Clinical trial results:
A Phase 3, Randomized, Observer-blind, Active-controlled Study to Evaluate the Safety and Efficacy of mRNA-1010 Candidate Seasonal Influenza Vaccine in Adults 50 Years and Older

Summary

EudraCT number	2022-001638-12
Trial protocol	ES DE EE BG DK PL
Global end of trial date	05 January 2024

Results information

Result version number	v1 (current)
This version publication date	05 January 2025
First version publication date	05 January 2025

Trial information

Trial identification

Sponsor protocol code	mRNA-1010-P302

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05566639
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ModernaTX, Inc.
Sponsor organisation address	325 Binney Street, Cambridge, United States, 02142
Public contact	Moderna Clinical Trials Support Center, ModernaTX, Inc., +1 877-777-7187, clinicaltrials@modernatx.com
Scientific contact	Moderna Clinical Trials Support Center, ModernaTX, Inc., +1 877-777-7187, clinicaltrials@modernatx.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	16 February 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 January 2024
Global end of trial reached?	Yes
Global end of trial date	05 January 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the safety and efficacy of mRNA-1010 in preventing seasonal influenza in adults 50 years and older.

Protection of trial subjects:

This study was conducted in accordance with the protocol and consensus ethical principles derived from international guidelines including the Declaration of Helsinki, Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines, applicable International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines, and other applicable laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 September 2022
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	Bulgaria: 1383
Country: Number of subjects enrolled	Canada: 1175
Country: Number of subjects enrolled	Denmark: 17
Country: Number of subjects enrolled	Estonia: 559
Country: Number of subjects enrolled	Germany: 782
Country: Number of subjects enrolled	Poland: 400
Country: Number of subjects enrolled	Spain: 129
Country: Number of subjects enrolled	Taiwan: 136
Country: Number of subjects enrolled	United Kingdom: 102
Country: Number of subjects enrolled	United States: 17819
Worldwide total number of subjects	22502
EEA total number of subjects	3270

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	11501
From 65 to 84 years	10791
85 years and over	210

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 22502 participants were randomized in this study, including 11252 participants in the mRNA-1010 group and 11250 participants in the Fluarix Quadrivalent group.

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, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Fluarix Quadrivalent

Arm description:

Participants received a single dose of Fluarix Quadrivalent by intramuscular (IM) injection on Day 1.

Arm type	Active comparator
Investigational medicinal product name	Fluarix Quadrivalent
Investigational medicinal product code	
Other name	Licensed quadrivalent inactivated seasonal influenza vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Fluarix Quadrivalent was administered per schedule specified in the arm description.

Arm title	mRNA-1010

Arm description:

Participants received a single dose of mRNA-1010 by IM injection on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1010
Investigational medicinal product code	
Other name	Seasonal influenza vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1010 was administered per schedule specified in the arm description.

Number of subjects in period 1	Fluarix Quadrivalent	mRNA-1010
Started	11250	11252
Full Analysis Set	11199	11211
Safety Set	11200	11210
Solicited Safety Set	11160	11168

Per-Protocol (PP) Set	11026	11055
PP Immunogenicity Set (PPIS)	408 [1]	444 [2]
Completed	10359	10359
Not completed	891	893
Adverse event, serious fatal	44	45
Physician decision	45	44
Consent withdrawn by subject	277	271
Other Than Specified	52	64
Adverse event, non-fatal	1	1
Protocol Deviation	4	4
Lost to follow-up	467	461
Serious Adverse Event	1	3

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: These are the number of participants in the PPIS.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: These are the number of participants in the PPIS.

Baseline characteristics

Reporting groups	
Reporting group title	Fluarix Quadrivalent
Reporting group description:	
Participants received a single dose of Fluarix Quadrivalent by intramuscular (IM) injection on Day 1.	
Reporting group title	mRNA-1010
Reporting group description:	
Participants received a single dose of mRNA-1010 by IM injection on Day 1.	

Reporting group values	Fluarix Quadrivalent	mRNA-1010	Total
Number of subjects	11250	11252	22502
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	63.8	63.9	
standard deviation	± 8.41	± 8.36	-
Sex: Female, Male Units: participants			
Female	6281	6256	12537
Male	4969	4996	9965
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	55	57	112
Asian	280	254	534
Native Hawaiian or Other Pacific Islander	15	11	26
Black or African American	1986	1950	3936
White	8790	8850	17640
More than one race	37	48	85
Unknown or Not Reported	87	82	169
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1837	1859	3696
Not Hispanic or Latino	9289	9273	18562
Unknown or Not Reported	124	120	244

End points

End points reporting groups

Reporting group title	Fluarix Quadrivalent
Reporting group description:	
Participants received a single dose of Fluarix Quadrivalent by intramuscular (IM) injection on Day 1.	
Reporting group title	mRNA-1010
Reporting group description:	
Participants received a single dose of mRNA-1010 by IM injection on Day 1.	

Primary: Number of Participants With Solicited Local and Systemic Reactogenicity Adverse Reactions (ARs)

End point title	Number of Participants With Solicited Local and Systemic Reactogenicity Adverse Reactions (ARs)[1]

End point description:

Solicited ARs (local and systemic) were collected in an electronic diary (eDiary). Local ARs: injection site pain, erythema, swelling/induration, and axillary (underarm) swelling or tenderness ipsilateral to the side of injection. Systemic ARs: fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills. All solicited ARs considered causally related to injection were graded 0-4 (per Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials); lower score indicates lower severity, and a higher score indicates greater severity. Note, not all solicited ARs were considered adverse events (AEs). Investigator reviewed whether solicited AR was also to be recorded as an AE. A Summary of serious AEs (SAEs) and nonserious AEs, regardless of causality, is located in "Reported Adverse Events" section. Solicited Safety Set: all randomized participants who received any study intervention and contributed to any solicited AR data.

End point type	Primary

End point timeframe:

7 days post-vaccination

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The endpoint is descriptive in nature.

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11160	11168		
Units: participants				
Any	5620	7989		
Grade 1	3840	4433		
Grade 2	1535	3050		
Grade 3	245	500		
Grade 4	0	6		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Unsolicited Adverse Events (AEs)

End point title	Number of Participants With Unsolicited Adverse Events (AEs)[2]

End point description:

An unsolicited AE was an AE that was not solicited using a participant diary and that was communicated by a participant who has signed informed consent. An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. Any abnormal laboratory test result (hematology, clinical chemistry, or prothrombin time [PT]/partial thromboplastin time [PTT]) or other safety assessment, including one that worsened from baseline and was considered clinically significant in the medical and scientific judgment of the Investigator was recorded as an AE. Number of participants with unsolicited AEs (SAEs and non-serious AEs) up to 28 days post-vaccination are reported in this endpoint. Safety Set included all randomized participants who received any study intervention. Participants were included in the vaccination group corresponding to the study intervention that they actually received.

End point type	Primary

End point timeframe:

Up to 28 days post-vaccination

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The endpoint is descriptive in nature.

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11200	11210		
Units: participants	1495	1351		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Serious Adverse Events (SAEs), AEs of Special Interest (AESIs), Medically Attended AEs (MAAEs), and AEs Leading to Discontinuation

End point title	Number of Participants With Serious Adverse Events (SAEs), AEs of Special Interest (AESIs), Medically Attended AEs (MAAEs), and AEs Leading to Discontinuation[3]

End point description:

An SAE was defined as any AE that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in disability/permanent damage, was a congenital anomaly/birth defect, or was an important medical event. AESIs included thrombocytopenia, new onset of or worsening of the protocol specified neurologic diseases, anaphylaxis, and myocarditis/pericarditis. An MAAE is an AE that lead to an unscheduled visit to an healthcare practitioner. This included visits to a study site for unscheduled assessments (for example, abnormal laboratory follow-up, and/or coronavirus disease 2019 [COVID-19] and visits to healthcare practitioners external to the study site (for example, urgent care, primary care physician). Safety Set included all randomized participants who received any study intervention. Participants were included in the vaccination group corresponding to the study intervention that they actually received.

End point type	Primary

End point timeframe:

Day 1 through Day 361 (Month 12)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The endpoint is descriptive in nature.

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11200	11210		
Units: participants				
SAEs	495	518		
AESIs	13	10		
MAAEs	3166	3126		
AEs Leading to Discontinuation	47	49		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With First Episode of RT-PCR-Confirmed Protocol-Defined Influenza-Like Illness (ILI) Caused by Any Seasonal Influenza A or B Virus Strains Regardless of Antigenic Match to Strains Selected for the Seasonal Vaccine

End point title	Number of Participants With First Episode of RT-PCR-Confirmed Protocol-Defined Influenza-Like Illness (ILI) Caused by Any Seasonal Influenza A or B Virus Strains Regardless of Antigenic Match to Strains Selected for the Seasonal Vaccine

End point description:

Protocol-defined ILI: The presence of body temperature ≥37.5 degrees celsius (°C) (≥99.5 degrees fahrenheit [°F]), accompanied by at least one of the respiratory illness symptoms (sore throat, cough, sputum production, wheezing, or difficulty breathing) and a positive Reverse Transcription Polymerase Chain Reaction (RT-PCR) for influenza. PP Set included all participants in the Modified Intent-to-Treat (mITT) Set (all randomized participants who received any study intervention except those who discontinued from the study prior to 14 days following administration of study intervention) who did not have major protocol deviations that could adversely impact efficacy, for example, disease or therapeutic intervention that might cause suboptimal response to the study intervention.

End point type	Primary

End point timeframe:

14 days post-vaccination through Day 181 (Month 6)

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11026	11055		
Units: participants	142	140		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

rVE = 100 * (1 − HR) % was defined as the percent reduction in the hazard (mRNA-1010 vs active comparator), where HR was the hazard ratio between mRNA-1010 vs the active comparator.

Comparison groups	Fluarix Quadrivalent v mRNA-1010

Number of subjects included in analysis	22081
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
P-value	= 0.1715
Method	Stratified Cox proportional hazards
Parameter estimate	Relative vaccine efficacy (rVE)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.1
upper limit	22.2

Notes:

[4] - Noninferiority margin = 10%

Secondary: Number of Participants With First Episode of RT-PCR-Confirmed Protocol-Defined ILI Caused by Influenza A or B Strains With Similarity to Those Selected for the Seasonal Vaccine

End point title	Number of Participants With First Episode of RT-PCR-Confirmed Protocol-Defined ILI Caused by Influenza A or B Strains With Similarity to Those Selected for the Seasonal Vaccine

End point description:

Protocol-defined ILI: The presence of body temperature ≥37.5°C (≥99.5°F), accompanied by at least one of the respiratory illness symptoms (sore throat, cough, sputum production, wheezing, or difficulty breathing) and a positive RT-PCR for influenza.

End point type	Secondary

End point timeframe:

14 days post-vaccination through Day 181 (Month 6)

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[5]	0[6]		
Units: participants				

Notes:

[5] - As pre-specified, the data for this endpoint was not collected and analyzed.

[6] - As pre-specified, the data for this endpoint was not collected and analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With First Episode of RT-PCR-Confirmed Protocol-Defined ILI Caused by influenza A or B Strains Antigenically Matched to the Vaccine Strains Selected for the Seasonal Vaccine

End point title	Number of Participants With First Episode of RT-PCR-Confirmed Protocol-Defined ILI Caused by influenza A or B Strains Antigenically Matched to the Vaccine Strains Selected for the Seasonal Vaccine

End point description:

Protocol-defined ILI: The presence of body temperature ≥37.5°C (≥99.5°F), accompanied by at least one of the respiratory illness symptoms (sore throat, cough, sputum production, wheezing, or difficulty

breathing) and a positive RT-PCR for influenza. PP Set included all participants in the mITT Set (all randomized participants who received any study intervention except those who discontinued from the study prior to 14 days following administration of study intervention) who did not have major protocol deviations that could adversely impact efficacy, for example, disease or therapeutic intervention that might cause suboptimal response to the study intervention.

End point type	Secondary

End point timeframe:

14 days post-vaccination through Day 181 (Month 6)

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11026	11055		
Units: participants	85	75		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With First Episode of RT-PCR CDC-Defined ILI Caused by Influenza A or B Strains With Similarity to Vaccine Strains

End point title	Number of Participants With First Episode of RT-PCR CDC-Defined ILI Caused by Influenza A or B Strains With Similarity to Vaccine Strains

End point description:

CDC-defined ILI: The presence of temperature ≥37.8°C [≥100°F], accompanied by at least one of the respiratory illness symptoms (cough and/or sore throat) and a positive RT-PCR for influenza.

End point type	Secondary

End point timeframe:

14 days post-vaccination through Day 181 (Month 6)

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[7]	0[8]		
Units: participants				

Notes:

[7] - As pre-specified, the data for this endpoint was not collected and analyzed.

[8] - As pre-specified, the data for this endpoint was not collected and analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With First Episode of RT-PCR CDC-Defined ILI Caused by Influenza A or B Strains That Were Antigenically Matched to Vaccine Strains

End point title	Number of Participants With First Episode of RT-PCR CDC-Defined ILI Caused by Influenza A or B Strains That Were Antigenically Matched to Vaccine Strains

End point description:

CDC-defined ILI: The presence of temperature ≥37.8°C [≥100°F], accompanied by at least one of the respiratory illness symptoms (cough and/or sore throat) and a positive RT-PCR for influenza. PP Set included all participants in the mITT Set (all randomized participants who received any study intervention except those who discontinued from the study prior to 14 days following administration of study intervention) who did not have major protocol deviations that could adversely impact efficacy, for example, disease or therapeutic intervention that might cause suboptimal response to the study intervention.

End point type	Secondary

End point timeframe:

14 days post-vaccination through Day 181 (Month 6)

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11026	11055		
Units: participants	44	38		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With First Episode of RT-PCR Confirmed United States (US) Centers for Disease Control and Prevention (CDC)-Defined ILI Caused by Any Influenza A or B Strains

End point title	Number of Participants With First Episode of RT-PCR Confirmed United States (US) Centers for Disease Control and Prevention (CDC)-Defined ILI Caused by Any Influenza A or B Strains

End point description:

CDC-defined ILI: The presence of temperature ≥37.8°C [≥100°F], accompanied by at least one of the respiratory illness symptoms (cough and/or sore throat) and a positive RT-PCR for influenza. PP Set included all participants in the mITT Set (all randomized participants who received any study intervention except those who discontinued from the study prior to 14 days following administration of study intervention) who did not have major protocol deviations that could adversely impact efficacy, for example, disease or therapeutic intervention that might cause suboptimal response to the study intervention.

End point type	Secondary

End point timeframe:

14 days post-vaccination through Day 181 (Month 6)

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11026	11055		
Units: participants	70	70		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With First Episode of Culture-Confirmed Protocol-Defined ILI Caused by Any Seasonal Influenza A or B Virus Strains Regardless of Antigenic Match to Strains Selected for the Seasonal Vaccine

End point title	Number of Participants With First Episode of Culture-Confirmed Protocol-Defined ILI Caused by Any Seasonal Influenza A or B Virus Strains Regardless of Antigenic Match to Strains Selected for the Seasonal Vaccine

End point description:

Protocol-defined ILI: The presence of body temperature ≥37.5°C (≥99.5°F), accompanied by at least one of the respiratory illness symptoms (sore throat, cough, sputum production, wheezing, or difficulty breathing) and a positive RT-PCR for influenza. PP Set included all participants in the mITT Set (all randomized participants who received any study intervention except those who discontinued from the study prior to 14 days following administration of study intervention) who did not have major protocol deviations that could adversely impact efficacy, for example, disease or therapeutic intervention that might cause suboptimal response to the study intervention.

End point type	Secondary

End point timeframe:

14 days post-vaccination through Day 181 (Month 6)

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11026	11055		
Units: participants	91	81		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer (GMT) of Anti-Hemagglutinin (HA) Antibodies at Day 29, as Measured by Hemagglutination Inhibition (HAI) Assay for Vaccine-matched Influenza A and B Strains

End point title	Geometric Mean Titer (GMT) of Anti-Hemagglutinin (HA) Antibodies at Day 29, as Measured by Hemagglutination Inhibition (HAI) Assay for Vaccine-matched Influenza A and B Strains

End point description:

Seasonal influenza A strains included H1N1 and H3N2 and seasonal influenza B strains included Victoria-lineage and Yamagata-lineage. 95% confidence interval (CI) was calculated based on the t-distribution

of log-transformed values for GM titer, then back transformed to original scale for presentation. PPIS included all randomized participants in the biomarker subset who received any study intervention; had baseline and Day 29 antibody assessment via HAI assay; complied with the immunogenicity testing schedule, and had no major protocol deviations that impacted the immunogenicity assessment.

End point type	Secondary

End point timeframe:

Day 29

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	408	444		
Units: titer				
geometric mean (confidence interval 95%)				
Influenza A H1N1 Antibody	105.34 (95.71 to 115.93)	149.14 (135.47 to 164.19)		
Influenza A H3N2 Antibody	85.99 (77.64 to 95.23)	104.06 (94.35 to 114.77)		
Influenza B/Yamagata Lineage	140.50 (127.49 to 154.85)	132.24 (121.25 to 144.23)		
Influenza B/Victoria Lineage	176.63 (162.42 to 192.08)	139.91 (129.71 to 150.91)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With First Episode of Culture-Confirmed CDC-Defined ILI Caused by Any Seasonal Influenza A or B Virus Strains Regardless of Antigenic Match to Strains Selected for the Seasonal Vaccine

End point title	Number of Participants With First Episode of Culture-Confirmed CDC-Defined ILI Caused by Any Seasonal Influenza A or B Virus Strains Regardless of Antigenic Match to Strains Selected for the Seasonal Vaccine

End point description:

CDC-defined ILI: The presence of temperature ≥37.8°C [≥100°F], accompanied by at least one of the respiratory illness symptoms (cough and/or sore throat) and a positive RT-PCR for influenza. PP Set included all participants in the mITT Set (all randomized participants who received any study intervention except those who discontinued from the study prior to 14 days following administration of study intervention) who did not have major protocol deviations that could adversely impact efficacy, for example, disease or therapeutic intervention that might cause suboptimal response to the study intervention.

End point type	Secondary

End point timeframe:

14 days post-vaccination through Day 181 (Month 6)

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11026	11055		
Units: participants	45	40		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Hospitalizations Associated With RT-PCR Confirmed Protocol-Defined ILI Caused by Any Seasonal Influenza A or B Virus Strains Regardless of Antigenic Match to Strains Selected for the Seasonal Vaccine

End point title	Number of Participants With Hospitalizations Associated With RT-PCR Confirmed Protocol-Defined ILI Caused by Any Seasonal Influenza A or B Virus Strains Regardless of Antigenic Match to Strains Selected for the Seasonal Vaccine

End point description:

Protocol-defined ILI: The presence of body temperature ≥37.5°C (≥99.5°F), accompanied by at least one of the respiratory illness symptoms (sore throat, cough, sputum production, wheezing, or difficulty breathing) and a positive RT-PCR for influenza. PP Set included all participants in the mITT Set (all randomized participants who received any study intervention except those who discontinued from the study prior to 14 days following administration of study intervention) who did not have major protocol deviations that could adversely impact efficacy, for example, disease or therapeutic intervention that might cause suboptimal response to the study intervention.

End point type	Secondary

End point timeframe:

14 days post-vaccination through Day 181 (Month 6)

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11026	11055		
Units: participants	3	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Reaching Seroconversion at Day 29, as Measured by HAI Assay for Vaccine-matched Influenza A and B Strains

End point title	Percentage of Participants Reaching Seroconversion at Day 29, as Measured by HAI Assay for Vaccine-matched Influenza A and B Strains

End point description:

Seroconversion was defined as either a Baseline HAI titer <1:10 and a post-Baseline titer ≥1:40 or a Baseline HAI titer ≥1:10 and a minimum 4-fold rise in post-Baseline HAI antibody titer. PPIS included all randomized participants in the biomarker subset who received any study intervention; had baseline and Day 29 antibody assessment via HAI assay; complied with the immunogenicity testing schedule, and

had no major protocol deviations that impacted the immunogenicity assessment.

End point type	Secondary

End point timeframe:

Day 29

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	408	444		
Units: percentage of participants				
number (confidence interval 95%)				
Influenza A H1N1 Antibody	29.4 (25.03 to 34.09)	44.8 (40.13 to 49.58)		
Influenza A H3N2 Antibody	39.7 (34.93 to 44.64)	52.0 (47.27 to 56.76)		
Influenza B/Yamagata Lineage	27.5 (23.18 to 32.06)	26.6 (22.52 to 30.95)		
Influenza B/Victoria Lineage	22.8 (18.81 to 27.18)	13.1 (10.07 to 16.56)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HAI Titer ≥ 1:40 at Day 29

End point title	Percentage of Participants With HAI Titer ≥ 1:40 at Day 29

End point description:

PPIS included all randomized participants in the biomarker subset who received any study intervention; had baseline and Day 29 antibody assessment via HAI assay; complied with the immunogenicity testing schedule, and had no major protocol deviations that impacted the immunogenicity assessment.

End point type	Secondary

End point timeframe:

Day 29

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	408	444		
Units: percentage of participants				
number (confidence interval 95%)				
Influenza A H1N1 Antibody	90.0 (86.61 to 92.69)	94.4 (91.80 to 96.32)		
Influenza A H3N2 Antibody	85.5 (81.75 to 88.81)	89.6 (86.42 to 92.31)		
Influenza B/Yamagata Lineage	94.6 (91.95 to 96.59)	94.8 (92.33 to 96.69)		

Influenza B/Victoria Lineage	98.3 (96.50 to 99.31)	98.0 (96.19 to 99.07)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) of Anti-HA Antibodies at Day 29, as Measured by HAI Assay for Vaccine-matched Influenza A and B Strains

End point title	Geometric Mean Fold Rise (GMFR) of Anti-HA Antibodies at Day 29, as Measured by HAI Assay for Vaccine-matched Influenza A and B Strains

End point description:

The GMFR measures the changes in immunogenicity titers or levels from Baseline within participants. Seasonal influenza A included H1N1 and H3N2 and seasonal influenza B strains included Victoria-lineage and Yamagata-lineage. Fold-rise was calculated by dividing post-vaccination results by the baseline value. 95% CI for GMFR was calculated based on the t distribution of the differences in the log-transformed values between analysis timepoint and baseline, then back transformed to the original scale for presentation. PPIS included all randomized participants in the biomarker subset who received any study intervention; had baseline and Day 29 antibody assessment via HAI assay; complied with the immunogenicity testing schedule, and had no major protocol deviations that impacted the immunogenicity assessment.

End point type	Secondary

End point timeframe:

Baseline, Day 29

End point values	Fluarix Quadrivalent	mRNA-1010		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	408	444		
Units: ratio				
geometric mean (confidence interval 95%)				
Influenza A H1N1 Antibody	2.42 (2.22 to 2.64)	3.42 (3.13 to 3.73)		
Influenza A H3N2 Antibody	3.04 (2.79 to 3.30)	3.74 (3.44 to 4.07)		
Influenza B/Yamagata Lineage	2.46 (2.26 to 2.69)	2.28 (2.14 to 2.43)		
Influenza B/Victoria Lineage	2.07 (1.92 to 2.24)	1.75 (1.65 to 1.85)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 up to the end of the study (Day 361)

Adverse event reporting additional description:

The all-cause mortality was based on the randomization set. The serious and other (not including serious) adverse events were based on the safety set which consisted of all participants who received one dose of study vaccination. Participants were included in the vaccination group corresponding to the study intervention that they actually received.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	mRNA-1010

Reporting group description:

Participants received a single dose of mRNA-1010 by IM injection on Day 1.

Reporting group title	Fluarix Quadrivalent

Reporting group description:

Participants received a single dose of Fluarix Quadrivalent by IM injection on Day 1.

Serious adverse events	mRNA-1010	Fluarix Quadrivalent	
Total subjects affected by serious adverse events			
subjects affected / exposed	518 / 11210 (4.62%)	495 / 11200 (4.42%)	
number of deaths (all causes)	45	44	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of colon			

subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal adenoma			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm malignant			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of testis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign uterine neoplasm			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (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 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone cancer			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign laryngeal neoplasm			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	3 / 11210 (0.03%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer stage III			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer stage IV			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cutaneous T-cell lymphoma			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			

subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid tumour pulmonary			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottic cancer			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder cancer			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	6 / 11210 (0.05%)	8 / 11200 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage I			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage II			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer metastatic			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Medullary thyroid cancer			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 11210 (0.01%)	5 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive lobular breast carcinoma			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lentigo maligna			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lobular breast carcinoma in situ			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung adenocarcinoma stage I			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant melanoma			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to central nervous system			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal squamous cell carcinoma			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal cancer			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteosarcoma			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian adenoma			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer metastatic			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatic carcinoma metastatic			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary myelofibrosis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	4 / 11210 (0.04%)	12 / 11200 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to liver			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell carcinoma of the cervix			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine adenocarcinoma			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine neuroendocrine tumour			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Transitional cell carcinoma			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer stage 0			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	1 / 11210 (0.01%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Giant cell arteritis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	5 / 11210 (0.04%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	2 / 11210 (0.02%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	1 / 11210 (0.01%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			

subjects affected / exposed	1 / 11210 (0.01%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	4 / 11210 (0.04%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	4 / 11210 (0.04%)	5 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral artery stenosis			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular stenosis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	2 / 11210 (0.02%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			

subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	8 / 11210 (0.07%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 8	0 / 4	
Generalised oedema			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	5 / 11210 (0.04%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent-graft endoleak			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated hernia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	3 / 11210 (0.03%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Drug withdrawal syndrome			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 11210 (0.00%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Vaginal haemorrhage			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Emphysema			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	8 / 11210 (0.07%)	10 / 11200 (0.09%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 2	
Asthma			
subjects affected / exposed	2 / 11210 (0.02%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	19 / 11210 (0.17%)	14 / 11200 (0.13%)	
occurrences causally related to treatment / all	0 / 25	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cough			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dyspnoea			
subjects affected / exposed	1 / 11210 (0.01%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	3 / 11210 (0.03%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum deviation			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organising pneumonia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			

subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	3 / 11210 (0.03%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Productive cough			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	8 / 11210 (0.07%)	12 / 11200 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 3	
Pulmonary fibrosis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary hypertension			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary mass			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercapnia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol use disorder			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			

subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Confusional state			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression suicidal			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug dependence			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Affective disorder			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizoaffective disorder			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance abuse			
subjects affected / exposed	0 / 11210 (0.00%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic stress disorder			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Prostatic specific antigen increased			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium decreased			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme abnormal			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio abnormal			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell count increased			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight increased			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Facial bones fracture			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal bite			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
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	4 / 11210 (0.04%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis chemical			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
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	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral nerve injury			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			

subjects affected / exposed	4 / 11210 (0.04%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture displacement			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal procedural complication			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun shot wound			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hand fracture			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heat exhaustion			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	4 / 11210 (0.04%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin abrasion			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			

subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Patella fracture			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic fracture			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			

subjects affected / exposed	3 / 11210 (0.03%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	3 / 11210 (0.03%)	5 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	2 / 11210 (0.02%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sacroiliac fracture			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb crushing injury			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic liver injury			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Snake bite			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			

subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant failure			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic lung injury			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft complication			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			

subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Congenital cystic kidney disease			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac disorder			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	12 / 11210 (0.11%)	11 / 11200 (0.10%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 1	
Angina pectoris			
subjects affected / exposed	3 / 11210 (0.03%)	5 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	2 / 11210 (0.02%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Arrhythmia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	16 / 11210 (0.14%)	14 / 11200 (0.13%)	
occurrences causally related to treatment / all	0 / 19	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	3 / 11210 (0.03%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	3 / 11210 (0.03%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 3	
Acute left ventricular failure			
subjects affected / exposed	2 / 11210 (0.02%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mitral valve incompetence			

subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	2 / 11210 (0.02%)	5 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiac failure chronic			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiac failure congestive			
subjects affected / exposed	11 / 11210 (0.10%)	10 / 11200 (0.09%)	
occurrences causally related to treatment / all	0 / 14	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	0 / 11210 (0.00%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
Cardiogenic shock			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery aneurysm			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (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	8 / 11210 (0.07%)	9 / 11200 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery dissection			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
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	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	2 / 11210 (0.02%)	5 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mitral valve prolapse			

subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	12 / 11210 (0.11%)	9 / 11200 (0.08%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 5	0 / 2	
Myocardial ischaemia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopericarditis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus arrhythmia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	0 / 11210 (0.00%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			

subjects affected / exposed	2 / 11210 (0.02%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	3 / 11210 (0.03%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pericarditis			
subjects affected / exposed	4 / 11210 (0.04%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral ventricle dilatation			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar stroke			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery embolism			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral venous sinus thrombosis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	2 / 11210 (0.02%)	5 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lacunar infarction			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar stroke			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrospinal fluid leakage			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	16 / 11210 (0.14%)	14 / 11200 (0.13%)	
occurrences causally related to treatment / all	0 / 16	0 / 14	
deaths causally related to treatment / all	0 / 3	0 / 2	
Cervical radiculopathy			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cranial nerve paralysis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (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	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	1 / 11210 (0.01%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord disorder			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine with aura			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple sclerosis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple sclerosis relapse			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve compression			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Piriformis syndrome			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post herpetic neuralgia			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radial nerve palsy			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	3 / 11210 (0.03%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord haematoma			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal meningeal cyst			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Syncope			
subjects affected / exposed	5 / 11210 (0.04%)	6 / 11200 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (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 / 11210 (0.01%)	0 / 11200 (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	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
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	2 / 11210 (0.02%)	6 / 11200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			

subjects affected / exposed	3 / 11210 (0.03%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypochromic anaemia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenia			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytosis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Methaemoglobinaemia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 11210 (0.00%)	5 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Disorder of orbit			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (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	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Duodenitis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
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	5 / 11210 (0.04%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	5 / 11210 (0.04%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diverticulum intestinal			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer perforation			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal adhesions			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis alcoholic			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	3 / 11210 (0.03%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intestinal mass			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	4 / 11210 (0.04%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia perforation			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (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	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	3 / 11210 (0.03%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	2 / 11210 (0.02%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	7 / 11210 (0.06%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal perforation			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			

subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			

subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	3 / 11210 (0.03%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	4 / 11210 (0.04%)	5 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatorenal failure			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Skin and subcutaneous tissue disorders			
Skin lesion			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Angioedema			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Excessive skin			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Chronic kidney disease			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	12 / 11210 (0.11%)	14 / 11200 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 15	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder stenosis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	3 / 11210 (0.03%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			

subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	5 / 11210 (0.04%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Primary hyperaldosteronism			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	3 / 11210 (0.03%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone demineralisation			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture nonunion			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	2 / 11210 (0.02%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	2 / 11210 (0.02%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	3 / 11210 (0.03%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyositis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue necrosis			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 11210 (0.00%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	2 / 11210 (0.02%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	12 / 11210 (0.11%)	22 / 11200 (0.20%)	
occurrences causally related to treatment / all	0 / 12	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	5 / 11210 (0.04%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal abscess			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	2 / 11210 (0.02%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	2 / 11210 (0.02%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis staphylococcal			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	9 / 11210 (0.08%)	4 / 11200 (0.04%)	
occurrences causally related to treatment / all	0 / 11	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			

subjects affected / exposed	2 / 11210 (0.02%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
COVID-19			
subjects affected / exposed	8 / 11210 (0.07%)	8 / 11200 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
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 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic abscess			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complicated appendicitis			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related bacteraemia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
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 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epstein-Barr virus infection			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia infection			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	4 / 11210 (0.04%)	7 / 11200 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Escherichia coli			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Human anaplasmosis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital cellulitis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	2 / 11210 (0.02%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metapneumovirus infection			

subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	4 / 11210 (0.04%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae viral bronchitis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella infection			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirectal abscess			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 11210 (0.00%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngolaryngeal abscess			

subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pilonidal disease			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	21 / 11210 (0.19%)	21 / 11200 (0.19%)	
occurrences causally related to treatment / all	0 / 22	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 5	
Pneumonia aspiration			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	2 / 11210 (0.02%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia chlamydial			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural sepsis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative abscess			

subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis Escherichia coli			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal abscess			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cellulitis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinovirus infection			

subjects affected / exposed	3 / 11210 (0.03%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal abscess			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	12 / 11210 (0.11%)	9 / 11200 (0.08%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 2	
Septic shock			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal skin infection			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tularaemia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			

subjects affected / exposed	11 / 11210 (0.10%)	6 / 11200 (0.05%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	2 / 11210 (0.02%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Alcoholic ketoacidosis			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	0 / 11210 (0.00%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic complication			
subjects affected / exposed	2 / 11210 (0.02%)	0 / 11200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Diabetic ketoacidosis			

subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Fluid retention			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	1 / 11210 (0.01%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	1 / 11210 (0.01%)	0 / 11200 (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	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	1 / 11210 (0.01%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	4 / 11210 (0.04%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	2 / 11210 (0.02%)	3 / 11200 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Steroid diabetes			

subjects affected / exposed	0 / 11210 (0.00%)	1 / 11200 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	2 / 11210 (0.02%)	2 / 11200 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	mRNA-1010	Fluarix Quadrivalent	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	572 / 11210 (5.10%)	603 / 11200 (5.38%)	
Infections and infestations			
COVID-19			
subjects affected / exposed	572 / 11210 (5.10%)	603 / 11200 (5.38%)	
occurrences (all)	581	621	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 February 2023	The main purpose of this amendment was to prespecify immunogenicity analysis for HAIs and alter the timing of the interim analysis (IA). The original plan was for 2 IAs at 45% and 75% of target cases. The first IA was removed because of the expected lower power and the timing of the second IA was set for February 2023 regardless of case accrual at the time. The planned statistical analyses were modified to accommodate the changes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported