



## Clinical trial results:

### **EMPACT-MI: A streamlined, multicentre, randomised, parallel group, double-blind placebo-controlled superiority trial to evaluate the effect of EMPagliflozin on hospitalisation for heart failure and mortality in patients with aCuTe Myocardial Infarction**

#### **Summary**

EudraCT number	2019-001037-13
Trial protocol	DE HU PL NL BG FR DK ES
Global end of trial date	05 November 2023

#### **Results information**

Result version number	v1 (current)
This version publication date	20 November 2024
First version publication date	20 November 2024

#### **Trial information**

##### **Trial identification**

Sponsor protocol code	1245-0202
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##### **Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04509674
WHO universal trial number (UTN)	-

Notes:

##### **Sponsors**

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, 55216
Public contact	Boehringer Ingelheim, Call Center, Boehringer Ingelheim, 001 18002430127, <a href="mailto:clintriage.rdg@boehringer-ingelheim.com">clintriage.rdg@boehringer-ingelheim.com</a>
Scientific contact	Boehringer Ingelheim, Call Center, Boehringer Ingelheim, 001 18002430127, <a href="mailto:clintriage.rdg@boehringer-ingelheim.com">clintriage.rdg@boehringer-ingelheim.com</a>

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	29 November 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 November 2023
Global end of trial reached?	Yes
Global end of trial date	05 November 2023
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The main objective of this event-driven trial was to demonstrate the superiority of empagliflozin 10 mg once daily versus placebo, in addition to standard of care, for the reduction of the composite endpoint of time to first hospitalisation for heart failure (HHF) or all-cause mortality in high-risk patients hospitalised for acute myocardial infarction (MI).

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were to be entered in the study. All subjects were free to withdraw from the clinical trial at any time for any reason given. Close monitoring of all subjects was adhered to throughout the trial conduct. Rescue medication was allowed for all subjects as required.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 December 2020
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	Argentina: 223
Country: Number of subjects enrolled	Australia: 41
Country: Number of subjects enrolled	Brazil: 359
Country: Number of subjects enrolled	Bulgaria: 422
Country: Number of subjects enrolled	Canada: 359
Country: Number of subjects enrolled	China: 215
Country: Number of subjects enrolled	Denmark: 42
Country: Number of subjects enrolled	France: 130
Country: Number of subjects enrolled	Germany: 234
Country: Number of subjects enrolled	Hungary: 253
Country: Number of subjects enrolled	India: 221
Country: Number of subjects enrolled	Israel: 403
Country: Number of subjects enrolled	Japan: 264
Country: Number of subjects enrolled	Korea, Republic of: 85
Country: Number of subjects enrolled	Netherlands: 229
Country: Number of subjects enrolled	Poland: 824
Country: Number of subjects enrolled	Romania: 868
Country: Number of subjects enrolled	Russian Federation: 112

Country: Number of subjects enrolled	Serbia: 379
Country: Number of subjects enrolled	Spain: 46
Country: Number of subjects enrolled	Ukraine: 373
Country: Number of subjects enrolled	United States: 528
Worldwide total number of subjects	6610
EEA total number of subjects	3048

Notes:

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### **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)	3308
From 65 to 84 years	3189
85 years and over	113

## Subject disposition

### Recruitment

Recruitment details:

Randomised, placebo-controlled, double-blind, parallel-group trial in acute myocardial infarction (MI) hospitalised patients with high-risk for subsequent hospitalization for heart failure (HHF) and mortality. Patients were treated and remained in the trial until approximately a total number of 532 had primary endpoint events (i.e. event driven).

### Pre-assignment

Screening details:

All patients were screened for eligibility prior to participation in the trial. Patients attended a specialist site to ensure that they strictly met all inclusion and none of the exclusion criteria. One patient was randomised in error after death (i.e. mis-randomization) and was excluded from the randomised set.

### 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, Monitor, Carer, Data analyst, Assessor

Blinding implementation details:

Patients, investigators, and everyone involved in trial conduct or analysis or with any other interest in this double-blind trial remained blinded to the randomised treatment assignments until after database lock.

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Placebo

Arm description:

Patients with an acute myocardial infarction event took, on top of standard of care, one placebo matching-empagliflozin 10 milligrams (mg) film-coated tablet, orally, once daily, at the same time every morning, with a glass of water.

Arm type	Placebo
Investigational medicinal product name	Placebo matching empagliflozin 10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients received, on top of standard of care, one placebo matching-empagliflozin 10 milligrams (mg) film-coated tablet, orally, once daily, at the same time every morning, with a glass of water.

<b>Arm title</b>	Empagliflozin 10 mg
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Arm description:

Patients with an acute myocardial infarction event took, on top of standard of care, one empagliflozin (Jardiance®) 10 milligrams (mg) film-coated tablet, orally, once daily, at the same time every morning, with a glass of water.

Arm type	Experimental
Investigational medicinal product name	Empagliflozin
Investigational medicinal product code	
Other name	Jardiance®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients received on top of standard of care, one empagliflozin (Jardiance®) 10 milligrams (mg) film-

coated tablet, orally, once daily, at the same time every morning, with a glass of water.

