Clinical trial results:
A Phase III, double-blind, randomized, placebo-controlled study to evaluate the safety, reactogenicity and immune response of a single intramuscular dose of unadjuvanted RSV Maternal vaccine, in high risk pregnant women aged 15 to 49 years and infants born to the vaccinated mothers

Summary

EudraCT number	2021-000994-96
Trial protocol	FI ES IT Outside EU/EEA
Global end of trial date	30 May 2023

Results information

Result version number	v2
This version publication date	06 March 2024
First version publication date	14 December 2023
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	214725

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04980391
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002821-PIP01-20
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	20 October 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 May 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

• To evaluate the safety and reactogenicity of a single IM dose of study intervention administered to maternal participants up to 42 days post-delivery.
• To evaluate the pregnancy outcomes and pregnancy-related AESIs up to 42 days post-delivery, in maternal participants who received a single IM dose of study intervention.
• To evaluate safety up to 42 days post-birth in infants born to maternal participants who received a single IM dose of study intervention.
• To evaluate the safety of the vaccine in infants up to 365 days post-birth.
• To evaluate the immunogenicity of a single IM dose of study intervention administered to maternal participants, at delivery.
• To evaluate the transfer of RSV-specific antibodies from maternal participants who received a single IM dose of study intervention to their infants at delivery.
• To evaluate the RSV-specific antibody levels at birth in infants born to maternal participants who received a single IM dose of study intervention.

Protection of trial subjects:

Maternal participants remained under observation for 30 minutes after the administration of the study intervention to ensure that immediate treatment would be provided in the event of a hypersensitivity reaction, or syncope.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 August 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Brazil: 21
Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	Finland: 15
Country: Number of subjects enrolled	India: 7
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Panama: 63
Country: Number of subjects enrolled	South Africa: 94
Country: Number of subjects enrolled	Spain: 81
Country: Number of subjects enrolled	United States: 83

Worldwide total number of subjects	384
EEA total number of subjects	101

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	37
Newborns (0-27 days)	161
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	20
Adults (18-64 years)	166
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Out of 384 participants who completed the informed consent process, 169 maternal participants were vaccinated, and 198 infants, including twins, were born to those exposed mothers (RSV_MAT Group-Mother and Control Group-Mother). Therefore, 367 participants were considered exposed.

Period 1

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

Blinding implementation details:

The study was originally double-blinded, but due to a safety signal, it was fully unblinded to ensure the safety monitoring of the participants.

Arms

Are arms mutually exclusive?	Yes
Arm title	RSV_MAT Group-Mother

Arm description:

Maternal participants randomized to the RSV_MAT Group received a single dose of the RSV MAT vaccine administered, between 24 and 36 weeks of gestation, at Day 1 in this study.

Arm type	Experimental
Investigational medicinal product name	RSV MAT
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose of the RSV MAT vaccine reconstituted with NaCl solution, administered intramuscularly in the non-dominant arm, at Day 1.

Arm title	Control Group-Mother

Arm description:

Maternal participants randomized to the Control Group received a single dose of Placebo administered, between 24 and 36 weeks of gestation, at Day 1 in this study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose of Placebo, administered intramuscularly in the non-dominant arm, at Day 1.

Arm title	RSV_MAT Group-Infant

Arm description:

This group consisted of infants born to mothers (from RSV_MAT Group-Mother) who received a single dose of RSV MAT vaccine during pregnancy.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Control Group-Infant

Arm description:

This group consisted of infants born to mothers (from Control Group-Mother) who received a single dose of placebo during pregnancy.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1[1]	RSV_MAT Group-Mother	Control Group-Mother	RSV_MAT Group-Infant
Started	113	56	132
Completed	107	52	124
Not completed	6	4	8
Death	-	-	1
WITHDRAWAL BY SUBJECT'S PARENT(S)/LAR(S)	-	-	3
MIGRATED / MOVED FROM THE STUDY AREA	1	1	2
Lost to follow-up	3	3	2
WITHDRAWAL BY SUBJECT, NOT DUE TO AN ADVERSE EVENT	2	-	-

Number of subjects in period 1[1]	Control Group-Infant
Started	66
Completed	61
Not completed	5
Death	1
WITHDRAWAL BY SUBJECT'S PARENT(S)/LAR(S)	-
MIGRATED / MOVED FROM THE STUDY AREA	1
Lost to follow-up	3
WITHDRAWAL BY SUBJECT, NOT DUE TO AN ADVERSE EVENT	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Out of 384 participants who completed the informed consent process, 169 maternal participants were vaccinated, and 198 infants, including twins, were born to those exposed mothers (RSV_MAT Group-Mother and Control Group-Mother). Therefore, 367 participants were considered exposed.

Baseline characteristics

Reporting groups	
Reporting group title	RSV_MAT Group-Mother
Reporting group description:	
Maternal participants randomized to the RSV_MAT Group received a single dose of the RSV MAT vaccine administered, between 24 and 36 weeks of gestation, at Day 1 in this study.	
Reporting group title	Control Group-Mother
Reporting group description:	
Maternal participants randomized to the Control Group received a single dose of Placebo administered, between 24 and 36 weeks of gestation, at Day 1 in this study.	
Reporting group title	RSV_MAT Group-Infant
Reporting group description:	
This group consisted of infants born to mothers (from RSV_MAT Group-Mother) who received a single dose of RSV MAT vaccine during pregnancy.	
Reporting group title	Control Group-Infant
Reporting group description:	
This group consisted of infants born to mothers (from Control Group-Mother) who received a single dose of placebo during pregnancy.	

Reporting group values	RSV_MAT Group-Mother	Control Group-Mother	RSV_MAT Group-Infant
Number of subjects	113	56	132
Age Categorical Units: Participants			
0 to 1 years of age	0	0	132
15 < 18 years of age	13	6	0
18 to 49 years of age	100	50	0
Sex: Female, Male Units: Participants			
Female	113	56	63
Male	0	0	69
Race/Ethnicity, Customized Units: Subjects			
Asian	4	1	4
Black or African American	33	18	33
White	52	24	67
Other, unspecified	24	13	28

Reporting group values	Control Group-Infant	Total	
Number of subjects	66	367	
Age Categorical Units: Participants			
0 to 1 years of age	66	198	
15 < 18 years of age	0	19	
18 to 49 years of age	0	150	
Sex: Female, Male Units: Participants			
Female	29	261	
Male	37	106	

Race/Ethnicity, Customized Units: Subjects			
Asian	1	10	
Black or African American	18	102	
White	34	177	
Other, unspecified	13	78	

End points

End points reporting groups

Reporting group title	RSV_MAT Group-Mother
Reporting group description:	
Maternal participants randomized to the RSV_MAT Group received a single dose of the RSV MAT vaccine administered, between 24 and 36 weeks of gestation, at Day 1 in this study.	
Reporting group title	Control Group-Mother
Reporting group description:	
Maternal participants randomized to the Control Group received a single dose of Placebo administered, between 24 and 36 weeks of gestation, at Day 1 in this study.	
Reporting group title	RSV_MAT Group-Infant
Reporting group description:	
This group consisted of infants born to mothers (from RSV_MAT Group-Mother) who received a single dose of RSV MAT vaccine during pregnancy.	
Reporting group title	Control Group-Infant
Reporting group description:	
This group consisted of infants born to mothers (from Control Group-Mother) who received a single dose of placebo during pregnancy.	
Subject analysis set title	RSV_MAT Group
Subject analysis set type	Per protocol
Subject analysis set description:	
This group consisted of pairs of maternal participants from RSV_MAT Group - Mother and infant participants from RSV_MAT Group - Infant.	
Subject analysis set title	Control Group
Subject analysis set type	Per protocol
Subject analysis set description:	
This group consisted of pairs of maternal participants from Control Group - Mother and infant participants from Control Group - Infant.	

Primary: Percentage of maternal participants reporting any solicited administration site events

End point title	Percentage of maternal participants reporting any solicited administration site events[1][2]
End point description:	
Assessed solicited administration site events included erythema, pain and swelling. Any pain = occurrence of the symptom regardless of intensity grade. Any erythema and swelling = symptom reported with a surface diameter greater than or equal to 20 millimeters. Analysis was performed on the Solicited Safety Set, which included all maternal participants who received 1 dose of a study intervention and who had solicited safety data available during the specified period.	
End point type	Primary
End point timeframe:	
From Day 1 to Day 7 included	

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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	54		
Units: Percentage of participants				
number (confidence interval 95%)				
Any Erythema	0.9 (0.0 to 4.8)	0 (0 to 6.6)		
Any Pain	44.2 (34.9 to 53.9)	14.8 (6.6 to 27.1)		
Any Swelling	0 (0 to 3.2)	1.9 (0.0 to 9.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal participants reporting any solicited systemic events

End point title	Percentage of maternal participants reporting any solicited systemic events[3][4]

End point description:

Assessed solicited systemic events included abdominal pain, diarrhea, fatigue, headache, nausea, fever [temperature equal to or above (>=) 38 degrees Celsius (°C)/100.4 degrees Fahrenheit (°F), regardless of the location of measurement] and vomiting. Any = occurrence of the adverse event regardless of intensity grade or relation to study vaccination. Analysis was performed on the Solicited Safety Set, which included all maternal participants who received 1 dose of a study intervention and who had solicited safety data available during the specified period.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 included

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	54		
Units: Percentage of participants				
number (confidence interval 95%)				
Any Abdominal pain	20.4 (13.4 to 29.0)	16.7 (7.9 to 29.3)		
Any Diarrhea	20.4 (13.4 to 29.0)	7.4 (2.1 to 17.9)		
Any Fatigue	28.3 (20.2 to 37.6)	27.8 (16.5 to 41.6)		
Any Headache	39.8 (30.7 to 49.5)	38.9 (25.9 to 53.1)		
Any Nausea	24.8 (17.1 to 33.8)	20.4 (10.6 to 33.5)		
Any Fever	0 (0 to 3.2)	0 (0 to 6.6)		

Any Vomiting	8.0 (3.7 to 14.6)	20.4 (10.6 to 33.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal participants reporting any serious adverse events (SAEs) from Day 1 up to 42 days post-delivery

End point title	Percentage of maternal participants reporting any serious adverse events (SAEs) from Day 1 up to 42 days post-delivery[5][6]

End point description:

An SAE was defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect in the offspring of a study participant or resulted in abnormal pregnancy outcomes or in other situations that were considered serious per medical or scientific judgment. Any = occurrence of any SAE regardless of intensity grade or relation to vaccination. Analysis was performed on the Exposed Set - Maternal, which included all maternal participants who received 1 dose of a study intervention.

End point type	Primary

End point timeframe:

From Day 1 up to 42 days post-delivery, an average of 2 months

Notes:

[5] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Percentage of participants				
number (confidence interval 95%)	29.2 (21.0 to 38.5)	19.6 (10.2 to 32.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal participants reporting any unsolicited adverse events (AEs)

End point title	Percentage of maternal participants reporting any unsolicited adverse events (AEs)[7][8]

End point description:

An unsolicited AE was defined as any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms

was reported as an unsolicited AE. Any = occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Analysis was performed on the Exposed Set - Maternal, which included all maternal participants who received 1 dose of a study intervention.

End point type	Primary

End point timeframe:

From Day 1 to Day 30 included

Notes:

[7] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Percentage of participants				
number (confidence interval 95%)	34.5 (25.8 to 44.0)	37.5 (24.9 to 51.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of maternal participants reporting (S)AEs leading to study withdrawal from Day 1 up to 42 days post-delivery

End point title	Number of maternal participants reporting (S)AEs leading to study withdrawal from Day 1 up to 42 days post-delivery[9][10]

End point description:

A participant was considered to have withdrawn from the study if no new study procedure had been performed or no new information had been collected for her since the date of withdrawal/last contact. (S)AEs leading to study withdrawal were (S)AEs identified by the investigator to cause participant withdrawal until the resolution of the event. These participant withdrawals were considered different from participant withdrawals for other reasons. Analysis was performed on the Exposed Set - Maternal, which included all maternal participants who received 1 dose of a study intervention.

End point type	Primary

End point timeframe:

From Day 1 up to 42 days post-delivery, an average of 2 months

Notes:

[9] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of live births with no congenital anomalies, live births with minor congenital anomaly(ies) and live births with at least 1 major congenital anomaly

End point title	Percentage of live births with no congenital anomalies, live births with minor congenital anomaly(ies) and live births with at least 1 major congenital anomaly[11][12]

End point description:

The percentage of live births with no congenital anomalies, live births with minor congenital anomaly(ies) only and live births with at least 1 major congenital anomaly is reported. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/legally acceptable representatives (LARs) completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From Day 1 up to 42 days post-delivery, an average of 2 months

Notes:

[11] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Percentage of live births				
number (confidence interval 95%)				
LIVE BIRTH WITH NO CONGENITAL ANOMALIES	86.4 (79.3 to 91.7)	84.8 (73.9 to 92.5)		
LIVE BIRTH WITH ONLY MINOR CONGENITAL ANOMALY(IES)	10.6 (5.9 to 17.2)	13.6 (6.4 to 24.3)		
LIVE BIRTH WITH >= MAJOR CONGENITAL ANOMALY	3.0 (0.8 to 7.6)	1.5 (0.0 to 8.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal participants reporting medically attended adverse events (MAEs) from Day 1 up to 42 days post-delivery

End point title	Percentage of maternal participants reporting medically attended adverse events (MAEs) from Day 1 up to 42 days post-delivery[13][14]

End point description:

An MAE was defined as an unsolicited AE for which the participant received medical attention such as hospitalization, or an emergency room visit, or visit to/by a health care provider. Analysis was performed on the Exposed Set - Maternal, which included all maternal participants who received 1 dose of a study intervention.

End point type	Primary

End point timeframe:

From Day 1 up to 42 days post-delivery, an average of 2 months

Notes:

[13] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Percentage of participants				
number (confidence interval 95%)	57.5 (47.9 to 66.8)	58.9 (45.0 to 71.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal participants reporting pregnancy-related adverse events of special interest (AESIs) from Day 1 up to 42 days post-delivery

End point title	Percentage of maternal participants reporting pregnancy-related adverse events of special interest (AESIs) from Day 1 up to 42 days post-delivery[15][16]

End point description:

Pregnancy-related AESIs included preterm labor, provider-initiated preterm birth, premature preterm rupture of membranes, pre-eclampsia, pre-eclampsia with severe features including eclampsia, gestational hypertension and fetal growth restriction. Analysis was performed on the Exposed Set - Maternal, which included all maternal participants who received 1 dose of a study intervention.

End point type	Primary

End point timeframe:

From Day 1 up to 42 days post-delivery, an average of 2 months

Notes:

[15] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline

period.

Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Percentage of participants				
number (confidence interval 95%)				
Preterm labor	8.0 (3.7 to 14.6)	7.1 (2.0 to 17.3)		
Provider-initiated preterm birth	3.5 (1.0 to 8.8)	5.4 (1.1 to 14.9)		
Premature preterm rupture of membranes	1.8 (0.2 to 6.2)	5.4 (1.1 to 14.9)		
Pre-eclampsia	4.4 (1.5 to 10.0)	3.6 (0.4 to 12.3)		
Pre-eclampsia with severe features	4.4 (1.5 to 10.0)	0 (0 to 6.4)		
Gestational hypertension	0.9 (0.0 to 4.8)	3.6 (0.4 to 12.3)		
Fetal growth restriction	1.8 (0.2 to 6.2)	3.6 (0.4 to 12.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal participants reporting worsening of pre-existing medical conditions and/or obstetric complications from Day 1 up to 42 days post-delivery

End point title	Percentage of maternal participants reporting worsening of pre-existing medical conditions and/or obstetric complications from Day 1 up to 42 days post-delivery[17][18]

End point description:

Worsening of pre-existing medical condition and/or obstetric complication was considered by the investigator, using clinical judgment and the following criteria:
- Change in medication and/or medication dose.
- Medically attended event in relation to pre-existing condition and/or obstetric complication that are outside the routine management of the condition/complication.
- SAE and/or hospitalization in relation to pre-existing condition and/or obstetric complication.
Analysis was performed on the Exposed Set - Maternal, which included all maternal participants who received 1 dose of a study intervention.

End point type	Primary

End point timeframe:

From Day 1 up to 42 days post-delivery, an average of 2 months

Notes:

[17] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Percentage of participants				
number (confidence interval 95%)				
Change In Medication And/Or Medication Dose	1.8 (0.2 to 6.2)	1.8 (0.0 to 9.6)		
Medically Attended Event	1.8 (0.2 to 6.2)	7.1 (2.0 to 17.3)		
SAE And/Or Hospitalization	1.8 (0.2 to 6.2)	3.6 (0.4 to 12.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant participants reporting neonatal/infant AESIs from birth up to 42 days post-birth

End point title	Percentage of infant participants reporting neonatal/infant AESIs from birth up to 42 days post-birth[19][20]

End point description:

Neonatal/infant AESIs included low birth weight (below [<] 2500 grams), very low birth weight (<1500 grams), extremely low birth weight (<1000 grams), preterm birth (<37 weeks of gestational age), small for gestational age (weight below 10th percentile for gestational age), congenital anomalies with internal structural defects and neonatal death in a preterm live birth (gestational age equal to or above [>=] 28 and <37 weeks). Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth up to 42 days post-birth, an average of 2 months

Notes:

[19] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Percentage of participants				
number (confidence interval 95%)				
Low Birth Weight (<2500 grams)	16.7 (10.7 to 24.1)	18.2 (9.8 to 29.6)		
Very Low Birth Weight (<1500 grams)	2.3 (0.5 to 6.5)	1.5 (0.0 to 8.2)		
Extremely Low Birth Weight (<1000 grams)	0 (0 to 2.8)	1.5 (0.0 to 8.2)		
Preterm Birth (<37 Weeks Of Gestational Age)	18.2 (12.0 to 25.8)	19.7 (10.9 to 31.3)		

Small For Gestational Age	14.4 (8.9 to 21.6)	27.3 (17.0 to 39.6)		
Congenital Anomalies	3.0 (0.8 to 7.6)	0 (0 to 5.4)		
Neonatal Death In A Preterm Live Birth	0.8 (0.0 to 4.1)	1.5 (0.0 to 8.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant participants reporting any SAEs from birth up to 42 days post-birth

End point title	Percentage of infant participants reporting any SAEs from birth up to 42 days post-birth[21][22]

End point description:

An SAE was defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect or resulted in other situations that were considered serious per medical or scientific judgment. Any = occurrence of any SAE regardless of intensity grade or relation to vaccination. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth up to 42 days post-birth, an average of 2 months

Notes:

[21] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Percentage of participants				
number (confidence interval 95%)	20.5 (13.9 to 28.3)	27.3 (17.0 to 39.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants reporting (S)AEs leading to study withdrawal from birth up to 42 days post-birth

End point title	Number of infant participants reporting (S)AEs leading to study withdrawal from birth up to 42 days post-birth[23][24]

End point description:

A participant was considered to have withdrawn from the study if no new study procedure had been

performed or no new information had been collected for her since the date of withdrawal/last contact. (S)AEs leading to study withdrawal were (S)AEs identified by the investigator to cause participant withdrawal until the resolution of the event. These participant withdrawals were considered different from participant withdrawals for other reasons. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth up to 42 days post-birth, an average of 2 months

Notes:

[23] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant participants reporting MAEs from birth up to 42 days post-birth

End point title	Percentage of infant participants reporting MAEs from birth up to 42 days post-birth[25][26]

End point description:

An MAE was defined as an unsolicited AE for which the participants received medical attention such as hospitalization, or an emergency room visit, or visit to/by a health care provider. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth up to 42 days post-birth, an average of 2 months

Notes:

[25] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Percentage of participants				
number (confidence interval 95%)	56.8 (47.9 to 65.4)	54.5 (41.8 to 66.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant participants reporting any SAEs from birth up to 180 days post-birth

End point title	Percentage of infant participants reporting any SAEs from birth up to 180 days post-birth[27][28]

End point description:

An SAE was defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect or resulted in other situations that were considered serious per medical or scientific judgment. Any = occurrence of any SAE regardless of intensity grade or relation to vaccination. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth up to 180 days post-birth

Notes:

[27] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Percentage of participants				
number (confidence interval 95%)	25.0 (17.9 to 33.3)	30.3 (19.6 to 42.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants reporting (S)AEs leading to study withdrawal from birth up to 180 days post-birth

End point title	Number of infant participants reporting (S)AEs leading to study

	withdrawal from birth up to 180 days post-birth[29][30]

End point description:

A participant was considered to have withdrawn from the study if no new study procedure had been performed or no new information had been collected for her since the date of withdrawal/last contact. (S)AEs leading to study withdrawal were (S)AEs identified by the investigator to cause participant withdrawal until the resolution of the event. These participant withdrawals were considered different from participant withdrawals for other reasons. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth up to 180 days post-birth

Notes:

[29] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant participants reporting MAEs from birth up to 180 days post-birth

End point title	Percentage of infant participants reporting MAEs from birth up to 180 days post-birth[31][32]

End point description:

An MAE was defined as an unsolicited AE for which the participants received medical attention such as hospitalization, or an emergency room visit, or visit to/by a health care provider. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth up to 180 days post-birth

Notes:

[31] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Percentage of participants				
number (confidence interval 95%)	77.3 (69.2 to 84.1)	69.7 (57.1 to 80.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant participants reporting MAEs from birth up to 365 days post-birth

End point title	Percentage of infant participants reporting MAEs from birth up to 365 days post-birth[33][34]

End point description:

An MAE was defined as an unsolicited AE for which the participants received medical attention such as hospitalization, or an emergency room visit, or visit to/by a health care provider. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth up to 365 days post-birth

Notes:

[33] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Percentage of participants				
number (confidence interval 95%)	86.4 (79.3 to 91.7)	75.8 (63.6 to 85.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant participants reporting any SAEs from birth up to 365 days post-birth

End point title	Percentage of infant participants reporting any SAEs from birth up to 365 days post-birth[35][36]

End point description:

An SAE was defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect or resulted in other situations that were considered serious per medical or scientific judgment. Any = occurrence of any SAE regardless of intensity grade or relation to vaccination. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth up to 365 days post-birth

Notes:

[35] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Percentage of participants				
number (confidence interval 95%)	26.5 (19.2 to 34.9)	31.8 (20.9 to 44.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants reporting (S)AEs leading to study withdrawal from birth up to 365 days post-birth

End point title	Number of infant participants reporting (S)AEs leading to study withdrawal from birth up to 365 days post-birth[37][38]

End point description:

A participant was considered to have withdrawn from the study if no new study procedure had been performed or no new information had been collected for her since the date of withdrawal/last contact. (S)AEs leading to study withdrawal were (S)AEs identified by the investigator to cause participant withdrawal until the resolution of the event. These participant withdrawals were considered different from participant withdrawals for other reasons. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth up to 365 days post-birth

Notes:

[37] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: RSV MAT IgG-specific antibody concentrations for maternal participants at delivery

End point title	RSV MAT IgG-specific antibody concentrations for maternal participants at delivery[39][40]

End point description:

RSV MAT IgG-specific antibody concentrations were determined by ELISA and expressed as GMCs in ELU/mL. Analysis was performed on the Per Protocol Set Immunogenicity - Maternal, which included all maternal participants who received 1 dose of a study intervention and had immunogenicity data available for the specified analysis at the specified time point (i.e. delivery), minus those participants with protocol deviations that lead to exclusion.

End point type	Primary

End point timeframe:

At delivery

Notes:

[39] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99	44		
Units: ELU/mL				
geometric mean (confidence interval 95%)	70337.1 (60711.34 to 81489.07)	4421 (3477.90 to 5619.80)		

Statistical analyses

No statistical analyses for this end point

Primary: RSV-A neutralizing titers for maternal participants at pre-dosing (Day 1)

End point title	RSV-A neutralizing titers for maternal participants at pre-dosing (Day 1)[41][42]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as geometric mean titers (GMTs). Analysis was performed on the Per Protocol Set Immunogenicity - Maternal, which

included all maternal participants who received 1 dose of a study intervention and had immunogenicity data available for the specified analysis at the specified time point (i.e. pre-dosing [Day 1]), minus those participants with protocol deviations that lead to exclusion.

End point type	Primary

End point timeframe:

At pre-dosing (Day 1)

Notes:

[41] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	48		
Units: Titers				
geometric mean (confidence interval 95%)	681.5 (578.33 to 803.11)	752.4 (580.25 to 975.50)		

Statistical analyses

No statistical analyses for this end point

Primary: RSV-A neutralizing titers for maternal participants at delivery

End point title	RSV-A neutralizing titers for maternal participants at

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. Analysis was performed on the Per Protocol Set Immunogenicity - Maternal, which included all maternal participants who received 1 dose of a study intervention and had immunogenicity data available for the specified analysis at the specified time point (i.e. delivery), minus those participants with protocol deviations that lead to exclusion.

End point type	Primary

End point timeframe:

At delivery

Notes:

[43] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99	44		
Units: Titers				
geometric mean (confidence interval 95%)	6240.3 (5026.02 to 7747.88)	612.8 (455.82 to 823.83)		

Statistical analyses

No statistical analyses for this end point

Primary: RSV MAT immunoglobulin G (IgG)-specific antibody concentrations for maternal participants at pre-dosing (Day 1)

End point title	RSV MAT immunoglobulin G (IgG)-specific antibody concentrations for maternal participants at pre-dosing (Day 1)[45][46]

End point description:

RSV MAT IgG-specific antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA) and expressed as geometric mean concentrations (GMCs) in ELISA units per milliliter (ELU/mL). Analysis was performed on the Per Protocol Set Immunogenicity - Maternal, which included all maternal participants who received 1 dose of a study intervention and had immunogenicity data available for the specified analysis at the specified time point (i.e. pre-dosing [Day 1]), minus those participants with protocol deviations that lead to exclusion.

End point type	Primary

End point timeframe:

At pre-dosing (Day 1)

Notes:

[45] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	48		
Units: ELU/mL				
geometric mean (confidence interval 95%)	4981.6 (4405.14 to 5633.53)	5981.7 (4908.71 to 7289.11)		

Statistical analyses

No statistical analyses for this end point

Primary: RSV-A neutralizing titers for infant participants at delivery or within 72 hours after birth

End point title	RSV-A neutralizing titers for infant participants at delivery or within 72 hours after birth[47][48]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. The titers were measured on the cord blood sample collected at delivery, or on a blood sample collected from the infant within 72 hours after birth (if no cord blood sample could be obtained). Analysis was performed on the Per Protocol Set Immunogenicity - Infant, which included all infant participants in the Exposed set who had post-delivery/birth immunogenicity data available for the specified analysis at the specified time points, minus those who (a) were born less than 4 weeks post-maternal participant dosing and/ or (b) have protocol deviations that lead to exclusion.

End point type	Primary

End point timeframe:

At delivery or within 72 hours after birth

Notes:

[47] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	37		
Units: Titers				
geometric mean (confidence interval 95%)	9080.2 (7449.56 to 11067.75)	694.6 (495.72 to 973.37)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Ratio (GMR) between cord blood and maternal RSV MAT IgG-specific antibody concentrations

End point title	Geometric Mean Ratio (GMR) between cord blood and maternal RSV MAT IgG-specific antibody concentrations[49]

End point description:

The placental transfer ratio of IgG-specific antibody concentration was determined from cord blood (or infant blood sample collected within 72 hours after birth [if no cord blood could be obtained]) over that of the blood sample from mother at delivery (if no blood sample was collected during delivery). Analysis was performed on all pairs of maternal participants (from Per Protocol Set Immunogenicity - Maternal) and their infants (from Per Protocol Set Immunogenicity - Infant) with available results for this outcome measure at the specified time points.

End point type	Primary

End point timeframe:

At delivery (for maternal participants) or within 72 hours after birth (for infant participants)

Notes:

[49] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV_MAT Group	Control Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	86	37		
Units: Ratio				
geometric mean (confidence interval 95%)	1.33 (1.04 to 1.70)	2.30 (1.63 to 3.25)		

Statistical analyses

No statistical analyses for this end point

Primary: RSV MAT IgG-specific antibody concentrations for infant participants at delivery or within 72 hours after birth

End point title	RSV MAT IgG-specific antibody concentrations for infant participants at delivery or within 72 hours after birth[50][51]

End point description:

RSV MAT IgG-specific antibody concentrations were determined by ELISA and expressed as GMCs in ELU/mL. The antibody concentrations were measured on the cord blood sample collected at delivery, or on a blood sample collected from the infant within 72 hours after birth (if no cord blood sample could be obtained). Analysis was performed on the Per Protocol Set Immunogenicity - Infant, which included all infant participants in the Exposed set who had post-delivery/birth immunogenicity data available for the specified analysis at the specified time points, minus those who (a) were born less than 4 weeks post-maternal participant dosing and/ or (b) had protocol deviations that lead to exclusion.

End point type	Primary

End point timeframe:

At delivery or within 72 hours after birth

Notes:

[50] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[51] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	37		
Units: ELU/mL				
geometric mean (confidence interval 95%)	77625.1 (63706.97 to 94583.89)	9228 (6540.47 to 13019.71)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants reporting (S)AEs leading to study withdrawal from Day 1 up to 180 days post-delivery

End point title	Number of maternal participants reporting (S)AEs leading to study withdrawal from Day 1 up to 180 days post-delivery[52]

End point description:

A participant was considered to have withdrawn from the study if no new study procedure had been performed or no new information had been collected for her since the date of withdrawal/last contact. (S)AEs leading to study withdrawal were (S)AEs identified by the investigator to cause participant withdrawal until the resolution of the event. These participant withdrawals were considered different from participant withdrawals for other reasons. Analysis was performed on the Exposed Set - Maternal, which included all maternal participants who received 1 dose of a study intervention.

End point type	Secondary

End point timeframe:

From Day 1 up to 180 days post-delivery

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of maternal participants reporting any SAEs from Day 1 up to 180 days post-delivery

End point title	Percentage of maternal participants reporting any SAEs from Day 1 up to 180 days post-delivery[53]

End point description:

An SAE was defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect in the offspring of a study participant or resulted in abnormal pregnancy outcomes or in other situations that were considered serious per medical or scientific judgment. Any = occurrence of any SAE regardless of intensity grade or relation to vaccination. Analysis was performed on the Exposed Set - Maternal, which included all maternal participants who received 1 dose of a study intervention.

End point type	Secondary

End point timeframe:

From Day 1 up to 180 days post-delivery

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Percentage of participants				
number (confidence interval 95%)	29.2 (21.0 to 38.5)	19.6 (10.2 to 32.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of maternal participants reporting MAEs from Day 1 up to 180 days post-delivery

End point title	Percentage of maternal participants reporting MAEs from Day 1 up to 180 days post-delivery[54]

End point description:

An MAE was defined as an unsolicited AE for which the participants received medical attention such as hospitalization, or an emergency room visit, or visit to/by a health care provider. Analysis was performed on the Exposed Set - Maternal, which included all maternal participants who received 1 dose of a study intervention.

End point type	Secondary

End point timeframe:

From Day 1 up to 180 days post-delivery

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Percentage of participants				
number (confidence interval 95%)	61.1 (51.4 to 70.1)	60.7 (46.8 to 73.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants reporting RSV-associated medically attended respiratory tract illnesses (MA-RTIs) from Day 1 up to 180 days post-delivery

End point title	Number of maternal participants reporting RSV-associated medically attended respiratory tract illnesses (MA-RTIs) from Day 1 up to 180 days post-delivery[55]

End point description:

RSV-associated MA-RTI was defined as a medically attended visit for RTI symptoms and confirmed RSV infection. Analysis was performed on the Exposed Set - Maternal, which included all maternal

participants who received 1 dose of a study intervention.

End point type	Secondary

End point timeframe:

From Day 1 up to 180 days post-delivery

Notes:

[55] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of maternal participants reporting worsening of pre-existing medical conditions and/or obstetric complications from Day 1 up to 180 days post-delivery

End point title	Percentage of maternal participants reporting worsening of pre-existing medical conditions and/or obstetric complications from Day 1 up to 180 days post-delivery[56]

End point description:

Worsening of pre-existing medical condition and/or obstetric complication was considered by the investigator, using clinical judgement and the following criteria:
- Change in medication and/or medication dose.
- Medically attended event in relation to pre-existing condition and/or obstetric complication that are outside the routine management of the condition/complication.
- SAE and/or hospitalization in relation to pre-existing condition and/or obstetric complication.
Analysis was performed on the Exposed Set - Maternal, which included all maternal participants who received 1 dose of a study intervention.

End point type	Secondary

End point timeframe:

From Day 1 up to 180 days post-delivery

Notes:

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	56		
Units: Percentage of participants				
number (confidence interval 95%)				
Change In Medication And/Or Medication Dose	1.8 (0.2 to 6.2)	1.8 (0.0 to 9.6)		
Medically Attended Event	1.8 (0.2 to 6.2)	7.1 (2.0 to 17.3)		

SAE And/Or Hospitalization	1.8 (0.2 to 6.2)	3.6 (0.4 to 12.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant participants reporting medically assessed, RSV-associated hospitalizations from birth up to 365 days post-birth

End point title	Percentage of infant participants reporting medically assessed, RSV-associated hospitalizations from birth up to 365 days post-birth[57]

End point description:

RSV-associated hospitalization was defined as a confirmed RSV infection and hospitalized for acute medical condition. Hospitalization was defined as admission for observation or treatment based on the judgment of a health care provider. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent.

End point type	Secondary

End point timeframe:

From birth up to 365 days post-birth

Notes:

[57] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Percentage of participants				
number (confidence interval 95%)	3.0 (0.8 to 7.6)	10.6 (4.4 to 20.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant participants reporting medically assessed, RSV-associated lower respiratory tract illness (LRTIs) of any severity and RSV-associated severe LRTIs from birth up to 365 days post-birth

End point title	Percentage of infant participants reporting medically assessed, RSV-associated lower respiratory tract illness (LRTIs) of any severity and RSV-associated severe LRTIs from birth up to 365 days post-birth[58]

End point description:

An RSV-associated LRTI is characterized by a history of cough OR difficulty in breathing, AND a blood oxygen saturation by pulse oximetry (SpO2) lower than (<) 95%, OR respiratory rate increase AND a confirmed RSV infection. An RSV-associated severe LRTI meets the case definition of RSV-LRTI AND is additionally characterized by a SpO2 <93%, OR lower chest wall in-drawing, OR inability to feed, OR

failure to respond/unconscious. Analysis was performed on the Exposed Set - Infant, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Secondary

End point timeframe:

From birth up to 365 days post-birth

Notes:

[58] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	66		
Units: Percentage of participants				
number (confidence interval 95%)				
Any RSV-associated LRTIs	0.8 (0.0 to 4.1)	3.0 (0.4 to 10.5)		
RSV-associated Severe LRTIs	0 (0 to 2.8)	0 (0 to 5.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT IgG-specific antibody concentrations for maternal participants at Day 31 post-dosing

End point title	RSV MAT IgG-specific antibody concentrations for maternal participants at Day 31 post-dosing[59]

End point description:

RSV MAT IgG-specific antibody concentrations were determined by ELISA and expressed as GMCs in ELU/mL. Analysis was performed on the Per Protocol Set Immunogenicity - Maternal, which included all maternal participants who received 1 dose of a study intervention and had immunogenicity data available for the specified analysis at the specified time point (i.e. Day 31 post-dosing), minus those participants with protocol deviations that lead to exclusion.

End point type	Secondary

End point timeframe:

At Day 31 post-dosing

Notes:

[59] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	38		
Units: ELU/mL				
geometric mean (confidence interval 95%)	113957.1 (102340.44 to 126892.37)	5510.6 (4370.30 to 6948.51)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing titers for maternal participants at Day 31 post-dosing

End point title	RSV-A neutralizing titers for maternal participants at Day 31 post-dosing[60]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. Analysis was performed on the Per Protocol Set Immunogenicity - Maternal, which included all maternal participants who received 1 dose of a study intervention and had immunogenicity data available for the specified analysis at the specified time point (i.e. Day 31 post-dosing), minus those participants with protocol deviations that lead to exclusion.

End point type	Secondary

End point timeframe:

At Day 31 post-dosing

Notes:

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	38		
Units: Titers				
geometric mean (confidence interval 95%)	9959.7 (8239.95 to 12038.40)	575.2 (418.40 to 790.84)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing titers for maternal participants at pre-dosing (Day 1), Day 31 post-dosing and delivery

End point title	RSV-B neutralizing titers for maternal participants at pre-dosing (Day 1), Day 31 post-dosing and delivery[61]

End point description:

RSV-B neutralizing titers were determined by neutralization assay and expressed as GMTs. Analysis was performed on the Per Protocol Set Immunogenicity - Maternal, which included all maternal participants who received 1 dose of a study intervention and had immunogenicity data available for the specified analysis at the specified time points, minus those participants with protocol deviations that lead to exclusion.

End point type	Secondary

End point timeframe:

At pre-dosing (Day 1), Day 31 post-dosing and delivery

Notes:

[61] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the maternal participants.

End point values	RSV_MAT Group-Mother	Control Group-Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	47		
Units: Titers				
geometric mean (confidence interval 95%)				
Day 1 (N=103;47)	756.6 (646.03 to 885.98)	863.4 (664.87 to 1121.12)		
Day 31 (N=89;38)	9928.9 (8331.29 to 11832.87)	640.7 (475.93 to 862.38)		
Delivery (N=99;43)	6336.9 (5261.95 to 7631.49)	650.2 (492.25 to 858.82)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing titers for infant participants at Day 43 post-birth

End point title	RSV-A neutralizing titers for infant participants at Day 43 post-birth[62]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. Analysis was performed on a sub-cohort from the Per Protocol Set Immunogenicity - Infant, which included the infant participants for whom blood samples were collected for the specified analysis at Day 43 post-birth.

End point type	Secondary

End point timeframe:

At Day 43 post-birth

Notes:

[62] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	5		
Units: Titers				
geometric mean (confidence interval 95%)	3203.8 (1919.77 to 5346.65)	240.5 (53.94 to 1072.76)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT IgG-specific antibody concentrations for infant participants at Day 181 post-birth

End point title	RSV MAT IgG-specific antibody concentrations for infant participants at Day 181 post-birth[63]

End point description:

RSV MAT IgG-specific antibody concentrations were determined by ELISA and expressed as GMCs in ELU/mL. Analysis was performed on a sub-cohort from the Per Protocol Set Immunogenicity - Infant, which included the infant participants for whom blood samples were collected for the specified analysis at Day 181 post-birth. There was only one participant in the Control Group - Infant for whom blood sample was collected, hence the 95% confidence interval (CI) associated with geometric mean could not be calculated for single participant, and therefore the low value of the confidence interval was entered as "0" and the high value of the confidence interval was entered as "241".

End point type	Secondary

End point timeframe:

At Day 181 post-birth

Notes:

[63] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: ELU/mL				
geometric mean (confidence interval 95%)	2857.8 (1836.27 to 4447.53)	241 (0 to 241)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT IgG-specific antibody concentrations for infant participants at Day 43 post-birth

End point title	RSV MAT IgG-specific antibody concentrations for infant participants at Day 43 post-birth[64]

End point description:

RSV MAT IgG-specific antibody concentrations were determined by ELISA and expressed as GMCs in ELU/mL. Analysis was performed on a sub-cohort from the Per Protocol Set Immunogenicity - Infant, which included the infant participants for whom blood samples were collected for the specified analysis at Day 43 post-birth.

End point type	Secondary

End point timeframe:

At Day 43 post-birth

Notes:

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	5		
Units: ELU/mL				
geometric mean (confidence interval 95%)	29932.5 (22576.08 to 39686.04)	1310 (546.48 to 3140.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing titers for infant participants at delivery or within 72 hours after birth

End point title	RSV-B neutralizing titers for infant participants at delivery or within 72 hours after birth[65]

End point description:

RSV-B neutralizing titers were determined by neutralization assay and expressed as GMTs. The titers were measured on the cord blood sample collected at delivery, or on a blood sample collected from the infant within 72 hours after birth (if no cord blood sample could be obtained). Analysis was performed on the Per Protocol Set Immunogenicity - Infant, which included all infant participants in the Exposed set who had post-delivery/birth immunogenicity data available for the specified analysis at the specified time points, minus those who (a) were born less than 4 weeks post-maternal participant dosing and/ or (b) had protocol deviations that lead to exclusion.

End point type	Secondary

End point timeframe:

At delivery or within 72 hours after birth

Notes:

[65] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	37		
Units: Titers				
geometric mean (confidence interval 95%)	9145.5 (7458.74 to 11213.76)	779.7 (566.83 to 1072.49)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT IgG-specific antibody concentrations for infant participants at Day 121 post-birth

End point title	RSV MAT IgG-specific antibody concentrations for infant participants at Day 121 post-birth[66]

End point description:

RSV MAT IgG-specific antibody concentrations were determined by ELISA and expressed as GMCs in ELU/mL. Analysis was performed on a sub-cohort from the Per Protocol Set Immunogenicity - Infant, which included the infant participants for whom blood samples were collected for the specified analysis at Day 121 post-birth.

End point type	Secondary

End point timeframe:

At Day 121 post-birth

Notes:

[66] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	3		
Units: ELU/mL				
geometric mean (confidence interval 95%)	4365.1 (12.84 to 1484365.32)	446.8 (151.14 to 1320.88)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing titers for infant participants at Day 43 post-birth

End point title	RSV-B neutralizing titers for infant participants at Day 43 post-birth[67]

End point description:

RSV-B neutralizing titers were determined by neutralization assay and expressed as GMTs. Analysis was performed on a sub-cohort from the Per Protocol Set Immunogenicity - Infant, which included the infant participants for whom blood samples were collected for the specified analysis at Day 43 post-birth.

End point type	Secondary

End point timeframe:

At Day 43 post-birth

Notes:

[67] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	5		
Units: Titers				
geometric mean (confidence interval 95%)	3012.8 (1789.81 to 5071.60)	273.3 (106.14 to 703.45)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing titers for infant participants at Day 121 post-birth

End point title	RSV-A neutralizing titers for infant participants at Day 121 post-birth[68]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. Analysis was performed on a sub-cohort from the Per Protocol Set Immunogenicity - Infant, which included the infant participants for whom blood samples were collected for the specified analysis at Day 121 post-birth.

End point type	Secondary

End point timeframe:

At Day 121 post-birth

Notes:

[68] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	3		
Units: Titers				
geometric mean (confidence interval 95%)	607.9 (0.28 to 1322707.87)	94.1 (68.10 to 130.08)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing titers for infant participants at Day 181 post-birth

End point title	RSV-A neutralizing titers for infant participants at Day 181 post-birth[69]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. Analysis was performed on a sub-cohort from the Per Protocol Set Immunogenicity - Infant, which included the infant participants for whom blood samples were collected for the specified analysis at Day 181 post-birth. There was only one participant in the Control Group - Infant for whom blood sample was collected, hence the 95% confidence interval (CI) associated with geometric mean could not be calculated for single participant, and therefore the low value of the confidence interval was entered as "0" and the high value of the confidence interval was entered as "115".

End point type	Secondary

End point timeframe:

At Day 181 post-birth

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: Titers				
geometric mean (confidence interval 95%)	755 (0.45 to 1262151.64)	115 (0 to 115)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing titers for infant participants at Day 121 post-birth

End point title	RSV-B neutralizing titers for infant participants at Day 121 post-birth[70]

End point description:

RSV-B neutralizing titers were determined by neutralization assay and expressed as GMTs. Analysis was performed on a sub-cohort from the Per Protocol Set Immunogenicity - Infant, which included the infant participants for whom blood samples were collected for the specified analysis at Day 121 post-birth.

End point type	Secondary

End point timeframe:

At Day 121 post-birth

Notes:

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	3		
Units: Titers				
geometric mean (confidence interval 95%)	622.7 (2.98 to 129923.70)	54.9 (27.69 to 108.83)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing titers for infant participants at Day 181 post-birth

End point title	RSV-B neutralizing titers for infant participants at Day 181 post-birth[71]

End point description:

RSV-B neutralizing titers were determined by neutralization assay and expressed as GMTs. Analysis was performed on a sub-cohort from the Per Protocol Set Immunogenicity - Infant, which included the infant participants for whom blood samples were collected for the specified analysis at Day 181 post-birth. There was only one participant in the Control Group - Infant for whom blood sample was collected, hence the 95% confidence interval (CI) associated with geometric mean could not be calculated for single participant, and therefore the low value of the confidence interval was entered as "0" and the high value of the confidence interval was entered as "63".

End point type	Secondary

End point timeframe:

At Day 181 post-birth

Notes:

[71] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the infants born to maternal participants.

End point values	RSV_MAT Group-Infant	Control Group-Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: Titers				
geometric mean (confidence interval 95%)	327.9 (6.57 to 16367.16)	63 (0 to 63)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Maternal groups: Solicited AEs -from Day 1 to Day 7 (included), Unsolicited AEs -from Day 1 to Day 30 (included) after vaccination. SAEs -from Day 1 up to 180 days post-delivery. Infant groups: SAEs & non-serious AEs -from birth up to 365 days post-birth.

Adverse event reporting additional description:

"Death neonatal" is considered a serious adverse event for the Control Group-Mother, since the death did not occur from a study pregnancy, but from a subsequent pregnancy. Therefore, due to the fact that the neonate was not considered a study participant, the "death neonatal" event was captured under maternal SAEs.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	RSV_MAT Group-Mother

Reporting group description:

Maternal participants randomized to the RSV_MAT Group received a single dose of the RSV MAT vaccine administered, between 24 and 36 weeks of gestation, at Day 1 in this study.

Reporting group title	Control Group-Infant

Reporting group description:

This group consisted of infants born to mothers (from Control Group-Mother) who received a single dose of placebo during pregnancy.

Reporting group title	RSV_MAT Group-Infant

Reporting group description:

This group consisted of infants born to mothers (from RSV_MAT Group-Mother) who received a single dose of RSV MAT vaccine during pregnancy.

Reporting group title	Control Group-Mother

Reporting group description:

Maternal participants randomized to the Control Group received a single dose of Placebo administered, between 24 and 36 weeks of gestation, at Day 1 in this study.

Serious adverse events	RSV_MAT Group-Mother	Control Group-Infant	RSV_MAT Group-Infant
Total subjects affected by serious adverse events			
subjects affected / exposed	33 / 113 (29.20%)	21 / 66 (31.82%)	35 / 132 (26.52%)
number of deaths (all causes)	0	1	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neuroblastoma			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	2 / 113 (1.77%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Medically induced preterm birth			
subjects affected / exposed	3 / 113 (2.65%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Foetal dystocia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal distress syndrome			
subjects affected / exposed	2 / 113 (1.77%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed induction of labour			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalo-pelvic disproportion			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breech delivery			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Low birth weight baby			
subjects affected / exposed	0 / 113 (0.00%)	4 / 66 (6.06%)	8 / 132 (6.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice neonatal			
subjects affected / exposed	0 / 113 (0.00%)	7 / 66 (10.61%)	5 / 132 (3.79%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intrapartum haemorrhage			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oligohydramnios			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	2 / 113 (1.77%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			
subjects affected / exposed	4 / 113 (3.54%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 113 (0.00%)	5 / 66 (7.58%)	14 / 132 (10.61%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	7 / 113 (6.19%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum haemorrhage			

subjects affected / exposed	4 / 113 (3.54%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placenta praevia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retained placenta or membranes			
subjects affected / exposed	2 / 113 (1.77%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small for dates baby			
subjects affected / exposed	0 / 113 (0.00%)	4 / 66 (6.06%)	3 / 132 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasa praevia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical cord prolapse			
subjects affected / exposed	3 / 113 (2.65%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Threatened labour			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superimposed pre-eclampsia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death neonatal			

subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Pyrexia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ABO incompatibility			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Meconium aspiration syndrome			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary dysplasia			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary hypertension			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	4 / 132 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	5 / 132 (3.79%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Neonatal respiratory distress			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	3 / 132 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal tachypnoea			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Foetal monitoring abnormal			
subjects affected / exposed	2 / 113 (1.77%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Medical observation			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Fibromatosis colli of infancy			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma congenital			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Newborn persistent pulmonary hypertension			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytogenetic abnormality			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital inguinal hernia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital arterial malformation			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial septal defect			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pectus excavatum			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankyloglossia congenital			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary valve stenosis congenital			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	2 / 132 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia foetal			
subjects affected / exposed	2 / 113 (1.77%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary valve stenosis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal heart rate deceleration abnormality			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tachycardia foetal			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Poor sucking reflex			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Dysphagia			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	2 / 132 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Dysentery			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida sepsis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis neonatal			
subjects affected / exposed	0 / 113 (0.00%)	3 / 66 (4.55%)	6 / 132 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sepsis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural cellulitis			

subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	3 / 132 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 113 (0.88%)	1 / 66 (1.52%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometritis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	3 / 132 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Control Group-Mother		
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 56 (19.64%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neuroblastoma			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Medically induced preterm birth			
subjects affected / exposed	2 / 56 (3.57%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Foetal dystocia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal distress syndrome			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failed induction of labour			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cephalo-pelvic disproportion			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gestational hypertension			

subjects affected / exposed	2 / 56 (3.57%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Breech delivery				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Low birth weight baby				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice neonatal				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intrapartum haemorrhage				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oligohydramnios				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Preterm premature rupture of membranes				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Premature labour				
subjects affected / exposed	2 / 56 (3.57%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Premature baby				

subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pre-eclampsia				
subjects affected / exposed	2 / 56 (3.57%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Postpartum haemorrhage				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Placenta praevia				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Retained placenta or membranes				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small for dates baby				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vasa praevia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical cord prolapse				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Threatened labour				

subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Superimposed pre-eclampsia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Death neonatal				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
ABO incompatibility				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Meconium aspiration syndrome				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				

subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopulmonary dysplasia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Apnoea				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary hypertension				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient tachypnoea of the newborn				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal respiratory distress syndrome				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal respiratory distress				

subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal tachypnoea				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Foetal monitoring abnormal				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Medical observation				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Fibromatosis colli of infancy				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemangioma congenital				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Newborn persistent pulmonary hypertension				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytogenetic abnormality				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Congenital inguinal hernia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital arterial malformation				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial septal defect				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pectus excavatum				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankyloglossia congenital				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary valve stenosis congenital				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular septal defect				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Bradycardia foetal				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia				

subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary valve stenosis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foetal heart rate deceleration abnormality				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia foetal				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Poor sucking reflex				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Normochromic normocytic anaemia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Dysphagia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intussusception				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis acute				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia neonatal				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Dysentery				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Candida sepsis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Sepsis neonatal				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural cellulitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometritis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchiolitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Hypoglycaemia neonatal				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				

subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	RSV_MAT Group-Mother	Control Group-Infant	RSV_MAT Group-Infant
Total subjects affected by non-serious adverse events			
subjects affected / exposed	89 / 113 (78.76%)	57 / 66 (86.36%)	118 / 132 (89.39%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Medically induced preterm birth			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Labial frenectomy			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Pregnancy, puerperium and perinatal conditions			
Premature labour			
subjects affected / exposed	2 / 113 (1.77%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	2	0	0
Postpartum haemorrhage			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Uterine atony			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
False labour			

subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Foetal hypokinesia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Gestational diabetes			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Gestational hypertension			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Pre-eclampsia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Foetal growth restriction			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Small for dates baby			
subjects affected / exposed	0 / 113 (0.00%)	14 / 66 (21.21%)	16 / 132 (12.12%)
occurrences (all)	0	14	16
Low birth weight baby			
subjects affected / exposed	0 / 113 (0.00%)	10 / 66 (15.15%)	17 / 132 (12.88%)
occurrences (all)	0	10	17
Premature baby			
subjects affected / exposed	0 / 113 (0.00%)	8 / 66 (12.12%)	10 / 132 (7.58%)
occurrences (all)	0	8	10
Jaundice neonatal			
subjects affected / exposed	0 / 113 (0.00%)	3 / 66 (4.55%)	7 / 132 (5.30%)
occurrences (all)	0	3	7
Cephalhaematoma			
subjects affected / exposed	0 / 113 (0.00%)	3 / 66 (4.55%)	0 / 132 (0.00%)
occurrences (all)	0	3	0
Shoulder dystocia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Large for dates baby			

subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	2 / 132 (1.52%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	32 / 113 (28.32%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	32	0	0
Administration site erythema			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Administration site swelling			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Administration site pain			
subjects affected / exposed	50 / 113 (44.25%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	50	0	0
Developmental delay			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Crying			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	2 / 132 (1.52%)
occurrences (all)	0	2	4
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Milk allergy			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			

Breast pain			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Testicular swelling			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Balanoposthitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Respiratory distress			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Meconium aspiration syndrome			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Bronchospasm			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Respiratory disorder			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	1 / 132 (0.76%)
occurrences (all)	0	2	1
Rhinorrhoea			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	3 / 132 (2.27%)
occurrences (all)	0	2	4
Cough			
subjects affected / exposed	0 / 113 (0.00%)	6 / 66 (9.09%)	2 / 132 (1.52%)
occurrences (all)	0	7	2
Nasal congestion			

subjects affected / exposed	0 / 113 (0.00%)	9 / 66 (13.64%)	15 / 132 (11.36%)
occurrences (all)	0	10	16
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Investigations			
Haematocrit decreased			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Haemoglobin decreased			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Cardiac murmur			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	2 / 132 (1.52%)
occurrences (all)	0	1	2
Body height below normal			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Breath sounds abnormal			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Seroma			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Concussion			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Post procedural complication			

subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
Congenital central nervous system anomaly			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Congenital umbilical hernia			
subjects affected / exposed	0 / 113 (0.00%)	4 / 66 (6.06%)	4 / 132 (3.03%)
occurrences (all)	0	4	4
Ankyloglossia congenital			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	4 / 132 (3.03%)
occurrences (all)	0	0	4
Congenital skin dimples			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Cryptorchism			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Haemangioma congenital			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Naevus flammeus			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Patent ductus arteriosus			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Talipes			

subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Congenital inguinal hernia			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	46 / 113 (40.71%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	46	0	0
Migraine			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Hypotonia			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Intraventricular haemorrhage neonatal			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Anaemia			
subjects affected / exposed	1 / 113 (0.88%)	1 / 66 (1.52%)	1 / 132 (0.76%)
occurrences (all)	1	1	1
Hypochromic anaemia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			

Cerumen impaction			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Dacryostenosis acquired			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Retinopathy of prematurity			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	23 / 113 (20.35%)	0 / 66 (0.00%)	2 / 132 (1.52%)
occurrences (all)	23	0	2
Nausea			
subjects affected / exposed	28 / 113 (24.78%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	28	0	0
Diarrhoea			
subjects affected / exposed	23 / 113 (20.35%)	1 / 66 (1.52%)	6 / 132 (4.55%)
occurrences (all)	24	1	6
Vomiting			
subjects affected / exposed	9 / 113 (7.96%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	9	1	0
Dyspepsia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Umbilical hernia			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Stomatitis			

subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Regurgitation			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	2	0
Eructation			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	1 / 132 (0.76%)
occurrences (all)	0	1	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 113 (0.00%)	4 / 66 (6.06%)	2 / 132 (1.52%)
occurrences (all)	0	4	2
Constipation			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	6 / 132 (4.55%)
occurrences (all)	0	1	9
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	2 / 132 (1.52%)
occurrences (all)	0	1	2
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	1 / 132 (0.76%)
occurrences (all)	0	1	1
Prurigo			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	2 / 132 (1.52%)
occurrences (all)	0	2	2
Dermatitis atopic			

subjects affected / exposed	0 / 113 (0.00%)	4 / 66 (6.06%)	0 / 132 (0.00%)
occurrences (all)	0	6	0
Eczema			
subjects affected / exposed	0 / 113 (0.00%)	4 / 66 (6.06%)	3 / 132 (2.27%)
occurrences (all)	0	4	4
Miliaria			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	8 / 132 (6.06%)
occurrences (all)	0	2	8
Dermatitis diaper			
subjects affected / exposed	0 / 113 (0.00%)	7 / 66 (10.61%)	10 / 132 (7.58%)
occurrences (all)	0	11	11
Acne infantile			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Blister			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Cafe au lait spots			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Intertrigo			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	2 / 132 (1.52%)
occurrences (all)	0	2	2
Urticaria			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1

Renal and urinary disorders			
Nephrocalcinosis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Acquired plagiocephaly			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	0 / 132 (0.00%)
occurrences (all)	0	2	0
Joint laxity			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Joint noise			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	3 / 113 (2.65%)	20 / 66 (30.30%)	38 / 132 (28.79%)
occurrences (all)	3	83	123
COVID-19			
subjects affected / exposed	5 / 113 (4.42%)	4 / 66 (6.06%)	4 / 132 (3.03%)
occurrences (all)	5	4	4
Urinary tract infection			
subjects affected / exposed	2 / 113 (1.77%)	1 / 66 (1.52%)	1 / 132 (0.76%)
occurrences (all)	2	1	1
Nasopharyngitis			
subjects affected / exposed	1 / 113 (0.88%)	11 / 66 (16.67%)	25 / 132 (18.94%)
occurrences (all)	1	24	62

Respiratory tract infection			
subjects affected / exposed	2 / 113 (1.77%)	1 / 66 (1.52%)	3 / 132 (2.27%)
occurrences (all)	2	1	3
Bacterial disease carrier			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Mastitis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 113 (0.88%)	7 / 66 (10.61%)	15 / 132 (11.36%)
occurrences (all)	1	11	17
Sinusitis			
subjects affected / exposed	1 / 113 (0.88%)	2 / 66 (3.03%)	0 / 132 (0.00%)
occurrences (all)	1	2	0
Vaginal infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 113 (0.00%)	4 / 66 (6.06%)	6 / 132 (4.55%)
occurrences (all)	0	4	6
Bronchiolitis			
subjects affected / exposed	0 / 113 (0.00%)	7 / 66 (10.61%)	22 / 132 (16.67%)
occurrences (all)	0	10	29
Lower respiratory tract infection			
subjects affected / exposed	0 / 113 (0.00%)	9 / 66 (13.64%)	6 / 132 (4.55%)
occurrences (all)	0	10	8
Rhinitis			
subjects affected / exposed	0 / 113 (0.00%)	3 / 66 (4.55%)	10 / 132 (7.58%)
occurrences (all)	0	5	10
Conjunctivitis			
subjects affected / exposed	0 / 113 (0.00%)	4 / 66 (6.06%)	4 / 132 (3.03%)
occurrences (all)	0	5	4

Pharyngotonsillitis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	1 / 132 (0.76%)
occurrences (all)	0	1	1
Oral candidiasis			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	6 / 132 (4.55%)
occurrences (all)	0	2	8
Suspected COVID-19			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	5 / 132 (3.79%)
occurrences (all)	0	2	5
Otitis media acute			
subjects affected / exposed	0 / 113 (0.00%)	3 / 66 (4.55%)	3 / 132 (2.27%)
occurrences (all)	0	3	3
Bronchitis			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	3 / 132 (2.27%)
occurrences (all)	0	2	4
Influenza			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	3 / 132 (2.27%)
occurrences (all)	0	1	3
Fungal skin infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	3 / 132 (2.27%)
occurrences (all)	0	0	3
Impetigo			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	3 / 132 (2.27%)
occurrences (all)	0	0	3
Pneumonia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	3 / 132 (2.27%)
occurrences (all)	0	0	3
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	1 / 132 (0.76%)
occurrences (all)	0	2	1
Candida nappy rash			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	2 / 132 (1.52%)
occurrences (all)	0	0	2
Epstein-Barr virus infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	2 / 132 (1.52%)
occurrences (all)	0	0	2

Gastroenteritis viral			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	2 / 132 (1.52%)
occurrences (all)	0	0	2
Laryngitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	2 / 132 (1.52%)
occurrences (all)	0	0	2
Ear infection			
subjects affected / exposed	0 / 113 (0.00%)	3 / 66 (4.55%)	5 / 132 (3.79%)
occurrences (all)	0	3	8
Tracheobronchitis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	1 / 132 (0.76%)
occurrences (all)	0	1	1
Pulmonary tuberculosis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Acute sinusitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Body tinea			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Bullous impetigo			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Candida infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Coxsackie viral infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Dacryocystitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Eye infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1

Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Norovirus infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Ophthalmia neonatorum			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Postoperative wound infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	2
Acarodermatitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Pyelonephritis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Pyoderma			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Rhinovirus infection			

subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Skin candida			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Typhoid fever			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Varicella			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Underweight			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Lactose intolerance			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	1 / 132 (0.76%)
occurrences (all)	0	0	1
Weight gain poor			

subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	2 / 132 (1.52%)
occurrences (all)	0	0	2
Failure to thrive			
subjects affected / exposed	0 / 113 (0.00%)	1 / 66 (1.52%)	1 / 132 (0.76%)
occurrences (all)	0	1	1
Hypoglycaemia			
subjects affected / exposed	0 / 113 (0.00%)	2 / 66 (3.03%)	4 / 132 (3.03%)
occurrences (all)	0	2	4

Non-serious adverse events	Control Group-Mother		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 56 (67.86%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Surgical and medical procedures			
Medically induced preterm birth			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Labial frenectomy			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
Premature labour			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Postpartum haemorrhage			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Uterine atony			

subjects affected / exposed	2 / 56 (3.57%)			
occurrences (all)	2			
False labour				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Foetal hypokinesia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Gestational diabetes				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Gestational hypertension				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences (all)	1			
Pre-eclampsia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Foetal growth restriction				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Small for dates baby				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Low birth weight baby				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Premature baby				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Jaundice neonatal				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Cephalhaematoma				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Shoulder dystocia				

subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Large for dates baby			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	15 / 56 (26.79%)		
occurrences (all)	15		
Administration site erythema			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Administration site swelling			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Injection site bruising			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Administration site pain			
subjects affected / exposed	8 / 56 (14.29%)		
occurrences (all)	8		
Developmental delay			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Crying			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Milk allergy			

subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Testicular swelling			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Balanoposthitis			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Rhinitis allergic			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Respiratory distress			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Meconium aspiration syndrome			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Bronchospasm			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Respiratory disorder			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Cough			

subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Investigations			
Haematocrit decreased			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Haemoglobin decreased			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Cardiac murmur			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Body height below normal			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Breath sounds abnormal			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Seroma			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Clavicle fracture			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Concussion			

subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Post procedural complication			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
Congenital central nervous system anomaly			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Congenital umbilical hernia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Ankyloglossia congenital			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Congenital skin dimples			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Cryptorchism			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Haemangioma congenital			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Naevus flammeus			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Patent ductus arteriosus			

subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Talipes			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Congenital inguinal hernia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	21 / 56 (37.50%)		
occurrences (all)	21		
Migraine			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Hypotonia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Intraventricular haemorrhage neonatal			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Hypochromic anaemia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Normochromic normocytic anaemia			

subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Ear pain			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dacryostenosis acquired			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Retinopathy of prematurity			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	10 / 56 (17.86%)		
occurrences (all)	10		
Nausea			
subjects affected / exposed	11 / 56 (19.64%)		
occurrences (all)	11		
Diarrhoea			
subjects affected / exposed	4 / 56 (7.14%)		
occurrences (all)	4		
Vomiting			
subjects affected / exposed	11 / 56 (19.64%)		
occurrences (all)	11		
Dyspepsia			
subjects affected / exposed	2 / 56 (3.57%)		
occurrences (all)	2		
Haemorrhoids			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Umbilical hernia			

subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Stomatitis subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Regurgitation subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Eructation subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Flatulence subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Constipation subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Hepatobiliary disorders Cholestasis subjects affected / exposed occurrences (all)	1 / 56 (1.79%) 1		
Hyperbilirubinaemia neonatal subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Skin and subcutaneous tissue disorders Dermatitis subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Prurigo subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Rash			

subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Dermatitis atopic				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Eczema				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Miliaria				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Dermatitis diaper				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Acne infantile				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Blister				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Cafe au lait spots				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Dry skin				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Intertrigo				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Palmar-plantar erythrodysaesthesia syndrome				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Seborrhoeic dermatitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			

Urticaria			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Nephrocalcinosis			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Acquired plagiocephaly			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Joint laxity			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Joint noise			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	4 / 56 (7.14%)		
occurrences (all)	5		
COVID-19			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		

Nasopharyngitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Bacterial disease carrier				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences (all)	1			
Bacterial vaginosis				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences (all)	1			
Mastitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences (all)	1			
Sinusitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Vaginal infection				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences (all)	1			
Otitis media				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Bronchiolitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			

Conjunctivitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Pharyngotonsillitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Oral candidiasis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Suspected COVID-19				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Otitis media acute				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Bronchitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Fungal skin infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Impetigo				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Viral upper respiratory tract infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Candida nappy rash				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			

Epstein-Barr virus infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Gastroenteritis viral				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Laryngitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Ear infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Tracheobronchitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Pulmonary tuberculosis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Acute sinusitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Body tinea				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Bullous impetigo				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Candida infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Coxsackie viral infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Dacryocystitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			

Eye infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Hand-foot-and-mouth disease				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Lower respiratory tract infection viral				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Norovirus infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Ophthalmia neonatorum				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Postoperative wound infection				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Acarodermatitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Pyelonephritis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Pyoderma				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	0 / 56 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus infection				

subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Rhinovirus infection			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Skin candida			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Subcutaneous abscess			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Typhoid fever			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Varicella			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Viral infection			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Underweight			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Lactose intolerance			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Hypoglycaemia neonatal			

subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Weight gain poor			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Failure to thrive			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Hypoglycaemia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 March 2022	Following a recommendation from the Independent Data Monitoring Committee of NCT04605159 (RSV MAT 009), GSK made the decision to stop enrolment and vaccination in the study. Ongoing participants at that time continued to be monitored as part of the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported