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	v1
This version publication date	14 December 2023
First version publication date	14 December 2023

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 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 unsolicited adverse events (AEs)

End point title	Percentage of maternal participants reporting any unsolicited adverse events (AEs)[5][6]

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:

[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%)	34.5 (25.8 to 44.0)	37.5 (24.9 to 51.5)		

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[7][8]

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

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

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 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%)				
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 >= ONE 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[9][10]

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

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: 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 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[11][12]

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

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 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: 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[13][14]

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

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: Participants	0	0		

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

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

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

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 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[21][22]

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

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%)	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[23][24]

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:

[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: 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 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[25][26]

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

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: Participants	0	0		

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[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 42 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%)	20.5 (13.9 to 28.3)	27.3 (17.0 to 39.6)		

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[29][30]

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:

[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: 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[31][32]

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:

[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%)	26.5 (19.2 to 34.9)	31.8 (20.9 to 44.4)		

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[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 180 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%)	77.3 (69.2 to 84.1)	69.7 (57.1 to 80.4)		

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[35][36]

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:

[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: Participants	0	0		

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[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 180 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: 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[39]

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:

[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.

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-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)[40][41]

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:

[40] - 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.
[41] - 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 MAT IgG-specific antibody concentrations for maternal participants at delivery

End point title	RSV MAT IgG-specific antibody concentrations for maternal participants at delivery[42][43]

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:

[42] - 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.
[43] - 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 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)[44][45]

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:

[44] - 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.
[45] - 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 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:

[46] - 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.
[47] - 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-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[48][49]

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:

[48] - 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.
[49] - 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: 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: 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[52]

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:

[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: 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: 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[53]

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:

[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: Participants	0	0		

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: 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[57]

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:

[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 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: 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[58]

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:

[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%)	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[59]

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:

[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 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-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 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 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[62]

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:

[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	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 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[63]

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:

[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	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 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-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[65]

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:

[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	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-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[66]

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:

[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	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[67]

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:

[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	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-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-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[69]

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:

[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%)	327.9 (6.57 to 16367.16)	63 (0 to 63)		

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[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 43 post-birth.

End point type	Secondary

End point timeframe:

At Day 43 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	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-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[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 121 post-birth.

End point type	Secondary

End point timeframe:

At Day 121 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	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

Adverse events

Adverse events information

Timeframe for reporting adverse events:

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

Adverse event reporting additional description:

Infants born to vaccinated mothers were only monitored for AESIs and MAEs. These results are presented in the outcome measures section. Post-vaccination solicited and unsolicited AEs were not collected for infants, as they were not vaccinated in this study.

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	0	0	0
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			
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
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
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
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
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

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
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
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
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
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
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
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
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
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
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			
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
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
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
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
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

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 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
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
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
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
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
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
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
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
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
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
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
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

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
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
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			
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
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
Gastrointestinal disorders			
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
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
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
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
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			
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
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
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
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
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
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
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
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
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
Metabolism and nutrition disorders			
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
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

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	0		

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			
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		
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		
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		
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			
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			
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			
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			
Oligohydramnios				
subjects affected / exposed	1 / 56 (1.79%)			
occurrences causally related to treatment / all	0 / 1			
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			
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			
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		
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		
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		
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		
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			
Apnoea			
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		
Bronchospasm			

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			
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			
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 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			
Pneumothorax				
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			
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			
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			
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			
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			
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			
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			

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

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			
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			
Dysphagia				
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				
Gastroenteritis				
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			
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			
Bronchiolitis				
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			
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			
Sepsis				
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			
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			
Metabolism and nutrition disorders				
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		
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		

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%)	0 / 66 (0.00%)	0 / 132 (0.00%)
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
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
Pre-eclampsia			
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
Gestational diabetes			
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
Foetal growth restriction			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
False labour			
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
Postpartum haemorrhage			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
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
Fatigue			
subjects affected / exposed	32 / 113 (28.32%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	32	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
Injection site bruising			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
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
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
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Investigations			
Haemoglobin decreased			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Haematocrit decreased			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
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
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
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
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	9 / 113 (7.96%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	9	0	0
Nausea			
subjects affected / exposed	28 / 113 (24.78%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	28	0	0
Abdominal pain			
subjects affected / exposed	23 / 113 (20.35%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	23	0	0
Diarrhoea			
subjects affected / exposed	23 / 113 (20.35%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	24	0	0
Haemorrhoids			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
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
Infections and infestations			
Mastitis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 113 (2.65%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	3	0	0
COVID-19			
subjects affected / exposed	5 / 113 (4.42%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	5	0	0
Urinary tract infection			
subjects affected / exposed	2 / 113 (1.77%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	2	0	0
Gastroenteritis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	2 / 113 (1.77%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	2	0	0
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
Vaginal infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 66 (0.00%)	0 / 132 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Control Group-Mother		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 56 (67.86%)		
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		
Pregnancy, puerperium and perinatal conditions			
Premature labour			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Pre-eclampsia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Gestational hypertension			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Gestational diabetes			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Foetal hypokinesia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Foetal growth restriction			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
False labour			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Uterine atony			

subjects affected / exposed	2 / 56 (3.57%)		
occurrences (all)	2		
Postpartum haemorrhage			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
General disorders and administration site conditions			
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		
Fatigue			
subjects affected / exposed	15 / 56 (26.79%)		
occurrences (all)	15		
Administration site pain			
subjects affected / exposed	8 / 56 (14.29%)		
occurrences (all)	8		
Injection site bruising			
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		
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Investigations			

Haemoglobin decreased subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Haematocrit decreased subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Injury, poisoning and procedural complications Seroma subjects affected / exposed occurrences (all)	1 / 56 (1.79%) 1		
Congenital, familial and genetic disorders Congenital central nervous system anomaly subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	21 / 56 (37.50%) 21		
Migraine subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 56 (1.79%) 1		
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all)	11 / 56 (19.64%) 11		

Nausea subjects affected / exposed occurrences (all)	11 / 56 (19.64%) 11		
Abdominal pain subjects affected / exposed occurrences (all)	10 / 56 (17.86%) 10		
Diarrhoea subjects affected / exposed occurrences (all)	4 / 56 (7.14%) 4		
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Dyspepsia subjects affected / exposed occurrences (all)	2 / 56 (3.57%) 2		
Hepatobiliary disorders Cholestasis subjects affected / exposed occurrences (all)	1 / 56 (1.79%) 1		
Musculoskeletal and connective tissue disorders Pain in extremity subjects affected / exposed occurrences (all)	1 / 56 (1.79%) 1		
Neck pain subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Back pain subjects affected / exposed occurrences (all)	1 / 56 (1.79%) 1		
Infections and infestations Mastitis subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	4 / 56 (7.14%) 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		
Gastroenteritis			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
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		
Vaginal infection			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
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