Clinical trial results:
A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk

Summary

EudraCT number	2017-002954-35
Trial protocol	SK HU LV SE NO LT EE DK ES FI BG IT RO
Global end of trial date	10 December 2020

Results information

Result version number	v1 (current)
This version publication date	06 November 2021
First version publication date	06 November 2021

Trial information

Trial identification

Sponsor protocol code	EFC14828

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03496298
WHO universal trial number (UTN)	U1111-1186-2533

Notes:

Sponsors

Sponsor organisation name	Sanofi-aventis Recherche & Développement
Sponsor organisation address	1 avenue Pierre Brossolette, Chilly Mazarin Cedex, France, 91380
Public contact	Sanofi aventis recherche & développement, Trial Transparency Team, Contact-US@sanofi.com
Scientific contact	Sanofi aventis recherche & développement, Trial Transparency Team, Contact-US@sanofi.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 April 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 December 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that, efpeglenatide 4 and 6 miligrams (mg) was noninferior to placebo on 3-point major adverse cardiac event (MACE) in Type 2 diabetes mellitus (T2DM) subjects at high cardiovascular (CV) risk.

Protection of trial subjects:

Subjects were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the subject and considering the local culture. During the course of the trial, subjects were provided with individual subject cards indicating the nature of the trial the subject is participating, contact details and any information needed in the event of a medical emergency. Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy:

Any antihyperglycemic treatment was allowed as background therapy with the exception of glucagon-like peptide-1 receptor agonists and dipeptidyl peptidase-4 inhibitors.

Evidence for comparator: -	
Actual start date of recruitment	27 April 2018
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	Norway: 25
Country: Number of subjects enrolled	Poland: 164
Country: Number of subjects enrolled	Slovakia: 132
Country: Number of subjects enrolled	Spain: 56
Country: Number of subjects enrolled	Sweden: 41
Country: Number of subjects enrolled	Bulgaria: 184
Country: Number of subjects enrolled	Denmark: 20
Country: Number of subjects enrolled	Estonia: 30
Country: Number of subjects enrolled	Finland: 34
Country: Number of subjects enrolled	Germany: 107
Country: Number of subjects enrolled	Hungary: 181
Country: Number of subjects enrolled	Italy: 60
Country: Number of subjects enrolled	Latvia: 35
Country: Number of subjects enrolled	Lithuania: 44

Country: Number of subjects enrolled	Argentina: 380
Country: Number of subjects enrolled	Canada: 325
Country: Number of subjects enrolled	Chile: 212
Country: Number of subjects enrolled	India: 98
Country: Number of subjects enrolled	Mexico: 251
Country: Number of subjects enrolled	Peru: 81
Country: Number of subjects enrolled	Romania: 96
Country: Number of subjects enrolled	Russian Federation: 224
Country: Number of subjects enrolled	Serbia: 76
Country: Number of subjects enrolled	South Africa: 90
Country: Number of subjects enrolled	Turkey: 118
Country: Number of subjects enrolled	United States: 754
Country: Number of subjects enrolled	Ukraine: 194
Country: Number of subjects enrolled	Korea, Republic of: 64
Worldwide total number of subjects	4076
EEA total number of subjects	1209

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1954
From 65 to 84 years	2108
85 years and over	14

Subject disposition

Recruitment

Recruitment details:

Study was conducted at 344 active sites in 28 countries. 5732 subjects were screened between 27 April 2018 and 25 April 2019; of whom 4076 subjects were randomised by interactive response technology (1:1:1 ratio) to receive placebo, efpeglenatide 4 mg or efpeglenatide 6 mg. Screen failures were mainly due to inclusion criteria not met.

Pre-assignment

Screening details:

Randomisation was stratified by the current or potential future use of a sodium-glucose co-transporter-2 (SGLT2) inhibitor: current use; potential future use; neither current nor potential future use.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received placebo (matched to Efpeglenatide) as subcutaneous (SC) injection once weekly up to end of treatment (median duration: 19.8 months).

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo (matched to Efpeglenatide) as SC injection once weekly up to end of treatment.

Arm title	Efpeglenatide 4mg

Arm description:

Subjects received Efpeglenatide as SC injection 2 milligrams (mg) per week for 4 weeks then 4 mg per week up to end of treatment (median duration: 19.9 months).

Arm type	Experimental
Investigational medicinal product name	Efpeglenatide 4mg
Investigational medicinal product code	SAR439977
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Efpeglenatide as SC injection 2 mg per week for 4 weeks then 4 mg per week up to end of treatment.

Arm title	Efpeglenatide 6 mg

Arm description:

Subjects received Efpeglenatide as SC injection 2 mg per week for 4 weeks, then 4 mg per week for 4 weeks and then 6 mg per week up to end of treatment (median duration: 20 months).

Arm type	Experimental

Investigational medicinal product name	Efpeglenatide 6 mg
Investigational medicinal product code	SAR439977
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Efpeglenatide as SC injection 2 mg per week for 4 weeks, then 4 mg per week for 4 weeks and then 6 mg per week up to end of treatment.

Number of subjects in period 1	Placebo	Efpeglenatide 4mg	Efpeglenatide 6 mg
Started	1359	1359	1358
Randomised and treated	1358	1358	1357
Completed	42	36	23
Not completed	1317	1323	1335
Randomised and not treated	1	1	1
Study terminated by Sponsor	1050	1063	1071
Adverse event	49	68	79
Unspecified	29	20	23
Physician decision (other than adverse event)	12	17	10
Withdrawal by subject	176	154	151

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo (matched to Efpeglenatide) as subcutaneous (SC) injection once weekly up to end of treatment (median duration: 19.8 months).	
Reporting group title	Efpeglenatide 4mg
Reporting group description:	
Subjects received Efpeglenatide as SC injection 2 milligrams (mg) per week for 4 weeks then 4 mg per week up to end of treatment (median duration: 19.9 months).	
Reporting group title	Efpeglenatide 6 mg
Reporting group description:	
Subjects received Efpeglenatide as SC injection 2 mg per week for 4 weeks, then 4 mg per week for 4 weeks and then 6 mg per week up to end of treatment (median duration: 20 months).	

Reporting group values	Placebo	Efpeglenatide 4mg	Efpeglenatide 6 mg
Number of subjects	1359	1359	1358
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	64.4	64.6	64.7
standard deviation	± 8.3	± 8.2	± 8.2
Gender categorical Units: Subjects			
Female	419	442	483
Male	940	917	875
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	11	8	8
Asian	98	87	82
Native Hawaiian or Other Pacific Islander	0	1	2
Black or African American	50	38	55
White	1162	1192	1180
More than one race	4	9	5
Unknown or Not Reported	34	24	26
Body Mass Index (BMI)			
In both Efpeglenatide 4 mg and Efpeglenatide 6 mg arm, only 1357 subjects were involved in the evaluation of the specified baseline measure.			
Units: kilogram metre per square (kg/m^2)			
arithmetic mean	32.40	32.81	32.90
standard deviation	± 6.01	± 6.22	± 6.21

Reporting group values	Total		
Number of subjects	4076		

Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	- -		
Gender categorical Units: Subjects			
Female	1344		
Male	2732		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	27		
Asian	267		
Native Hawaiian or Other Pacific Islander	3		
Black or African American	143		
White	3534		
More than one race	18		
Unknown or Not Reported	84		
Body Mass Index (BMI)			
In both Efpeglenatide 4 mg and Efpeglenatide 6 mg arm, only 1357 subjects were involved in the evaluation of the specified baseline measure.			
Units: kilogram metre per square (kg/m^2) arithmetic mean standard deviation	 - -		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects received placebo (matched to Efpeglenatide) as subcutaneous (SC) injection once weekly up to end of treatment (median duration: 19.8 months).	
Reporting group title	Efpeglenatide 4mg
Reporting group description:	
Subjects received Efpeglenatide as SC injection 2 milligrams (mg) per week for 4 weeks then 4 mg per week up to end of treatment (median duration: 19.9 months).	
Reporting group title	Efpeglenatide 6 mg
Reporting group description:	
Subjects received Efpeglenatide as SC injection 2 mg per week for 4 weeks, then 4 mg per week for 4 weeks and then 6 mg per week up to end of treatment (median duration: 20 months).	
Subject analysis set title	Efpeglenatide 4 mg+6 mg
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Included all subjects who received either Efpeglenatide 4 mg or 6 mg as SC injection once weekly up to end of treatment (median duration: 19.9 months).	

Primary: Time to First Occurrence of Major Adverse Cardiovascular Events (MACE): Event Rate Per 100 Subject-years for First Occurrence of Major Cardiovascular (CV) Event - Non-Inferiority Analysis

End point title	Time to First Occurrence of Major Adverse Cardiovascular Events (MACE): Event Rate Per 100 Subject-years for First Occurrence of Major Cardiovascular (CV) Event - Non-Inferiority Analysis[1]
End point description:	
All MACE positively adjudicated by the clinical endpoint committee (CEC) were used in the analysis of the composite outcome of first occurrence to CV death, non-fatal myocardial infarction (MI), and non-fatal stroke. Kaplan-Meier curves of the cumulative event rate by treatment groups were used to depict the first occurrence of MACE over time. The event rate per 100 subject-years (calculated by 100*number of subjects with events/sum of time at risk (days) over all subjects/365.25) measured in terms of number of events per 100 subject-years was reported. Analysis was performed on intent-to-treat (ITT) population that included all randomised subjects irrespective of compliance with the study protocol and procedures and were analysed in the treatment group to which they were randomised. Data for this endpoint was planned to be collected and analysed for pooled population of subjects who received Efpeglenatide (at any dose: 4 mg and 6 mg) as pre-specified in the protocol.	
End point type	Primary
End point timeframe:	
From Day 1 until the date of first adjudicated and confirmed occurrence of major CV event (maximum duration: up to 31.5 months)	
Notes:	
[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Data was reported for applicable arms in the endpoint.	

End point values	Placebo	Efpeglenatide 4 mg+6 mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1359	2717		
Units: events per 100 subject-years				
number (confidence interval 95%)	5.3 (4.4 to 6.3)	3.9 (3.4 to 4.5)		

Statistical analyses

Statistical analysis title	Efpeglenatide 4 mg+6 mg versus Placebo

Statistical analysis description:

Hazard ratio and 95% Confidence Interval (CI) were obtained from a Cox proportional hazards model with region (North America, Latin America, Europe, other), randomisation stratum of SGLT2 inhibitor use (current use, potential future use, neither current nor potential future use) and treatment (efpeglenatide 4 mg, efpeglenatide 6 mg, placebo) as fixed effect factor.

Comparison groups	Placebo v Efpeglenatide 4 mg+6 mg
Number of subjects included in analysis	4076
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
P-value	< 0.0001 [3]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.732
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.583
upper limit	0.918

Notes:

[2] - Non-inferiority of efpeglenatide 4 mg+6 mg versus placebo was to be claimed if the upper bound of the 2-sided 95% CI of the hazard ratio for the incidence was <=1.8 and <=1.3.

[3] - One-sided p-value based on log rank test of hazard ratio for the incidence <=1.8 and <=1.3.

Secondary: Time to First Occurrence of Major Adverse Cardiovascular Events: Event Rate Per 100 Subject-years for First Occurrence of Major Cardiovascular Event - Superiority Analysis

End point title	Time to First Occurrence of Major Adverse Cardiovascular Events: Event Rate Per 100 Subject-years for First Occurrence of Major Cardiovascular Event - Superiority Analysis[4]

End point description:

All MACE positively adjudicated by the CEC were used in the analysis of the composite outcome of first occurrence to CV death, non-fatal MI, and non-fatal stroke. Kaplan-Meier curves of the cumulative event rate by treatment groups were used to depict the first occurrence of MACE over time. The event rate per 100 subject-years (calculated by 100*number of subjects with events/sum of time at risk (days) over all subjects/365.25) measured in terms of number of events per 100 subject-years was reported. Analysis was performed on ITT population. Data for this endpoint was planned to be collected and analysed for pooled population of subjects who received Efpeglenatide (at any dose: 4 mg and 6 mg) as pre-specified in the protocol.

End point type	Secondary

End point timeframe:

From Day 1 until the date of first adjudicated and confirmed occurrence of major CV event (maximum duration: up to 31.5 months)

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was reported for applicable arms in the endpoint.

End point values	Placebo	Efpeglenatide 4 mg+6 mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1359	2717		
Units: events per 100 subject-years				
number (confidence interval 95%)	5.3 (4.4 to 6.3)	3.9 (3.4 to 4.5)		

Statistical analyses

Statistical analysis title	Efpeglenatide 4 mg+6 mg versus Placebo

Statistical analysis description:

Hazard ratio and 95% CI were obtained from a Cox proportional hazards model with region (North America, Latin America, Europe, other), randomisation stratum of SGLT2 inhibitor use (current use, potential future use, neither current nor potential future use) and treatment (efpeglenatide 4 mg, efpeglenatide 6 mg, placebo) as fixed effect factor.

Comparison groups	Placebo v Efpeglenatide 4 mg+6 mg
Number of subjects included in analysis	4076
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	= 0.0069 [6]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.732
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.583
upper limit	0.918

Notes:

[5] - Superiority was claimed when the upper bound of the 2-sided 95% CI of hazard ratio was less than 1.
[6] - Two-sided p-values based on log rank test of hazard ratio.

Secondary: Time to First Occurrence of the Expanded Major Adverse Cardiovascular Events Composite Events: Event Rate Per 100 Subject-years for First Occurrence of Expanded Major Cardiovascular Event

End point title	Time to First Occurrence of the Expanded Major Adverse Cardiovascular Events Composite Events: Event Rate Per 100 Subject-years for First Occurrence of Expanded Major Cardiovascular Event[7]

End point description:

All MACE positively adjudicated by the CEC were used in the analysis of the expanded outcome of first occurrence to CV death (including fatal MI and fatal stroke), non-fatal MI, non-fatal stroke, coronary revascularisation or hospitalisation for unstable angina. Kaplan-Meier curves of the cumulative event rate by treatment groups were used to depict the first occurrence of MACE over time. The event rate per 100 subject-years (calculated by 100*number of subjects with events/sum of time at risk (days) over all subjects/365.25) measured in terms of number of events per 100 subject-years was reported. Data analysis was also performed independently by external steering committee for the publication. Analysis was performed on ITT population. Data for this endpoint was planned to be collected and analysed for pooled population of subjects who received Efpeglenatide (at any dose: 4 mg and 6 mg) as pre-specified in the protocol.

End point type	Secondary

End point timeframe:

From Day 1 until the date of first adjudicated and confirmed occurrence of major CV event (maximum duration: up to 31.5 months)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was reported for applicable arms in the endpoint.

End point values	Placebo	Efpeglenatide 4 mg+6 mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1359	2717		
Units: events per 100 subject-years				
number (not applicable)	6.8	5.4		

Statistical analyses

Statistical analysis title	Efpeglenatide 4 mg+6 mg versus Placebo

Statistical analysis description:

Hazard ratio and 95% CI were obtained from a Cox proportional hazards model with region (North America, Latin America, Europe, other), randomisation stratum of SGLT2 inhibitor use (current use, potential future use, neither current nor potential future use) and treatment (efpeglenatide 4 mg, efpeglenatide 6 mg, placebo) as fixed effect factor.

Comparison groups	Placebo v Efpeglenatide 4 mg+6 mg
Number of subjects included in analysis	4076
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	= 0.02 [9]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.96

Notes:

[8] - Superiority was claimed when the upper bound of the 2-sided 95% CI of hazard ratio was less than 1.
[9] - Two-sided p-values based on log rank test of hazard ratio.

Secondary: Time to First Occurrence of Composite Renal Endpoint: Event Rate Per 100 Subject-years for First Occurrence of Composite Renal Endpoint

End point title	Time to First Occurrence of Composite Renal Endpoint: Event Rate Per 100 Subject-years for First Occurrence of Composite Renal Endpoint[10]

End point description:

Composite renal endpoint: incident macroalbuminuria (defined as urinary albumin-to-creatinine ratio of greater than (>) 300, measured in mg of albumin to grams of creatinine or >33.9, measured in mg of albumin to millimoles of creatinine), plus increase in urinary albumin-to-creatinine ratio of at least 30% from Baseline, sustained decrease in eGFR of at least 40% for 30 days or more, renal-replacement therapy for 90 days or more and sustained eGFR of less than 15 ml per minute per 1.73 m^2 for 30 days or more. Kaplan-Meier curves of cumulative event rate depicted 1st occurrence of renal endpoint over time. Event rate per 100 subject-years (calculated by 100*number of subjects with events/sum of time at risk (days) over all subjects/365.25) measured in terms of number of events per 100 subject-years was reported. ITT population. Data was planned to be collected and analysed for pooled population of subjects who received Efpeglenatide (at any dose:4mg/6mg) as pre-specified in protocol.

End point type	Secondary

End point timeframe:

From Day 1 until the confirmed occurrence of composite renal endpoint (maximum duration: up to 31.5 months)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was reported for applicable arms in the endpoint.

End point values	Placebo	Efpeglenatide 4 mg+6 mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1359	2717		
Units: events per 100 subject-years				
number (confidence interval 95%)	11.6 (10.2 to 13.1)	7.7 (6.9 to 8.6)		

Statistical analyses

Statistical analysis title	Efpeglenatide 4 mg+6 mg versus Placebo

Statistical analysis description:

Hazard ratio and 95% CI were obtained from a Cox proportional hazards model with region (North America, Latin America, Europe, other), randomisation stratum of SGLT2 inhibitor use (current use, potential future use, neither current nor potential future use) and treatment (efpeglenatide 4 mg, efpeglenatide 6 mg, placebo) as fixed effect factor.

Comparison groups	Placebo v Efpeglenatide 4 mg+6 mg
Number of subjects included in analysis	4076
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	< 0.0001 [12]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.675
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.574
upper limit	0.794

Notes:

[11] - Superiority was claimed when the upper bound of the 2-sided 95% CI of hazard ratio was less than 1.
[12] - Two-sided p-values based on log rank test of hazard ratio.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs) data were collected from time of first injection of investigational medicinal product (IMP) to the last injection of IMP + 30 days (i.e., up to maximum duration of 31.5 months).

Adverse event reporting additional description:

AEs and deaths were treatment-emergent AEs (TEAEs): AEs that developed/worsened/became serious during the TEAE period (time from 1st to last injection of IMP + 30 days). Safety population: all randomised subjects who received at least 1 dose of double-blind treatment, regardless of amount of treatment administered, analysed according to treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects received placebo (matched to Efpeglenatide) as SC injection once weekly up to end of treatment (median duration: 19.8 months).

Reporting group title	Efpeglenatide 4 mg

Reporting group description:

Subjects received Efpeglenatide as SC injection 2 mg per week for 4 weeks then 4 mg per week up to end of treatment (median duration: 19.9 months).

Reporting group title	Efpeglenatide 6 mg

Reporting group description:

Subjects received Efpeglenatide as SC injection 2 mg per week for 4 weeks, then 4 mg per week for 4 weeks and then 6 mg per week up to end of treatment (median duration: 20 months).

Serious adverse events	Placebo	Efpeglenatide 4 mg	Efpeglenatide 6 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	298 / 1355 (21.99%)	312 / 1360 (22.94%)	275 / 1358 (20.25%)
number of deaths (all causes)	49	40	25
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma Metastatic			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Adenocarcinoma Of Colon			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Adenocarcinoma Pancreas			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal Cell Carcinoma			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm Of Scrotum			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm Of Skin			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Cancer			
subjects affected / exposed	2 / 1355 (0.15%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Cancer Recurrent			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Neoplasm			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Transitional Cell Carcinoma			
subjects affected / exposed	0 / 1355 (0.00%)	3 / 1360 (0.22%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			

subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer Metastatic			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cholangiocarcinoma			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Chronic Lymphocytic Leukaemia			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal Cancer Metastatic			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cutaneous T-Cell Lymphoma			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse Large B-Cell Lymphoma Stage Iv			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Cancer			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular Carcinoma			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Adenocarcinoma			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Neoplasm Malignant			
subjects affected / exposed	4 / 1355 (0.30%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Lung Cancer Metastatic			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases To Liver			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastases To Lung			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Neuroendocrine Tumour Of The Lung Metastatic			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Small Cell Lung Cancer Stage Iv			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Adenocarcinoma Stage Iv			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Oesophageal Carcinoma			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic Carcinoma			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pancreatic Carcinoma Metastatic			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary Thyroid Cancer			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	1 / 1355 (0.07%)	2 / 1360 (0.15%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer Metastatic			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer Recurrent			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic Adenoma			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectosigmoid Cancer Metastatic			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cancer			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cell Carcinoma			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cell Carcinoma Stage Iv			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Neoplasm			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Oncocytoma			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Cell Lung Cancer Metastatic			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Spinal Cord Neoplasm			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma Of The Oral Cavity			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Cancer			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional Cell Carcinoma			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Arterial Haemorrhage			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Stenosis			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Occlusive Disease			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dry Gangrene			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Vascular Disorder			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential Hypertension			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity Necrosis			
subjects affected / exposed	2 / 1355 (0.15%)	2 / 1360 (0.15%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	3 / 1355 (0.22%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Emergency			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Crisis			
subjects affected / exposed	4 / 1355 (0.30%)	4 / 1360 (0.29%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypotension			
subjects affected / exposed	2 / 1355 (0.15%)	4 / 1360 (0.29%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent Claudication			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic Hypotension			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	8 / 1355 (0.59%)	7 / 1360 (0.51%)	10 / 1358 (0.74%)
occurrences causally related to treatment / all	0 / 8	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Stenosis			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Occlusion			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Circulatory Failure			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Thrombosis			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Peripheral Embolism			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Ischaemia			
subjects affected / exposed	3 / 1355 (0.22%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Vascular Disorder			

subjects affected / exposed	5 / 1355 (0.37%)	2 / 1360 (0.15%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous Thrombosis Limb			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Accidental Death			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Asthenia			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Death			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Chest Pain			
subjects affected / exposed	1 / 1355 (0.07%)	2 / 1360 (0.15%)	0 / 1358 (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
Death			
subjects affected / exposed	4 / 1355 (0.30%)	5 / 1360 (0.37%)	4 / 1358 (0.29%)
occurrences causally related to treatment / all	0 / 4	1 / 5	0 / 4
deaths causally related to treatment / all	0 / 4	1 / 5	0 / 4
Fatigue			

subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Healing			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	2 / 1355 (0.15%)	6 / 1360 (0.44%)	5 / 1358 (0.37%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Swelling			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Cardiac Death			
subjects affected / exposed	2 / 1355 (0.15%)	5 / 1360 (0.37%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 2	1 / 5	0 / 2
deaths causally related to treatment / all	0 / 2	1 / 5	0 / 2
Vascular Stent Stenosis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Death			
subjects affected / exposed	1 / 1355 (0.07%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Vascular Stent Thrombosis			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Cervical Polyp			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometriosis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postmenopausal Haemorrhage			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic Atrophy			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Prostatitis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	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	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute Respiratory Distress Syndrome			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Acute Respiratory Failure			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Asthma			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis Chronic			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	2 / 1355 (0.15%)	4 / 1360 (0.29%)	4 / 1358 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	0 / 1358 (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

Epistaxis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Disorder			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural Effusion			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pleurocutaneous Fistula			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	2 / 1355 (0.15%)	2 / 1360 (0.15%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pulmonary Oedema			

subjects affected / exposed	0 / 1355 (0.00%)	3 / 1360 (0.22%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	3 / 1355 (0.22%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sleep Apnoea Syndrome			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major Depression			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panic Attack			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			

Device Fastener Issue			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Lead Issue			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Loosening			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anticoagulation Drug Level Above Therapeutic			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Glucose Increased			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Pressure Decreased			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood Pressure Increased			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart Rate Abnormal			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Enzyme Increased			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase Increased			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver Function Test Abnormal			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasminogen Activator Inhibitor Increased			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin Increased			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight Decreased			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Accidental Overdose			
subjects affected / exposed	2 / 1355 (0.15%)	2 / 1360 (0.15%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic Complication			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Bypass Occlusion			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Bypass Stenosis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachial Plexus Injury			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral Injury			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	4 / 1358 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			

subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	3 / 1360 (0.22%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula Fracture			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat Exhaustion			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Injury			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb Injury			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb Traumatic Amputation			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			
subjects affected / exposed	1 / 1355 (0.07%)	2 / 1360 (0.15%)	0 / 1358 (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
Neck Injury			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Patella Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Restenosis			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Respiratory Failure			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Site Reaction			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	2 / 1355 (0.15%)	2 / 1360 (0.15%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Scapula Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Laceration			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Fracture			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomal Hernia			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haematoma			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Limb Fracture			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular Graft Thrombosis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular Pseudoaneurysm			

subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypertrophic Cardiomyopathy			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Left Ventricular Failure			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Myocardial Infarction			
subjects affected / exposed	2 / 1355 (0.15%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Angina Pectoris			
subjects affected / exposed	10 / 1355 (0.74%)	8 / 1360 (0.59%)	17 / 1358 (1.25%)
occurrences causally related to treatment / all	0 / 13	0 / 8	1 / 17
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Angina Unstable			
subjects affected / exposed	23 / 1355 (1.70%)	20 / 1360 (1.47%)	10 / 1358 (0.74%)
occurrences causally related to treatment / all	0 / 29	0 / 23	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0

Aortic Valve Stenosis			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia Supraventricular			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis Coronary Artery			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	12 / 1355 (0.89%)	15 / 1360 (1.10%)	12 / 1358 (0.88%)
occurrences causally related to treatment / all	0 / 16	0 / 17	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Atrial Flutter			
subjects affected / exposed	2 / 1355 (0.15%)	2 / 1360 (0.15%)	5 / 1358 (0.37%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Tachycardia			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block Complete			
subjects affected / exposed	4 / 1355 (0.30%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyarrhythmia			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bundle Branch Block Left			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	5 / 1355 (0.37%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 0
Cardiac Discomfort			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	12 / 1355 (0.89%)	4 / 1360 (0.29%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 12	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 0
Cardiac Failure Acute			
subjects affected / exposed	3 / 1355 (0.22%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac Failure Chronic			
subjects affected / exposed	2 / 1355 (0.15%)	4 / 1360 (0.29%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac Failure Congestive			

subjects affected / exposed	3 / 1355 (0.22%)	2 / 1360 (0.15%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Cardiac Valve Disease			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-Respiratory Arrest			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiogenic Shock			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Cardiomyopathy			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy Acute			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular Insufficiency			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Coronary Artery Disease			
subjects affected / exposed	10 / 1355 (0.74%)	14 / 1360 (1.03%)	5 / 1358 (0.37%)
occurrences causally related to treatment / all	0 / 11	0 / 14	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Coronary Artery Occlusion			

subjects affected / exposed	2 / 1355 (0.15%)	2 / 1360 (0.15%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Stenosis			
subjects affected / exposed	1 / 1355 (0.07%)	3 / 1360 (0.22%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left Ventricular Dysfunction			
subjects affected / exposed	2 / 1355 (0.15%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left Ventricular Failure			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Mitral Valve Incompetence			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	9 / 1355 (0.66%)	4 / 1360 (0.29%)	6 / 1358 (0.44%)
occurrences causally related to treatment / all	0 / 10	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 5	0 / 2	0 / 3
Myocardial Ischaemia			
subjects affected / exposed	4 / 1355 (0.30%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Node Dysfunction			

subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Tachycardia			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	0 / 1358 (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
Tricuspid Valve Incompetence			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Arrhythmia			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Tachycardia			
subjects affected / exposed	3 / 1355 (0.22%)	3 / 1360 (0.22%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain Injury			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Artery Disease			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Artery Stenosis			
subjects affected / exposed	2 / 1355 (0.15%)	3 / 1360 (0.22%)	4 / 1358 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Sinus Syndrome			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 1355 (0.00%)	3 / 1360 (0.22%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	1 / 1355 (0.07%)	2 / 1360 (0.15%)	0 / 1358 (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
Cerebrovascular Disorder			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cerebrovascular Insufficiency			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Radiculopathy			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial Syndrome			

subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Hyperosmolar Coma			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Paralysis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic Stroke			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Headache			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Encephalopathy			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic Encephalopathy			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic Seizure			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic Unconsciousness			
subjects affected / exposed	4 / 1355 (0.30%)	2 / 1360 (0.15%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	1 / 4	0 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar Stroke			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbosacral Radiculopathy			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic Encephalopathy			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia Gravis			

subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy Peripheral			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Senile Dementia			

subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	4 / 1355 (0.30%)	4 / 1360 (0.29%)	7 / 1358 (0.52%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic Encephalopathy			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	3 / 1355 (0.22%)	4 / 1360 (0.29%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vith Nerve Paralysis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal Cord Paresis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Acquired Haemophilia			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	3 / 1355 (0.22%)	2 / 1360 (0.15%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia Vitamin B12 Deficiency			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune Haemolytic Anaemia			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Loss Anaemia			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypochromic Anaemia			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	2 / 1355 (0.15%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness Neurosensory			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness Unilateral			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniere's Disease			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo Positional			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular Disorder			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid Ptosis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open Angle Glaucoma			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Artery Embolism			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous Haemorrhage			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Incarcerated Hernia			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Strangulated Hernia			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Gastritis			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	0 / 1358 (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
Colitis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	5 / 1358 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ischaemic			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Gastroparesis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	3 / 1355 (0.22%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum Intestinal Haemorrhagic			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			

subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	0 / 1358 (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
Gastric Ulcer			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis Erosive			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Perforation			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal Sphincter Insufficiency			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Inguinal Hernia			
subjects affected / exposed	1 / 1355 (0.07%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Ischaemia			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intestinal Obstruction			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-Abdominal Haemorrhage			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss Syndrome			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical Ileus			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric Artery Stenosis			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	0 / 1358 (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 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive Pancreatitis			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Disorder			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palatal Disorder			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	4 / 1355 (0.30%)	3 / 1360 (0.22%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	3 / 4	3 / 3	1 / 2
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 1
Pancreatitis Chronic			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic Ulcer			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal Haemorrhage			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices Oesophageal			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 1355 (0.07%)	3 / 1360 (0.22%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune Hepatitis			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bile Duct Stone			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 1355 (0.07%)	4 / 1360 (0.29%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Acute			
subjects affected / exposed	0 / 1355 (0.00%)	4 / 1360 (0.29%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	2 / 1355 (0.15%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Hepatitis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Cirrhosis			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Cyst			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperplastic Cholecystopathy			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermal Cyst			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Foot			
subjects affected / exposed	8 / 1355 (0.59%)	8 / 1360 (0.59%)	4 / 1358 (0.29%)
occurrences causally related to treatment / all	0 / 9	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage Subcutaneous			

subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Skin Ulcer			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Ulcer			
subjects affected / exposed	2 / 1355 (0.15%)	5 / 1360 (0.37%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	9 / 1355 (0.66%)	10 / 1360 (0.74%)	10 / 1358 (0.74%)
occurrences causally related to treatment / all	0 / 9	0 / 10	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Chronic Kidney Disease			
subjects affected / exposed	1 / 1355 (0.07%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Nephropathy			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	2 / 1355 (0.15%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			

subjects affected / exposed	1 / 1355 (0.07%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy Toxic			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Impairment			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial Nephritis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Bladder Polyp			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Mass			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroiditis Chronic			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	1 / 1355 (0.07%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cervical Spinal Stenosis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin Pain			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	3 / 1355 (0.22%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscal Degeneration			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			

subjects affected / exposed	4 / 1355 (0.30%)	2 / 1360 (0.15%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondritis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain In Extremity			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological Fracture			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia Rheumatica			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	1 / 1355 (0.07%)	3 / 1360 (0.22%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Osteoarthritis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Pain			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Stenosis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess Soft Tissue			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	3 / 1355 (0.22%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	0 / 1358 (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
Atypical Pneumonia			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	4 / 1355 (0.30%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis Bacterial			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Covid-19			

subjects affected / exposed	5 / 1355 (0.37%)	1 / 1360 (0.07%)	5 / 1358 (0.37%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Covid-19 Pneumonia			
subjects affected / exposed	5 / 1355 (0.37%)	7 / 1360 (0.51%)	6 / 1358 (0.44%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 3
Campylobacter Gastroenteritis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	6 / 1355 (0.44%)	3 / 1360 (0.22%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis Infective			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Chronic Sinusitis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis Infected			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Foot Infection			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Gangrene			
subjects affected / exposed	2 / 1355 (0.15%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated Tuberculosis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	2 / 1355 (0.15%)	3 / 1360 (0.22%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal Bacteraemia			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Bacteraemia			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Sepsis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			

subjects affected / exposed	3 / 1355 (0.22%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	6 / 1358 (0.44%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Salmonella			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Infection			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin Abscess			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1n1 Influenza			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster Infection Neurological			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 1355 (0.07%)	4 / 1360 (0.29%)	0 / 1358 (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
Joint Abscess			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella Sepsis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Infection			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
subjects affected / exposed	4 / 1355 (0.30%)	2 / 1360 (0.15%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			

subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinitis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Abscess			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	5 / 1355 (0.37%)	2 / 1360 (0.15%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	0 / 1358 (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
Pilonidal Cyst			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	15 / 1355 (1.11%)	14 / 1360 (1.03%)	9 / 1358 (0.66%)
occurrences causally related to treatment / all	0 / 16	0 / 14	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 2
Pneumonia Bacterial			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Influenzal			

subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Klebsiella			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Mycoplasmal			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Staphylococcal			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Viral			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Wound Infection			
subjects affected / exposed	0 / 1355 (0.00%)	5 / 1360 (0.37%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Tuberculosis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Chronic			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cyst Infection			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingitis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrub Typhus			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	9 / 1355 (0.66%)	4 / 1360 (0.29%)	4 / 1358 (0.29%)
occurrences causally related to treatment / all	0 / 9	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Septic Shock			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Sinusitis			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Infection			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft Tissue Infection			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Bacteraemia			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Sepsis			
subjects affected / exposed	2 / 1355 (0.15%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (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
Suspected Covid-19			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis Gastrointestinal			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	2 / 1355 (0.15%)	7 / 1360 (0.51%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Enterococcal			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval Abscess			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Sepsis			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	5 / 1355 (0.37%)	3 / 1360 (0.22%)	6 / 1358 (0.44%)
occurrences causally related to treatment / all	0 / 5	0 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			

subjects affected / exposed	3 / 1355 (0.22%)	0 / 1360 (0.00%)	3 / 1358 (0.22%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	0 / 1355 (0.00%)	3 / 1360 (0.22%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			
subjects affected / exposed	3 / 1355 (0.22%)	2 / 1360 (0.15%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 3	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Diabetic Metabolic Decompensation			
subjects affected / exposed	0 / 1355 (0.00%)	2 / 1360 (0.15%)	0 / 1358 (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
Food Intolerance			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	1 / 1355 (0.07%)	1 / 1360 (0.07%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	5 / 1355 (0.37%)	8 / 1360 (0.59%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 7	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemic Hyperosmolar Nonketotic Syndrome			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			

subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	3 / 1355 (0.22%)	8 / 1360 (0.59%)	4 / 1358 (0.29%)
occurrences causally related to treatment / all	0 / 3	1 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 1355 (0.00%)	1 / 1360 (0.07%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic Acidosis			
subjects affected / exposed	1 / 1355 (0.07%)	0 / 1360 (0.00%)	1 / 1358 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic Acidosis			

subjects affected / exposed	0 / 1355 (0.00%)	0 / 1360 (0.00%)	2 / 1358 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 Diabetes Mellitus			
subjects affected / exposed	2 / 1355 (0.15%)	0 / 1360 (0.00%)	0 / 1358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo	Efpeglenatide 4 mg	Efpeglenatide 6 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	151 / 1355 (11.14%)	348 / 1360 (25.59%)	342 / 1358 (25.18%)
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	64 / 1355 (4.72%)	116 / 1360 (8.53%)	117 / 1358 (8.62%)
occurrences (all)	69	139	153
Nausea			
subjects affected / exposed	51 / 1355 (3.76%)	196 / 1360 (14.41%)	167 / 1358 (12.30%)
occurrences (all)	60	282	194
Vomiting			
subjects affected / exposed	18 / 1355 (1.33%)	85 / 1360 (6.25%)	75 / 1358 (5.52%)
occurrences (all)	19	106	95
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	15 / 1355 (1.11%)	68 / 1360 (5.00%)	77 / 1358 (5.67%)
occurrences (all)	16	74	80
Hypoglycaemia			
subjects affected / exposed	37 / 1355 (2.73%)	73 / 1360 (5.37%)	53 / 1358 (3.90%)
occurrences (all)	81	159	97

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 May 2018	The following substantial amendment was done - Clarified the contraception requirements for male and woman of childbearing potential (WOCBP): contraception for male subjects not required, ova donation restrictions added, change in contraceptive methods to be used for WOCBP, follow-up of pregnancy extended to one year.
30 July 2018	The following substantial amendment was done - Added an electrocardiogram assessment at Week 12, when steady state had been achieved, to allow Investigators to assess the effects of efpeglenatide on the heart earlier in the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The study was terminated early by the Sponsor but not due to any safety concerns.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/34215025