<b>Number of subjects in period 1<sup>[1]</sup></b>	Placebo	Empagliflozin 10 mg
Started	3262	3260
Treated	3229	3234
Completed	2513	2550
Not completed	749	710
Patient refusal to continue, not due to AE	452	418
Other reason than listed	106	95
Adverse event, serious fatal event	11	4
Lost to follow-up	31	39
Not treated	33	26
Protocol deviation	9	10
Adverse event, non-fatal event	107	118

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Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Out of the 6610 subjects enrolled, 6522 were randomised to a treatment.

## Baseline characteristics

### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Patients with an acute myocardial infarction event took, on top of standard of care, one placebo matching-empagliflozin 10 milligrams (mg) film-coated tablet, orally, once daily, at the same time every morning, with a glass of water.

Reporting group title	Empagliflozin 10 mg
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Reporting group description:

Patients with an acute myocardial infarction event took, on top of standard of care, one empagliflozin (Jardiance®) 10 milligrams (mg) film-coated tablet, orally, once daily, at the same time every morning, with a glass of water.

Reporting group values	Placebo	Empagliflozin 10 mg	Total
Number of subjects	3262	3260	6522
Age categorical			
Randomised set (RS): All randomised patients, whether treated or not.			
Units: Patients			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1623	1639	3262
From 65-84 years	1593	1556	3149
85 years and over	46	65	111
Age Continuous			
Randomised set (RS): All randomised patients, whether treated or not.			
Units: years			
arithmetic mean	63.7	63.6	
standard deviation	± 10.8	± 11.0	-
Sex: Female, Male			
Randomised set (RS): All randomised patients, whether treated or not.			
Units: Patients			
Female	813	812	1625
Male	2449	2448	4897
Race/Ethnicity, Customized			
Randomised set (RS): All randomised patients, whether treated or not.			
Units: Subjects			
White	2721	2730	5451
Black/African-American	48	44	92
Asian	413	421	834
Other, including mixed race	7	9	16
Missing	73	56	129
Ethnicity (NIH/OMB)			
Randomised set (RS): All randomised patients, whether treated or not.			
Units: Subjects			

Hispanic or Latino	331	338	669
Not Hispanic or Latino	2859	2866	5725
Unknown or Not Reported	72	56	128

## End points

### End points reporting groups

Reporting group title	Placebo
Reporting group description: Patients with an acute myocardial infarction event took, on top of standard of care, one placebo matching-empagliflozin 10 milligrams (mg) film-coated tablet, orally, once daily, at the same time every morning, with a glass of water.	
Reporting group title	Empagliflozin 10 mg
Reporting group description: Patients with an acute myocardial infarction event took, on top of standard of care, one empagliflozin (Jardiance®) 10 milligrams (mg) film-coated tablet, orally, once daily, at the same time every morning, with a glass of water.	

### Primary: Composite of time to first heart failure hospitalisation or all-cause mortality

End point title	Composite of time to first heart failure hospitalisation or all-cause mortality
End point description: Incidence rate of the first occurrence of hospitalisation for heart failure (HHF) or death, whichever earliest, is reported. Median time-to-event was not estimable due to insufficient events being experienced.  The incidence rate was calculated as: the number of patients with an event for hospitalization for heart failure or death by treatment group during time at risk divided by the total time patients were at risk in that treatment group multiplied by 100 (per 100 Pt-years, Pt as abbreviation of patient).  The analysis was performed on the randomised set (RS) which contained all randomised patients, whether treated or not.	
End point type	Primary
End point timeframe: From randomisation or first study drug administration (if randomisation occurred after first drug administration), until individual day of trial completion. Up to 1004 days.	

End point values	Placebo	Empagliflozin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3262	3260		
Units: Pt with events/100 pt-years at risk				
number (confidence interval 95%)	6.58 (5.86 to 7.35)	5.85 (5.17 to 6.57)		

### Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: The primary endpoint was analysed using a Cox proportional hazards model with treatment, type-2 diabetes at baseline, geographical region, age at baseline, estimated glomerular filtration rate at	

baseline, left ventricular ejection fraction at baseline, persistent or permanent atrial fibrillation at baseline, prior myocardial infarction at baseline, peripheral artery disease at baseline and smoking at baseline as covariates.

Comparison groups	Placebo v Empagliflozin 10 mg
Number of subjects included in analysis	6522
Analysis specification	Pre-specified
Analysis type	superiority <sup>[1]</sup>
P-value	= 0.2061
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.06

Notes:

[1] - Null hypothesis: there is no difference regarding the risk of the endpoint in question between empagliflozin and placebo.

$p <= 0.05$  required for testing of subsequent key secondary endpoint hypotheses

Results are presented as Empagliflozin vs. Placebo.

### **Secondary: Key secondary endpoint - Total number of hospitalisations for heart failure (HHF) or all-cause mortality**

End point title	Key secondary endpoint - Total number of hospitalisations for heart failure (HHF) or all-cause mortality
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End point description:

The total number of hospitalisations for heart failure (HHF) or all-cause mortality is reported using the adjusted event rate.

The adjusted event rate is based on a negative binomial model adjusted for treatment and type-2 diabetes at baseline, geographical region, age at baseline, estimated glomerular filtration rate at baseline, left ventricular ejection fraction at baseline, persistent or permanent atrial fibrillation at baseline, prior myocardial infarction at baseline, peripheral artery disease at baseline and smoking at baseline as covariates. The log(observation time) was used as an offset variable.

The analysis was performed on the randomised set (RS) which contained all randomised patients, whether treated or not.

End point type	Secondary
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End point timeframe:

From randomisation or first study drug administration (if randomisation occurred after first drug administration), until individual day of trial completion. Up to 1004 days.

<b>End point values</b>	Placebo	Empagliflozin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3262	3260		
Units: Events/100 patient-years at risk				
number (confidence interval 95%)	8.25 (6.92 to 9.83)	7.14 (5.91 to 8.63)		

## Statistical analyses

<b>Statistical analysis title</b>	Statistical analysis 1
Statistical analysis description:	
The statistical model used was a negative binomial model, including factors for treatment and type-2 diabetes at baseline, geographical region, age at baseline, estimated glomerular filtration rate at baseline, left ventricular ejection fraction at baseline, persistent or permanent atrial fibrillation at baseline, prior myocardial infarction at baseline, peripheral artery disease at baseline and smoking at baseline as covariates. The log(observation time) was used as an offset variable.	
Comparison groups	Placebo v Empagliflozin 10 mg
Number of subjects included in analysis	6522
Analysis specification	Pre-specified
Analysis type	other <sup>[2]</sup>
P-value	= 0.2423
Method	Negative binomial regression
Parameter estimate	Adjusted event rate ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.1

Notes:

[2] - Results are presented as Empagliflozin vs. Placebo.

### Secondary: Key secondary endpoint - Total number of non-elective cardiovascular (CV) hospitalisations or all-cause mortality

End point title	Key secondary endpoint - Total number of non-elective cardiovascular (CV) hospitalisations or all-cause mortality
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End point description:

The total number of non-elective cardiovascular (CV) hospitalisations or all-cause mortality is reported using the adjusted event rate.

The adjusted event rate is based on a negative binomial model adjusted for treatment and type-2 diabetes at baseline, geographical region, age at baseline, estimated glomerular filtration rate at baseline, left ventricular ejection fraction at baseline, persistent or permanent atrial fibrillation at baseline, prior myocardial infarction at baseline, peripheral artery disease at baseline and smoking at baseline as covariates. The log(observation time) was used as an offset variable.

The analysis was performed on the randomised set (RS) which contained all randomised patients, whether treated or not.

End point type	Secondary
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End point timeframe:

From randomisation or first study drug administration (if randomisation occurred after first drug administration), until individual day of trial completion. Up to 1004 days.

End point values	Placebo	Empagliflozin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3262	3260		
Units: Events/100 patient-years at risk				
number (confidence interval 95%)	16.90 (15.10 to 18.92)	15.52 (13.82 to 17.43)		

## Statistical analyses

<b>Statistical analysis title</b>	Statistical analysis 1
Statistical analysis description:	
The statistical model used was a negative binomial model, including factors for treatment and type-2 diabetes at baseline, geographical region, age at baseline, estimated glomerular filtration rate at baseline, left ventricular ejection fraction at baseline, persistent or permanent atrial fibrillation at baseline, prior myocardial infarction at baseline, peripheral artery disease at baseline and smoking at baseline as covariates. The log(observation time) was used as an offset variable.	
Comparison groups	Placebo v Empagliflozin 10 mg
Number of subjects included in analysis	6522
Analysis specification	Pre-specified
Analysis type	other <sup>[3]</sup>
P-value	= 0.2867
Method	Negative binomial regression
Parameter estimate	Adjusted event rate ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.07

Notes:

[3] - Results are presented as Empagliflozin vs. Placebo.

## Secondary: Key secondary endpoint - Total number of non-elective all-cause hospitalisations or all-cause mortality

End point title	Key secondary endpoint - Total number of non-elective all-cause hospitalisations or all-cause mortality
End point description:	
The total number of non-elective all-cause hospitalisations or all-cause mortality is reported using the adjusted event rate.	
The adjusted event rate is based on a negative binomial model adjusted for treatment and type-2 diabetes at baseline, geographical region, age at baseline, estimated glomerular filtration rate at baseline, left ventricular ejection fraction at baseline, persistent or permanent atrial fibrillation at baseline, prior myocardial infarction at baseline, peripheral artery disease at baseline and smoking at baseline as covariates. The log(observation time) was used as an offset variable.	
The analysis was performed on the randomised set (RS) which contained all randomised patients, whether treated or not.	
End point type	Secondary
End point timeframe:	
From randomisation or first study drug administration (if randomisation occurred after first drug administration), until individual day of trial completion. Up to 1004 days.	

<b>End point values</b>	Placebo	Empagliflozin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3262	3260		
Units: Events/100 patient-years at risk				
number (confidence interval 95%)	26.28 (23.92 to 28.87)	22.96 (20.84 to 25.31)		

## Statistical analyses

<b>Statistical analysis title</b>	Statistical analysis 1
Statistical analysis description:	
The statistical model used was a negative binomial model, including factors for treatment and type-2 diabetes at baseline, geographical region, age at baseline, estimated glomerular filtration rate at baseline, left ventricular ejection fraction at baseline, persistent or permanent atrial fibrillation at baseline, prior myocardial infarction at baseline, peripheral artery disease at baseline and smoking at baseline as covariates. The log(observation time) was used as an offset variable.	
Comparison groups	Placebo v Empagliflozin 10 mg
Number of subjects included in analysis	6522
Analysis specification	Pre-specified
Analysis type	other <sup>[4]</sup>
P-value	= 0.0463
Method	Negative binomial regression
Parameter estimate	Adjusted event rate ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7654
upper limit	0.9978

Notes:

[4] - Results are presented as Empagliflozin vs. Placebo.

## Secondary: Key secondary endpoint - Total number of hospitalisations for myocardial infarction (MI) or all-cause mortality

End point title	Key secondary endpoint - Total number of hospitalisations for myocardial infarction (MI) or all-cause mortality
End point description:	
The total number of hospitalisations for myocardial infarction (MI) or all-cause mortality is reported using the adjusted event rate.	
The adjusted event rate is based on a negative binomial model adjusted for factors for treatment and type-2 diabetes at baseline, geographical region, age at baseline, estimated glomerular filtration rate at baseline, left ventricular ejection fraction at baseline, persistent or permanent atrial fibrillation at baseline, prior myocardial infarction at baseline, peripheral artery disease at baseline and smoking at baseline as covariates. The log(observation time) was used as an offset variable.	
The analysis was performed on the randomised set (RS) which contained all randomised patients, whether treated or not.	
End point type	Secondary
End point timeframe:	
From randomisation or first study drug administration (if randomisation occurred after first drug administration), until individual day of trial completion. Up to 1004 days.	

<b>End point values</b>	Placebo	Empagliflozin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3262	3260		
Units: Events/100 patient-years at risk				
number (confidence interval 95%)	6.27 (5.19 to 7.58)	6.66 (5.49 to 8.08)		

## Statistical analyses

<b>Statistical analysis title</b>	Statistical analysis 1
Statistical analysis description:	
The statistical model used was a negative binomial model, including factors for treatment and type-2 diabetes at baseline, geographical region, age at baseline, estimated glomerular filtration rate at baseline, left ventricular ejection fraction at baseline, persistent or permanent atrial fibrillation at baseline, prior myocardial infarction at baseline, peripheral artery disease at baseline and smoking at baseline as covariates. The log(observation time) was used as an offset variable.	
Comparison groups	Placebo v Empagliflozin 10 mg
Number of subjects included in analysis	6522
Analysis specification	Pre-specified
Analysis type	other <sup>[5]</sup>
P-value	= 0.6311
Method	Negative binomial regression
Parameter estimate	Adjusted event rate ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.35

Notes:

[5] - Results are presented as Empagliflozin vs. Placebo.

## Secondary: Time to cardiovascular (CV) mortality

<b>End point title</b>	Time to cardiovascular (CV) mortality
End point description:	
Incidence rate of cardiovascular (CV) mortality, including deaths of unknown cause , is reported. Median time-to-event was not estimable due to insufficient events being experienced.	
The incidence rate was calculated as: the number of patients with a cardiovascular death event by treatment group during time at risk divided by the total time patients were at risk in that treatment group multiplied by 100 (per 100 Pt-years, Pt as abbreviation of patient).	
The analysis was performed on the randomised set (RS) which contained all randomised patients, whether treated or not.	
End point type	Secondary
End point timeframe:	
From randomisation or first study drug administration (if randomisation occurred after first drug administration), until individual day of trial completion. Up to 1004 days.	

<b>End point values</b>	Placebo	Empagliflozin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3262	3260		
Units: Pt with events/100 pt-years at risk				
number (confidence interval 95%)	2.76 (2.31 to 3.25)	2.78 (2.33 to 3.28)		

## Statistical analyses

<b>Statistical analysis title</b>	Statistical analysis 1
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Statistical analysis description:

The statistical analysis was performed using a Cox proportional hazards model with treatment, type-2 diabetes at baseline, geographical region, age at baseline, estimated glomerular filtration rate at baseline, left ventricular ejection fraction at baseline, persistent or permanent atrial fibrillation at baseline, prior myocardial infarction at baseline, peripheral artery disease at baseline and smoking at baseline as covariates.

Comparison groups	Placebo v Empagliflozin 10 mg
Number of subjects included in analysis	6522
Analysis specification	Pre-specified
Analysis type	other <sup>[6]</sup>
P-value	= 0.8124
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.31

Notes:

[6] - Results are presented as Empagliflozin vs. Placebo.

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

From first study drug administration to last study drug administration plus 7 days (residual effect period). Up to 1004 days.

Adverse event reporting additional description:

Treated set: all patients who were dispensed study medication and were documented to have taken at least one dose of investigational treatment.

In the randomised set, the deaths due to any cause were 178 in the Placebo group and 169 in the Empagliflozin group.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

### Reporting groups

Reporting group title	Empagliflozin 10 mg
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Reporting group description:

Patients with an acute myocardial infarction event took, on top of standard of care, one empagliflozin (Jardiance®) 10 milligrams (mg) film-coated tablet, orally, once daily, at the same time every morning, with a glass of water.

Reporting group title	Placebo
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Reporting group description:

Patients with an acute myocardial infarction event took, on top of standard of care, one placebo matching-empagliflozin 10 milligrams (mg) film-coated tablet, orally, once daily, at the same time every morning, with a glass of water.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There were no subjects affect with non-serious adverse events at a rate higher than 5%. The total number of no-serious adverse events is depicted in the initial table.

Serious adverse events	Empagliflozin 10 mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	765 / 3234 (23.65%)	798 / 3229 (24.71%)	
number of deaths (all causes)	165	175	
number of deaths resulting from adverse events	137	140	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Adenocarcinoma			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	0 / 3234 (0.00%)	3 / 3229 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
B-cell lymphoma			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of skin			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			
subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm malignant			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Keratoacanthoma			

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac myxoma</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervix cancer metastatic</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Cervix carcinoma</b>		
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Colon cancer</b>		
subjects affected / exposed	4 / 3234 (0.12%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Colon neoplasm</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Colorectal adenoma</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diffuse large B-cell lymphoma</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Endometrial cancer</b>		

subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Essential thrombocythaemia</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastric cancer</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrointestinal carcinoma</b>		
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hepatic cancer metastatic</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast cancer</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Large intestine benign neoplasm</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastatic gastric cancer</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Lung adenocarcinoma</b>		

subjects affected / exposed	2 / 3234 (0.06%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	2 / 3234 (0.06%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Lung squamous cell carcinoma recurrent		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	2 / 3234 (0.06%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm progression		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Mantle cell lymphoma		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Mesothelioma		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to liver		
subjects affected / exposed	1 / 3234 (0.03%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lung		

subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to lymph nodes</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to peritoneum</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to pleura</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Laryngeal cancer</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastatic renal cell carcinoma</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal adenocarcinoma</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myelodysplastic syndrome</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Neoplasm prostate</b>		

subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal neoplasm		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer metastatic		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Penile squamous cell carcinoma		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal cancer		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	0 / 3234 (0.00%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Plasmacytoma		

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural neoplasm		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	6 / 3234 (0.19%)	4 / 3229 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mucoepidermoid carcinoma		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	1 / 3234 (0.03%)	4 / 3229 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer metastatic		

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Soft tissue neoplasm</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tonsil cancer metastatic</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Transitional cell carcinoma</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Rectosigmoid cancer stage III</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vascular disorders</b>			
<b>Arteriosclerosis</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Acute aortic syndrome</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic aneurysm</b>			
subjects affected / exposed	3 / 3234 (0.09%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic stenosis</b>			

subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic thrombosis			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial thrombosis			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure inadequately controlled			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	3 / 3234 (0.09%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery embolism			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			

subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	3 / 3234 (0.09%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	7 / 3234 (0.22%)	5 / 3229 (0.15%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive urgency		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	8 / 3234 (0.25%)	7 / 3229 (0.22%)
occurrences causally related to treatment / all	0 / 8	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery arteriosclerosis		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	2 / 3234 (0.06%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vasoconstriction		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery stenosis		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian vein stenosis		

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial vein thrombosis			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	3 / 3234 (0.09%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3234 (0.00%)	4 / 3229 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular stent thrombosis			
subjects affected / exposed	3 / 3234 (0.09%)	3 / 3229 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	9 / 3234 (0.28%)	12 / 3229 (0.37%)	
occurrences causally related to treatment / all	0 / 9	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 0	

Death			
subjects affected / exposed	21 / 3234 (0.65%)	21 / 3229 (0.65%)	
occurrences causally related to treatment / all	0 / 21	0 / 21	
deaths causally related to treatment / all	0 / 21	0 / 21	
Gait disturbance			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site haematoma			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	28 / 3234 (0.87%)	27 / 3229 (0.84%)	
occurrences causally related to treatment / all	1 / 33	0 / 31	
deaths causally related to treatment / all	0 / 2	0 / 0	
Physical deconditioning			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	4 / 3234 (0.12%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	9 / 3234 (0.28%)	7 / 3229 (0.22%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 9	0 / 7	
Sudden death			
subjects affected / exposed	11 / 3234 (0.34%)	12 / 3229 (0.37%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 11	0 / 12	
Systemic inflammatory response syndrome			

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vascular stent stenosis</b>			
subjects affected / exposed	2 / 3234 (0.06%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac death</b>			
subjects affected / exposed	3 / 3234 (0.09%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
<b>Immune system disorders</b>			
<b>Anaphylactic shock</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Drug hypersensitivity</b>			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Social circumstances</b>			
<b>Physical assault</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tobacco user</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			
<b>Benign prostatic hyperplasia</b>			
subjects affected / exposed	2 / 3234 (0.06%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Penile scarring			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 3234 (0.00%)	3 / 3229 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	6 / 3234 (0.19%)	4 / 3229 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchiectasis			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

Chronic obstructive pulmonary disease			
subjects affected / exposed	4 / 3234 (0.12%)	3 / 3229 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	4 / 3234 (0.12%)	5 / 3229 (0.15%)	
occurrences causally related to treatment / all	1 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiccups			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Obstructive sleep apnoea syndrome			

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal fistula		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory acidosis		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	7 / 3234 (0.22%)	7 / 3229 (0.22%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary fibrosis		
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	1 / 3234 (0.03%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		

subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Pleural effusion</b>			
subjects affected / exposed	1 / 3234 (0.03%)	4 / 3229 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Respiratory failure</b>			
subjects affected / exposed	5 / 3234 (0.15%)	5 / 3229 (0.15%)	
occurrences causally related to treatment / all	0 / 5	1 / 5	
deaths causally related to treatment / all	0 / 2	0 / 1	
<b>Sleep apnoea syndrome</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Psychiatric disorders</b>			
<b>Confusional state</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Delirium</b>			
subjects affected / exposed	1 / 3234 (0.03%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Depression</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Mania</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Mental status changes</b>			

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Investigations</b>			
<b>Blood pressure increased</b>			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Clostridium test positive</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatic enzyme increased</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>International normalised ratio increased</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Stress echocardiogram abnormal</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Injury, poisoning and procedural complications</b>			
<b>Foot fracture</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal injury</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ankle fracture			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic injury			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac procedure complication			
subjects affected / exposed	3 / 3234 (0.09%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Craniofacial fracture			
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis postoperative			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face injury			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			

subjects affected / exposed	2 / 3234 (0.06%)	5 / 3229 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Femur fracture</b>		
subjects affected / exposed	1 / 3234 (0.03%)	4 / 3229 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Head injury</b>		
subjects affected / exposed	2 / 3234 (0.06%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Procedural pneumothorax</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint dislocation</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Limb traumatic amputation</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lower limb fracture</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar vertebral fracture</b>		
subjects affected / exposed	1 / 3234 (0.03%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neck injury</b>		

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Overdose</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic fracture</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumothorax traumatic</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post procedural complication</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post procedural haemorrhage</b>		
subjects affected / exposed	9 / 3234 (0.28%)	4 / 3229 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post procedural stroke</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Postoperative delirium</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hip fracture</b>		

subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Strangulated incisional hernia		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	2 / 3234 (0.06%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Surgical procedure repeated		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		

subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Traumatic haematoma			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Buried penis syndrome			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal dystrophy			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			

Acute coronary syndrome			
subjects affected / exposed	5 / 3234 (0.15%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	30 / 3234 (0.93%)	28 / 3229 (0.87%)	
occurrences causally related to treatment / all	0 / 32	0 / 29	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	52 / 3234 (1.61%)	54 / 3229 (1.67%)	
occurrences causally related to treatment / all	1 / 57	0 / 58	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	3 / 3234 (0.09%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia supraventricular			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmic storm			
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			

subjects affected / exposed	18 / 3234 (0.56%)	17 / 3229 (0.53%)
occurrences causally related to treatment / all	0 / 19	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial flutter</b>		
subjects affected / exposed	6 / 3234 (0.19%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial tachycardia</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial thrombosis</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac arrest</b>		
subjects affected / exposed	11 / 3234 (0.34%)	17 / 3229 (0.53%)
occurrences causally related to treatment / all	0 / 11	0 / 17
deaths causally related to treatment / all	0 / 9	0 / 11
<b>Atrioventricular block complete</b>		
subjects affected / exposed	3 / 3234 (0.09%)	5 / 3229 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bradyarrhythmia</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bradycardia</b>		
subjects affected / exposed	2 / 3234 (0.06%)	5 / 3229 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac aneurysm</b>		

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		
subjects affected / exposed	159 / 3234 (4.92%)	230 / 3229 (7.12%)
occurrences causally related to treatment / all	1 / 194	2 / 306
deaths causally related to treatment / all	0 / 17	0 / 23
Cardiac perforation		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac tamponade		
subjects affected / exposed	2 / 3234 (0.06%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac ventricular disorder		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ventricular thrombosis		
subjects affected / exposed	11 / 3234 (0.34%)	4 / 3229 (0.12%)
occurrences causally related to treatment / all	0 / 12	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	6 / 3234 (0.19%)	5 / 3229 (0.15%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 5	0 / 4
Coronary artery occlusion		

subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular disorder		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic coronary syndrome		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	14 / 3234 (0.43%)	14 / 3229 (0.43%)
occurrences causally related to treatment / all	0 / 14	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 1
Coronary artery dissection		
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery insufficiency		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiogenic shock		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	4 / 3234 (0.12%)	4 / 3229 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery thrombosis		

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dilated cardiomyopathy		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dressler's syndrome		
subjects affected / exposed	3 / 3234 (0.09%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Interventricular septum rupture		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracardiac thrombus		
subjects affected / exposed	2 / 3234 (0.06%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial rupture		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Microvascular coronary artery disease		
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	1 / 3234 (0.03%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		

subjects affected / exposed	110 / 3234 (3.40%)	94 / 3229 (2.91%)
occurrences causally related to treatment / all	0 / 119	0 / 104
deaths causally related to treatment / all	0 / 20	0 / 10
<b>Myocardial injury</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocardial ischaemia</b>		
subjects affected / exposed	0 / 3234 (0.00%)	6 / 3229 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic cardiomyopathy</b>		
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nodal rhythm</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ventricle rupture</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Papillary muscle rupture</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Pericardial effusion</b>		
subjects affected / exposed	4 / 3234 (0.12%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial haemorrhage</b>		

subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pericarditis		
subjects affected / exposed	3 / 3234 (0.09%)	4 / 3229 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Postinfarction angina		
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal angina		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrest		
subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	1 / 3234 (0.03%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Stress cardiomyopathy		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		

subjects affected / exposed	3 / 3234 (0.09%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	3 / 3234 (0.09%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	2 / 3234 (0.06%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	2 / 3234 (0.06%)	3 / 3229 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular flutter			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	18 / 3234 (0.56%)	22 / 3229 (0.68%)	
occurrences causally related to treatment / all	0 / 29	0 / 26	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
Cerebral hypoperfusion			

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Aphasia</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ataxia</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery stenosis</b>		
subjects affected / exposed	4 / 3234 (0.12%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	1 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery thrombosis</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebral haemorrhage</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebral infarction</b>		
subjects affected / exposed	6 / 3234 (0.19%)	4 / 3229 (0.12%)
occurrences causally related to treatment / all	1 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebral ischaemia</b>		
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebrovascular accident</b>		

subjects affected / exposed	8 / 3234 (0.25%)	8 / 3229 (0.25%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 3	0 / 0
Cortical laminar necrosis		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial mass		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	0 / 3234 (0.00%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic stroke		

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Headache</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hemiparesis</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dizziness</b>		
subjects affected / exposed	4 / 3234 (0.12%)	5 / 3229 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic stroke</b>		
subjects affected / exposed	7 / 3234 (0.22%)	11 / 3229 (0.34%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 2
<b>Syncope</b>		
subjects affected / exposed	16 / 3234 (0.49%)	19 / 3229 (0.59%)
occurrences causally related to treatment / all	2 / 18	1 / 19
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Lumbar radiculopathy</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metabolic encephalopathy</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nervous system disorder</b>		

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Paraesthesia</b>			
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Peroneal nerve palsy</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Post-traumatic epilepsy</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Presyncope</b>			
subjects affected / exposed	0 / 3234 (0.00%)	3 / 3229 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Radiculopathy</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ruptured cerebral aneurysm</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Seizure</b>			
subjects affected / exposed	2 / 3234 (0.06%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Status epilepticus</b>			

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	2 / 3234 (0.06%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Lacunar infarction		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	1 / 3234 (0.03%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular encephalopathy		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery occlusion		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar stroke		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	9 / 3234 (0.28%)	11 / 3229 (0.34%)	
occurrences causally related to treatment / all	0 / 9	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Microcytic anaemia</b>			
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Pancytopenia</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thrombocytopenia</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thrombocytosis</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Haemolysis</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ear and labyrinth disorders</b>			
<b>Sudden hearing loss</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertigo</b>			

subjects affected / exposed	3 / 3234 (0.09%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Eye disorders</b>			
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular hole			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular degeneration			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery embolism			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal infarction			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	3 / 3234 (0.09%)	5 / 3229 (0.15%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal polyp			

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dyspepsia</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Enteritis</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Food poisoning</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastric ulcer</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mechanical ileus</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrointestinal angiodysplasia</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrointestinal haemorrhage</b>		
subjects affected / exposed	28 / 3234 (0.87%)	22 / 3229 (0.68%)
occurrences causally related to treatment / all	1 / 29	0 / 23
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Gastrointestinal necrosis</b>		

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroesophageal reflux disease</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ileus</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ileus paralytic</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Inguinal hernia</b>		
subjects affected / exposed	3 / 3234 (0.09%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal angina</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal metaplasia</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal obstruction</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Irritable bowel syndrome</b>		

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	3 / 3234 (0.09%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vomiting		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal stenosis		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oronasal fistula		

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis acute</b>		
subjects affected / exposed	3 / 3234 (0.09%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis chronic</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic floor hernia</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal haemorrhage</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal polyp</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Small intestinal obstruction</b>		
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Volvulus</b>		

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric vein thrombosis			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	2 / 3234 (0.06%)	3 / 3229 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cholangitis			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic cholecystitis			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	6 / 3234 (0.19%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary obstruction			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	2 / 3234 (0.06%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	4 / 3234 (0.12%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Rash</b>			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Renal and urinary disorders</b>			
<b>Chronic kidney disease</b>			
subjects affected / exposed	1 / 3234 (0.03%)	4 / 3229 (0.12%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Acute kidney injury</b>			
subjects affected / exposed	27 / 3234 (0.83%)	43 / 3229 (1.33%)	
occurrences causally related to treatment / all	6 / 32	8 / 51	
deaths causally related to treatment / all	0 / 1	0 / 4	
<b>Bladder disorder</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Calculus urinary</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cystitis haemorrhagic</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ureterolithiasis</b>			
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Haematuria</b>			

subjects affected / exposed	5 / 3234 (0.15%)	10 / 3229 (0.31%)
occurrences causally related to treatment / all	1 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hydronephrosis</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephritis</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephrolithiasis</b>		
subjects affected / exposed	1 / 3234 (0.03%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephropathy toxic</b>		
subjects affected / exposed	6 / 3234 (0.19%)	9 / 3229 (0.28%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oliguria</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Polyuria</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal colic</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal failure</b>		

subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal haematoma			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	1 / 3234 (0.03%)	2 / 3229 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal infarct			
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	1 / 3234 (0.03%)	4 / 3229 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chondrocalcinosis</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc disorder</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc protrusion</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mobility decreased</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscular weakness</b>		
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myalgia</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Back pain</b>		
subjects affected / exposed	1 / 3234 (0.03%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oligoarthritis</b>		

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Pain in extremity</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Polymyalgia rheumatica</b>			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Rotator cuff syndrome</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Spinal osteoarthritis</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Osteoarthritis</b>			
subjects affected / exposed	3 / 3234 (0.09%)	3 / 3229 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Abdominal abscess</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abscess limb</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Coronavirus infection</b>			

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	5 / 3234 (0.15%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Arthritis bacterial		
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
COVID-19		
subjects affected / exposed	20 / 3234 (0.62%)	25 / 3229 (0.77%)
occurrences causally related to treatment / all	0 / 20	0 / 26
deaths causally related to treatment / all	0 / 3	0 / 4
COVID-19 pneumonia		
subjects affected / exposed	14 / 3234 (0.43%)	10 / 3229 (0.31%)
occurrences causally related to treatment / all	0 / 14	0 / 10
deaths causally related to treatment / all	0 / 3	0 / 3
Campylobacter gastroenteritis		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		

subjects affected / exposed	0 / 3234 (0.00%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridial infection		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Colonic abscess		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Complicated appendicitis		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronavirus pneumonia		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dental fistula		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	3 / 3234 (0.09%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endotoxic shock		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis bacterial		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Fungal infection		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal infection		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis aeromonas		

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis viral</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Herpes zoster</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Infected fistula</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Infection</b>		
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint abscess</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Localised infection</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neutropenic sepsis</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Norovirus infection</b>		

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes zoster		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fungal skin infection		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SARS-CoV-2 viraemia		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	9 / 3234 (0.28%)	8 / 3229 (0.25%)
occurrences causally related to treatment / all	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0
Sepsis		
subjects affected / exposed	2 / 3234 (0.06%)	3 / 3229 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Septic shock		
subjects affected / exposed	0 / 3234 (0.00%)	6 / 3229 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 4
Staphylococcal bacteraemia		

subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Staphylococcal sepsis</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Tooth abscess</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urinary tract infection</b>		
subjects affected / exposed	9 / 3234 (0.28%)	7 / 3229 (0.22%)
occurrences causally related to treatment / all	3 / 9	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritonitis</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumonia</b>		
subjects affected / exposed	31 / 3234 (0.96%)	30 / 3229 (0.93%)
occurrences causally related to treatment / all	0 / 31	0 / 33
deaths causally related to treatment / all	0 / 4	0 / 3
<b>Postoperative wound infection</b>		
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyelonephritis</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyelonephritis acute</b>		

subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Renal abscess</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Salmonellosis</b>			
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Urosepsis</b>			
subjects affected / exposed	2 / 3234 (0.06%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Viral infection</b>			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vestibular neuronitis</b>			
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Metabolism and nutrition disorders</b>			
<b>Hypovolaemia</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cell death</b>			
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Decreased appetite</b>			

subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dehydration		
subjects affected / exposed	0 / 3234 (0.00%)	4 / 3229 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus		
subjects affected / exposed	0 / 3234 (0.00%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	3 / 3234 (0.09%)	6 / 3229 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		

subjects affected / exposed	3 / 3234 (0.09%)	2 / 3229 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypokalaemia</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyponatraemia</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Iron deficiency</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ketoacidosis</b>		
subjects affected / exposed	2 / 3234 (0.06%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metabolic acidosis</b>		
subjects affected / exposed	1 / 3234 (0.03%)	0 / 3229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Polydipsia</b>		
subjects affected / exposed	0 / 3234 (0.00%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Type 1 diabetes mellitus</b>		
subjects affected / exposed	1 / 3234 (0.03%)	1 / 3229 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

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

<b>Non-serious adverse events</b>	Empagliflozin 10 mg	Placebo	
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 3234 (0.00%)	0 / 3229 (0.00%)	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 April 2022	This amendment introduced mainly a major change regarding the increase in the number of randomised patients.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported