



Clinical trial results:

A Phase II, randomised, observer-blind, placebo controlled multi-country study to assess the safety, reactogenicity and immunogenicity of a single intramuscular dose of GSK Biologicals' investigational RSV Maternal unadjuvanted vaccine (GSK3888550A), in healthy pregnant women aged 18 to 40 years and infants born to vaccinated mothers

Summary

EudraCT number	2019-001991-12
Trial protocol	FI FR GB ES
Global end of trial date	14 May 2021

Results information

Result version number	v1 (current)
This version publication date	29 November 2021
First version publication date	29 November 2021

Trial information

Trial identification

Sponsor protocol code	209544
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04126213
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 September 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 July 2020
Global end of trial reached?	Yes
Global end of trial date	14 May 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the safety and immune response to a single intramuscular (IM) dose of GSK Biologicals' investigational RSV maternal vaccine (RSVPreF3) in healthy pregnant women 18-40 years of age and in infants born to vaccinated mothers.

Protection of trial subjects:

Maternal subjects were observed closely for at least 60 minutes after administration of the study vaccine/product. Appropriate medical treatment was readily available in case of anaphylaxis and syncope. Vaccines were administered by qualified and trained personnel. Infants and mothers were kept under surveillance and evaluation through 12 and 6 months post- delivery, respectively.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 November 2019
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	Australia: 16
Country: Number of subjects enrolled	Canada: 11
Country: Number of subjects enrolled	Finland: 34
Country: Number of subjects enrolled	France: 6
Country: Number of subjects enrolled	New Zealand: 39
Country: Number of subjects enrolled	Panama: 72
Country: Number of subjects enrolled	South Africa: 13
Country: Number of subjects enrolled	Spain: 59
Country: Number of subjects enrolled	United States: 284
Worldwide total number of subjects	534
EEA total number of subjects	99

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	8

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	198
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	328
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 42 centers in 9 countries (Australia, Canada, Finland, France, New Zealand, Panama, South Africa, Spain, United States).

Pre-assignment

Screening details:

Out of 534 participants who signed the informed consent 213 maternal subjects were vaccinated, and 206 infants were born to those exposed mothers. Therefore, a total of 419 are considered exposed.

Period 1

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

Blinding implementation details:

The overall study design was observer-blind. The study staff administering the vaccine was unblinded.

Arms

Are arms mutually exclusive?	Yes
Arm title	RSV MAT 60 Group-Mother

Arm description:

Maternal subjects randomized to RSV MAT 60 Group received a single dose of RSV MAT (60 µg) vaccine at Day 1, and were followed up until the study end.

Arm type	Experimental
Investigational medicinal product name	RSV MAT 60 µg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection, Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One single dose of RSV MAT 60 µg vaccine administered intramuscularly in the deltoid region of the non-dominant arm on Day 1.

Arm title	RSV MAT 120 Group-Mother
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Arm description:

Maternal subjects randomized to RSV MAT 120 group received a single dose of RSV MAT (120 µg) vaccine at Day 1, and were followed up until the study end.

Arm type	Experimental
Investigational medicinal product name	RSV MAT 120 µg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection, Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One single dose of RSV MAT 120 µg vaccine administered intramuscularly in the deltoid region of the non-dominant arm on Day 1.

Arm title	Control Group-Mother
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Arm description:

Maternal subjects randomized to the Control Group received a single dose of Placebo at Day 1, and were followed up until the study end.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
One single dose of placebo (NaCl solution) administered intramuscularly in the deltoid region of the non-dominant arm on Day 1.	
Arm title	RSV MAT 60 Group-Infant
Arm description:	
This group consisted of infants born to mothers (from RSV MAT 60 Group-Mother) who received a single dose of RSV MAT (60 µg) vaccine during pregnancy.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	RSV MAT 120 Group-Infant
Arm description:	
This group consisted of infants born to mothers (from RSV MAT 120 Group-Mother) who received a single dose of RSV MAT (120 µg) 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 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother
Started	70	75	68
Completed	58	70	59
Not completed	12	5	9
Consent withdrawn by subject	3	2	1
MIGRATED / MOVED FROM THE STUDY AREA	-	2	1
Lost to follow-up	9	1	5
UNSPECIFIED	-	-	2

Number of subjects in period 1^[1]	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant
Started	67	73	66
Completed	54	67	55
Not completed	13	6	11
Consent withdrawn by subject	1	1	1
MIGRATED / MOVED FROM THE STUDY AREA	-	1	2

Lost to follow-up	10	4	7
UNSPECIFIED	2	-	1

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 534 participants who signed the informed consent 213 maternal subjects were vaccinated, and 206 infants were born to those exposed mothers. Therefore, a total of 419 are considered exposed.

Baseline characteristics

Reporting groups

Reporting group title	RSV MAT 60 Group-Mother
Reporting group description: Maternal subjects randomized to RSV MAT 60 Group received a single dose of RSV MAT (60 µg) vaccine at Day 1, and were followed up until the study end.	
Reporting group title	RSV MAT 120 Group-Mother
Reporting group description: Maternal subjects randomized to RSV MAT 120 group received a single dose of RSV MAT (120 µg) vaccine at Day 1, and were followed up until the study end.	
Reporting group title	Control Group-Mother
Reporting group description: Maternal subjects randomized to the Control Group received a single dose of Placebo at Day 1, and were followed up until the study end.	
Reporting group title	RSV MAT 60 Group-Infant
Reporting group description: This group consisted of infants born to mothers (from RSV MAT 60 Group-Mother) who received a single dose of RSV MAT (60 µg) vaccine during pregnancy.	
Reporting group title	RSV MAT 120 Group-Infant
Reporting group description: This group consisted of infants born to mothers (from RSV MAT 120 Group-Mother) who received a single dose of RSV MAT (120 µg) 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 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother
Number of subjects	70	75	68
Age Categorical Units: Participants			
0 to 1 years	0	0	0
18 < 35 years	59	62	56
>= 35 years	11	13	12
Sex: Female, Male Units: Participants			
Female	70	75	68
Male	0	0	0
Race/Ethnicity, Customized Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	0	2	0
ASIAN	0	0	2
BLACK OR AFRICAN AMERICAN	12	12	13
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	3	1	0
OTHER	10	10	7
UNKNOWN	0	2	1
WHITE	45	48	45

Reporting group values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant
Number of subjects	67	73	66
Age Categorical Units: Participants			
0 to 1 years	67	73	66
18 < 35 years	0	0	0
>= 35 years	0	0	0
Sex: Female, Male Units: Participants			
Female	28	30	37
Male	39	43	29
Race/Ethnicity, Customized Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	0	1	0
ASIAN	0	0	1
BLACK OR AFRICAN AMERICAN	12	9	9
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	3	2	1
OTHER	10	11	8
UNKNOWN	0	1	1
WHITE	42	49	46

Reporting group values	Total		
Number of subjects	419		
Age Categorical Units: Participants			
0 to 1 years	206		
18 < 35 years	177		
>= 35 years	36		
Sex: Female, Male Units: Participants			
Female	308		
Male	111		
Race/Ethnicity, Customized Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	3		
ASIAN	3		
BLACK OR AFRICAN AMERICAN	67		
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	10		
OTHER	56		
UNKNOWN	5		
WHITE	275		

End points

End points reporting groups

Reporting group title	RSV MAT 60 Group-Mother
Reporting group description: Maternal subjects randomized to RSV MAT 60 Group received a single dose of RSV MAT (60 µg) vaccine at Day 1, and were followed up until the study end.	
Reporting group title	RSV MAT 120 Group-Mother
Reporting group description: Maternal subjects randomized to RSV MAT 120 group received a single dose of RSV MAT (120 µg) vaccine at Day 1, and were followed up until the study end.	
Reporting group title	Control Group-Mother
Reporting group description: Maternal subjects randomized to the Control Group received a single dose of Placebo at Day 1, and were followed up until the study end.	
Reporting group title	RSV MAT 60 Group-Infant
Reporting group description: This group consisted of infants born to mothers (from RSV MAT 60 Group-Mother) who received a single dose of RSV MAT (60 µg) vaccine during pregnancy.	
Reporting group title	RSV MAT 120 Group-Infant
Reporting group description: This group consisted of infants born to mothers (from RSV MAT 120 Group-Mother) who received a single dose of RSV MAT (120 µg) 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 60 Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: This group consisted of pairs of maternal subjects from RSV MAT 60- Mother Group and infant subjects from RSV MAT 60-Infants Group.	
Subject analysis set title	RSV MAT 120 Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: This group consisted of pairs of maternal subjects from RSV MAT 120- Mother Group and infant subjects from RSV MAT 120-Infants Group.	
Subject analysis set title	Control Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: This group consisted of pairs of maternal subjects from Control- Mother Group and infant subjects from Control-Infants Group.	

Primary: Percentage of maternal subjects with any solicited administration site events

End point title	Percentage of maternal subjects with any solicited administration site events ^{[1][2]}
End point description: Assessed solicited administration site events were pain, erythema and swelling. Any = occurrence of the symptom regardless of intensity grade. Any erythema and swelling symptom = symptom reported with a surface diameter greater than 0 millimeters.	
End point type	Primary
End point timeframe: During the 7-day follow-up period after vaccination (i.e. day of vaccination and 6 subsequent days)	

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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	66	
Units: Percentage of maternal subjects				
number (confidence interval 95%)				
Any Pain (N=70,75,66)	57.1 (44.7 to 68.9)	52 (40.2 to 63.7)	15.2 (7.5 to 26.1)	
Any Erythema (N=70,75,66)	1.4 (0 to 7.7)	6.7 (2.2 to 14.9)	0 (0 to 5.4)	
Any Swelling (N=70,75,66)	4.3 (0.9 to 12)	4 (0.8 to 11.2)	0 (0 to 5.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal subjects with any solicited systemic events

End point title	Percentage of maternal subjects with any solicited systemic events ^[3] ^[4]
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End point description:

Assessed solicited systemic events were fatigue, headache, nausea, vomiting, diarrhea, abdominal pain and fever [temperature equal to or above ($\geq$) 38 degrees Celsius ($^{\circ}$ C)]. Any = occurrence of the symptom regardless of intensity grade or relation to study intervention.

End point type	Primary
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End point timeframe:

During the 7-day follow-up period after vaccination (i.e. day of vaccination and 6 subsequent days)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

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

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	66	
Units: Percentage of maternal subjects				
number (confidence interval 95%)				
Any Fatigue (N=70,75,66)	40 (28.5 to 52.4)	34.7 (24 to 46.5)	25.8 (15.8 to 38)	
Any Headache (N=70,75,66)	34.3 (23.3 to 46.6)	28 (18.2 to 39.6)	19.7 (10.9 to 31.3)	

Any Nausea (N=70,75,66)	25.7 (16 to 37.6)	22.7 (13.8 to 33.8)	13.6 (6.4 to 24.3)	
Any Vomiting (N=70,75,66)	7.1 (2.4 to 15.9)	9.3 (3.8 to 18.3)	4.5 (0.9 to 12.7)	
Any Diarrhea (N=70,75,66)	14.3 (7.1 to 24.7)	17.3 (9.6 to 27.8)	13.6 (6.4 to 24.3)	
Any Abdominal pain (N=70,75,66)	12.9 (6.1 to 23)	22.7 (13.8 to 33.8)	9.1 (3.4 to 18.7)	
Any Fever (N=70,75,66)	0 (0 to 5.1)	0 (0 to 4.8)	0 (0 to 5.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of maternal subjects with any haematological laboratory abnormalities at Day 8 by baseline ranges

End point title	Number of maternal subjects with any haematological laboratory abnormalities at Day 8 by baseline ranges ^{[5][6]}
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End point description:

[4:07 PM] Cornelia Ungurean

Hematological parameters assessed were Eosinophils (EOS), Erythrocytes (ERY), Hematocrit (HEM), Lymphocytes (LYMP), Mean Corpuscular Volume (MCV), Neutrophils (NEU), Platelets (PLA), and White Blood Cells (WBC) count. The increase and/or decrease of these parameters were evaluated at Day 8. Abnormal laboratory values refer to range indicator at Day 8 (D8) categorized as Missing, Below, Within and Above normal values and compared to the baseline (B) range indicator of the same parameter, at Screening (up to 15 days before vaccination) i.e. Missing, Below, Within and Above. E.g. 'WBC decrease Below (B) - Within (D8)' = WBC decrease in subjects with below normal values at baseline and within normal values at Day 8.

End point type	Primary
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End point timeframe:

At Day 8

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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Participants				
EOS Increase Below (B)-Below (D8) (N=70,75,68)	6	5	2	
EOS Increase Below (B)-Within (D8) (N=70,75,68)	6	2	4	
EOS Increase Below (B)-Above (D8) (N=70,75,68)	0	0	0	
EOS Increase Below (B)-Unknown (D8) (N=70,75,68)	0	0	1	
EOS Increase Within (B)-Below (D8) (N=70,75,68)	2	5	2	
EOS Increase Within (B)-Within (D8) (N=70,75,68)	53	58	56	

EOS Increase Within (B)-Above (D8) (N=70,75,68)	0	0	0	
EOS Increase Within (B)-Unknown (D8) (N=70,75,68)	2	3	1	
EOS Increase Above (B)-Below (D8) (N=70,75,68)	0	0	0	
EOS Increase Above (B)-Within (D8) (N=70,75,68)	0	1	0	
EOS Increase Above (B)-Above (D8) (N=70,75,68)	1	1	0	
EOS Increase, Above (B)-Unknown (D8) (N=70,75,68)	0	0	0	
EOS Increase Unknown (B)-Below (D8) (N=70,75,68)	0	0	0	
EOS Increase Unknown (B)-Within (D8) (N=70,75,68)	0	0	2	
EOS Increase Unknown (B)-Above (D8) (N=70,75,68)	0	0	0	
EOS Increase Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	
ERY Decrease, Below (B)-Below (D8)(N=70,75,68)	24	35	23	
ERY Decrease Below (B)-Within (D8)(N=70,75,68)	4	2	5	
ERY Decrease Below (B)-Above (D8)(N=70,75,68)	0	0	0	
ERY Decrease Below (B)-Unknown (D8)(N=70,75,68)	1	2	2	
ERY Decrease Within (B)-Below (D8)(N=70,75,68)	6	2	7	
ERY Decrease Within (B)-Within (D8)(N=70,75,68)	34	34	29	
ERY Decrease Within (B)-Above (D8)(N=70,75,68)	0	0	0	
ERY Decrease Within(B)-Unknown (D8)(N=70,75,68)	1	0	0	
ERY Decrease Above (B)-Below (D8)(N=70,75,68)	0	0	0	
ERY Decrease Above (B)-Within (D8)(N=70,75,68)	0	0	0	
ERY Decrease Above (B)-Above (D8)(N=70,75,68)	0	0	0	
ERY Decrease Above (B)-Unknown (D8)(N=70,75,68)	0	0	0	
ERY Decrease Unknown (B)-Below (D8)(N=70,75,68)	0	0	2	
ERY Decrease Unknown (B)-Within (D8)(N=70,75,68)	0	0	0	
ERY Decrease Unknown (B)-Above (D8)(N=70,75,68)	0	0	0	
ERY Decrease Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	
ERY Increase Below (B)-Below (D8) (N=70,75,68)	24	35	23	
ERY Increase Below (B)-Within (D8) (N=70,75,68)	4	2	5	
ERY Increase Below (B)-Above (D8) (N=70,75,68)	0	0	0	
ERY Increase Below (B)-Unknown (D8) (N=70,75,68)	1	2	2	
ERY Increase Within (B)-Below (D8) (N=70,75,68)	6	2	7	

ERY Increase Within (B)-Within (D8) (N=70,75,68)	34	34	29	
ERY Increase Within (B)-Above (D8) (N=70,75,68)	0	0	0	
ERY Increase Within (B)-Unknown (D8) (N=70,75,68)	1	0	0	
ERY Increase Above (B)-Below (D8) (N=70,75,68)	0	0	0	
ERY Increase Above (B)-Within (D8) (N=70,75,68)	0	0	0	
ERY Increase Above (B)-Above (D8) (N=70,75,68)	0	0	0	
ERY Increase Above (B)-Unknown (D8) (N=70,75,68)	0	0	0	
ERY Increase Unknown (B)-Below (D8)(N=70,75,68)	0	0	2	
ERY Increase Unknown (B)-Within (D8)(N=70,75,68)	0	0	0	
ERY Increase Unknown (B)-Above (D8)(N=70,75,68)	0	0	0	
ERY Increase Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	
HEM Decrease Below (B)-Below (D8)(N=70,75,68)	25	26	24	
HEM Decrease Below (B)-Within (D8)(N=70,75,68)	2	3	2	
HEM Decrease Below (B)-Above (D8)(N=70,75,68)	0	0	0	
HEM Decrease Below (B)-Unknown (D8)(N=70,75,68)	1	1	1	
HEM Decrease Within (B)-Below (D8)(N=70,75,68)	7	9	7	
HEM Decrease Within (B)-Within (D8)(N=70,75,68)	34	35	31	
HEM Decrease Within (B)-Above (D8)(N=70,75,68)	0	0	0	
HEM Decrease Within (B)-Unknown (D8)(N=70,75,68)	1	1	1	
HEM Decrease Above (B)-Below (D8)(N=70,75,68)	0	0	0	
HEM Decrease Above (B)-Within (D8)(N=70,75,68)	0	0	0	
HEM Decrease Above (B)-Above (D8)(N=70,75,68)	0	0	0	
HEM Decrease Above (B)-Unknown (D8)(N=70,75,68)	0	0	0	
HEM Decrease Unknown (B)-Below (D8)(N=70,75,68)	0	0	2	
HEM Decrease Unknown (B)-Within (D8)(N=70,75,68)	0	0	0	
HEM Decrease Unknown (B)-Above (D8)(N=70,75,68)	0	0	0	
HEM Decrease Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	
HEM Increase Below (B)-Below (D8) (N=70,75,68)	25	26	24	
HEM Increase Below (B)-Within (D8)(N=70,75,68)	2	3	2	
HEM Increase, Below (B)-Above (D8)(N=70,75,68)	0	0	0	
HEM Increase Below (B)-Unknown (D8)(N=70,75,68)	1	1	1	

HEM Increase Within (B)-Below (D8)(N=70,75,68)	7	9	7	
HEM Increase Within (B)-Within (D8)(N=70,75,68)	34	35	31	
HEM Increase Within (B)-Above (D8)(N=70,75,68)	0	0	0	
HEM Increase Within (B)-Unknown (D8)(N=70,75,68)	1	1	1	
HEM Increase Above (B)-Below (D8)(N=70,75,68)	0	0	0	
HEM Increase Above (B)-Within (D8)(N=70,75,68)	0	0	0	
HEM Increase Above (B)-Above (D8)(N=70,75,68)	0	0	0	
HEM Increase Above (B)-Unknown (D8)(N=70,75,68)	0	0	0	
HEM Increase Unknown (B)-Below (D8)(N=70,75,68)	0	0	2	
HEM Increase Unknown (B)-Within (D8)(N=70,75,68)	0	0	0	
HEM Increase Unknown (B)-Above (D8)(N=70,75,68)	0	0	0	
HEM Increase Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Below (B)-Below (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Below (B)-Within (D8)(N=70,75,68)	0	0	1	
LYMP Decrease Below (B)-Above (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Below (B)-Unknown (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Within (B)-Below (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Within (B)-Within (D8)(N=70,75,68)	68	72	63	
LYMP Decrease Within (B)-Above (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Within (B)-Unknown (D8)(N=70,75,68)	2	3	2	
LYMP Decrease Above (B)-Below (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Above (B)-Within (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Above (B)-Above (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Above (B)-Unknown (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Unknown (B)-Below (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Unknown (B)-Within (D8)(N=70,75,68)	0	0	2	
LYMP Decrease Unknown (B)-Above (D8)(N=70,75,68)	0	0	0	
LYMP Decrease Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	
LYMP Increase Below (B)-Below (D8)(N=70,75,68)	0	0	0	
LYMP Increase Below (B)-Within (D8)(N=70,75,68)	0	0	1	
LYMP Increase Below (B)-Above (D8)(N=70,75,68)	0	0	0	

LYMP Increase Below (B)-Unknown (D8)(N=70,75,68)	0	0	0
LYMP Increase Within (B)-Below (D8)(N=70,75,68)	0	0	0
LYMP Increase Within (B)-Within (D8)(N=70,75,68)	68	72	63
LYMP Increase Within (B)-Above (D8)(N=70,75,68)	0	0	0
LYMP Increase Within (B)-Unknown (D8)(N=70,75,68)	2	3	2
LYMP Increase Above (B)-Below (D8)(N=70,75,68)	0	0	0
LYMP Increase Above (B)-Within (D8)(N=70,75,68)	0	0	0
LYMP Increase Above (B)-Above (D8)(N=70,75,68)	0	0	0
LYMP Increase Above (B)-Unknown (D8)(N=70,75,68)	0	0	0
LYMP Increase Unknown (B)-Below (D8)(N=70,75,68)	0	0	0
LYMP Increase Unknown (B)-Within (D8)(N=70,75,68)	0	0	2
LYMP Increase Unknown (B)-Above (D8)(N=70,75,68)	0	0	0
LYMP Increase Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0
MCV Decrease Below (B)-Below (D8)(N=70,75,68)	2	1	1
MCV Decrease Below (B)-Within (D8)(N=70,75,68)	0	0	0
MCV Decrease Below (B)-Above (D8)(N=70,75,68)	0	0	0
MCV Decrease Below (B)-Unknown (D8)(N=70,75,68)	0	0	0
MCV Decrease Within (B)-Below (D8)(N=70,75,68)	0	0	1
MCV Decrease Within (B)-Within (D8)(N=70,75,68)	62	66	57
MCV Decrease Within (B)-Above (D8)(N=70,75,68)	2	2	1
MCV Decrease Within (B)-Unknown (D8)(N=70,75,68)	2	1	2
MCV Decrease Above (B)-Below (D8)(N=70,75,68)	0	0	0
MCV Decrease Above (B)-Within (D8)(N=70,75,68)	0	2	1
MCV Decrease Above (B)-Above (D8)(N=70,75,68)	2	2	3
MCV Decrease Above (B)-Unknown (D8)(N=70,75,68)	0	1	0
MCV Decrease Unknown (B)-Below (D8)(N=70,75,68)	0	0	0
MCV Decrease Unknown (B)-Within (D8)(N=70,75,68)	0	0	2
MCV Decrease Unknown (B)-Above (D8)(N=70,75,68)	0	0	0
MCV Decrease Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0
MCV Increase Below (B)-Below (D8)(N=70,75,68)	2	1	1
MCV Increase Below (B)-Within (D8)(N=70,75,68)	0	0	0

MCV Increase Below (B)-Above (D8)(N=70,75,68)	0	0	0	
MCV Increase Below (B)-Unknown (D8)(N=70,75,68)	0	0	0	
MCV Increase Within (B)-Below (D8)(N=70,75,68)	0	0	1	
MCV Increase Within (B)-Within (D8)(N=70,75,68)	62	66	57	
MCV Increase Within (B)-Above (D8)(N=70,75,68)	2	2	1	
MCV Increase Within (B)-Unknown (D8)(N=70,75,68)	2	1	2	
MCV Increase Above (B)-Below (D8)(N=70,75,68)	0	0	0	
MCV Increase Above (B)-Within (D8)(N=70,75,68)	0	2	1	
MCV Increase Above (B)-Above (D8)(N=70,75,68)	2	2	3	
MCV Increase Above (B)-Unknown (D8)(N=70,75,68)	0	1	0	
MCV Increase Unknown (B)-Below (D8)(N=70,75,68)	0	0	0	
MCV Increase Unknown (B)-Within (D8)(N=70,75,68)	0	0	2	
MCV Increase Unknown (B)-Above (D8)(N=70,75,68)	0	0	0	
MCV Increase Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	
NEU Decrease Below (B)-Below (D8)(N=70,75,68)	0	0	0	
NEU Decrease Below (B)-Within (D8)(N=70,75,68)	0	0	0	
NEU Decrease Below (B)-Above (D8)(N=70,75,68)	0	0	0	
NEU Decrease Below (B)-Unknown (D8)(N=70,75,68)	0	0	0	
NEU Decrease Within (B)-Below (D8)(N=70,75,68)	0	0	0	
NEU Decrease Within (B)-Within (D8)(N=70,75,68)	42	46	41	
NEU Decrease Within (B)-Above (D8)(N=70,75,68)	8	9	9	
NEU Decrease Within (B)-Unknown (D8)(N=70,75,68)	0	2	1	
NEU Decrease Above (B)-Below (D8)(N=70,75,68)	0	0	0	
NEU Decrease Above (B)-Within (D8)(N=70,75,68)	5	5	6	
NEU Decrease Above (B)-Above (D8)(N=70,75,68)	13	12	8	
NEU Decrease Above (B)-Unknown (D8)(N=70,75,68)	2	1	1	
NEU Decrease Unknown (B)-Below (D8)(N=70,75,68)	0	0	0	
NEU Decrease Unknown (B)-Within (D8)(N=70,75,68)	0	0	1	
NEU Decrease Unknown (B)-Above (D8)(N=70,75,68)	0	0	1	
NEU Decrease Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	
PLA Decrease Below (B)-Below (D8)(N=70,75,68)	0	0	0	

PLA Decrease Below (B)-Within (D8)(N=70,75,68)	1	1	0
PLA Decrease Below (B)-Above (D8)(N=70,75,68)	0	0	0
PLA Decrease Below (B)-Unknown (D8)(N=70,75,68)	0	0	0
PLA Decrease Within (B)-Below (D8)(N=70,75,68)	0	0	0
PLA Decrease Within (B)-Within (D8)(N=70,75,68)	67	72	63
PLA Decrease Within (B)-Above (D8)(N=70,75,68)	0	0	0
PLA Decrease Within (B)-Unknown (D8)(N=70,75,68)	2	2	2
PLA Decrease Above (B)-Below (D8)(N=70,75,68)	0	0	0
PLA Decrease Above (B)-Within (D8)(N=70,75,68)	0	0	1
PLA Decrease Above (B)-Above (D8)(N=70,75,68)	0	0	0
PLA Decrease Above (B)-Unknown (D8)(N=70,75,68)	0	0	0
PLA Decrease Unknown (B)-Below (D8)(N=70,75,68)	0	0	0
PLA Decrease Unknown (B)-Within (D8)(N=70,75,68)	0	0	2
PLA Decrease Unknown (B)-Above (D8)(N=70,75,68)	0	0	0
PLA Decrease Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0
PLA Increase Below (B)-Below (D8)(N=70,75,68)	0	0	0
PLA Increase Below (B)-Within (D8)(N=70,75,68)	1	1	0
PLA Increase Below (B)-Above (D8)(N=70,75,68)	0	0	0
PLA Increase Below (B)-Unknown (D8)(N=70,75,68)	0	0	0
PLA Increase Within (B)-Below (D8)(N=70,75,68)	0	0	0
PLA Increase Within (B)-Within (D8)(N=70,75,68)	67	72	63
PLA Increase Within (B)-Above (D8)(N=70,75,68)	0	0	0
PLA Increase Within (B)-Unknown (D8)(N=70,75,68)	2	2	2
PLA Increase Above (B)-Below (D8)(N=70,75,68)	0	0	0
PLA Increase Above (B)-Within (D8)(N=70,75,68)	0	0	1
PLA Increase Above (B)-Above (D8)(N=70,75,68)	0	0	0
PLA Increase Above (B)-Unknown (D8)(N=70,75,68)	0	0	0
PLA Increase Unknown (B)-Below (D8)(N=70,75,68)	0	0	0
PLA Increase Unknown (B)-Within (D8)(N=70,75,68)	0	0	2
PLA Increase Unknown (B)-Above (D8)(N=70,75,68)	0	0	0
PLA Increase Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0

WBC Decrease Below (B)-Below (D8)(N=70,75,68)	0	0	0
WBC Decrease Below (B)-Within (D8)(N=70,75,68)	0	0	0
WBC Decrease Below (B)-Above (D8)(N=70,75,68)	0	0	0
WBC Decrease Below (B)-Unknown (D8)(N=70,75,68)	0	0	0
WBC Decrease Within (B)-Below (D8)(N=70,75,68)	0	0	0
WBC Decrease Within (B)-Within (D8)(N=70,75,68)	46	48	46
WBC Decrease Within (B)-Above (D8)(N=70,75,68)	5	8	5
WBC Decrease Within (B)-Unknown (D8)(N=70,75,68)	1	1	2
WBC Decrease Above (B)-Below (D8)(N=70,75,68)	0	0	0
WBC Decrease Above (B)-Within (D8)(N=70,75,68)	3	5	3
WBC Decrease Above (B)-Above (D8)(N=70,75,68)	14	12	10
WBC Decrease Above (B)-Unknown (D8)(N=70,75,68)	1	1	0
WBC Decrease Unknown (B)-Below (D8)(N=70,75,68)	0	0	0
WBC Decrease Unknown (B)-Within (D8)(N=70,75,68)	0	0	1
WBC Decrease Unknown (B)-Above (D8)(N=70,75,68)	0	0	1
WBC Decrease Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0
WBC Increase Below (B)-Below (D8)(N=70,75,68)	0	0	0
WBC Increase Below (B)-Within (D8)(N=70,75,68)	0	0	0
WBC Increase Below (B)-Above (D8)(N=70,75,68)	0	0	0
WBC Increase Below (B)-Unknown (D8)(N=70,75,68)	0	0	0
WBC Increase Within (B)-Below (D8)(N=70,75,68)	0	0	0
WBC Increase Within (B)-Within (D8)(N=70,75,68)	46	48	46
WBC Increase Within (B)-Above (D8)(N=70,75,68)	5	8	5
WBC Increase Within (B)-Unknown (D8)(N=70,75,68)	1	1	2
WBC Increase Above (B)-Below (D8)(N=70,75,68)	0	0	0
WBC Increase Above (B)-Within (D8)(N=70,75,68)	3	5	3
WBC Increase Above (B)-Above (D8)(N=70,75,68)	14	12	10
WBC Increase Above (B)-Unknown (D8)(N=70,75,68)	1	1	0
WBC Increase Unknown (B)-Below (D8)(N=70,75,68)	0	0	0
WBC Increase Unknown (B)-Within (D8)(N=70,75,68)	0	0	1
WBC Increase Unknown (B)-Above (D8)(N=70,75,68)	0	0	1

WBC Increase Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	
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Statistical analyses

No statistical analyses for this end point

Primary: Number of maternal subjects with any biochemical laboratory abnormalities at Day 8 by baseline ranges

End point title	Number of maternal subjects with any biochemical laboratory abnormalities at Day 8 by baseline ranges ^{[7][8]}
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End point description:

[4:07 PM] Cornelia Ungurean

Biochemical parameters assessed were Alanine Amino-Transferase (ALT), Aspartate Amino-Transferase (AST), Creatinine (CRE) and Urea nitrogen (URN). The increase was evaluated only for AST and ALT parameters at Day 8. Abnormal laboratory values refer to range indicator at Day 8 (D8) categorized as Missing, Below, Within and Above normal values and compared to the baseline (B) range indicator of the same parameter, at Screening (up to 15 days before vaccination) i.e. Missing, Below, Within and Above. E.g. 'AST increase Below (B) - Within (D8)' = AST increase in subjects with below normal values at baseline and within normal values at Day 8.

End point type	Primary
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End point timeframe:

At Day 8

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

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

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Participants				
ALT increase Below (B)-Below (D8)(N=70,75,68)	0	0	0	
ALT increase Below (B)- Within (D8)(N=70,75,68)	0	0	0	
ALT increase Below (B)- Above (D8) (N=70,75,68)	0	0	0	
ALT increase Below (B)-Unknown (D8) (N=70,75,68)	0	0	0	
ALT increase Within (B)- Below (D8) (N=70,75,68)	0	0	0	
ALT increase Within (B)-Within (D8) (N=70,75,68)	64	69	65	
ALT increase Within (B)- Above (D8)(N=70,75,68)	1	0	0	
ALT increase Within (B)-Unknown (D8) (N=70,75,68)	2	3	1	
ALT increase Above (B)- Below (D8)(N=70,75,68)	0	0	0	

ALT increase Above (B)- Within (D8) (N=70,75,68)	1	2	0	
ALT - increase Above (B)- Above (D8) (N=70,75,68)	1	1	0	
ALT increase Above (B)-Unknown (D8) (N=70,75,68)	0	0	0	
ALT increase Unknown (B)-Below (D8) (N=70,75,68)	0	0	0	
ALT increase Unknown (B)-Within (D8) (N=70,75,68)	1	0	2	
ALT increase Unknown (B)-Above (D8) (N=70,75,68)	0	0	0	
ALT increase Unknown (B)-Unknown (D8) (N=70,75,68)	0	0	0	
AST increase Below (B)-Below (D8)(N=70,75,68)	0	0	0	
AST increase Below (B)- Within (D8)(N=70,75,68)	0	0	0	
AST increase Below (B)- Above (D8)(N=70,75,68)	0	0	0	
AST increase Below (B)-Unknown (D8) (N=70,75,68)	0	0	0	
AST increase Within (B)- Below (D8)(N=70,75,68)	0	0	0	
AST increase Within (B)-Within (D8)(N=70,75,68)	67	71	65	
AST increase Within (B)- Above (D8) (N=70,75,68)	0	1	0	
AST increase Within (B)-Unknown (D8) (N=70,75,68)	1	2	1	
AST increase Above (B)- Below (D8)(N=70,75,68)	0	0	0	
AST increase Above (B)-Within (D8) (N=70,75,68)	0	1	0	
AST increase Above (B)-Above (D8)(N=70,75,68)	1	0	0	
AST increase Above (B)-Unknown (D8) (N=70,75,68)	0	0	0	
AST increase Unknown (B)-Below (D8) (N=70,75,68)	0	0	0	
AST increase Unknown (B)-Within (D8) (N=70,75,68)	1	0	2	
AST increase Unknown (B)-Above (D8) (N=70,75,68)	0	0	0	
AST increase Unknown (B)-Unknown (D8) (N=70,75,68)	0	0	0	
Creatinine Below (B)-Below (D8) (N=70,75,68)	16	18	18	
Creatinine Below (B)-Within (D8) (N=70,75,68)	6	9	4	
Creatinine Below (B)-Above (D8) (N=70,75,68)	0	0	0	
Creatinine Below (B)- Unknown (D8) (N=70,75,68)	0	0	1	
Creatinine Within (B)-Below (D8) (N=70,75,68)	2	4	6	
Creatinine Within (B)-Within (D8) (N=70,75,68)	45	42	37	
Creatinine Within (B)-Above (D8)(N=70,75,68)	0	0	0	
Creatinine Within (B)-Unknown (D8) (N=70,75,68)	1	2	0	

Creatinine Above (B)-Below (D8)(N=70,75,68)	0	0	0	
Creatinine Above (B)-Within (D8)(N=70,75,68)	0	0	0	
Creatinine Above (B)-Above (D8)(N=70,75,68)	0	0	0	
Creatinine Above (B)-Unknown (D8)(N=70,75,68)	0	0	0	
Creatinine Unknown (B)-Below (D8)(N=70,75,68)	0	0	1	
Creatinine Unknown (B)-Within (D8)(N=70,75,68)	0	0	1	
Creatinine Unknown (B)-Above (D8)(N=70,75,68)	0	0	0	
Creatinine Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	
URN Below (B)- Below (D8)(N=70,75,68)	13	15	13	
URN Below (B)-Within (D8)(N=70,75,68)	6	4	3	
URN Below (B)-Above (D8)(N=70,75,68)	0	0	0	
URN Below (B)-Unknown (D8)(N=70,75,68)	0	1	1	
URN Within (B)-Below (D8)(N=70,75,68)	5	4	9	
URN Within (B)-Within (D8)(N=70,75,68)	45	49	39	
URN Within (B)-Above (D8)(N=70,75,68)	0	0	0	
URN Within (B)-Unknown (D8)(N=70,75,68)	1	1	0	
URN Above (B)-Below (D8)(N=70,75,68)	0	0	0	
URN Above (B)-Within (D8)(N=70,75,68)	0	0	0	
URN Above (B)-Above (D8)(N=70,75,68)	0	0	0	
URN Above (B)-Unknown (D8)(N=70,75,68)	0	0	0	
URN Unknown (B)-Below (D8)(N=70,75,68)	0	0	0	
URN Unknown (B)-Within (D8)(N=70,75,68)	0	1	3	
URN Unknown (B)-Above (D8)(N=70,75,68)	0	0	0	
URN Unknown (B)-Unknown (D8)(N=70,75,68)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal subjects with any unsolicited adverse events (AEs)

End point title	Percentage of maternal subjects with any unsolicited adverse events (AEs) ^{[9][10]}
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End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Unsolicited AE is any AE reported in addition to those solicited during the clinical study and that was spontaneously communicated by a maternal subject. Also, any solicited symptom with onset outside the specified period of follow-up for solicited symptoms is to be reported as an unsolicited AE. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

End point type	Primary
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End point timeframe:

During 30-day follow-up period after vaccination (i.e. the day of vaccination and 29 subsequent days)

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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Percentage of maternal subjects				
number (confidence interval 95%)	30 (19.6 to 42.1)	33.3 (22.9 to 45.2)	33.8 (22.8 to 46.3)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal subjects with any serious adverse events (SAEs)

End point title	Percentage of maternal subjects with any serious adverse events (SAEs) ^{[11][12]}
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End point description:

SAEs assessed included any untoward medical occurrences that resulted in death, were life-threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity, was a congenital anomaly/birth defect in the offspring of a study subject or abnormal pregnancy outcomes (spontaneous abortion, foetal death, stillbirth, congenital anomalies, ectopic pregnancy), other situations (medical events that might jeopardize the participant or required medical/surgical intervention to prevent one of the other SAEs listed above: e.g. invasive/malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that did not result in hospitalization). Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination.

End point type	Primary
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End point timeframe:

From Day 1 to Day 43 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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Percentage of maternal subjects				
number (confidence interval 95%)	22.9 (13.7 to 34.4)	26.7 (17.1 to 38.1)	22.1 (12.9 to 33.8)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal subjects with AEs leading to study withdrawal

End point title	Percentage of maternal subjects with AEs leading to study withdrawal ^{[13][14]}
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End point description:

An AE is any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. AEs leading to study withdrawal = AEs identified by investigators to cause subject(s) withdrawal until the resolution of the event. These subject withdrawals were considered different from subject withdrawals for other reasons.

End point type	Primary
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End point timeframe:

From Day 1 to Day 43 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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Percentage of maternal subjects				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal subjects with any medically attended AEs (MAE)

End point title	Percentage of maternal subjects with any medically attended AEs (MAE) ^{[15][16]}
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End point description:

MAEs were defined as adverse events with medically-attended visits that were not routine visits for physical examination or vaccination, such as visits for hospitalization, an emergency room visit, or an

otherwise unscheduled visit to or from medical personnel (medical doctor) for any reason. Also, for instances where, due to the special circumstances, the subject could not seek medical advice for symptoms/an illness by visiting a medical facility or arranging for a home visit, the subject sought this advice instead via telephone, SMS, email, videotelephony or telemedicine, or other means. Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination.

End point type	Primary
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End point timeframe:

From Day 1 to Day 43 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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Percentage of maternal subjects				
number (confidence interval 95%)	41.4 (29.8 to 53.8)	48 (36.3 to 59.8)	42.6 (30.7 to 55.2)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal subjects with pregnancy outcomes

End point title	Percentage of maternal subjects with pregnancy
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End point description:

Pregnancy outcomes were: live birth with no congenital anomalies, live birth with congenital anomalies, Fetal death/still birth (FD/SB) with no Congenital Anomalies (CA) - Antepartum and Unknown (Subjects withdrew from the study before delivery and pregnancy outcome information was not available for them).

End point type	Primary
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End point timeframe:

From Day 1 to Day 43 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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group- Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Percentage of maternal subjects				
number (confidence interval 95%)				
Live birth, no congenital anomalies (N=70,75,68)	84.3 (73.6 to 91.9)	81.3 (70.7 to 89.4)	80.9 (69.5 to 89.4)	
Live birth, congenital anomalies (N=70,75,68)	12.9 (6.1 to 23)	16 (8.6 to 26.3)	16.2 (8.4 to 27.1)	
FD/SB, no CA- Antepartum (N=70,75,68)	0 (0 to 5.1)	0 (0 to 4.8)	1.5 (0 to 7.9)	
Unknown (N=70,75,68)	2.9 (0.3 to 9.9)	2.7 (0.3 to 9.3)	1.5 (0 to 7.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of maternal subjects with pregnancy-related Adverse Events of Special Interest (AESIs)

End point title	Percentage of maternal subjects with pregnancy-related Adverse Events of Special Interest (AESIs) ^{[19][20]}
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End point description:

Pregnancy-related AESIs were: Non-Reassuring Fetal Status, Hypertensive Disorders of Pregnancy (HDP), Oligohydramnios, Pathways to Preterm Birth (PPB), Chorioamnionitis, Fetal Growth Restriction, Gestational Liver Disease (GLD)-Intrahepatic Cholestasis Of Pregnancy (ICP), Postpartum Haemorrhage and Gestational Diabetes Mellitus.

End point type	Primary
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End point timeframe:

From Day 1 to Day 43 post-delivery

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 maternal subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group- Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Percentage of maternal subjects				
number (confidence interval 95%)				
Non-Reassuring Fetal Status (N=70,75,68)	8.6 (3.2 to 17.7)	12 (5.6 to 21.6)	11.8 (5.2 to 21.9)	
HDP-Gestational Hypertensions (N=70,75,68)	4.3 (0.9 to 12)	2.7 (0.3 to 9.3)	1.5 (0 to 7.9)	
HDP-Pre-Eclampsias (N=70,75,68)	5.7 (1.6 to 14)	2.7 (0.3 to 9.3)	0 (0 to 5.3)	
Oligohydramnios (N=70,75,68)	4.3 (0.9 to 12)	2.7 (0.3 to 9.3)	1.5 (0 to 7.9)	
PPB-Preterm Labors (N=70,75,68)	0 (0 to 5.1)	2.7 (0.3 to 9.3)	2.9 (0.4 to 10.2)	

PPB-Preterm Rupture Of Membranes (N=70,75,68)	1.4 (0 to 7.7)	0 (0 to 4.8)	1.5 (0 to 7.9)	
PPB-Provider-Initiated Preterm Births (N=70,75,68)	0 (0 to 5.1)	1.3 (0 to 7.2)	0 (0 to 5.3)	
Chorioamnionitis (N=70,75,68)	2.9 (0.3 to 9.9)	2.7 (0.3 to 9.3)	1.5 (0 to 7.9)	
Fetal Growth Restrictions (N=70,75,68)	1.4 (0 to 7.7)	2.7 (0.3 to 9.3)	0 (0 to 5.3)	
GLD-ICP (N=70,75,68)	2.9 (0.3 to 9.9)	1.3 (0 to 7.2)	0 (0 to 5.3)	
Postpartum Haemorrhages (N=70,75,68)	1.4 (0 to 7.7)	0 (0 to 4.8)	1.5 (0 to 7.9)	
Gestational Diabetes Mellitus (N=70,75,68)	1.4 (0 to 7.7)	0 (0 to 4.8)	0 (0 to 5.3)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant subjects with neonatal AESIs

End point title	Percentage of infant subjects with neonatal AESIs ^[21] ^[22]
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End point description:

Neonatal AESIs, reported up to 6 weeks after birth were: Respiratory Distress In The Neonate, Macrosomia, Low Birth Weight, Small For Gestational Age, Preterm Birth, Large For Gestational Age, Neonatal Invasive Blood Stream Infections (NIBSI): Bacterial/Fungal/Viral (B/F/V), Bacterial/Fungal/Viral Meningitis (B/F/VM), Respiratory Bacterial/Fungal/Viral Infection (B/F/VI), and Congenital Anomalies (CA).

End point type	Primary
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End point timeframe:

From birth to Day 43 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)				
Respiratory Distress In The Neonate (N=67,73,66)	6 (1.7 to 14.6)	6.8 (2.3 to 15.3)	6.1 (1.7 to 14.8)	
Macrosomia (N=67,73,66)	3 (0.4 to 10.4)	2.7 (0.3 to 9.5)	7.6 (2.5 to 16.8)	
Low Birth Weight (N=67,73,66)	1.5 (0 to 8)	5.5 (1.5 to 13.4)	3 (0.4 to 10.5)	
Small For Gestational Age (N=67,73,66)	3 (0.4 to 10.4)	4.1 (0.9 to 11.5)	3 (0.4 to 10.5)	
Preterm Birth (N=67,73,66)	1.5 (0 to 8)	4.1 (0.9 to 11.5)	3 (0.4 to 10.5)	
Large For Gestational Age (N=67,73,66)	3 (0.4 to 10.4)	0 (0 to 4.9)	4.5 (0.9 to 12.7)	

NIBSI: B/F/V (N=67,73,66)	0 (0 to 5.4)	1.4 (0 to 7.4)	1.5 (0 to 8.2)	
NIBSI: B/F/VM (N=67,73,66)	0 (0 to 5.4)	1.4 (0 to 7.4)	0 (0 to 5.4)	
NIBSI: B/F/VI (N=67,73,66)	0 (0 to 5.4)	0 (0 to 4.9)	1.5 (0 to 8.2)	
CA-Major External Structural Defects (N=67,73,66)	0 (0 to 5.4)	2.7 (0.3 to 9.5)	0 (0 to 5.4)	
CA-Functional Defects (N=67,73,66)	0 (0 to 5.4)	1.4 (0 to 7.4)	0 (0 to 5.4)	
CA-Internal Structural Defects (N=67,73,66)	0 (0 to 5.4)	1.4 (0 to 7.4)	0 (0 to 5.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant subjects with any SAEs

End point title	Percentage of infant subjects with any SAEs ^[23] ^[24]
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End point description:

SAEs assessed included any untoward medical occurrences that resulted in death, were life-threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity or is a congenital anomaly/birth defect, other situations (medical events that might jeopardize the participant or required medical/surgical intervention to prevent one of the other SAEs listed above: e.g. invasive/malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that did not result in hospitalization). Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination.

End point type	Primary
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End point timeframe:

From birth to Day 43 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	22.4 (13.1 to 34.2)	27.4 (17.6 to 39.1)	28.8 (18.3 to 41.3)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant subjects with AEs leading to study withdrawal

End point title	Percentage of infant subjects with AEs leading to study withdrawal ^[25] ^[26]
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End point description:

An AE is any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. AEs leading to study withdrawal = AEs identified by investigators to cause subject(s) withdrawal until the resolution of the event. These subject withdrawals were considered different from subject withdrawals for other reasons.

End point type	Primary
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End point timeframe:

From birth to Day 43 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of infant subjects with any MAEs

End point title	Percentage of infant subjects with any MAEs ^[27] ^[28]
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End point description:

MAEs were defined as adverse events with medically-attended visits that were not routine visits for physical examination or vaccination, such as visits for hospitalization, an emergency room visit, or an otherwise unscheduled visit to or from medical personnel (medical doctor) for any reason. Also, for instances where, due to the special circumstances, the subject could not seek medical advice for symptoms/an illness by visiting a medical facility or arranging for a home visit, the subject sought this advice instead via telephone, SMS, email, videotelephony or telemedicine, or other means. Any = occurrence of the symptom regardless of intensity grade.

End point type	Primary
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End point timeframe:

From birth to Day 43 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	25.4 (15.5 to 37.5)	35.6 (24.7 to 47.7)	30.3 (19.6 to 42.9)	

Statistical analyses

No statistical analyses for this end point

Primary: RSV MAT Immunoglobulin G (IgG)-specific antibody concentrations in terms of Geometric Mean Concentrations (GMCs) in maternal subjects

End point title	RSV MAT Immunoglobulin G (IgG)-specific antibody concentrations in terms of Geometric Mean Concentrations (GMCs) in maternal subjects ^{[29][30]}
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End point description:

Serological assays for the determination of IgG antibodies against RSV MAT were performed by Enzyme-linked immunosorbent assay (ELISA). The corresponding antibody concentrations were expressed in ELISA units per milliliter (EU/mL) and were measured on blood samples collected from vaccinated maternal subjects.

End point type	Primary
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End point timeframe:

At Day 1 (before vaccination), Day 31 and at delivery

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 maternal subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	72	68	
Units: EU/mL				
geometric mean (confidence interval 95%)				
Day 1 (N=68,72,68)	5681 (4851 to 6653)	5837 (4962 to 6865)	6147 (5224 to 7234)	
Day 31 (N=58,68,60)	80986 (66746 to 98263)	105138 (93657 to 118025)	6597 (5252 to 8288)	
Delivery (N=64,67,62)	59395 (50742 to 69524)	59715 (51417 to 69352)	5555 (4568 to 6755)	

Statistical analyses

No statistical analyses for this end point

Primary: RSV-A neutralizing antibody Geometric Mean Titers (GMTs) in maternal subjects

End point title	RSV-A neutralizing antibody Geometric Mean Titers (GMTs) in maternal subjects ^{[31][32]}
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End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay. The corresponding antibody titers were expressed in Estimated Dilution 60 (ED60) and were measured on blood samples collected from vaccinated maternal subjects.

End point type	Primary
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End point timeframe:

At Day 1 (before vaccination), Day 31 and at delivery

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 maternal subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	73	68	
Units: Titers				
geometric mean (confidence interval 95%)				
Day 1 (N=68,73,68)	671.8 (544.1 to 829.4)	694.7 (565.8 to 852.9)	735.6 (586.7 to 922.1)	
Day 31 (N=58,68,60)	9534.2 (7758.5 to 11716.3)	10781.2 (9150 to 12703.2)	799.1 (622.2 to 1026.2)	
Delivery (N=64,67,62)	6162.1 (4981.2 to 7623)	6661 (5490.7 to 8080.7)	761.1 (612.1 to 946.3)	

Statistical analyses

No statistical analyses for this end point

Primary: RSV MAT IgG antibody GMCs in infants born to maternal subjects

End point title	RSV MAT IgG antibody GMCs in infants born to maternal subjects ^{[33][34]}
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End point description:

Serological assays for the determination of IgG antibodies against RSV MAT were performed by ELISA. The corresponding antibody concentrations were expressed in EU/mL. The antibodies were measured on the cord blood sample collected at delivery, or on a blood sample collected from the infant within 3 days after birth (if no cord blood sample could be obtained).

End point type	Primary
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End point timeframe:

At delivery or within 3 days after 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	64	60	
Units: EU/mL				
geometric mean (confidence interval 95%)	91606.9 (76414.1 to 109820.3)	114529.8 (100023.3 to 131140.1)	9272.3 (7669.8 to 11209.5)	

Statistical analyses

No statistical analyses for this end point

Primary: RSV-A neutralizing antibody GMTs in infants born to maternal subjects

End point title	RSV-A neutralizing antibody GMTs in infants born to maternal subjects ^[35] ^[36]
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End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay. The corresponding antibody titers were presented as GMTs, expressed in ED60. The antibodies were measured on the cord blood sample collected at delivery, or on a blood sample collected from the infant within 3 days after birth (if no cord blood sample could be obtained).

End point type	Primary
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End point timeframe:

At delivery or within 3 days after 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	64	61	
Units: Titers				
geometric mean (confidence interval 95%)	8414.7 (6813.4 to 10392.5)	10262.5 (8709.9 to 12091.9)	1244.7 (981.3 to 1578.8)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Geometric Mean Ratio between cord blood and maternal RSV MAT IgG-specific antibody concentrations ^[37]
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End point description:

The placental transfer ratio of IgG specific antibody concentration was determined from cord blood (or blood sample collected within 3 days after birth from infants if cord blood was not collected) over that of the blood sample from mother at delivery if blood sample was not collected during delivery). Serological assays for the determination of IgG antibodies against RSV MAT were performed by ELISA. The analysis was performed on all pairs of maternal subjects (from PPSM) and their infants (from PPSI) with available results for this outcome measure at the specified time point.

End point type	Primary
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End point timeframe:

At delivery (for maternal subjects) or within 3 days after birth (for infants)

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.

End point values	RSV MAT 60 Group	RSV MAT 120 Group	Control Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	59	63	58	
Units: Ratio				
geometric mean (confidence interval 95%)	1.62 (1.44 to 1.82)	1.9 (1.75 to 2.06)	1.6 (1.47 to 1.75)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of maternal subjects with any SAE from Day 1 to Day 181 post delivery

End point title	Percentage of maternal subjects with any SAE from Day 1 to Day 181 post delivery ^[38]
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End point description:

SAEs assessed included any untoward medical occurrences that resulted in death, were life-threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity, was a congenital anomaly/birth defect in the offspring of a study subject or abnormal pregnancy outcomes (spontaneous abortion, foetal death, stillbirth, congenital anomalies, ectopic pregnancy), other situations (medical events that might jeopardize the participant or required medical/surgical intervention to prevent one of the other SAEs listed above: e.g. invasive/malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that did not result in hospitalization). Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination.

End point type	Secondary
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End point timeframe:

From Day 1 to Day 181 post-delivery

Notes:

[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 maternal subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Percentage of maternal subjects				
number (confidence interval 95%)	22.9 (13.7 to 34.4)	28 (18.2 to 39.6)	22.1 (12.9 to 33.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of maternal subjects with any MAE from Day 1 to Day 181 post delivery

End point title	Percentage of maternal subjects with any MAE from Day 1 to Day 181 post delivery ^[39]
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End point description:

MAEs were defined as adverse events with medically-attended visits that were not routine visits for physical examination or vaccination, such as visits for hospitalization, an emergency room visit, or an otherwise unscheduled visit to or from medical personnel (medical doctor) for any reason. Also, for instances where, due to the special circumstances, the subject could not seek medical advice for symptoms/an illness by visiting a medical facility or arranging for a home visit, the subject sought this advice instead via telephone, SMS, email, videotelephony or telemedicine, or other means. Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination.

End point type	Secondary
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End point timeframe:

From Day 1 to Day 181 post-delivery

Notes:

[39] - 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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Percentage of maternal subjects				
number (confidence interval 95%)	47.1 (35.1 to 59.4)	53.3 (41.4 to 64.9)	47.1 (34.8 to 59.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of maternal subjects with AE leading to study withdrawal from Day 1 to Day 181 post delivery

End point title	Percentage of maternal subjects with AE leading to study withdrawal from Day 1 to Day 181 post delivery ^[40]
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End point description:

An AE is any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. AEs leading to study withdrawal = AEs identified by investigators to cause subject(s) withdrawal until the resolution of the event. These subject withdrawals were considered different from subject withdrawals for other reasons.

End point type	Secondary
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End point timeframe:

From Day 1 to Day 181 post-delivery

Notes:

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

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

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Percentage of maternal subjects				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant subjects with any SAE from birth to Day 181 post-birth

End point title	Percentage of infant subjects with any SAE from birth to Day 181 post-birth ^[41]
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End point description:

SAEs assessed included any untoward medical occurrences that resulted in death, were life-threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity, or is a congenital anomaly/birth defect in the offspring of a study subject, other situations (medical events that might jeopardize the participant or required medical/surgical intervention to prevent one of the other SAEs listed above: e.g. invasive/malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that did not result in hospitalization). Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination.

End point type	Secondary
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End point timeframe:

From birth to Day 181 post-birth

Notes:

[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 infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	25.4 (15.5 to 37.5)	28.8 (18.8 to 40.6)	30.3 (19.6 to 42.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant subjects with AE leading to study withdrawal from birth to Day 181 post-birth

End point title	Percentage of infant subjects with AE leading to study withdrawal from birth to Day 181 post-birth ^[42]
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End point description:

An AE is any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. AEs leading to study withdrawal = AEs identified by investigators to cause subject(s) withdrawal until the resolution of the event. These subject withdrawals were considered different from subject withdrawals for other reasons.

End point type	Secondary
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End point timeframe:

From birth to Day 181 post-birth

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant subjects with any MAE from birth to Day 181 post-birth

End point title	Percentage of infant subjects with any MAE from birth to Day 181 post-birth ^[43]
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End point description:

MAEs were defined as adverse events with medically-attended visits that were not routine visits for physical examination or vaccination, such as visits for hospitalization, an emergency room visit, or an otherwise unscheduled visit to or from medical personnel (medical doctor) for any reason. Also, for instances where, due to the special circumstances, the subject could not seek medical advice for

symptoms/an illness by visiting a medical facility or arranging for a home visit, the subject sought this advice instead via telephone, SMS, email, videotelephony or telemedicine, or other means. Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination.

End point type	Secondary
End point timeframe:	
From birth to Day 181 post-birth	

Notes:

[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 infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	40.3 (28.5 to 53)	52.1 (40 to 63.9)	39.4 (27.6 to 52.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant subjects with any SAE from birth to Month 12 post-birth

End point title	Percentage of infant subjects with any SAE from birth to Month 12 post-birth ^[44]
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End point description:

SAEs assessed included any untoward medical occurrences that resulted in death, were life-threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity, or is a congenital anomaly/birth defect in the offspring of a study subject, other situations (medical events that might jeopardize the participant or required medical/surgical intervention to prevent one of the other SAEs listed above: e.g. invasive/malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that did not result in hospitalization). Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination.

End point type	Secondary
End point timeframe:	
From birth to Month 12 post-birth	

Notes:

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	25.4 (15.5 to 37.5)	28.8 (18.8 to 40.6)	31.8 (20.9 to 44.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant subjects with any AE leading to study withdrawal from birth to Month 12 post-birth

End point title	Percentage of infant subjects with any AE leading to study withdrawal from birth to Month 12 post-birth ^[45]
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End point description:

An AE is any untoward medical occurrence in a subject or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. AEs leading to study withdrawal = AEs identified by investigators to cause subject(s) withdrawal until the resolution of the event. These subject withdrawals were considered different from subject withdrawals for other reasons.

End point type	Secondary
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End point timeframe:

From birth to Month 12 post-birth

Notes:

[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 infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant subjects with any MAE from birth to Month 12 post-birth

End point title	Percentage of infant subjects with any MAE from birth to Month 12 post-birth ^[46]
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End point description:

MAEs were defined as adverse events with medically-attended visits that were not routine visits for physical examination or vaccination, such as visits for hospitalization, an emergency room visit, or an otherwise unscheduled visit to or from medical personnel (medical doctor) for any reason. Also, for instances where, due to the special circumstances, the subject could not seek medical advice for symptoms/an illness by visiting a medical facility or arranging for a home visit, the subject sought this advice instead via telephone, SMS, email, videotelephony or telemedicine, or other means. Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination.

End point type	Secondary
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End point timeframe:

From birth to Month 12 post-birth

Notes:

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	43.3 (31.2 to 56)	57.5 (45.4 to 69)	43.9 (31.7 to 56.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of maternal subjects with RSV-associated Medically Attended Respiratory Tract Illnesses (MA-RTI)

End point title	Percentage of maternal subjects with RSV-associated Medically Attended Respiratory Tract Illnesses (MA-RTI) ^[47]
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End point description:

A maternal MA-RTI occurs when the maternal subject visits a healthcare professional for any respiratory symptom, including cough, sputum production and difficulty breathing. An RSV associated MA-RTI is characterised by a medically attended visit for RTI symptoms (runny nose or blocked nose or cough) and a confirmed RSV infection.

End point type	Secondary
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End point timeframe:

From delivery to Day 181 post-delivery

Notes:

[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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	75	68	
Units: Percentage of maternal subjects				
number (confidence interval 95%)	0 (0 to 5.1)	0 (0 to 4.8)	0 (0 to 5.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant subjects with RSV-associated Lower respiratory

tract illness (LRTI)

End point title	Percentage of infant subjects with RSV-associated Lower respiratory tract illness (LRTI) ^[48]
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End point description:

An RSV-associated LRTI is characterised by a history of cough or difficulty in breathing, a blood oxygen saturation by pulse oximetry (SpO₂) lesser than (<) 95% or respiratory rate increase and a confirmed RSV infection.

End point type	Secondary
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End point timeframe:

From birth to Day 181 post-birth

Notes:

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	0 (0 to 5.4)	0 (0 to 4.9)	0 (0 to 5.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant subjects with RSV-associated severe LRTI

End point title	Percentage of infant subjects with RSV-associated severe
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End point description:

A RSV-associated severe LRTI is characterised by a history of cough or difficulty in breathing, a SpO₂ < 93% or lower chest wall in-drawing and a confirmed RSV infection.

End point type	Secondary
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End point timeframe:

From birth to Day 181 post-birth

Notes:

[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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	0 (0 to 5.4)	0 (0 to 4.9)	0 (0 to 5.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant subjects with RSV-associated very severe LRTI

End point title	Percentage of infant subjects with RSV-associated very severe LRTI ^[50]
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End point description:

A RSV-associated very severe LRTI is characterised by a history of cough or difficulty in breathing, a SpO₂ < 90% or inability to feed or failure to respond/unconscious and a confirmed RSV infection.

End point type	Secondary
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End point timeframe:

From birth to Day 181 post-birth

Notes:

[50] - 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	0 (0 to 5.4)	0 (0 to 4.9)	0 (0 to 5.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infant subjects with RSV-associated hospitalisation

End point title	Percentage of infant subjects with RSV-associated hospitalisation ^[51]
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End point description:

An RSV-associated hospitalisation is characterised by a confirmed RSV infection and a hospitalisation for an acute medical condition.

End point type	Secondary
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End point timeframe:

From birth to Day 181 post-birth

Notes:

[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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	66	
Units: Percentage of infant subjects				
number (confidence interval 95%)	0 (0 to 5.4)	0 (0 to 4.9)	0 (0 to 5.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT IgG antibody GMCs in maternal subjects, at day 43 post-delivery

End point title	RSV MAT IgG antibody GMCs in maternal subjects, at day 43 post-delivery ^[52]
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End point description:

Serological assays for the determination of IgG antibodies against RSV MAT were performed by ELISA. The corresponding antibody concentration were expressed in EU/mL.

End point type	Secondary
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End point timeframe:

At Day 43 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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	59	50	
Units: EU/mL				
geometric mean (confidence interval 95%)	61925 (51966 to 73792)	62871 (53878 to 73364)	8350 (6723 to 10372)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody GMTs in maternal subjects, at day 43 post-delivery

End point title	RSV-A neutralizing antibody GMTs in maternal subjects, at day 43 post-delivery ^[53]
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End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay. The corresponding antibody titers were expressed in ED60.

End point type	Secondary
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End point timeframe:

At Day 43 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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	58	50	
Units: Titers				
geometric mean (confidence interval 95%)	6451.3 (4842.4 to 8594.6)	6290.7 (5000.6 to 7913.7)	943.6 (733.4 to 1213.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing antibody GMTs in maternal subjects

End point title	RSV-B neutralizing antibody GMTs in maternal subjects ^[54]
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End point description:

Serological assays for the determination of antibodies against RSV-B are performed by neutralization assay. The corresponding antibody titers were expressed in ED60.

End point type	Secondary
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End point timeframe:

At Day 1 (before vaccination), Day 31, at delivery and Day 43 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 subjects.

End point values	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	73	68	
Units: Titers				
geometric mean (confidence interval 95%)				
Day 1 (N=67,73,68)	1066.3 (833.7 to 1363.9)	1144.7 (933.1 to 1404.4)	969.5 (790.5 to 1188.9)	
Day 31 (N=58,68,58)	13766.2 (10692.6 to 17723.2)	15849.4 (13101 to 19174.4)	1065.8 (846.5 to 1341.8)	
Delivery (N=63,66,61)	8983.1 (7079.7 to 11398.1)	13335.6 (10507 to 16925.8)	1190.7 (922.8 to 1536.5)	
Day 43 post-delivery (N=53,59,49)	12297.7 (9464.3 to 15979.4)	10027.2 (8033.2 to 12516.2)	1473.8 (1111.1 to 1954.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT IgG antibody GMCs in infants born to maternal subjects, at Day 43 after birth

End point title	RSV MAT IgG antibody GMCs in infants born to maternal subjects, at Day 43 after birth ^[55]
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End point description:

Serological assays for the determination of IgG antibodies against RSV MAT were performed by ELISA. The corresponding antibody concentration were expressed in EU/mL. The analysis was performed on a subcohort (subcohort V2-New borns) from PPSI, for the subjects who provided sample for this outcome measure at the specified time point.

End point type	Secondary
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End point timeframe:

At Day 43 after birth

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 infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	15	11	
Units: EU/mL				
geometric mean (confidence interval 95%)	30194.5 (18677.2 to 48813.8)	39378.2 (33586.7 to 46168.4)	2576.1 (1566.4 to 4236.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT IgG antibody GMCs in infants born to maternal subjects, at Day 121 after birth

End point title	RSV MAT IgG antibody GMCs in infants born to maternal subjects, at Day 121 after birth ^[56]
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End point description:

Serological assays for the determination of IgG antibodies against RSV MAT were performed by ELISA. The corresponding antibody concentration were expressed in EU/mL. The analysis was performed on a subcohort (subcohort V2-New borns) from PPSI, for the subjects who provided sample for this outcome measure at the specified time point.

End point type	Secondary
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End point timeframe:

At Day 121 after birth

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 infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	19	10	
Units: EU/mL				
geometric mean (confidence interval 95%)	4292.9 (3263 to 5648)	4656.9 (3539.4 to 6127.4)	445.5 (291.4 to 681)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT IgG antibody GMCs in infants born to maternal subjects, at Day 181 after birth

End point title	RSV MAT IgG antibody GMCs in infants born to maternal subjects, at Day 181 after birth ^[57]
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End point description:

Serological assays for the determination of IgG antibodies against RSV MAT were performed by ELISA. The corresponding antibody concentration were expressed in EU/mL. The analysis was performed on a subcohort (subcohort V2-New borns) from PPSI, for the subjects who provided samples for this outcome measure at the specified time point.

End point type	Secondary
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End point timeframe:

At Day 181 after birth

Notes:

[57] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	19	11	
Units: EU/mL				
geometric mean (confidence interval 95%)	1224.1 (815.1 to 1838.4)	1433.5 (1116.7 to 1840.1)	179.6 (97.7 to 330.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody GMTs in infants born to maternal subjects, at Day 43 after birth

End point title	RSV-A neutralizing antibody GMTs in infants born to maternal subjects, at Day 43 after birth ^[58]
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End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay. The corresponding antibody titers were expressed in ED60. The analysis was performed on a subcohort (subcohort V2-New borns) from PPSI, for the subjects who provided sample for this outcome

measure at the specified time point.

End point type	Secondary
End point timeframe:	
At Day 43 after 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	15	11	
Units: Titers				
geometric mean (confidence interval 95%)	3384.2 (2200.1 to 5205.5)	3509.6 (2525.2 to 4877.6)	613.3 (298.6 to 1259.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody GMTs in infants born to maternal subjects, at Day 121 after birth

End point title	RSV-A neutralizing antibody GMTs in infants born to maternal subjects, at Day 121 after birth ^[59]
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End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay. The corresponding antibody titers were expressed in ED60. The analysis was performed on a subcohort (subcohort V2-New borns) from PPSI, for the subjects who provided sample for this outcome measure at the specified time point.

End point type	Secondary
End point timeframe:	
At Day 121 after 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	19	10	
Units: Titers				
geometric mean (confidence interval 95%)	762.3 (458.3 to 1268.2)	890.9 (648.5 to 1224)	91.2 (56.8 to 146.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody GMTs in infants born to maternal subjects, at Day 181 after birth

End point title	RSV-A neutralizing antibody GMTs in infants born to maternal subjects, at Day 181 after birth ^[60]
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End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay. The corresponding antibody titers were expressed in ED60. The analysis was performed on a subcohort (subcohort V2-New borns) from PPSI, for the subjects who provided sample for this outcome measure at the specified time point.

End point type	Secondary
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End point timeframe:

At Day 181 after birth

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 infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	20	12	
Units: Titers				
geometric mean (confidence interval 95%)	278.4 (146 to 530.9)	324.8 (194.6 to 542.3)	47.8 (23.8 to 96)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at birth

End point title	RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at birth ^[61]
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End point description:

Serological assays for the determination of antibodies against RSV-B were performed by neutralization assay. The corresponding antibody titers were expressed in ED60. The antibodies were measured on the cord blood sample collected at delivery, or on a blood sample collected from the infant within 3 days after birth (if no cord blood sample could be obtained).

End point type	Secondary
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End point timeframe:

At delivery or within 3 days after birth

Notes:

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

Justification: This endpoint is only reporting values for the infants born to maternal subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	64	60	
Units: Titers				
geometric mean (confidence interval 95%)	13585.6 (10453.9 to 17655.4)	18955 (15694.7 to 22892.6)	1656.8 (1320.3 to 2079)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at Day 43 after birth

End point title	RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at Day 43 after birth ^[62]
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End point description:

Serological assays for the determination of antibodies against RSV-B were performed by neutralization assay. The corresponding antibody titers were expressed in ED60. The analysis was performed on a subcohort (subcohort V2-New borns) from PPSI, for the subjects who provided sample for this outcome measure at the specified time point.

End point type	Secondary
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End point timeframe:

At Day 43 after 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	15	11	
Units: Titers				
geometric mean (confidence interval 95%)	5932.1 (2562.6 to 13731.7)	6905.5 (4373.3 to 10903.8)	548.2 (292.1 to 1028.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at Day 121 after birth

End point title	RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at Day 121 after birth ^[63]
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End point description:

Serological assays for the determination of antibodies against RSV-B were performed by neutralization assay. The corresponding antibody titers were expressed in ED60. The analysis was performed on a subcohort (subcohort V2-New borns) from PPSI, for the subjects who provided sample for this outcome

measure at the specified time point.

End point type	Secondary
End point timeframe:	
At Day 121 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	19	10	
Units: Titers				
geometric mean (confidence interval 95%)	1119 (705.3 to 1775.4)	1367 (950.5 to 1965.9)	141.6 (82 to 244.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at Day 181 after birth

End point title	RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at Day 181 after birth ^[64]
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End point description:

Serological assays for the determination of antibodies against RSV-B were performed by neutralization assay. The corresponding antibody titers were expressed in ED60. The analysis was performed on a subcohort (subcohort V2-New borns) from PPSI, for the subjects who provided sample for this outcome measure at the specified time point.

End point type	Secondary
End point timeframe:	
At Day 181 after 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 subjects.

End point values	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	20	12	
Units: Titers				
geometric mean (confidence interval 95%)	459.8 (245.9 to 859.7)	574 (368.9 to 893.3)	68.8 (27.1 to 174.7)	

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Maternal groups (Grs.): administration site & systemic AEs collected during 7-day follow-up (FU) after vaccination, unsolicited AEs during 30-day FU after vaccination, SAEs: Day 1- Month 6 post-delivery.
Infant Grs. SAEs: Birth-12 months 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 the study.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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Reporting groups

Reporting group title	RSV MAT 60 Group-Mother
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Reporting group description:

Maternal subjects randomized to RSV MAT 60 Group received a single dose of RSV MAT (60 µg) vaccine at Day 1, and were followed up until the study end.

Reporting group title	RSV MAT 120 Group-Mother
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Reporting group description:

Maternal subjects randomized to RSV MAT 120 group received a single dose of RSV MAT (120 µg) vaccine at Day 1, and were followed up until the study end.

Reporting group title	Control Group-Mother
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Reporting group description:

Maternal subjects randomized to the Control Group received a single dose of Placebo at Day 1, and were followed up until the study end.

Reporting group title	RSV MAT 60 Group-Infant
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Reporting group description:

This group consisted of infants born to mothers (from RSV MAT 60 Group-Mother) who received a single dose of RSV MAT (60 µg) vaccine during pregnancy.

Reporting group title	RSV MAT 120 Group-Infant
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Reporting group description:

This group consisted of infants born to mothers (from RSV MAT 120 Group-Mother) who received a single dose of RSV MAT (120 µg) vaccine during pregnancy.

Reporting group title	Control Group-Infant
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Reporting group description:

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

Serious adverse events	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 70 (22.86%)	21 / 75 (28.00%)	15 / 68 (22.06%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Haemangioma of skin			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Infantile haemangioma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (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
Pregnancy, puerperium and perinatal conditions			
Foetal distress syndrome			
subjects affected / exposed	2 / 70 (2.86%)	9 / 75 (12.00%)	6 / 68 (8.82%)
occurrences causally related to treatment / all	0 / 2	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	3 / 70 (4.29%)	2 / 75 (2.67%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged labour			
subjects affected / exposed	0 / 70 (0.00%)	2 / 75 (2.67%)	3 / 68 (4.41%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth restriction			
subjects affected / exposed	1 / 70 (1.43%)	3 / 75 (4.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oligohydramnios			
subjects affected / exposed	2 / 70 (2.86%)	1 / 75 (1.33%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gestational hypertension				
subjects affected / exposed	2 / 70 (2.86%)	0 / 75 (0.00%)	1 / 68 (1.47%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Premature labour				
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	2 / 68 (2.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Obstructed labour				
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	1 / 68 (1.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Premature delivery				
subjects affected / exposed	0 / 70 (0.00%)	2 / 75 (2.67%)	0 / 68 (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	
Preterm premature rupture of membranes				
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	1 / 68 (1.47%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Arrested labour				
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (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	
Breech presentation				
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (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	
Foetal cardiac disorder				
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (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	
Prolonged rupture of membranes				

subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stillbirth			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical cord compression			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (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
Premature baby			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Low birth weight baby			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
General disorders and administration site conditions			
Cyst			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Respiratory, thoracic and mediastinal disorders			
Neonatal respiratory distress			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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

Meconium aspiration syndrome			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (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
Choking			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Neonatal aspiration			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Neonatal respiratory depression			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Neonatal respiratory failure			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Tachypnoea			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Investigations			

Cardiac murmur			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Injury, poisoning and procedural complications			
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (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
Road traffic accident			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (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			
Congenital naevus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Ankyloglossia congenital			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Cryptorchism			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Hypospadias			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Birth mark			

subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Congenital acrochordon			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Congenital arterial malformation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Congenital foot malformation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Congenital pneumonia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Congenital skin dimples			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Congenital viral hepatitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Hooded prepuce			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Naevus flammeus			

subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Patent ductus arteriosus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Phimosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Polydactyly			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Preauricular cyst			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Supernumerary nipple			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Ventricular septal defect			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Cardiac disorders			
Cardiomegaly			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Nervous system disorders			

Bell's palsy			
subjects affected / exposed	1 / 70 (1.43%)	1 / 75 (1.33%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia neonatal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Eye disorders			
Dacryostenosis acquired			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Gastrointestinal disorders			
Umbilical hernia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Constipation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Inguinal hernia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Meconium ileus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Hepatobiliary disorders			
Cholestasis of pregnancy			

subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (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			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Neonatal cholestasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Skin and subcutaneous tissue disorders			
Macule			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Skin discolouration			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Renal and urinary disorders			
Pelvi-ureteric obstruction			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	1 / 70 (1.43%)	2 / 75 (2.67%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Mastitis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
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 pneumonia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (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
Pyelonephritis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (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
Bacterial sepsis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Meningitis viral			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Sepsis neonatal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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
Urinary tract infection			

subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	0 / 68 (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

Serious adverse events	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 67 (25.37%)	21 / 73 (28.77%)	21 / 66 (31.82%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma of skin			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile haemangioma			
subjects affected / exposed	1 / 67 (1.49%)	0 / 73 (0.00%)	0 / 66 (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
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Pregnancy, puerperium and perinatal conditions			
Foetal distress syndrome			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Pre-eclampsia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Prolonged labour			

subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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 growth restriction			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Oligohydramnios			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Gestational hypertension			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Premature labour			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Obstructed labour			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Premature delivery			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Arrested labour			

subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Breech presentation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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 cardiac disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Prolonged rupture of membranes			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Stillbirth			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Umbilical cord compression			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Premature baby			
subjects affected / exposed	1 / 67 (1.49%)	3 / 73 (4.11%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice neonatal			
subjects affected / exposed	1 / 67 (1.49%)	1 / 73 (1.37%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Low birth weight baby			

subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
General disorders and administration site conditions			
Cyst			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Respiratory, thoracic and mediastinal disorders			
Neonatal respiratory distress			
subjects affected / exposed	2 / 67 (2.99%)	2 / 73 (2.74%)	4 / 66 (6.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium aspiration syndrome			
subjects affected / exposed	1 / 67 (1.49%)	1 / 73 (1.37%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choking			
subjects affected / exposed	1 / 67 (1.49%)	0 / 73 (0.00%)	0 / 66 (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
Neonatal aspiration			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
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 respiratory depression			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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 syndrome			

subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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 failure			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Tachypnoea			
subjects affected / exposed	1 / 67 (1.49%)	0 / 73 (0.00%)	0 / 66 (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
Transient tachypnoea of the newborn			
subjects affected / exposed	1 / 67 (1.49%)	0 / 73 (0.00%)	0 / 66 (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
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Road traffic accident			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Congenital, familial and genetic disorders			
Congenital naevus			

subjects affected / exposed	4 / 67 (5.97%)	3 / 73 (4.11%)	4 / 66 (6.06%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankyloglossia congenital			
subjects affected / exposed	0 / 67 (0.00%)	2 / 73 (2.74%)	3 / 66 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypospadias			
subjects affected / exposed	0 / 67 (0.00%)	2 / 73 (2.74%)	0 / 66 (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
Birth mark			
subjects affected / exposed	1 / 67 (1.49%)	0 / 73 (0.00%)	0 / 66 (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
Congenital acrochordon			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
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	1 / 67 (1.49%)	0 / 73 (0.00%)	0 / 66 (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
Congenital foot malformation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
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 pneumonia			

subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
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 skin dimples			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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 viral hepatitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Hooded prepuce			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Naevus flammeus			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Patent ductus arteriosus			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Phimosis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Polydactyly			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preauricular cyst			

subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supernumerary nipple			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
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 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiomegaly			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Nervous system disorders			
Bell's palsy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Blood and lymphatic system disorders			
Anaemia neonatal			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Eye disorders			
Dacryostenosis acquired			
subjects affected / exposed	1 / 67 (1.49%)	0 / 73 (0.00%)	0 / 66 (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
Gastrointestinal disorders			
Umbilical hernia			

subjects affected / exposed	1 / 67 (1.49%)	2 / 73 (2.74%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Inguinal hernia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Meconium ileus			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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			
Cholestasis of pregnancy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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 cholestasis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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
Skin and subcutaneous tissue disorders			

Macule			
subjects affected / exposed	2 / 67 (2.99%)	0 / 73 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin discolouration			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Pelvi-ureteric obstruction			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Mastitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Breast abscess			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Influenza			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Neonatal pneumonia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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

Pyelonephritis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (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
Bacterial sepsis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 73 (1.37%)	0 / 66 (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

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

Non-serious adverse events	RSV MAT 60 Group-Mother	RSV MAT 120 Group-Mother	Control Group-Mother
Total subjects affected by non-serious adverse events			
subjects affected / exposed	56 / 70 (80.00%)	66 / 75 (88.00%)	47 / 68 (69.12%)
Pregnancy, puerperium and perinatal conditions			
Foetal hypokinesia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences (all)	1	0	1
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 70 (0.00%)	2 / 75 (2.67%)	0 / 68 (0.00%)
occurrences (all)	0	2	0
Gestational diabetes			

subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 75 (0.00%) 0	0 / 68 (0.00%) 0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	40 / 70 (57.14%)	39 / 75 (52.00%)	10 / 68 (14.71%)
occurrences (all)	40	39	10
Fatigue			
subjects affected / exposed	28 / 70 (40.00%)	26 / 75 (34.67%)	17 / 68 (25.00%)
occurrences (all)	28	28	17
Injection site erythema			
subjects affected / exposed	1 / 70 (1.43%)	5 / 75 (6.67%)	0 / 68 (0.00%)
occurrences (all)	1	5	0
Injection site swelling			
subjects affected / exposed	3 / 70 (4.29%)	3 / 75 (4.00%)	0 / 68 (0.00%)
occurrences (all)	3	3	0
Oedema peripheral			
subjects affected / exposed	2 / 70 (2.86%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences (all)	2	0	1
Influenza like illness			
subjects affected / exposed	1 / 70 (1.43%)	1 / 75 (1.33%)	0 / 68 (0.00%)
occurrences (all)	1	1	0
Asthenia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Feeling hot			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Induration			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Injection site irritation			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Malaise			

subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Swelling			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 70 (1.43%)	3 / 75 (4.00%)	2 / 68 (2.94%)
occurrences (all)	1	3	2
Cough			
subjects affected / exposed	1 / 70 (1.43%)	1 / 75 (1.33%)	1 / 68 (1.47%)
occurrences (all)	1	1	1
Nasal congestion			
subjects affected / exposed	1 / 70 (1.43%)	1 / 75 (1.33%)	0 / 68 (0.00%)
occurrences (all)	1	1	0
Asthma			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Asthmatic crisis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Respiratory disorder			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			

subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 75 (0.00%) 0	1 / 68 (1.47%) 1
Sinus congestion subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 75 (1.33%) 2	0 / 68 (0.00%) 0
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 75 (1.33%) 1	1 / 68 (1.47%) 1
Depression subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 75 (0.00%) 0	0 / 68 (0.00%) 0
Injury, poisoning and procedural complications Fall subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 75 (1.33%) 1	0 / 68 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	25 / 70 (35.71%) 25	21 / 75 (28.00%) 23	14 / 68 (20.59%) 14
Dizziness subjects affected / exposed occurrences (all)	2 / 70 (2.86%) 2	0 / 75 (0.00%) 0	1 / 68 (1.47%) 1
Migraine subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	0 / 75 (0.00%) 0	1 / 68 (1.47%) 1
Blood and lymphatic system disorders Anaemia of pregnancy subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 75 (1.33%) 1	0 / 68 (0.00%) 0
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	0 / 75 (0.00%) 0	0 / 68 (0.00%) 0
Gastrointestinal disorders			

Nausea			
subjects affected / exposed	18 / 70 (25.71%)	17 / 75 (22.67%)	9 / 68 (13.24%)
occurrences (all)	18	17	9
Abdominal pain			
subjects affected / exposed	9 / 70 (12.86%)	17 / 75 (22.67%)	7 / 68 (10.29%)
occurrences (all)	9	18	9
Diarrhoea			
subjects affected / exposed	11 / 70 (15.71%)	13 / 75 (17.33%)	9 / 68 (13.24%)
occurrences (all)	11	13	9
Vomiting			
subjects affected / exposed	5 / 70 (7.14%)	7 / 75 (9.33%)	4 / 68 (5.88%)
occurrences (all)	5	7	4
Abdominal discomfort			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	1 / 68 (1.47%)
occurrences (all)	0	1	1
Abdominal pain lower			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Mouth cyst			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Teething			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0

Toothache subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 75 (1.33%) 1	0 / 68 (0.00%) 0
Hepatobiliary disorders Cholestasis of pregnancy subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1	1 / 75 (1.33%) 1	0 / 68 (0.00%) 0
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0	1 / 75 (1.33%) 1	0 / 68 (0.00%) 0
Renal and urinary disorders Glycosuria subjects affected / exposed occurrences (all) Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0 0 / 70 (0.00%) 0	1 / 75 (1.33%) 1 1 / 75 (1.33%) 1	0 / 68 (0.00%) 0 0 / 68 (0.00%) 0
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all) Arthralgia subjects affected / exposed occurrences (all) Groin pain subjects affected / exposed occurrences (all) Ligament pain subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1 1 / 70 (1.43%) 1 1 / 70 (1.43%) 1 1 / 70 (1.43%) 1 1 / 70 (1.43%) 1	3 / 75 (4.00%) 3 0 / 75 (0.00%) 0 0 / 75 (0.00%) 0 0 / 75 (0.00%) 0 0 / 75 (0.00%) 0	0 / 68 (0.00%) 0 1 / 68 (1.47%) 1 0 / 68 (0.00%) 0 0 / 68 (0.00%) 0 0 / 68 (0.00%) 0
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	4 / 68 (5.88%)
occurrences (all)	0	1	4
Urinary tract infection			
subjects affected / exposed	2 / 70 (2.86%)	1 / 75 (1.33%)	2 / 68 (2.94%)
occurrences (all)	2	1	2
Influenza			
subjects affected / exposed	0 / 70 (0.00%)	3 / 75 (4.00%)	1 / 68 (1.47%)
occurrences (all)	0	3	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 70 (0.00%)	2 / 75 (2.67%)	1 / 68 (1.47%)
occurrences (all)	0	2	1
Acute sinusitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 75 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 70 (1.43%)	0 / 75 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Tooth abscess			
subjects affected / exposed	0 / 70 (0.00%)	1 / 75 (1.33%)	0 / 68 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	RSV MAT 60 Group-Infant	RSV MAT 120 Group-Infant	Control Group-Infant
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
Pregnancy, puerperium and perinatal conditions			
Foetal hypokinesia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Gestational diabetes			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Feeling hot			

subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Induration subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Injection site irritation subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Swelling subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Reproductive system and breast disorders Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Vulvovaginal discomfort subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Asthma			

subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Asthmatic crisis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia of pregnancy subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Gastrointestinal disorder			

subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Mouth cyst subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Teething subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Hepatobiliary disorders Cholestasis of pregnancy subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Renal and urinary disorders Glycosuria subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	0 / 67 (0.00%) 0	0 / 73 (0.00%) 0	0 / 66 (0.00%) 0

Groin pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Ligament pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			

subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 67 (0.00%)	0 / 73 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 January 2020	1. To increase enrolment from 150 to 300 maternal subjects, thereby providing additional safety and immune response data in support of subsequent studies. 2. To better facilitate protocol implementation and analysis by correcting the end of study definition and clarifying the language used to describe: several inclusion and exclusion criteria, the NaCl formulation, and several study procedures. 3. Other administrative changes have been made, and typographical errors have been corrected.
11 May 2020	To provide measures that may be applicable during special circumstances (e.g., COVID-19 pandemic). The purpose of the amendment is to protect participant's welfare and safety, and as far as possible ensure the potential benefit to the participant and promote data integrity.
30 September 2020	This protocol is amended to reflect the possibility of inadvertent unblinding of investigators and site staff to some subjects' treatment assignments in the context of Investigator's Brochure (IB) safety data updates following analysis 2. After the second analysis, the study will not be considered observer blind as the investigator brochure will be updated to include safety information presented by treatment group. In addition, this amendment outlines a plan to implement additional contacts for safety monitoring in the event of problems with electronic diary data capture.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported