



## 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
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##### 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  $\geq 18$  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
<b>Arm title</b>	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

<b>Arm title</b>	Placebo
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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

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Consent withdrawn by subject	36	24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

## Baseline characteristics

### Reporting groups

Reporting group title	AZD7442
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Reporting group description:

Single dose 300 mg IM (AZD8895 and AZD1061)

Reporting group title	Placebo
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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 <sup>[1]</sup>
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

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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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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### Reporting groups

Reporting group title	AZD7442
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Reporting group description: -

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

<b>Non-serious adverse events</b>	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 occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Behcet's syndrome subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Flushing subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Hypotension subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 2	0 / 372 (0.00%) 0	
Pallor subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Visceral congestion subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	2 / 372 (0.54%) 2	
General disorders and administration site conditions			
Vaccination site pain subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	2 / 372 (0.54%) 2	
Thirst subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Swelling subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Pyrexia subjects affected / exposed occurrences (all)	46 / 749 (6.14%) 57	32 / 372 (8.60%) 34	
Pain subjects affected / exposed occurrences (all)	39 / 749 (5.21%) 44	35 / 372 (9.41%) 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 occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Feeling abnormal subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Feeling cold subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Generalised oedema subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Influenza like illness subjects affected / exposed occurrences (all)	4 / 749 (0.53%) 4	2 / 372 (0.54%) 3	
Immune system disorders			
Seasonal allergy subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 2	2 / 372 (0.54%) 2	
Hypersensitivity subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Allergy to arthropod sting subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Mycotic allergy subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Drug hypersensitivity subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 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 occurrences (all)	1 / 749 (0.13%) 1	1 / 372 (0.27%) 1	
Upper respiratory tract congestion subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Wheezing subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	1 / 372 (0.27%) 1	
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 2	0 / 372 (0.00%) 0	
Depression subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	4 / 372 (1.08%) 4	
Confusional state subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Anxiety subjects affected / exposed occurrences (all)	6 / 749 (0.80%) 6	2 / 372 (0.54%) 2	
Adjustment disorder subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Adjustment disorder with depressed mood subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Attention deficit hyperactivity disorder subjects affected / exposed occurrences (all)	3 / 749 (0.40%) 3	0 / 372 (0.00%) 0	
Depressed mood subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 2	0 / 372 (0.00%) 0	
Panic attack			

subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 2	1 / 372 (0.27%) 1	
Panic disorder subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	5 / 372 (1.34%) 5	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	5 / 749 (0.67%) 5	4 / 372 (1.08%) 4	
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	12 / 749 (1.60%) 15	4 / 372 (1.08%) 4	
Blood creatinine increased subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 3	1 / 372 (0.27%) 1	
Blood glucose increased subjects affected / exposed occurrences (all)	5 / 749 (0.67%) 5	1 / 372 (0.27%) 1	
Glomerular filtration rate decreased subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 2	2 / 372 (0.54%) 2	
Blood potassium decreased subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Blood pressure increased subjects affected / exposed occurrences (all)	3 / 749 (0.40%) 3	2 / 372 (0.54%) 2	
C-reactive protein increased subjects affected / exposed occurrences (all)	9 / 749 (1.20%) 10	3 / 372 (0.81%) 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 occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Middle ear effusion subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Tympanic membrane disorder subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Tympanic membrane hyperaemia subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Vertigo positional subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Eye disorders			
Eye pain subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	1 / 372 (0.27%) 2	
Eye swelling subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Vision blurred subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Eye movement disorder subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Eye pruritus subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 1	
Lacrimation increased subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Visual impairment			

subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	1 / 372 (0.27%) 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 occurrences (all)	14 / 749 (1.87%) 14	3 / 372 (0.81%) 3
Tooth infection subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 2	0 / 372 (0.00%) 0
Tooth abscess subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	1 / 372 (0.27%) 1
Tonsillitis subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 2	0 / 372 (0.00%) 0
Superinfection bacterial subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0
Sepsis subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0
Respiratory tract infection subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0
Post procedural infection subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	16 / 749 (2.14%) 17	4 / 372 (1.08%) 6
Periorbital cellulitis subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0
Pharyngitis streptococcal subjects affected / exposed occurrences (all)	3 / 749 (0.40%) 3	2 / 372 (0.54%) 2
Pilonidal cyst subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 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 occurrences (all)	1 / 749 (0.13%) 1	0 / 372 (0.00%) 0	
Metabolism and nutrition disorders			
Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	4 / 749 (0.53%) 4	2 / 372 (0.54%) 2	
Hypophosphataemia subjects affected / exposed occurrences (all)	1 / 749 (0.13%) 1	2 / 372 (0.54%) 2	
Hypokalaemia subjects affected / exposed occurrences (all)	3 / 749 (0.40%) 4	1 / 372 (0.27%) 1	
Hypoglycaemia subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 2	2 / 372 (0.54%) 2	
Hyperkalaemia subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 2	2 / 372 (0.54%) 2	
Hyperglycaemia subjects affected / exposed occurrences (all)	3 / 749 (0.40%) 3	4 / 372 (1.08%) 4	
Hypercholesterolaemia subjects affected / exposed occurrences (all)	2 / 749 (0.27%) 2	0 / 372 (0.00%) 0	
Gout subjects affected / exposed occurrences (all)	0 / 749 (0.00%) 0	2 / 372 (0.54%) 2	
Diabetes mellitus subjects affected / exposed occurrences (all)	3 / 749 (0.40%) 3	3 / 372 (0.81%) 3	
Decreased appetite subjects affected / exposed occurrences (all)	4 / 749 (0.53%) 4	5 / 372 (1.34%) 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	<p>Key amendment and rationale for change:</p> <p>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.</p> <p>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.</p> <p>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.</p>

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: