposed	9 / 1478 (0.61%)		
occurrences (all)	9		
Emphysema			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Epiglottic oedema			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Haemoptysis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hiccups			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hypoxia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bronchial secretion retention			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		

Pneumothorax			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Pleuritic pain			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Laryngeal ulceration			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Lung infiltration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Lung opacity			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nasal congestion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nasal mucosal blistering			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Nasal polyps			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nasal septum deviation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Obstructive airways disorder			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Obstructive sleep apnoea syndrome			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Oropharyngeal pain			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		

Paranasal cyst			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Paranasal sinus discomfort			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Paranasal sinus inflammation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	12 / 1478 (0.81%)		
occurrences (all)	12		
Pleural thickening			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pleurisy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Interstitial lung disease			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Productive cough			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Pulmonary calcification			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pulmonary congestion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pulmonary embolism			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pulmonary fibrosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		



Pulmonary hypertension			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pulmonary mass			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Pulmonary oedema			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Rales			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Reflux laryngitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Respiratory acidosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Respiratory disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Respiratory failure			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Rhinitis allergic			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Rhinorrhoea			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Sinus congestion			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	4		
Sinus disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Sinus polyp			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Sleep apnoea syndrome			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Sneezing			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Throat tightness			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Upper respiratory tract congestion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Vocal cord cyst			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Wheezing			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Throat irritation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Bipolar II disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Abnormal behaviour			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Abnormal dreams			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Acute stress disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Adjustment disorder with depressed mood			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Agitation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Alcohol abuse			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Alcoholism			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	21 / 1478 (1.42%)		
occurrences (all)	21		
Anxiety disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Attention deficit hyperactivity disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Bipolar disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Obsessive-compulsive disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Delirium			

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Delusion			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Depressed mood			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Depression			
subjects affected / exposed	19 / 1478 (1.29%)		
occurrences (all)	19		
Grief reaction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Habit cough			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hallucination			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hallucination, visual			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Initial insomnia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	15 / 1478 (1.01%)		
occurrences (all)	15		
Irritability			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Libido decreased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Loss of libido			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Mental status changes			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nightmare			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Confusional state			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Panic attack			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Post-traumatic stress disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Restlessness			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Schizoaffective disorder bipolar type			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Stress			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Suicidal ideation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Poor quality sleep			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Product issues			

Device dislocation subjects affected / exposed occurrences (all)	2 / 1478 (0.14%) 2		
Device malfunction subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Device physical property issue subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Hepatobiliary disorders			
Alcoholic liver disease subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Biliary colic subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Biliary dilatation subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Cholecystitis subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Cholecystitis acute subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Cholecystitis chronic subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Cholelithiasis subjects affected / exposed occurrences (all)	16 / 1478 (1.08%) 16		
Gallbladder polyp subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Hepatic calcification			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hepatic cirrhosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hepatic cyst			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Hepatic fibrosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hepatic function abnormal			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Hepatic haematoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hepatic lesion			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Hepatomegaly			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hyperbilirubinaemia			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Hypertransaminasaemia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Liver injury			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Non-alcoholic fatty liver			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Hepatic steatosis			

subjects affected / exposed	17 / 1478 (1.15%)		
occurrences (all)	17		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	5		
Aortic bruit			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Arteriogram coronary normal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	7		
Bilirubin conjugated increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood alkaline phosphatase increased			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Blood bilirubin increased			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Blood bilirubin unconjugated increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood calcium decreased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood calcium increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Antiphospholipid antibodies			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood cholesterol increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood sodium decreased			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Blood creatine phosphokinase increased			
subjects affected / exposed	31 / 1478 (2.10%)		
occurrences (all)	33		
Blood creatinine increased			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Blood folate decreased			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Blood glucose abnormal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood glucose increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood homocysteine increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood iron decreased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood lactic acid increased			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood potassium decreased			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Blood potassium increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood pressure ambulatory increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood pressure decreased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood pressure diastolic decreased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood pressure increased			
subjects affected / exposed	14 / 1478 (0.95%)		
occurrences (all)	16		
Blood pressure systolic increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood creatine abnormal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood sodium increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		

Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood triglycerides increased			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	9		
Blood urea increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood urine present			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Body temperature abnormal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Borrelia test positive			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Brain natriuretic peptide increased			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
C-reactive protein increased			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Carbohydrate antigen 15-3 increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cardiac murmur			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Cardiac stress test abnormal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Carotid bruit			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Coronavirus test positive			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Ejection fraction decreased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood testosterone decreased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hepatic enzyme abnormal			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Helicobacter test positive			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Electrocardiogram ST-T change			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Electrocardiogram abnormal			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Electrocardiogram repolarisation abnormality			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Fibrin D dimer increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Gamma-glutamyltransferase abnormal			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Gamma-glutamyltransferase increased			
subjects affected / exposed	23 / 1478 (1.56%)		
occurrences (all)	24		
Glomerular filtration rate decreased			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	8		
Glucose urine present			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Glycosylated haemoglobin increased			
subjects affected / exposed	15 / 1478 (1.01%)		
occurrences (all)	15		
Haematology test abnormal			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Haemoglobin decreased			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Haemoglobin increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Heart rate decreased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Heart rate irregular			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Hepatic enzyme increased			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Immunoglobulins decreased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		

Immunoglobulins increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
International normalised ratio increased			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Intraocular pressure increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Laboratory test abnormal			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Lipase increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Lipids increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Lipoprotein (a) increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Lipoprotein increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Liver function test abnormal			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Liver function test increased			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Low density lipoprotein increased			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Mean cell volume increased			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Monofilament pressure perception test abnormal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nitrite urine			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Occult blood positive			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Oxygen saturation decreased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Thyroxine increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Vitamin D decreased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Serum ferritin decreased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Scan myocardial perfusion abnormal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
SARS-CoV-2 test positive			

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Romberg test positive			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Respiratory rate increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Protein urine present			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Prostatic specific antigen increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Transaminases increased			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Troponin increased			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Tryptase increased			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Ultrasound Doppler abnormal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Ultrasound scan abnormal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Urinary system x-ray abnormal			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Urine analysis abnormal			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Urine output decreased			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Serum ferritin increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
White blood cells urine positive			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
White blood cell count increased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Weight increased			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Weight decreased			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Injury, poisoning and procedural complications			
Back injury			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Accident			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Administration related reaction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Alcohol poisoning			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Anaemia postoperative			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	3		
Animal bite			

subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Animal scratch			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Ankle fracture			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Arterial injury			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	8		
Arthropod sting			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Avulsion fracture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bone contusion			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Facial bones fracture			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Burns first degree			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cartilage injury			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Chest injury			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Clavicle fracture			

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Comminuted fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Complications of transplanted lung			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Concussion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	21 / 1478 (1.42%)		
occurrences (all)	22		
Corneal abrasion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Costochondral separation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Ear injury			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Electric shock			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Epicondylitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eye contusion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Eye injury			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Face injury			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Brain contusion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Fall			
subjects affected / exposed	42 / 1478 (2.84%)		
occurrences (all)	51		
Jaw fracture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Fibula fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Foot fracture			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Forearm fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Foreign body			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Foreign body in ear			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Foreign body in eye			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Fractured sacrum			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hand fracture			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Head injury			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Heat exhaustion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Humerus fracture			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Incisional hernia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Injection related reaction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Injury			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Intra-ocular injection complication			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Femur fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Joint dislocation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pelvic fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Ligament rupture			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Ligament sprain			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	8		
Limb crushing injury			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Limb fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Limb injury			
subjects affected / exposed	15 / 1478 (1.01%)		
occurrences (all)	18		
Limb traumatic amputation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Lower limb fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Lumbar vertebral fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Meniscus injury			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Multiple injuries			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Muscle injury			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Muscle rupture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Muscle strain			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Musculoskeletal foreign body			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Neck injury			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Patella fracture			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Joint injury			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Peripancreatic fluid collection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Rib fracture			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	8		
Post procedural constipation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Post procedural haemorrhage			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	3		
Post procedural hypothyroidism			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Post procedural inflammation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Post vaccination syndrome			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Post-traumatic pain			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Postoperative thoracic procedure complication			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Postoperative wound complication subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Procedural complication subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Procedural headache subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Procedural nausea subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Procedural pain subjects affected / exposed occurrences (all)	10 / 1478 (0.68%) 11		
Radiation injury subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Radiation proctitis subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Radius fracture subjects affected / exposed occurrences (all)	4 / 1478 (0.27%) 4		
Post procedural complication subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Road traffic accident subjects affected / exposed occurrences (all)	2 / 1478 (0.14%) 2		
Traumatic arthrosis subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Skin injury subjects affected / exposed occurrences (all)	2 / 1478 (0.14%) 2		



Skin laceration			
subjects affected / exposed	11 / 1478 (0.74%)		
occurrences (all)	11		
Skull fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Soft tissue injury			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Spinal compression fracture			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Spinal fracture			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Splinter			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Subdural haematoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Synovial rupture			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Tendon injury			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Tendon rupture			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Thermal burn			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Thoracic vertebral fracture			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		

Tibia fracture			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Tobacco poisoning			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Tooth fracture			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Skin abrasion			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Wrist fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Ulna fracture			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Upper limb fracture			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Vaccination complication			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Wound			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Wound dehiscence			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Wound haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Wound necrosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Congenital, familial and genetic disorders			
Genetic polymorphism			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Adenomatous polyposis coli			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Apolipoprotein E e4 gene carrier			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Atrial septal defect			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Congenital cystic kidney disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Developmental hip dysplasia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hydrocele			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Phimosi			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
SF3B1 gene mutation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Atrioventricular block complete			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Atrial thrombosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Atrial tachycardia			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Atrial flutter			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Atrial fibrillation			
subjects affected / exposed	36 / 1478 (2.44%)		
occurrences (all)	37		
Atrial enlargement			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Arrhythmia supraventricular			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Arrhythmia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Aortic valve stenosis			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Aortic valve sclerosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Aortic valve incompetence			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Angina unstable			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Angina pectoris			
subjects affected / exposed	32 / 1478 (2.17%)		
occurrences (all)	32		
Acute myocardial infarction			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Atrioventricular block			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cardiac amyloidosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cardiac aneurysm			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cardiac disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cardiac failure			
subjects affected / exposed	19 / 1478 (1.29%)		
occurrences (all)	22		
Cardiac failure acute			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cardiac failure chronic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cardiac failure congestive			
subjects affected / exposed	11 / 1478 (0.74%)		
occurrences (all)	11		
Cardiac flutter			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cardiac hypertrophy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cardiac perfusion defect			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cardiac sarcoidosis			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cardiac valve disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Atrioventricular block first degree			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Atrioventricular block second degree			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Bradycardia			
subjects affected / exposed	13 / 1478 (0.88%)		
occurrences (all)	13		
Bundle branch block			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bundle branch block left			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Bundle branch block right			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hypertensive heart disease			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cardiomegaly			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cardiomyopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cardiorenal syndrome			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cardiovascular disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Chronic left ventricular failure			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Chronotropic incompetence			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Conduction disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Congestive cardiomyopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Coronary artery disease			
subjects affected / exposed	24 / 1478 (1.62%)		
occurrences (all)	24		
Coronary artery occlusion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Coronary artery stenosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	4		
Diastolic dysfunction			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Dressler's syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Extrasystoles			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Heart valve incompetence			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hypertensive cardiomyopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cardiogenic shock			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Ischaemic cardiomyopathy			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Left atrial enlargement			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Left ventricular dysfunction			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Left ventricular enlargement			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Left ventricular failure			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Left ventricular hypertrophy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Mitral valve calcification			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Mitral valve incompetence			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Mitral valve prolapse			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Mitral valve stenosis			



subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Myocardial ischaemia			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Palpitations			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	10		
Pericardial effusion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pericarditis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Prinzmetal angina			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pulmonary valve incompetence			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Right atrial dilatation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Sinus arrhythmia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Sinus bradycardia			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Sinus node dysfunction			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Supraventricular extrasystoles			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Supraventricular tachycardia			

subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	9		
Systolic dysfunction			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Tachycardia paroxysmal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Tricuspid valve incompetence			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Ventricular arrhythmia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Ventricular dysfunction			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Ventricular extrasystoles			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Ventricular tachycardia			
subjects affected / exposed	9 / 1478 (0.61%)		
occurrences (all)	15		
Sinus tachycardia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Nervous system disorders			
Ageusia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Akinesia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Altered state of consciousness			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Amnesia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Aphasia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Arachnoid cyst			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Balance disorder			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Bell's palsy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cervicogenic headache			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Carotid arteriosclerosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Carotid artery disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Carotid artery occlusion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Carotid artery stenosis			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Carpal tunnel syndrome			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	9		

Cerebellar atrophy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cerebral atrophy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cerebral ischaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cerebral microangiopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cerebral small vessel ischaemic disease			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Cerebrovascular accident			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cerebrovascular disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cervical radiculopathy			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Cervicobrachial syndrome			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Burning sensation			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Dysgeusia			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Dysarthria			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Epilepsy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Essential tremor			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Facial paralysis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Facial paresis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Head discomfort			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	37 / 1478 (2.50%)		
occurrences (all)	38		
Hemiparesis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cognitive disorder			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Cortical laminar necrosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cubital tunnel syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Dementia			

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Dementia Alzheimer's type			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Diabetic neuropathy			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Disturbance in attention			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	42 / 1478 (2.84%)		
occurrences (all)	44		
Encephalopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hepatic encephalopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Myelopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	8		
Hyporeflexia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Hyposmia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Intercostal neuralgia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Intracranial aneurysm			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Intracranial mass			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Ischaemic stroke			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Loss of consciousness			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Lumbar radiculopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Memory impairment			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Migraine			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Morton's neuralgia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Muscle contractions involuntary			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hyperaesthesia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Nerve compression			

subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Restless legs syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Neuropathy peripheral			
subjects affected / exposed	11 / 1478 (0.74%)		
occurrences (all)	11		
Pachymeningitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	5		
Paralysis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Parkinson's disease			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Partial seizures			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Periodic limb movement disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Peripheral sensorimotor neuropathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Peroneal nerve palsy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Polyneuropathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Post herpetic neuralgia			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Post polio syndrome			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Quadrantanopia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Radiculopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Neuralgia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Sciatica			
subjects affected / exposed	22 / 1478 (1.49%)		
occurrences (all)	23		
Vlith nerve paralysis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Senile dementia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Sensory disturbance			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Sensory loss			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Speech disorder			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Spinal claudication			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Syncope			
subjects affected / exposed	15 / 1478 (1.01%)		
occurrences (all)	20		
Taste disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Tension headache			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Thoracic radiculopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Thunderclap headache			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Transient global amnesia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Transient ischaemic attack			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Tremor			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Trigeminal neuralgia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Ulnar neuritis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Seizure			

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Vascular dementia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Vascular parkinsonism			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vocal cord paralysis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Vascular encephalopathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	33 / 1478 (2.23%)		
occurrences (all)	37		
Anaemia macrocytic			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Anaemia megaloblastic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cytopenia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blood loss anaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Bone marrow oedema			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Coagulopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Bicytopenia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Eosinophilia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Haemolytic anaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Polycythaemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pancytopenia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Normocytic anaemia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nephrogenic anaemia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Monoclonal B-cell lymphocytosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Microcytic anaemia			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Macrocytosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Lymph node fibrosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Leukopenia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Leukocytosis			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Iron deficiency anaemia			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Increased tendency to bruise			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hypochromic anaemia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Hilar lymphadenopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Splenomegaly			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Thrombocytosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Thrombocytopenia subjects affected / exposed occurrences (all)	8 / 1478 (0.54%) 8		
Ear and labyrinth disorders			
Deafness neurosensory subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Deafness bilateral subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Ear canal stenosis subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Ear haemorrhage subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Ear pain subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Ear pruritus subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Eustachian tube dysfunction subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Excessive cerumen production subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Haematotympanum subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Hypoacusis subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Mastoid disorder			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Meniere's disease			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cerumen impaction			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Conductive deafness			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Deafness			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Deafness unilateral			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Otolithiasis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Sudden hearing loss			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Tinnitus			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences (all)	10		
Vertigo			
subjects affected / exposed	14 / 1478 (0.95%)		
occurrences (all)	14		
Vertigo positional			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Otorrhoea			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eye disorders			

Age-related macular degeneration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Amaurosis fugax			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Exfoliation syndrome			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blepharospasm			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Blindness			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Cataract			
subjects affected / exposed	23 / 1478 (1.56%)		
occurrences (all)	31		
Chalazion			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Choroidal neovascularisation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Conjunctival haemorrhage			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Conjunctivitis allergic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Corneal degeneration			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Corneal erosion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		



Dermatochalasis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Diabetic retinopathy			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Diplopia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Dry eye			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Ectropion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Epiretinal membrane			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blepharitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Neovascular age-related macular degeneration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Macular oedema			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Ocular hypertension			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Periorbital swelling			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eye discharge			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eye haemorrhage			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Eye irritation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eye pain			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eye pruritus			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eye swelling			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eyelid cyst			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Eyelid ptosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Glaucoma			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Iridocyclitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Iritis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Keratitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Lacrimation increased			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Macular degeneration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Non-proliferative retinopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Posterior capsule opacification			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Retinal artery embolism			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Retinal artery occlusion			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Retinal detachment			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Retinal haemorrhage			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Retinal ischaemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Retinal vascular thrombosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Retinal vein occlusion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Retinopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Retinopathy hypertensive			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Swelling of eyelid			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Ulcerative keratitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Visual acuity reduced			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Visual impairment			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Vitreous detachment			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Vitreous floaters			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Vitreous haemorrhage			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vitreous opacities			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Change of bowel habit			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Abdominal distension			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		

Abdominal hernia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Abdominal mass			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	16 / 1478 (1.08%)		
occurrences (all)	18		
Abdominal pain lower			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Abdominal pain upper			
subjects affected / exposed	11 / 1478 (0.74%)		
occurrences (all)	11		
Abdominal wall haematoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Acquired oesophageal web			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Anal fissure			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Anal incontinence			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Anal prolapse			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Anal skin tags			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Anorectal discomfort			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Ascites			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Barrett's oesophagus			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Abdominal discomfort			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Defaecation disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Crohn's disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	31 / 1478 (2.10%)		
occurrences (all)	34		
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Diverticulitis oesophageal			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Diverticulum			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Diverticulum intestinal			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences (all)	10		
Dry mouth			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Duodenal polyp			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Duodenal ulcer			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Duodenitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Duodenogastric reflux			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Dyspepsia			
subjects affected / exposed	9 / 1478 (0.61%)		
occurrences (all)	9		
Chronic gastritis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Colitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Colitis microscopic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Colitis ulcerative			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	25 / 1478 (1.69%)		
occurrences (all)	25		
Dental caries			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Dysphagia			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Gastrointestinal pain			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Eosinophilic oesophagitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Epigastric discomfort			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Erosive duodenitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eructation			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Faeces discoloured			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Faeces soft			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Food poisoning			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Frequent bowel movements			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Gastric disorder			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Gastric mucosa erythema			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		



Gastric ulcer			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	13 / 1478 (0.88%)		
occurrences (all)	13		
Gastritis erosive			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Enteritis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Gastrooesophageal reflux disease			
subjects affected / exposed	23 / 1478 (1.56%)		
occurrences (all)	23		
Odynophagia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Haematochezia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Haemorrhoids			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences (all)	10		
Hiatus hernia			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences (all)	10		
Ileus			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Ileus paralytic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		

Inflammatory bowel disease subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Inguinal hernia subjects affected / exposed occurrences (all)	7 / 1478 (0.47%) 7		
Intestinal ischaemia subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Intestinal polyp subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Irritable bowel syndrome subjects affected / exposed occurrences (all)	2 / 1478 (0.14%) 2		
Large intestine polyp subjects affected / exposed occurrences (all)	7 / 1478 (0.47%) 7		
Lip swelling subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Melaena subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Mouth ulceration subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Nausea subjects affected / exposed occurrences (all)	17 / 1478 (1.15%) 19		
Haematemesis subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Proctalgia subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		

Pneumoperitoneum			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Rectal discharge			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Rectal haemorrhage			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Rectal polyp			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Rectal prolapse			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Oesophageal stenosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Oesophagitis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Pancreatic cyst			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pancreatic duct dilatation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pancreatic failure			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pancreatic steatosis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Pancreatitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Pancreatitis acute			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pancreatitis chronic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Peptic ulcer			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Peritoneal adhesions			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Proctitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Regurgitation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Retroperitoneal haematoma			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Salivary gland enlargement			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Salivary gland mass			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Tongue cyst			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Tongue ulceration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Tooth impacted subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Toothache subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Umbilical hernia subjects affected / exposed occurrences (all)	5 / 1478 (0.34%) 5		
Vomiting subjects affected / exposed occurrences (all)	9 / 1478 (0.61%) 10		
Skin and subcutaneous tissue disorders Dermatitis allergic subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 7		
Acne subjects affected / exposed occurrences (all)	2 / 1478 (0.14%) 2		
Actinic keratosis subjects affected / exposed occurrences (all)	4 / 1478 (0.27%) 4		
Alopecia subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Alopecia areata subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Angioedema subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Blister subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Cutaneous calcification			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Decubitus ulcer			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Dermal cyst			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Dermatitis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	4		
Dermatitis acneiform			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	3		
Lichen planus			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Diabetic foot			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Diabetic ulcer			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Dry skin			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Dyshidrotic eczema			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Ecchymosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Eczema			

subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Eczema asteatotic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	3		
Hand dermatitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Hidradenitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Hyperkeratosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hypertrophic scar			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Ingrowing nail			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Intertrigo			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Lentigo			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Dermatitis diaper			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Pityriasis			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pemphigus			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Polymorphic light eruption			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	9		
Pruritus allergic			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Psoriasis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	5		
Purpura senile			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	9 / 1478 (0.61%)		
occurrences (all)	9		
Rash erythematous			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Reactive perforating collagenosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Rosacea			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Lipohypertrophy			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Milia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nail dystrophy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Night sweats			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Panniculitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pityriasis rosea			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Sebaceous hyperplasia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Skin discolouration			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Skin fibrosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Skin indentation			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Skin lesion			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Skin reaction			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Skin texture abnormal			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Skin ulcer			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	7		
Stasis dermatitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Subcutaneous emphysema			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Xanthoma			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Sensitive skin			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Renal and urinary disorders			
Cystitis haemorrhagic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Acute kidney injury			
subjects affected / exposed	18 / 1478 (1.22%)		
occurrences (all)	19		
Albuminuria			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Azotaemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bladder disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		

Bladder diverticulum			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Bladder irritation			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bladder outlet obstruction			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Bladder prolapse			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bladder stenosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Chronic kidney disease			
subjects affected / exposed	20 / 1478 (1.35%)		
occurrences (all)	20		
Cystitis noninfective			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Neurogenic bladder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Dysuria			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
End stage renal disease			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Genitourinary symptom			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Glycosuria			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		

Haematuria			
subjects affected / exposed	13 / 1478 (0.88%)		
occurrences (all)	13		
Hydronephrosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hypertensive nephropathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hypertonic bladder			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Leukocyturia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Lower urinary tract symptoms			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	4		
Microalbuminuria			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Micturition urgency			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nephritic syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nephrolithiasis			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences (all)	10		
Nephropathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Diabetic nephropathy			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		

Nocturia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Polyuria			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Proteinuria			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Pyelocaliectasis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Renal aneurysm			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Renal artery stenosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Renal colic			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Renal cyst			
subjects affected / exposed	22 / 1478 (1.49%)		
occurrences (all)	23		
Renal disorder			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Renal failure			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Renal impairment			
subjects affected / exposed	30 / 1478 (2.03%)		
occurrences (all)	31		

Renal mass			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Renal necrosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Renal pain			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Strangury			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Stress urinary incontinence			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Ureterolithiasis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Urge incontinence			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Urinary incontinence			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Urinary retention			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Urinary tract disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Urinary tract inflammation subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Urine odour abnormal subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Urethral stenosis subjects affected / exposed occurrences (all)	2 / 1478 (0.14%) 3		
Endocrine disorders			
Adrenal mass subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Autoimmune thyroiditis subjects affected / exposed occurrences (all)	4 / 1478 (0.27%) 4		
Goitre subjects affected / exposed occurrences (all)	4 / 1478 (0.27%) 4		
Hyperparathyroidism subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Hyperparathyroidism primary subjects affected / exposed occurrences (all)	0 / 1478 (0.00%) 0		
Hyperprolactinaemia subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Hyperthyroidism subjects affected / exposed occurrences (all)	5 / 1478 (0.34%) 5		
Hypogonadism subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Hypothyroidism			

subjects affected / exposed	10 / 1478 (0.68%)		
occurrences (all)	10		
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Thyroid calcification			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Thyroid mass			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Dupuytren's contracture			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Ankle impingement			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	102 / 1478 (6.90%)		
occurrences (all)	116		
Arthritis			
subjects affected / exposed	12 / 1478 (0.81%)		
occurrences (all)	12		
Arthropathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	51 / 1478 (3.45%)		
occurrences (all)	56		
Bone atrophy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bone cyst			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Bursitis			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Cervical spinal stenosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Chondrocalcinosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Chondropathy			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Chronic kidney disease-mineral and bone disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Coccydynia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Costochondritis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Degenerative bone disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Diffuse idiopathic skeletal hyperostosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Exostosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Limb discomfort			

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Flank pain			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Foot deformity			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Fracture pain			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Greater trochanteric pain syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Groin pain			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Haemarthrosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Haematoma muscle			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Intervertebral disc degeneration			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Intervertebral disc disorder			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Intervertebral disc protrusion			
subjects affected / exposed	9 / 1478 (0.61%)		
occurrences (all)	10		
Joint effusion			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Joint instability			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Joint stiffness			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Joint swelling			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Ligament calcification			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Fibromyalgia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Lumbar spinal stenosis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Neck mass			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Mobility decreased			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Muscle atrophy			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Muscle contracture			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Muscle discomfort			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Muscle fatigue			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Muscle oedema			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Muscle rigidity			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences (all)	10		
Muscle tightness			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Muscular weakness			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Musculoskeletal chest pain			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Musculoskeletal discomfort			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Musculoskeletal disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Musculoskeletal pain			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Myalgia			
subjects affected / exposed	26 / 1478 (1.76%)		
occurrences (all)	27		
Myopathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Meniscal degeneration			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pain in jaw			

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Pain in extremity			
subjects affected / exposed	38 / 1478 (2.57%)		
occurrences (all)	45		
Periarthritis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Periostitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Plantar fasciitis			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Polymyalgia rheumatica			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Psoriatic arthropathy			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Rheumatoid arthritis			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	5		
Rib deformity			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Rotator cuff syndrome			
subjects affected / exposed	14 / 1478 (0.95%)		
occurrences (all)	15		
Neck pain			
subjects affected / exposed	14 / 1478 (0.95%)		
occurrences (all)	14		
Osteoarthritis			
subjects affected / exposed	53 / 1478 (3.59%)		
occurrences (all)	59		
Osteochondrosis			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Osteonecrosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Osteopenia			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Osteoporosis			
subjects affected / exposed	8 / 1478 (0.54%)		
occurrences (all)	8		
Osteoporosis postmenopausal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Patellofemoral pain syndrome			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
SLE arthritis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Tenosynovitis stenosans			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Sacroiliac joint dysfunction			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Sacroiliitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Scoliosis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Soft tissue swelling			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Spinal osteoarthritis			

subjects affected / exposed	15 / 1478 (1.01%)		
occurrences (all)	15		
Spinal pain			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	8		
Spinal stenosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Spondylitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Spondylolisthesis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Synovial cyst			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Systemic lupus erythematosus			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Tendon disorder			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Tendonitis			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Tenosynovitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Sacral pain			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Torticollis			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Trismus			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Trigger finger			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	9		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Abscess			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	27 / 1478 (1.83%)		
occurrences (all)	31		
Abscess of eyelid			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Acarodermatitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Acute sinusitis			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Appendicitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Arthritis infective			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Aspergillus infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		



Asymptomatic COVID-19			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bacteraemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bacterial infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bacterial vaginosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bartholinitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Blister infected			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Body tinea			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Borrelia infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Breast cellulitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Abscess limb			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Dacryocystitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Cystitis			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	7		
Device related infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Diverticulitis			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	8		
Ear infection			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences (all)	13		
Eczema infected			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Epididymitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bronchitis viral			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	176 / 1478 (11.91%)		
occurrences (all)	180		
COVID-19 pneumonia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Candida infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Cellulitis			

subjects affected / exposed	20 / 1478 (1.35%)		
occurrences (all)	20		
Chronic sinusitis			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	6		
Conjunctivitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Conjunctivitis bacterial			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Coronavirus infection			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Dermatophytosis of nail			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Erysipelas			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Genital herpes			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Escherichia urinary tract infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
External ear cellulitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eye infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Eye infection viral			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Eyelid infection			

subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Folliculitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Fungal foot infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Fungal infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Fungal skin infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Furuncle			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Gangrene			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	13 / 1478 (0.88%)		
occurrences (all)	13		
Gastroenteritis clostridial			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Gastroenteritis viral			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Gastrointestinal viral infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Genital candidiasis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Erythema migrans			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Gingivitis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Influenza			
subjects affected / exposed	15 / 1478 (1.01%)		
occurrences (all)	16		
Gynaecological chlamydia infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Helicobacter gastritis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Helicobacter infection			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Herpes dermatitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Herpes simplex			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Herpes virus infection			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Herpes zoster			
subjects affected / exposed	9 / 1478 (0.61%)		
occurrences (all)	12		
Herpes zoster infection neurological			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hordeolum			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Infected bite			

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Infected dermal cyst			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Infected skin ulcer			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Groin abscess			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Injection site cellulitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Oral fungal infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Klebsiella infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Labyrinthitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Laryngitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Localised infection			
subjects affected / exposed	10 / 1478 (0.68%)		
occurrences (all)	10		

Lower respiratory tract infection			
subjects affected / exposed	19 / 1478 (1.29%)		
occurrences (all)	35		
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Lyme disease			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Lymphangitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Mastitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Nail bed infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	3		
Nail infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	44 / 1478 (2.98%)		
occurrences (all)	53		
Onychomycosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	3		
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Oral candidiasis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Kidney infection			

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Oral herpes			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Pseudomonas infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Orchitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Osteomyelitis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	6		
Otitis externa			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Otitis media			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Otitis media acute			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Otitis media chronic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Paronychia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Parotitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Penile infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Perineal infection			



subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Periodontitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Pharyngitis streptococcal			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	20 / 1478 (1.35%)		
occurrences (all)	20		
Post procedural infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Oral infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pulmonary tuberculosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Pulpitis dental			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Pyelonephritis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Pyelonephritis chronic			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Rectal abscess			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Respiratory tract infection			
subjects affected / exposed	9 / 1478 (0.61%)		
occurrences (all)	9		
Respiratory tract infection viral			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Rhinitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Root canal infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Rotavirus infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Sepsis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Septic shock			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Sinobronchitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	2		
Sinusitis			
subjects affected / exposed	30 / 1478 (2.03%)		
occurrences (all)	33		
Sinusitis bacterial			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	3		
Skin candida			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Skin infection			

subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Tinea infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Vestibular neuronitis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Tonsillitis			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	5		
Staphylococcal infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Staphylococcal sepsis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Staphylococcal skin infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Subcutaneous abscess			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Suspected COVID-19			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Tick-borne fever			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Tooth abscess			
subjects affected / exposed	12 / 1478 (0.81%)		
occurrences (all)	13		
Tooth infection			

subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Tracheitis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Tracheobronchitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	50 / 1478 (3.38%)		
occurrences (all)	57		
Urinary tract infection			
subjects affected / exposed	60 / 1478 (4.06%)		
occurrences (all)	94		
Vaginal infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Varicella zoster virus infection			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Tinea pedis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Viral infection			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Vulvitis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Wound infection			

subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Carbohydrate intolerance			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Cachexia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Acidosis			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Abnormal loss of weight			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Dehydration			
subjects affected / exposed	11 / 1478 (0.74%)		
occurrences (all)	11		
Fructose intolerance			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Folate deficiency			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Fluid retention			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Electrolyte imbalance			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		

Diabetic metabolic decompensation subjects affected / exposed occurrences (all)	4 / 1478 (0.27%) 4		
Diabetic ketoacidosis subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Diabetic complication subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	109 / 1478 (7.37%) 118		
Diabetes mellitus subjects affected / exposed occurrences (all)	100 / 1478 (6.77%) 110		
Glucose tolerance impaired subjects affected / exposed occurrences (all)	10 / 1478 (0.68%) 10		
Hypokalaemia subjects affected / exposed occurrences (all)	13 / 1478 (0.88%) 13		
Hypercalcaemia subjects affected / exposed occurrences (all)	3 / 1478 (0.20%) 3		
Hypercholesterolaemia subjects affected / exposed occurrences (all)	2 / 1478 (0.14%) 2		
Hyperglycaemia subjects affected / exposed occurrences (all)	9 / 1478 (0.61%) 9		
Hyperhomocysteinaemia subjects affected / exposed occurrences (all)	1 / 1478 (0.07%) 1		
Hyperkalaemia subjects affected / exposed occurrences (all)	8 / 1478 (0.54%) 8		

Hyperlipidaemia			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Hypermagnesaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hypoglycaemia			
subjects affected / exposed	4 / 1478 (0.27%)		
occurrences (all)	4		
Hypocalcaemia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Hypoalbuminaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hypervolaemia			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Hypervitaminosis D			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hyperuricaemia			
subjects affected / exposed	7 / 1478 (0.47%)		
occurrences (all)	7		
Hypertriglyceridaemia			
subjects affected / exposed	6 / 1478 (0.41%)		
occurrences (all)	6		
Hyperphosphataemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hypernatraemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Gout			
subjects affected / exposed	21 / 1478 (1.42%)		
occurrences (all)	28		

Latent autoimmune diabetes in adults			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Magnesium deficiency			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Malnutrition			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Metabolic acidosis			
subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	5		
Metabolic disorder			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Obesity			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Overweight			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Postprandial hypoglycaemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Type 2 diabetes mellitus			
subjects affected / exposed	41 / 1478 (2.77%)		
occurrences (all)	41		
Vitamin B complex deficiency			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Hyponatraemia			



subjects affected / exposed	5 / 1478 (0.34%)		
occurrences (all)	6		
Hypophosphataemia			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Hypovolaemia			
subjects affected / exposed	0 / 1478 (0.00%)		
occurrences (all)	0		
Impaired fasting glucose			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Insulin resistance			
subjects affected / exposed	1 / 1478 (0.07%)		
occurrences (all)	1		
Iron deficiency			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	3		
Lactic acidosis			
subjects affected / exposed	2 / 1478 (0.14%)		
occurrences (all)	2		
Vitamin B12 deficiency			
subjects affected / exposed	3 / 1478 (0.20%)		
occurrences (all)	3		
Vitamin D deficiency			
subjects affected / exposed	15 / 1478 (1.01%)		
occurrences (all)	16		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 November 2018	-To account for the need to provide an initial inclisiran dose and a second dose of inclisiran at Day 90 for the subjects receiving placebo in the Phase III feeder studies (Study ORION-9/ORION-10/ORION-11). -the first dose on Day 1 of Study ORION-8 will be blinded (placebo or inclisiran) so that the integrity of the blind of the feeder studies is maintained. -All subjects on placebo in the Phase III feeder studies will receive their first dose of inclisiran on Day 1, and all subjects receiving inclisiran in the Phase III feeder studies will receive placebo on Day 1 of Study ORION-8 (thereby maintaining their every 6-month administration of inclisiran).
06 October 2020	-Address the change in sponsorship from The Medicines Company to Novartis after acquisition of The Medicines Company by Novartis in January 2020. -Introduction of Novartis protocol number and IMP code: CKJX83906 and KJX839 respectively - Handling of protocol deviations including those for COVID-19 related issues - COVID-19 considerations: remote visits and extended visit windows. -Removing Section 7.3 Assessment of Pharmacodynamics as deem not relevant -Updating Section 5.1.5 about reporting of drug and device deficiencies when using pre-filled syringe -Incorporation of language about Sweden Specific Protocol Amendment in Section 3.1 -Amending Section 8.4.3.2 – Pregnancy, to include follow up on newborns for 12 months -Additional feeder study to Study ORION-8 was added: Study A12201E1 (also referred to as ORION-3) subjects can move over to Study ORION-8 after completing the treatment in the Phase II study. -Study A12302 (ORION-5) was deleted as feeder study to Study ORION-8

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported