Clinical trial results:
A Phase III Randomized, Double-blind, Placebo-controlled, Multi-center Study in Adults to Determine the Safety and Efficacy of AZD7442, a Combination Product of Two Monoclonal Antibodies (AZD8895 and AZD1061), for Post-exposure Prophylaxis of COVID-19

Summary

EudraCT number	2020-004719-28
Trial protocol	GB
Global end of trial date	25 July 2022

Results information

Result version number	v1 (current)
This version publication date	03 August 2023
First version publication date	03 August 2023

Trial information

Trial identification

Sponsor protocol code	D8850C00003

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AstraZeneca
Sponsor organisation address	S-151, Södertälje, Sweden,
Public contact	Global Clinical Lead, AstraZeneca, 1 8772409479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, 1 8772409479, information.center@astrazeneca.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	12 November 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 July 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Show efficacy and safety of AZD7442 single dose in post-exposure prophylaxis

Protection of trial subjects:

External DSMB involved (Everest) and monthly meeting to ensure subject safety

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 December 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	15 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 98
Country: Number of subjects enrolled	United States: 1023
Worldwide total number of subjects	1121
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	987
From 65 to 84 years	126
85 years and over	8

Subject disposition

Recruitment

Recruitment details:

Target sample size was 1125. As this was a multi-site study there was a lag on the information of the number of subjects recruited, hence we ended up with a population slightly over 1125 (N=1131). 10 subjects were randomised in error so the full analysis set included 1121 subjects.

Pre-assignment

Screening details:

Participants will be adults ≥ 18 years of age with potential exposure, within 8 days, to a specific identified individual with laboratory-confirmed SARS-COV-2 infection, symptomatic or asymptomatic.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	AZD7442

Arm description:

Single dose 300 mg IM (AZD8895 and AZD1061)

Arm type	Experimental
Investigational medicinal product name	EVUSHELD
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

300mg

Arm title	Placebo

Arm description:

Saline placebo

Arm type	Placebo
Investigational medicinal product name	Saline Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

300mg

Number of subjects in period 1	AZD7442	Placebo
Started	749	372
Completed	624	304
Not completed	125	68
Adverse event, serious fatal	3	2
Physician decision	1	-
Consent withdrawn by subject	36	24
Not specified elsewhere	3	4
Lost to follow-up	82	38

Baseline characteristics

Reporting groups	
Reporting group title	AZD7442
Reporting group description:	
Single dose 300 mg IM (AZD8895 and AZD1061)	
Reporting group title	Placebo
Reporting group description:	
Saline placebo	

Reporting group values	AZD7442	Placebo	Total
Number of subjects	749	372	1121
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	658	329	987
From 65-84 years	85	41	126
85 years and over	6	2	8
Age Continuous			
Units: Years			
arithmetic mean	46.62	45.97	
standard deviation	± 15.74	± 16.20	-
Sex: Female, Male			
Full analysis set (N=1121)			
Units: Participants			
Female	375	182	557
Male	374	190	564
Race (NIH/OMB)			
Full analysis set (N=1121)			
Units: Subjects			
Unknown	3	0	3
American Indian or Alaska Native	6	1	7
Asian	15	13	28
Black or African American	76	36	112
Multiple	4	4	8
Native Hawaiian or Other Pacific Islander	2	1	3
Not reported	15	3	18
White	628	314	942
Ethnicity (NIH/OMB)			
Full analysis set (N=1121)			
Units: Subjects			
Hispanic or Latino	435	210	645

Not Hispanic or Latino	299	159	458
Not reported	11	1	12
Unknown	4	2	6
Any COVID-19 comorbidities at baseline			
Full analysis set (N=1121)			
Units: Subjects			
Yes	418	210	628
MISSING	331	162	493
Any high risk for severe COVID-19 at baseline			
Full analysis set (N=1121)			
Units: Subjects			
Yes	486	243	729
MISSING	263	129	392
SARS-CoV-2 status at baseline			
Full analysis set (N=1121)			
Units: Subjects			
Negative	651	327	978
Positive	34	14	48
MISSING	64	31	95
Height			
Units: cm			
arithmetic mean	168.43	168.57	
standard deviation	± 10.56	± 10.32	-
Baseline BMI (kg/m^2)			
Units: kg/m^2			
arithmetic mean	29.60	29.80	
standard deviation	± 6.67	± 6.68	-

End points

End points reporting groups	
Reporting group title	AZD7442
Reporting group description:	
Single dose 300 mg IM (AZD8895 and AZD1061)	
Reporting group title	Placebo
Reporting group description:	
Saline placebo	

Primary: Number of Participants with First Case of SARS-CoV-2 RT-PCR Positive Symptomatic Illness

End point title	Number of Participants with First Case of SARS-CoV-2 RT-PCR Positive Symptomatic Illness
End point description:	
To estimate the efficacy of a single IM dose of AZD7442 compared to placebo for the prevention of COVID-19	
End point type	Primary
End point timeframe:	
Planned to be evaluated through Day 183, however, the number of participants required was achieved 127 days after the study start date	

End point values	AZD7442	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	749	372		
Units: Participants				
n (%)	23	17		

Statistical analyses

Statistical analysis title	Primary analysis
Comparison groups	Placebo v AZD7442
Number of subjects included in analysis	1121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.212 [1]
Method	Poisson regression
Parameter estimate	Relative Risk Reduction
Point estimate	33.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.92
upper limit	64.68

Notes:
[1] - not significant

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first dose of study drug until last study visit	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups	
Reporting group title	AZD7442
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	AZD7442	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 749 (2.67%)	16 / 372 (4.30%)	
number of deaths (all causes)	3	2	
number of deaths resulting from adverse events	3	2	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung cancer metastatic			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adrenal adenoma			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Unevaluable event			

subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
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	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar I disorder			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (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			
Overdose			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns second degree			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
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 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Near drowning			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Congenital, familial and genetic disorders			
Trisomy 21			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac arrest			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (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	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocardial infarction			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (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	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Basal ganglia haemorrhage			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (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 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			

subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
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 / 749 (0.13%)	0 / 372 (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			
Nephrolithiasis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal infarct			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Pneumonia			
subjects affected / exposed	3 / 749 (0.40%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 749 (0.00%)	3 / 372 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Diabetic ketoacidosis			
subjects affected / exposed	0 / 749 (0.00%)	2 / 372 (0.54%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	AZD7442	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	345 / 749 (46.06%)	191 / 372 (51.34%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Fibrous histiocytoma			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	2	
Skin papilloma			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Thrombophlebitis superficial			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	11 / 749 (1.47%)	5 / 372 (1.34%)	
occurrences (all)	11	5	
Hot flush			
subjects affected / exposed	1 / 749 (0.13%)	3 / 372 (0.81%)	
occurrences (all)	1	3	
Haematoma			
subjects affected / exposed	0 / 749 (0.00%)	2 / 372 (0.54%)	
occurrences (all)	0	2	
Deep vein thrombosis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	2	0	

Accelerated hypertension			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Behcet's syndrome			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Flushing			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Hypotension			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Pallor			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Visceral congestion			
subjects affected / exposed	0 / 749 (0.00%)	2 / 372 (0.54%)	
occurrences (all)	0	2	
General disorders and administration site conditions			
Vaccination site pain			
subjects affected / exposed	1 / 749 (0.13%)	2 / 372 (0.54%)	
occurrences (all)	1	2	
Thirst			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Swelling			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	46 / 749 (6.14%)	32 / 372 (8.60%)	
occurrences (all)	57	34	
Pain			
subjects affected / exposed	39 / 749 (5.21%)	35 / 372 (9.41%)	
occurrences (all)	44	40	
Malaise			

subjects affected / exposed	7 / 749 (0.93%)	1 / 372 (0.27%)	
occurrences (all)	7	1	
Localised oedema			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Injection site reaction			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Injection site pruritus			
subjects affected / exposed	1 / 749 (0.13%)	2 / 372 (0.54%)	
occurrences (all)	1	2	
Injection site pain			
subjects affected / exposed	3 / 749 (0.40%)	1 / 372 (0.27%)	
occurrences (all)	3	1	
Impaired healing			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	57 / 749 (7.61%)	39 / 372 (10.48%)	
occurrences (all)	67	50	
Energy increased			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Chills			
subjects affected / exposed	32 / 749 (4.27%)	23 / 372 (6.18%)	
occurrences (all)	34	26	
Non-cardiac chest pain			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Asthenia			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Chest discomfort			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Drug withdrawal syndrome			

subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Feeling abnormal			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Feeling cold			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Generalised oedema			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Influenza like illness			
subjects affected / exposed	4 / 749 (0.53%)	2 / 372 (0.54%)	
occurrences (all)	4	3	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Hypersensitivity			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Allergy to arthropod sting			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Mycotic allergy			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Drug hypersensitivity			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Vaginal haemorrhage			

subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Pelvic congestion			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Dysmenorrhoea			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Heavy menstrual bleeding			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Menstruation irregular			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	80 / 749 (10.68%)	46 / 372 (12.37%)	
occurrences (all)	95	58	
Acute respiratory failure			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Throat irritation			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Sneezing			
subjects affected / exposed	3 / 749 (0.40%)	1 / 372 (0.27%)	
occurrences (all)	3	1	
Upper-airway cough syndrome			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Dyspnoea			
subjects affected / exposed	29 / 749 (3.87%)	14 / 372 (3.76%)	
occurrences (all)	33	18	
Epistaxis			

subjects affected / exposed	4 / 749 (0.53%)	1 / 372 (0.27%)	
occurrences (all)	4	1	
Nasal congestion			
subjects affected / exposed	50 / 749 (6.68%)	34 / 372 (9.14%)	
occurrences (all)	64	41	
Nasal obstruction			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal pain			
subjects affected / exposed	59 / 749 (7.88%)	28 / 372 (7.53%)	
occurrences (all)	71	34	
Pharyngeal erythema			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Productive cough			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Pulmonary congestion			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Rales			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Rhinorrhoea			
subjects affected / exposed	61 / 749 (8.14%)	27 / 372 (7.26%)	
occurrences (all)	73	32	
Sinus congestion			
subjects affected / exposed	13 / 749 (1.74%)	3 / 372 (0.81%)	
occurrences (all)	16	3	
Tonsillar inflammation			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Aphonia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Asthma			

subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Hypoxia			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Paranasal sinus discomfort			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Paranasal sinus inflammation			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Pharyngeal ulceration			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Respiratory depression			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Respiratory disorder			
subjects affected / exposed	2 / 749 (0.27%)	1 / 372 (0.27%)	
occurrences (all)	2	1	
Respiratory failure			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Respiratory tract congestion			
subjects affected / exposed	3 / 749 (0.40%)	0 / 372 (0.00%)	
occurrences (all)	3	0	
Rhinitis allergic			
subjects affected / exposed	3 / 749 (0.40%)	0 / 372 (0.00%)	
occurrences (all)	3	0	
Sinus pain			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	

Tonsillar hypertrophy			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Upper respiratory tract congestion			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Wheezing			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Depression			
subjects affected / exposed	1 / 749 (0.13%)	4 / 372 (1.08%)	
occurrences (all)	1	4	
Confusional state			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Anxiety			
subjects affected / exposed	6 / 749 (0.80%)	2 / 372 (0.54%)	
occurrences (all)	6	2	
Adjustment disorder			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Adjustment disorder with depressed mood			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Attention deficit hyperactivity disorder			
subjects affected / exposed	3 / 749 (0.40%)	0 / 372 (0.00%)	
occurrences (all)	3	0	
Depressed mood			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Panic attack			

subjects affected / exposed	2 / 749 (0.27%)	1 / 372 (0.27%)	
occurrences (all)	2	1	
Panic disorder			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 749 (0.13%)	5 / 372 (1.34%)	
occurrences (all)	1	5	
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 749 (0.67%)	4 / 372 (1.08%)	
occurrences (all)	5	4	
Blood creatine phosphokinase increased			
subjects affected / exposed	12 / 749 (1.60%)	4 / 372 (1.08%)	
occurrences (all)	15	4	
Blood creatinine increased			
subjects affected / exposed	2 / 749 (0.27%)	1 / 372 (0.27%)	
occurrences (all)	3	1	
Blood glucose increased			
subjects affected / exposed	5 / 749 (0.67%)	1 / 372 (0.27%)	
occurrences (all)	5	1	
Glomerular filtration rate decreased			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Blood potassium decreased			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Blood pressure increased			
subjects affected / exposed	3 / 749 (0.40%)	2 / 372 (0.54%)	
occurrences (all)	3	2	
C-reactive protein increased			
subjects affected / exposed	9 / 749 (1.20%)	3 / 372 (0.81%)	
occurrences (all)	10	3	
Gamma-glutamyltransferase increased			

subjects affected / exposed	8 / 749 (1.07%)	4 / 372 (1.08%)	
occurrences (all)	8	4	
Blood iron decreased			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Haematocrit decreased			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Hepatic enzyme increased			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Liver function test abnormal			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Lymph node palpable			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Platelet count decreased			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Red blood cell count decreased			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Red blood cells urine positive			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Urine analysis abnormal			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
White blood cell count increased			
subjects affected / exposed	3 / 749 (0.40%)	0 / 372 (0.00%)	
occurrences (all)	3	0	
White blood cells urine positive			
subjects affected / exposed	4 / 749 (0.53%)	1 / 372 (0.27%)	
occurrences (all)	4	1	
Haemoglobin decreased			

subjects affected / exposed	2 / 749 (0.27%)	1 / 372 (0.27%)	
occurrences (all)	2	1	
Weight decreased			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Red blood cells urine			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Neutrophil count increased			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Liver function test increased			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Body temperature increased			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Blood uric acid increased			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Blood pressure diastolic increased			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Blood potassium increased			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Blood phosphorus decreased			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Blood creatine increased			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Blood cholesterol increased			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Aspartate aminotransferase			

abnormal			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Alanine aminotransferase abnormal			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Influenza A virus test positive			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Muscle strain			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Ligament rupture			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Fall			
subjects affected / exposed	5 / 749 (0.67%)	1 / 372 (0.27%)	
occurrences (all)	7	1	
Contusion			
subjects affected / exposed	1 / 749 (0.13%)	3 / 372 (0.81%)	
occurrences (all)	1	5	
Arthropod bite			
subjects affected / exposed	0 / 749 (0.00%)	2 / 372 (0.54%)	
occurrences (all)	0	2	
Road traffic accident			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Skin laceration			
subjects affected / exposed	1 / 749 (0.13%)	2 / 372 (0.54%)	
occurrences (all)	1	2	
Upper limb fracture			

subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Traumatic haemorrhage			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Tooth fracture			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Soft tissue injury			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Ankle fracture			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Arthropod sting			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Back injury			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Bone contusion			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Concussion			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Exposure to toxic agent			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Face injury			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Fibula fracture			
subjects affected / exposed	0 / 749 (0.00%)	2 / 372 (0.54%)	
occurrences (all)	0	2	
Joint injury			

subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Ligament sprain			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Meniscus injury			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Neck injury			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Post procedural haematoma			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Post-traumatic pain			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Procedural pain			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Radius fracture			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Rib fracture			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Tendon injury			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Vaccination complication			
subjects affected / exposed	4 / 749 (0.53%)	5 / 372 (1.34%)	
occurrences (all)	7	12	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 749 (0.00%)	3 / 372 (0.81%)	
occurrences (all)	0	3	

Sinus tachycardia			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Chronic left ventricular failure			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Cardiac failure chronic			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Atrioventricular block complete			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Angina pectoris			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Palpitations			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Ventricular hypokinesia			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Nervous system disorders			
Ageusia			
subjects affected / exposed	18 / 749 (2.40%)	14 / 372 (3.76%)	
occurrences (all)	18	14	
Bell's palsy			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Central pain syndrome			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Disturbance in attention			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Dizziness			

subjects affected / exposed	4 / 749 (0.53%)	3 / 372 (0.81%)	
occurrences (all)	4	3	
Encephalopathy			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	86 / 749 (11.48%)	52 / 372 (13.98%)	
occurrences (all)	109	61	
Paraesthesia			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Presyncope			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Restless legs syndrome			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Sciatica			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Sinus headache			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Somnolence			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Syncope			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Anosmia			
subjects affected / exposed	18 / 749 (2.40%)	13 / 372 (3.49%)	
occurrences (all)	18	13	
Dysgeusia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Hypoaesthesia			

subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Lacunar infarction			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Lethargy			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Migraine			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Neuropathy peripheral			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Seizure			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Tremor			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Balance disorder			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Cerebral small vessel ischaemic disease			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Dizziness exertional			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Normocytic anaemia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Anaemia			

subjects affected / exposed	5 / 749 (0.67%)	1 / 372 (0.27%)	
occurrences (all)	6	1	
Leukocytosis			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Lymphadenopathy			
subjects affected / exposed	2 / 749 (0.27%)	1 / 372 (0.27%)	
occurrences (all)	2	1	
Lymphocytosis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Monocytosis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Neutropenia			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Blood loss anaemia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Increased tendency to bruise			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Leukopenia			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Pancytopenia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	3 / 749 (0.40%)	1 / 372 (0.27%)	
occurrences (all)	3	1	
Vertigo			
subjects affected / exposed	3 / 749 (0.40%)	2 / 372 (0.54%)	
occurrences (all)	3	3	

Cerumen impaction			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Middle ear effusion			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Tympanic membrane disorder			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Tympanic membrane hyperaemia			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Vertigo positional			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Eye pain			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	2	
Eye swelling			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Vision blurred			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Eye movement disorder			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Eye pruritus			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Lacrimation increased			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Visual impairment			

subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Abdominal pain			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Abdominal pain upper			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Constipation			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Diarrhoea			
subjects affected / exposed	19 / 749 (2.54%)	23 / 372 (6.18%)	
occurrences (all)	22	28	
Dyspepsia			
subjects affected / exposed	4 / 749 (0.53%)	1 / 372 (0.27%)	
occurrences (all)	4	1	
Dysphagia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Gingival swelling			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Mouth ulceration			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	22 / 749 (2.94%)	23 / 372 (6.18%)	
occurrences (all)	24	26	
Toothache			
subjects affected / exposed	4 / 749 (0.53%)	0 / 372 (0.00%)	
occurrences (all)	4	0	

Umbilical hernia			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	8 / 749 (1.07%)	7 / 372 (1.88%)	
occurrences (all)	10	7	
Chronic gastritis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Diverticulum			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Erosive oesophagitis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Food poisoning			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Gastritis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal pain			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Haemorrhoids			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Hiatus hernia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Impaired gastric emptying			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	

Inguinal hernia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Large intestine polyp			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Oesophagitis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Periodontal disease			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Stomach mass			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Pancreatitis acute			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Cholecystitis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Gallbladder polyp			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			

Blister			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Cullen's sign			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Dermatitis allergic			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Eczema			
subjects affected / exposed	1 / 749 (0.13%)	2 / 372 (0.54%)	
occurrences (all)	1	2	
Hyperhidrosis			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Pruritus			
subjects affected / exposed	1 / 749 (0.13%)	4 / 372 (1.08%)	
occurrences (all)	4	4	
Rash			
subjects affected / exposed	3 / 749 (0.40%)	1 / 372 (0.27%)	
occurrences (all)	3	1	
Alopecia			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Dermatitis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Rosacea			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Urticaria			
subjects affected / exposed	2 / 749 (0.27%)	1 / 372 (0.27%)	
occurrences (all)	2	1	
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Dysuria			
subjects affected / exposed	1 / 749 (0.13%)	2 / 372 (0.54%)	
occurrences (all)	1	2	
Glycosuria			
subjects affected / exposed	1 / 749 (0.13%)	2 / 372 (0.54%)	
occurrences (all)	1	2	
Haematuria			
subjects affected / exposed	3 / 749 (0.40%)	2 / 372 (0.54%)	
occurrences (all)	3	2	
Micturition urgency			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Nephrolithiasis			
subjects affected / exposed	1 / 749 (0.13%)	3 / 372 (0.81%)	
occurrences (all)	1	4	
Pollakiuria			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Proteinuria			
subjects affected / exposed	5 / 749 (0.67%)	0 / 372 (0.00%)	
occurrences (all)	5	0	
Leukocyturia			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Renal cyst			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Urethral stenosis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Urinary bladder polyp			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Endocrine disorders			

Hypothyroidism			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Hyperplasia adrenal			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	12 / 749 (1.60%)	2 / 372 (0.54%)	
occurrences (all)	13	2	
Back pain			
subjects affected / exposed	10 / 749 (1.34%)	7 / 372 (1.88%)	
occurrences (all)	12	7	
Seronegative arthritis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Tendonitis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Rhabdomyolysis			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Pain in extremity			
subjects affected / exposed	5 / 749 (0.67%)	5 / 372 (1.34%)	
occurrences (all)	5	5	
Neck pain			
subjects affected / exposed	1 / 749 (0.13%)	2 / 372 (0.54%)	
occurrences (all)	1	2	
Myalgia			
subjects affected / exposed	25 / 749 (3.34%)	27 / 372 (7.26%)	
occurrences (all)	29	30	
Musculoskeletal stiffness			
subjects affected / exposed	1 / 749 (0.13%)	2 / 372 (0.54%)	
occurrences (all)	1	3	
Muscle spasms			

subjects affected / exposed	4 / 749 (0.53%)	0 / 372 (0.00%)	
occurrences (all)	4	0	
Rheumatoid arthritis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Arthritis			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Costochondritis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Exostosis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Fibromyalgia			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	3	0	
Foot deformity			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	2	
Myositis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Osteoarthritis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Plantar fasciitis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Rotator cuff syndrome			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Spinal osteoarthritis			

subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Bacterial vaginosis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Acute sinusitis			
subjects affected / exposed	3 / 749 (0.40%)	0 / 372 (0.00%)	
occurrences (all)	3	0	
Gastroenteritis			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Influenza			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Furuncle			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Eye infection			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Ear infection			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Diverticulitis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Cellulitis			
subjects affected / exposed	3 / 749 (0.40%)	1 / 372 (0.27%)	
occurrences (all)	4	1	
Bacteriuria			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Urinary tract infection			
subjects affected / exposed	22 / 749 (2.94%)	13 / 372 (3.49%)	
occurrences (all)	24	15	

Upper respiratory tract infection			
subjects affected / exposed	14 / 749 (1.87%)	3 / 372 (0.81%)	
occurrences (all)	14	3	
Tooth infection			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Tooth abscess			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Tonsillitis			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Superinfection bacterial			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Sepsis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Respiratory tract infection			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Post procedural infection			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	16 / 749 (2.14%)	4 / 372 (1.08%)	
occurrences (all)	17	6	
Periorbital cellulitis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Pharyngitis streptococcal			
subjects affected / exposed	3 / 749 (0.40%)	2 / 372 (0.54%)	
occurrences (all)	3	2	
Pilonidal cyst			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	

Abscess			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Abscess limb			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Appendicitis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Atypical pneumonia			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Bacterial infection			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Bacterial vulvovaginitis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Bronchitis			
subjects affected / exposed	6 / 749 (0.80%)	3 / 372 (0.81%)	
occurrences (all)	6	3	
Conjunctivitis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Diarrhoea infectious			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Fungal skin infection			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis viral			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Hand-foot-and-mouth disease			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	

Herpes zoster			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Hordeolum			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Labyrinthitis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	2	
Localised infection			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Lower respiratory tract infection			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Myringitis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Onychomycosis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Oral herpes			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Otitis externa			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Otitis media			
subjects affected / exposed	4 / 749 (0.53%)	1 / 372 (0.27%)	
occurrences (all)	4	1	
Pharyngitis			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Pneumonia			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	

Respiratory syncytial virus infection			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Rhinitis			
subjects affected / exposed	1 / 749 (0.13%)	2 / 372 (0.54%)	
occurrences (all)	1	2	
Sinusitis			
subjects affected / exposed	7 / 749 (0.93%)	4 / 372 (1.08%)	
occurrences (all)	7	5	
Sinusitis bacterial			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Skin infection			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Vaginal infection			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Viral infection			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Wound infection			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Pyelonephritis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Suspected COVID-19			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Asymptomatic COVID-19			
subjects affected / exposed	7 / 749 (0.93%)	5 / 372 (1.34%)	
occurrences (all)	7	5	
COVID-19			
subjects affected / exposed	117 / 749 (15.62%)	53 / 372 (14.25%)	
occurrences (all)	125	54	

Epstein-Barr virus infection			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	4 / 749 (0.53%)	2 / 372 (0.54%)	
occurrences (all)	4	2	
Hypophosphataemia			
subjects affected / exposed	1 / 749 (0.13%)	2 / 372 (0.54%)	
occurrences (all)	1	2	
Hypokalaemia			
subjects affected / exposed	3 / 749 (0.40%)	1 / 372 (0.27%)	
occurrences (all)	4	1	
Hypoglycaemia			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Hyperkalaemia			
subjects affected / exposed	2 / 749 (0.27%)	2 / 372 (0.54%)	
occurrences (all)	2	2	
Hyperglycaemia			
subjects affected / exposed	3 / 749 (0.40%)	4 / 372 (1.08%)	
occurrences (all)	3	4	
Hypercholesterolaemia			
subjects affected / exposed	2 / 749 (0.27%)	0 / 372 (0.00%)	
occurrences (all)	2	0	
Gout			
subjects affected / exposed	0 / 749 (0.00%)	2 / 372 (0.54%)	
occurrences (all)	0	2	
Diabetes mellitus			
subjects affected / exposed	3 / 749 (0.40%)	3 / 372 (0.81%)	
occurrences (all)	3	3	
Decreased appetite			
subjects affected / exposed	4 / 749 (0.53%)	5 / 372 (1.34%)	
occurrences (all)	4	5	
Hyperlipidaemia			

subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Dehydration			
subjects affected / exposed	4 / 749 (0.53%)	1 / 372 (0.27%)	
occurrences (all)	4	1	
Glucose tolerance impaired			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Hypomagnesaemia			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Lactic acidosis			
subjects affected / exposed	0 / 749 (0.00%)	1 / 372 (0.27%)	
occurrences (all)	0	1	
Metabolic acidosis			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	
Hyponatraemia			
subjects affected / exposed	1 / 749 (0.13%)	1 / 372 (0.27%)	
occurrences (all)	1	1	
Vitamin B12 deficiency			
subjects affected / exposed	1 / 749 (0.13%)	0 / 372 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 March 2021	Key amendment and rationale for change: Highly efficacious vaccines against SARS-CoV-2 are being deployed on a mass scale in the participating countries, leading to substantially decreasing attack rates for COVID-19. Given that the probability of a participant being exposed to COVID-19 will diminish with increased vaccination roll-out, the primary analysis will be conducted 30 days after the 25th primary endpoint event has been confirmed. This period, of 30 days, allows sufficient time for the 25th event to be monitored, and any other events occurring during this time interval will also be evaluated. To reflect this change in the timing of the primary analysis the interim analysis has been removed. Enrollment will be stopped after the 25th primary endpoint event has been confirmed, or after 1125 participants have been randomized, whichever comes first. To provide data on AZD7442 for 5 half-lives, the study has been extended to 15 months allowing a safety assessment via a phone call and an optional serum sample for PK, ADA and nAb to be added at Day 457. Study endpoints have been adjusted accordingly.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Results are reported for the Primary analysis conducted during the study.

Notes: