Clinical trial results:
A Multicenter, Observational, 6-Month Follow-up Study of Patients With COVID-19 Previously Enrolled in a RO7496998 (AT-527) Study

Summary

EudraCT number	2021-000627-12
Trial protocol	BE PT DK DE IT RO
Global end of trial date	16 March 2022

Results information

Result version number	v1 (current)
This version publication date	25 September 2022
First version publication date	25 September 2022

Trial information

Trial identification

Sponsor protocol code	CV43140

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05059080
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, 41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, 41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002963-PIP01-21
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	16 March 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 March 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This study evaluated the long-term sequelae of COVID-19 in subjects diagnosed with COVID-19 who previously enrolled in a RO7496998 (AT-527) study (i.e. parent study 2020-005759-18 [CV43043]), for approximately 6 months after the end of the parent study.

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 1
Country: Number of subjects enrolled	Belgium: 8
Country: Number of subjects enrolled	Brazil: 5
Country: Number of subjects enrolled	Denmark: 2
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Mexico: 15
Country: Number of subjects enrolled	Romania: 1
Country: Number of subjects enrolled	Switzerland: 1
Country: Number of subjects enrolled	Turkey: 19
Country: Number of subjects enrolled	Ukraine: 17
Worldwide total number of subjects	72
EEA total number of subjects	14

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)	1
Adults (18-64 years)	69
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled into the study at 27 investigational sites in 10 countries: Mexico, Ukraine, Turkey, Brazil, Belgium, Denmark, Argentina, Germany, Romania, and Switzerland.

Pre-assignment

Screening details:

Participants diagnosed with COVID-19, who previously enrolled in a RO7496998 (AT-527) study (i.e. parent study 2020-005759-18 [CV43043]), were enrolled in this study after the end of the parent study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	All Participants

Arm description:

Participants were previously enrolled in a RO7496998 (AT-527) study (i.e. parent study 2020-005759-18 [CV43043]).

Arm type	No intervention
Investigational medicinal product name	AT-527
Investigational medicinal product code	
Other name	RO7496998
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

In the parent study participants were randomized 1:2 to receive either placebo or AT-527 550 milligrams (mg). AT-527 (RO7496998) was administered twice daily (BID) for 5 days. No study drug was administered in this follow-up study.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

In the parent study participants were randomized 1:2 to receive either placebo or AT-527 550 milligrams (mg). The dose and regimen of the placebo matched that of AT-527 (RO7496998). No placebo was administered in this follow-up study.

Number of subjects in period 1	All Participants
Started	72
Completed	5
Not completed	67
Consent withdrawn by subject	3
Study Ended by Sponsor	64

Baseline characteristics

Reporting groups	
Reporting group title	All Participants
Reporting group description:	
Participants were previously enrolled in a RO7496998 (AT-527) study (i.e. parent study 2020-005759-18 [CV43043]).	

Reporting group values	All Participants	Total	
Number of subjects	72	72	
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	40.4		
standard deviation	± 13.4	-	
Sex: Female, Male Units:			
Female	43	43	
Male	29	29	

End points

End points reporting groups

Reporting group title	All Participants

Reporting group description:

Participants were previously enrolled in a RO7496998 (AT-527) study (i.e. parent study 2020-005759-18 [CV43043]).

Primary: Percentage of Participants With COVID-19 Symptoms Assessed through the COVID-19 Symptom Diary from Baseline up to Month 6

End point title	Percentage of Participants With COVID-19 Symptoms Assessed through the COVID-19 Symptom Diary from Baseline up to Month 6[1]

End point description:

COVID-19 symptoms were evaluated using the COVID-19 Symptom Diary. The COVID-19 Symptom Diary included the following 14 items: nasal congestion or runny nose, sore throat, cough, shortness of breath, muscle or body aches, fatigue, headache, chills/sweats, feeling hot or feverish, nausea, vomiting, diarrhea, sense of smell over the past 7 days and sense of taste over the past 7 days. The severity of items 1-12 were recorded on a 4-point Likert scale (i.e none/mild/moderate/severe). Items 13-14 were recorded on a 3-point Likert scale (i.e. same as usual/less than usual/no sense). Reported here is the percentage of participants with COVID-19 symptoms (mild/moderate/severe or less than usual/no sense) recorded during week 4 of each month following the baseline assessment. Here, n indicates the number of participants analyzed at each time point. BL=Baseline, M1=Month 1 -Week 4, M2=Month 2 - Week 4, M3=Month 3 - Week 4, M4=Month 4 - Week 4, M5=Month 5 - Week 4, M6=Month 6 - Week 4

End point type	Primary

End point timeframe:

Baseline, Month 1 - Week 4, Month 2 - Week 4, Month 3 - Week 4, Month 4 - Week 4, Month 5 - Week 4, Month 6 - Week 4

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The primary analysis was planned to be descriptive in nature and there were no plans for formal hypothesis testing in the analysis of the primary endpoint.

End point values	All Participants			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: percentage of participants				
number (not applicable)				
Nasal Congestion or Runny Nose: BL (n=69)	17.4			
Nasal Congestion or Runny Nose: M1 (n=61)	18.0			
Nasal Congestion or Runny Nose: M2 (n=64)	17.2			
Nasal Congestion or Runny Nose: M3 (n=59)	18.6			
Nasal Congestion or Runny Nose: M4 (n=32)	15.6			
Nasal Congestion or Runny Nose: M5 (n=14)	21.4			
Nasal Congestion or Runny Nose: M6 (n=3)	0			
Sore Throat: BL (n=69)	7.2			

Sore Throat: M1 (n=61)	9.8			
Sore Throat: M2 (n=64)	14.1			
Sore Throat: M3 (n=59)	15.3			
Sore Throat: M4 (n=32)	18.8			
Sore Throat: M5 (n=14)	0			
Sore Throat: M6 (n=3)	0			
Cough: BL (n=69)	21.7			
Cough: M1 (n=61)	16.4			
Cough: M2 (n=64)	17.2			
Cough: M3 (n=59)	16.9			
Cough: M4 (n=32)	15.6			
Cough: M5 (n=14)	7.1			
Cough: M6 (n=3)	0			
Shortness of Breath: BL (n=69)	5.8			
Shortness of Breath: M1 (n=61)	11.5			
Shortness of Breath: M2 (n=64)	12.5			
Shortness of Breath: M3 (n=59)	18.6			
Shortness of Breath: M4 (n=32)	12.5			
Shortness of Breath: M5 (n=14)	7.1			
Shortness of Breath: M6 (n=3)	0			
Muscle or Body Aches: BL (n=69)	21.7			
Muscle or Body Aches: M1 (n=61)	13.1			
Muscle or Body Aches: M2 (n=64)	18.8			
Muscle or Body Aches: M3 (n=59)	18.6			
Muscle or Body Aches: M4 (n=32)	12.5			
Muscle or Body Aches: M5 (n=14)	14.3			
Muscle or Body Aches: M6 (n=3)	0			
Fatigue: BL (n=69)	31.9			
Fatigue: M1 (n=61)	27.9			
Fatigue: M2 (n=64)	26.6			
Fatigue: M3 (n=59)	35.6			
Fatigue: M4 (n=32)	25.0			
Fatigue: M5 (n=14)	28.6			
Fatigue: M6 (n=3)	0			
Headache: BL (n=69)	13.0			
Headache: M1 (n=61)	6.6			
Headache: M2 (n=64)	7.8			
Headache: M3 (n=59)	20.3			
Headache: M4 (n=32)	12.5			
Headache: M5 (n=14)	0			
Headache: M6 (n=3)	0			
Chills/Sweats: BL (n=69)	5.8			
Chills/Sweats: M1 (n=61)	0			
Chills/Sweats: M2 (n=64)	7.8			
Chills/Sweats: M3 (n=59)	6.8			
Chills/Sweats: M4 (n=32)	6.3			
Chills/Sweats: M5 (n=14)	0			
Chills/Sweats: M6 (n=3)	0			
Feeling Hot or Feverish: BL (n=69)	4.3			
Feeling Hot or Feverish: M1 (n=61)	3.3			
Feeling Hot or Feverish: M2 (n=64)	6.3			
Feeling Hot or Feverish: M3 (n=59)	5.1			

Feeling Hot or Feverish: M4 (n=32)	3.1			
Feeling Hot or Feverish: M5 (n=14)	0			
Feeling Hot or Feverish: M6 (n=3)	0			
Nausea: BL (n=69)	4.3			
Nausea: M1 (n=61)	0			
Nausea: M2 (n=64)	6.3			
Nausea: M3 (n=59)	10.2			
Nausea: M4 (n=32)	6.3			
Nausea: M5 (n=14)	0			
Nausea: M6 (n=3)	0			
Vomiting: BL (n=69)	0			
Vomiting: M1 (n=61)	0			
Vomiting: M2 (n=64)	1.6			
Vomiting: M3 (n=59)	3.4			
Vomiting: M4 (n=32)	0			
Vomiting: M5 (n=14)	0			
Vomiting: M6 (n=3)	0			
Diarrhea: BL (n=69)	2.9			
Diarrhea: M1 (n=61)	1.6			
Diarrhea: M2 (n=64)	4.7			
Diarrhea: M3 (n=59)	5.1			
Diarrhea: M4 (n=32)	9.4			
Diarrhea: M5 (n=14)	0			
Diarrhea: M6 (n=3)	0			
Reduction or Loss of Sense of Smell: BL (n=69)	23.2			
Reduction or Loss of Sense of Smell: M1 (n=61)	18.0			
Reduction or Loss of Sense of Smell: M2 (n=64)	18.8			
Reduction or Loss of Sense of Smell: M3 (n=59)	18.6			
Reduction or Loss of Sense of Smell: M4 (n=32)	15.6			
Reduction or Loss of Sense of Smell: M5 (n=14)	21.4			
Reduction or Loss of Sense of Smell: M6 (n=3)	0			
Reduction or Loss of Sense of Taste: BL (n=69)	17.4			
Reduction or Loss of Sense of Taste: M1 (n=61)	11.5			
Reduction or Loss of Sense of Taste: M2 (n=64)	15.6			
Reduction or Loss of Sense of Taste: M3 (n=59)	13.6			
Reduction or Loss of Sense of Taste: M4 (n=32)	15.6			
Reduction or Loss of Sense of Taste: M5 (n=14)	21.4			
Reduction or Loss of Sense of Taste: M6 (n=3)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Dyspnea Symptoms Assessment Score through the Patient Reported Outcomes Measurement Information System - Short Form (PROMIS-SF) - Dyspnea Questionnaire

End point title	Dyspnea Symptoms Assessment Score through the Patient Reported Outcomes Measurement Information System - Short Form (PROMIS-SF) - Dyspnea Questionnaire

End point description:

The PROMIS-SF-Dyspnea Questionnaire is a 10-item questionnaire to evaluate the impact of dyspnea on specific activities. Participants self-assessed the severity of shortness of breath and difficulty of breathing in response to specific activities with a recall of the past 7 days. The PROMIS SF-Dyspnea Severity instrument is scored on a 4-point Likert scale, with an option to indicate that an activity had not been performed. Total score range is 0-30, where a higher score indicates a higher symptom severity of dyspnea.

End point type	Secondary

End point timeframe:

Baseline, Month 1, Month 2, Month 3, Month 4, Month 5, Month 6

End point values	All Participants			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=70)	2.04 (± 3.62)			
Month 1 (n=59)	1.94 (± 3.49)			
Month 2 (n=63)	2.12 (± 3.69)			
Month 3 (n=58)	1.97 (± 2.97)			
Month 4 (n=30)	1.33 (± 2.95)			
Month 5 (n=13)	0.69 (± 1.70)			
Month 6 (n=3)	0.00 (± 0.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Respiratory-specific Health-related Quality of Life Score as Assessed by the St. George's Respiratory Questionnaire (SGRQ)

End point title	Respiratory-specific Health-related Quality of Life Score as Assessed by the St. George's Respiratory Questionnaire (SGRQ)

End point description:

The SGRQ is a 50-item respiratory-specific health-related quality of life instrument that measures health impairment. The questionnaire contains 3 domains: symptoms, activity, and impacts. Items were assessed on various response scales, including a 5-point Likert scale and True/False scale. Each scale is scored from 0 to 100, and the total score represents the weighted average of these three subscores. Higher scores correspond to worse quality of life. The SGRQ had a recall specification of 4 weeks. Here, n indicates the number of participants analyzed at each time point.

End point type	Secondary

End point timeframe:

Baseline, Month 1, Month 2, Month 3, Month 4, Month 5, Month 6

End point values	All Participants			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=70)	12.93 (± 16.57)			
Month 1 (n=59)	11.13 (± 16.27)			
Month 2 (n=60)	11.39 (± 16.35)			
Month 3 (n=59)	11.40 (± 16.27)			
Month 4 (n=32)	13.88 (± 23.91)			
Month 5 (n=13)	6.66 (± 14.70)			
Month 6 (n=3)	3.46 (± 4.11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with COVID-19 Related Medically-Attended Visits

End point title	Percentage of Participants with COVID-19 Related Medically-Attended Visits

End point description:

COVID-19-related medically-attended visits were defined as hospitalization, ER visit, urgent care visit, physician’s office visit, or telemedicine visit with the primary reason for the visit being COVID-19 or COVID-19-related symptoms. The analysis population included all enrolled participants in the study.

End point type	Secondary

End point timeframe:

Up to 6 months

End point values	All Participants			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: percentage of participants				
number (confidence interval 97.5%)	2.8 (0.00 to 7.81)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Death Attributable to Progression of COVID-19

End point title	Percentage of Participants with Death Attributable to Progression of COVID-19
End point description:	
The analysis population included all enrolled participants in the study.	
End point type	Secondary
End point timeframe:	
Up to 6 months	

End point values	All Participants			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: percentage of participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with any Post-Treatment Infection

End point title	Percentage of Participants with any Post-Treatment Infection
End point description:	
Post-treatment infections were defined as any adverse event with a primary system organ class of infections and infestations. The analysis population included all enrolled participants in the study.	
End point type	Secondary
End point timeframe:	
Up to 6 months	

End point values	All Participants			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: percentage of participants				
number (confidence interval 97.5%)	8.3 (0.34 to 16.33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Re-Infected with Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2)

End point title	Percentage of Participants Re-Infected with Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2)

End point description:

Reinfection was defined as any nasopharyngeal (NP) swab that was positive for SARS-CoV-2 infection via reverse-transcriptase polymerase chain reaction (RT-PCR), taken when clinically indicated based on symptoms. The analysis population included all enrolled participants in the study.

End point type	Secondary

End point timeframe:

Up to 6 months

End point values	All Participants			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: percentage of participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with COVID-19-Related Complications

End point title	Percentage of Participants with COVID-19-Related Complications

End point description:

COVID-19 related complications included pneumonia, acute respiratory failure, sepsis, coagulopathy, pericarditis and/or myocarditis, and cardiac failure. The analysis population included all enrolled participants in the study.

End point type	Secondary

End point timeframe:

Up to 6 months

End point values	All Participants			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: percentage of participants				
number (confidence interval 97.5%)	0 (0.00 to 0.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Adverse Events (AEs)

End point title	Percentage of Participants with Adverse Events (AEs)

End point description:

An AE is any untoward medical occurrence in a clinical investigation subject administered a pharmaceutical product, regardless of causal attribution. An AE can therefore be any of the following: any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the medicinal product, any new disease or exacerbation of an existing disease, recurrence of an intermittent medical condition not present at baseline or related to a protocol-mandated intervention. The safety population included all enrolled participants in the study.

End point type	Secondary

End point timeframe:

Up to 6 months

End point values	All Participants			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: percentage of participants				
number (not applicable)	26.4			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 6 months

Adverse event reporting additional description:

All AEs/Serious AEs continuing/persisting from the parent study or any new AEs with an onset date on or after the first day of enrollment and during this follow-up study are displayed. The safety population included all participants enrolled in the study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	All Participants

Reporting group description:

Participants were previously enrolled in a RO7496998 (AT-527) study (i.e. parent study 2020-005759-18 [CV43043]).

Serious adverse events	All Participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 72 (2.78%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
Arterial occlusive disease			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	All Participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 72 (23.61%)		
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Fall			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Muscle strain			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 72 (2.78%)		
occurrences (all)	3		
Hyposmia			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Taste disorder			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Chest pain			

subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Hangover			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Vaccination site pain			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Gastrointestinal disorders			
Food poisoning			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Sneezing			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Psychiatric disorders			

Depression			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Anxiety			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Intervertebral disc protrusion			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Tenosynovitis			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Rhinitis			

subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		
Vaginal infection			
subjects affected / exposed	1 / 72 (1.39%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
16 March 2022	Based on program revaluation and in agreement with the co-development partner the sponsor took the decision to terminate this study.	-

Notes:

Limitations and caveats

None reported