



Clinical trial results:

A Phase 3b, non-randomized, open label, multi-country, cohort study to describe the safety of study participants who received RSVPreF3 maternal vaccination (any dose) or controls from previous RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-010, RSV MAT-011, RSV MAT-009, RSV MAT-012 and RSV MAT-039) during any pregnancy conceived post vaccination/control

Summary

EudraCT number	2022-003124-41
Trial protocol	FI BE DE FR ES
Global end of trial date	15 January 2025

Results information

Result version number	v1
This version publication date	31 July 2025
First version publication date	31 July 2025

Trial information

Trial identification

Sponsor protocol code	219510
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05705440
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	79 New Oxford Street, London, WC1A 1DG, United Kingdom, TW8 9GS
Public contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	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	19 March 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	15 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the incidence of pregnancy outcomes, pregnancy related adverse events of special interest (AESIs) and infant AESIs during the first pregnancy conceived within 2 years post-vaccination in participants enrolled in RSV MAT studies (by study arm, those previously received RSVPreF3 and control) up to Day 42 post-delivery.

Protection of trial subjects:

The investigator or his/her representative explained the nature of the study to the participant or his/her legally authorized representative and answered all questions regarding the study.

Participants and/or their legally authorized representative were informed that their participation was voluntary. Participants or their legally authorized representative were required to sign a statement of informed consent that met the requirements of 21 Code of Federal Regulations (CFR) 50, local regulations, International Council for Harmonization (ICH) guidelines, Health Insurance Portability and Accountability Act (HIPAA) requirements, privacy and data protection requirements, where applicable, and the Institutional Review Board/Independent Ethics Committee (IRB/IEC) or study center.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 February 2023
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 206
Country: Number of subjects enrolled	France: 12
Country: Number of subjects enrolled	Germany: 32
Country: Number of subjects enrolled	Honduras: 20
Country: Number of subjects enrolled	India: 44
Country: Number of subjects enrolled	Italy: 10
Country: Number of subjects enrolled	Korea, Republic of: 91
Country: Number of subjects enrolled	New Zealand: 84
Country: Number of subjects enrolled	Panama: 448
Country: Number of subjects enrolled	Philippines: 258
Country: Number of subjects enrolled	South Africa: 401
Country: Number of subjects enrolled	Spain: 854
Country: Number of subjects enrolled	Taiwan: 87
Country: Number of subjects enrolled	Thailand: 49
Country: Number of subjects enrolled	United States: 376

Country: Number of subjects enrolled	Argentina: 76
Country: Number of subjects enrolled	Australia: 21
Country: Number of subjects enrolled	Bangladesh: 278
Country: Number of subjects enrolled	Belgium: 28
Country: Number of subjects enrolled	Brazil: 59
Country: Number of subjects enrolled	Canada: 290
Country: Number of subjects enrolled	Colombia: 115
Country: Number of subjects enrolled	Dominican Republic: 16
Worldwide total number of subjects	3855
EEA total number of subjects	1142

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	457
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	10
Adults (18-64 years)	3388
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 3855 participants (3398 mothers & 457 infants) completed the informed consent process, of which 475 mothers with pregnancy conceived within and beyond 2 years post-vaccination were included in the Maternal Full Analysis Set (FAS). 438 infants who were born to those mothers and had post-birth data were included in the Infant FAS.

Pre-assignment

Screening details:

Out of the 475 mothers included in the Maternal FAS, a total of 448 mothers who conceived within 2 years post-vaccination were considered for the primary, secondary and safety analyses. 411 infants born to the 448 mothers were considered for the primary, secondary and safety analyses.

Period 1

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

Arms

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

Arm description:

Maternal participants who received the RSVPreF3 vaccine during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-009, RSV MAT-010, RSV MAT-011, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study.

Arm type	No intervention
Investigational medicinal product name	RSVPreF3 vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

No intervention is administered in this extension study. Participants received the RSVPreF3 vaccine during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-010, RSV MAT-011, RSV MAT-009, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study. In all prior RSV MAT studies, participants received one dose of RSVPreF3 vaccine except in RSV MAT-011 study, where some participants received a second dose as well.

Arm title	Control Group - Mother
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Arm description:

Maternal participants who received any control (placebo, Tdap or influenza vaccine) during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-009, RSV MAT-010, RSV MAT-011, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study.

Arm type	No intervention
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:

No intervention is administered in this extension study. Participants received any control (placebo, Tdap or influenza vaccine) during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-010, RSV MAT-011, RSV MAT-009, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study. In all prior RSV MAT studies, participants received one dose of any control

(placebo, Tdap or influenza vaccine).

Investigational medicinal product name	Influenza vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

No intervention is administered in this extension study. Participants received any control (placebo, Tdap or influenza vaccine) during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-010, RSV MAT-011, RSV MAT-009, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study. In all prior RSV MAT studies, participants received one dose of any control (placebo, Tdap or influenza vaccine).

Investigational medicinal product name	Tdap vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

No intervention is administered in this extension study. Participants received any control (placebo, Tdap or influenza vaccine) during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-010, RSV MAT-011, RSV MAT-009, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study. In all prior RSV MAT studies, participants received one dose of any control (placebo, Tdap or influenza vaccine).

Arm title	RSV MAT Group - Infant
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Arm description:

This group consisted of infants live-born to maternal participants in the RSV MAT Group - Mother.

Arm type	No intervention
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No investigational medicinal product assigned in this arm

Arm title	Control Group - Infant
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Arm description:

This group consisted of infants live-born to maternal participants in the Control Group - Mother.

Arm type	No intervention
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No investigational medicinal product assigned in this arm

Number of subjects in period 1^[1]	RSV MAT Group - Mother	Control Group - Mother	RSV MAT Group - Infant
Started	296	152	275
Completed	269	136	256
Not completed	27	16	19
Adverse Event leading to study discontinuation	1	-	-
Adverse event, serious fatal	-	-	1
Physician decision	4	-	-
Migrated / moved from the study area	-	1	-
Not specified	18	12	17
Lost to follow-up	4	3	1

Number of subjects in period 1	Control Group - Infant
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[1]	
Started	136
Completed	118
Not completed	18
Adverse Event leading to study discontinuation	-
Adverse event, serious fatal	-
Physician decision	-
Migrated / moved from the study area	-
Not specified	17
Lost to follow-up	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: A total of 3855 participants (3398 mothers & 457 infants) completed the informed consent process. Out of the 475 mothers included in the Maternal FAS, a total of 448 mothers who conceived within 2 years post-vaccination were considered for the primary, secondary and safety analyses. 411 infants born to the 448 mothers were considered for the primary, secondary and safety analyses.

Baseline characteristics

Reporting groups

Reporting group title	RSV MAT Group - Mother
Reporting group description: Maternal participants who received the RSVPreF3 vaccine during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-009, RSV MAT-010, RSV MAT-011, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study.	
Reporting group title	Control Group - Mother
Reporting group description: Maternal participants who received any control (placebo, Tdap or influenza vaccine) during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-009, RSV MAT-010, RSV MAT-011, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study.	
Reporting group title	RSV MAT Group - Infant
Reporting group description: This group consisted of infants live-born to maternal participants in the RSV MAT Group - Mother.	
Reporting group title	Control Group - Infant
Reporting group description: This group consisted of infants live-born to maternal participants in the Control Group - Mother.	

Reporting group values	RSV MAT Group - Mother	Control Group - Mother	RSV MAT Group - Infant
Number of subjects	296	152	275
Age Categorical			
Descriptive summaries of age are presented for the maternal participants (age at the time of vaccination in prior RSV MAT studies) included in the RSV MAT Group - Mother and Control Group - Mother and for the infants included in the RSV MAT Group - Infant and Control Group - Infant.			
Units: Participants			
0 to 1 years of age	0	0	275
<18 years of age	2	0	0
18 to 24 years of age	76	29	0
25 to 34 years of age	181	97	0
>=35 years of age	37	26	0
Sex: Female, Male			
Units: Participants			
Female	296	152	144
Male	0	0	131
Race/Ethnicity, Customized			
The "All Other Races" category (i.e., American Indian Or Alaska Native, Black Or African American, and Native Hawaiian Or Other Pacific Islander where 0<n<11) are combined into one category to maintain participant confidentiality and privacy.			
Units: Subjects			
All Other Races	26	19	22
Asian	41	22	39
White	199	102	179
Multiple	16	6	19
Not Reported	2	1	3
Unknown, Not Specified	12	2	13

Reporting group values	Control Group - Infant	Total	
Number of subjects	136	859	

Age Categorical			
Descriptive summaries of age are presented for the maternal participants (age at the time of vaccination in prior RSV MAT studies) included in the RSV MAT Group - Mother and Control Group – Mother and for the infants included in the RSV MAT Group – Infant and Control Group - Infant.			
Units: Participants			
0 to 1 years of age	136	411	
<18 years of age	0	2	
18 to 24 years of age	0	105	
25 to 34 years of age	0	278	
>=35 years of age	0	63	
Sex: Female, Male			
Units: Participants			
Female	65	657	
Male	71	202	
Race/Ethnicity, Customized			
The "All Other Races" category (i.e., American Indian Or Alaska Native, Black Or African American, and Native Hawaiian Or Other Pacific Islander where 0<n<11) are combined into one category to maintain participant confidentiality and privacy.			
Units: Subjects			
All Other Races	12	79	
Asian	19	121	
White	92	572	
Multiple	8	49	
Not Reported	1	7	
Unknown, Not Specified	4	31	

End points

End points reporting groups

Reporting group title	RSV MAT Group - Mother
Reporting group description: Maternal participants who received the RSVPreF3 vaccine during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-009, RSV MAT-010, RSV MAT-011, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study.	
Reporting group title	Control Group - Mother
Reporting group description: Maternal participants who received any control (placebo, Tdap or influenza vaccine) during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-009, RSV MAT-010, RSV MAT-011, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study.	
Reporting group title	RSV MAT Group - Infant
Reporting group description: This group consisted of infants live-born to maternal participants in the RSV MAT Group - Mother.	
Reporting group title	Control Group - Infant
Reporting group description: This group consisted of infants live-born to maternal participants in the Control Group - Mother.	

Primary: Number of maternal participants with pregnancy outcomes from conception until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of maternal participants with pregnancy outcomes from conception until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies ^{[1][2]}
End point description: Assessed pregnancy outcomes were live infant with no apparent congenital anomaly (CA); spontaneous abortion with no apparent congenital anomaly (CA); ectopic pregnancy; elective termination with no apparent congenital anomaly (CA); live infant with congenital anomaly (CA), and stillbirth with congenital anomaly (CA). Analysis was performed on the Full Analysis set (first pregnancy) - Maternal, which included all maternal participants with first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies and with pregnancy outcomes data available for the specified analysis during the specified period of the first pregnancy.	
End point type	Primary
End point timeframe: From conception until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies	

Notes:

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

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

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

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

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[3]	151 ^[4]		
Units: Participants				
Live infant with no apparent CA	249	120		
Spontaneous abortion with no apparent CA	28	14		
Ectopic pregnancy	1	1		
Elective termination with no apparent CA	1	2		
Live infant with CA	17	13		
Stillbirth with CA	0	1		

Notes:

[3] - Number of participants analyzed in each row = 296.

[4] - Number of participants analyzed in each row = 151.

Statistical analyses

No statistical analyses for this end point

Primary: Number of maternal participants with pregnancy-related adverse events of special interest (AESIs) from conception until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of maternal participants with pregnancy-related adverse events of special interest (AESIs) from conception until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies ^{[5][6]}
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End point description:

Assessed pregnancy-related AESIs were chorioamnionitis, fetal growth restriction, gestational diabetes mellitus, gestational hypertension, pre-eclampsia, pre-eclampsia with severe features including eclampsia, premature preterm ruptures of membranes, preterm labor and provider-initiated preterm birth.

Analysis was performed on the Full Analysis set (first pregnancy) - Maternal, which included all maternal participants with first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies and with pregnancy-related AESIs data available for the specified analysis during the specified period of the first pregnancy.

End point type	Primary
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End point timeframe:

From conception until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

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

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

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

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

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[7]	151 ^[8]		
Units: Participants				
Chorioamnionitis	2	0		
Fetal growth restriction	3	3		

Gestational diabetes mellitus	12	7		
Gestational hypertension	8	1		
Pre-eclampsia	0	2		
Pre-eclampsia with severe features	2	3		
Premature preterm ruptures of membrane	2	1		
Preterm labor	11	3		
Provider-initiated preterm birth	10	3		

Notes:

[7] - Number of participants analyzed in each row = 296.

[8] - Number of participants analyzed in each row = 151.

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with AESIs from birth until Day 42 post-birth of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of infant participants with AESIs from birth until Day 42 post-birth of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies ^{[9][10]}
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End point description:

Assessed AESIs were congenital anomalies (CA) with internal structural defects, congenital anomalies (CA) with major external structural defects, low birth weight [greater than or equal to (\geq) 1500 grams (G) and below ($<$) 2500 G], very low birth weight (\geq 1000 G and $<$ 1500 G), neonatal death in a term live birth (\geq 37 weeks of gestational age), preterm birth ($<$ 37 weeks of gestational age) and small for gestational age.

Analysis was performed on the Full Analysis Set (first pregnancy) - Infant, which included all infant participants born to maternal participants from the first study pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies and with post-birth AESIs data available for the specified analysis during the specified period.

End point type	Primary
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End point timeframe:

From birth until Day 42 post-birth of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

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 infant participants.

End point values	RSV MAT Group - Infant	Control Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	265 ^[11]	132 ^[12]		
Units: Participants				
CA with internal structural defects	3	0		
CA with major external structural defects	1	0		
Low birth weight	18	5		
Very low birth weight	1	1		
Neonatal death in a term live birth	1	0		
Preterm birth	23	8		

Small for gestational age	18	13		
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Notes:

[11] - Number of participants analyzed in each row = 265.

[12] - Number of participants analyzed in each row = 132.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of pregnancies with pregnancy outcomes from conception until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of pregnancies with pregnancy outcomes from conception until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies ^[13]
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End point description:

Assessed pregnancy outcomes were live infant with no apparent congenital anomaly (CA); spontaneous abortion with no apparent congenital anomaly (CA); ectopic pregnancy; elective termination with no apparent congenital anomaly (CA); live infant with congenital anomaly (CA); molar pregnancy; stillbirth with congenital anomaly (CA) and stillbirth with no apparent congenital anomaly (CA).

Analysis was performed on the Full Analysis set (any pregnancy) - Maternal, which included any pregnancies conceived by the maternal participants within 2 years post-vaccination received in prior RSV MAT studies and with pregnancy outcomes data available for the specified analysis during the specified period of any pregnancy.

End point type	Secondary
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End point timeframe:

From conception until Day 42 post-delivery of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

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

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

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[14]	152 ^[15]		
Units: Pregnancies				
Live infant with no apparent CA	257	123		
Spontaneous abortion with no apparent CA	31	16		
Ectopic pregnancy	1	1		
Elective termination with no apparent CA	1	2		
Live infant with CA	18	14		
Molar pregnancy	1	1		
Stillbirth with CA	0	1		
Stillbirth with no apparent CA	1	0		

Notes:

[14] - Number of participants analyzed in each row = 296.

Number of pregnancies analyzed in each row = 310.

[15] - Number of participants analyzed in each row = 152.

Number of pregnancies analyzed in each row = 158.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of pregnancies with pregnancy-related AESIs from conception until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of pregnancies with pregnancy-related AESIs from conception until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies ^[16]
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End point description:

Assessed pregnancy-related AESIs were preterm labor, provider-initiated preterm birth, premature preterm rupture of membranes, gestational diabetes mellitus, gestational hypertension, pre-eclampsia with severe features including eclampsia, pre-eclampsia, fetal growth restriction and chorioamnionitis. Analysis was performed on the Full Analysis set (any pregnancy) - Maternal, which included any pregnancies conceived by the maternal participants within 2 years post-vaccination received in prior RSV MAT studies and with pregnancy-related AESIs data available for the specified analysis during the specified period of any pregnancy.

End point type	Secondary
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End point timeframe:

From conception until Day 42 post-delivery of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

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

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

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[17]	152 ^[18]		
Units: Pregnancies				
Preterm labor	12	3		
Provider-initiated preterm birth	10	3		
Premature preterm ruptures of membranes	2	1		
Gestational diabetes mellitus	12	8		
Gestational hypertension	10	1		
Pre-eclampsia with severe features	3	3		
Pre-eclampsia	1	2		
Fetal growth restriction	4	3		
Chorioamnionitis	2	0		

Notes:

[17] - Number of participants analyzed in each row = 296.

Number of pregnancies analyzed in each row = 310.

[18] - Number of participants analyzed in each row = 152.

Number of pregnancies analyzed in each row = 158.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with AESIs from birth until Day 42 post-birth of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of infant participants with AESIs from birth until Day
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End point description:

Assessed AESIs were congenital anomalies (CA) with internal structural defects, congenital anomalies (CA) with major external structural defects, low birth weight (≥ 1500 G and < 2500 G), very low birth weight (≥ 1000 G and < 1500 G), neonatal death in a term live birth (≥ 37 weeks of gestational age), preterm birth (< 37 weeks of gestational age) and small for gestational age.

Analysis was performed on the Full Analysis Set (any pregnancy) - Infant, which included all infant participants born to maternal participants from any study pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies and with post-birth AESIs data available for the specified analysis during the specified period.

End point type	Secondary
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End point timeframe:

From birth until Day 42 post-birth of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

[19] - 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 infant participants.

End point values	RSV MAT Group - Infant	Control Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	275 ^[20]	136 ^[21]		
Units: Participants				
CA with internal structural defects	4	0		
CA with major external structural defects	1	0		
Low birth weight	20	5		
Very low birth weight	1	1		
Neonatal death in a term live birth	1	0		
Preterm birth	24	8		
Small for gestational age	20	13		

Notes:

[20] - Number of participants analyzed in each row = 275.

[21] - Number of participants analyzed in each row = 136.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of pregnancies with preterm birth event stratified by selected risk factors, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of pregnancies with preterm birth event stratified by selected risk factors, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies ^[22]
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End point description:

The selected risk factors assessed were prior preterm delivery, pregnancy complications, gestational diabetes mellitus, chorioamnionitis during pregnancy, hypertensive disorders of pregnancy, pre-existing hypertension, pre-existing diabetes, vaginal bleeding during pregnancy, polyhydramnios or oligohydramnios during pregnancy and fetal growth restriction.

The below presented data is read as follows:

With PTB = the assessed pregnancy resulted in a preterm birth (PTB) event.

Without PTB = the assessed pregnancy did not result in a preterm birth (PTB) event.

Analysis was performed on the Full Analysis set (any pregnancy) - Maternal, which included any

pregnancies that had an outcome of live birth and were conceived by the maternal participants within 2 years post-vaccination received in prior RSV MAT studies and with pre-term birth event (PTB) (stratified by selected risk factors) data available for the specified analysis during the specified period of any pregnancy.

End point type	Secondary
End point timeframe:	
From Day 1 until Day 42 post-delivery of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies	

Notes:

[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 maternal participants.

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[23]	152 ^[24]		
Units: Pregnancies				
Prior preterm delivery with PTB	5	1		
Pregnancy complications with PTB	4	0		
Gestational diabetes mellitus with PTB	0	0		
Chorioamnionitis during pregnancy with PTB	0	0		
Hypertensive disorders of preg. with PTB	0	0		
Pre-existing hypertension with PTB	1	0		
Pre-existing diabetes with PTB	1	0		
Vaginal bleeding during pregnancy with PTB	1	0		
Polyhydramnios/oligohydramnios with PTB	1	0		
Fetal growth restriction with PTB	0	0		
Prior preterm delivery without PTB	2	3		
Pregnancy complications without PTB	28	16		
Gestational diabetes mellitus without PTB	13	8		
Chorioamnionitis during pregnancy without PTB	2	0		
Hypertensive disorders of preg. without PTB	0	0		
Pre-existing hypertension without PTB	1	2		
Pre-existing diabetes without PTB	0	0		
Vaginal bleeding during pregnancy without PTB	5	2		
Polyhydramnios/oligohydramnios without PTB	3	1		
Fetal growth restriction without PTB	4	3		
No prior preterm delivery with PTB	18	6		
No pregnancy complications with PTB	19	7		
No gestational diabetes mellitus with PTB	23	7		
No chorioamnionitis during pregnancy with PTB	23	7		
No hypertensive disorders of preg. with PTB	23	7		
No pre-existing hypertension with PTB	22	7		
No pre-existing diabetes with PTB	22	7		

No vaginal bleeding during pregnancy with PTB	22	7		
No polyhydramnios/oligohydramnios with PTB	22	7		
No fetal growth restriction with PTB	23	7		
No prior preterm delivery without PTB	250	127		
No pregnancy complications without PTB	224	114		
No gestational diabetes mellitus without PTB	239	122		
No chorioamnionitis during pregnancy without PTB	250	130		
No hypertensive disorders of preg. without PTB	252	130		
No pre-existing hypertension without PTB	251	128		
No pre-existing diabetes without PTB	252	130		
No vaginal bleeding during pregnancy without PTB	247	128		
No Polyhydramnios/oligohydramnios without PTB	249	129		
No fetal growth restriction without PTB	248	127		

Notes:

[23] - Number of participants analyzed in each row = 296.

Number of pregnancies analyzed in each row = 275.

[24] - Number of participants analyzed in each row = 152.

Number of pregnancies analyzed in each row = 137.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of pregnancies with preterm birth event stratified by age group at vaccination, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of pregnancies with preterm birth event stratified by age group at vaccination, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies ^[25]
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End point description:

The age groups at vaccination assessed were <18 years, 18-24 years, 25-34 years and ≥35 years. Analysis was performed on the Full Analysis set (any pregnancy) - Maternal, which included any pregnancies that had an outcome of live birth and were conceived by the maternal participants within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by age group) data available for the specified analysis during the specified period of any pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

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

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

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[26]	152 ^[27]		
Units: Pregnancies				
<18 years: With PTB	0	0		
<18 years: Without PTB	2	0		
18-24 years: With PTB	11	2		
18-24 years: Without PTB	61	23		
25-34 years: With PTB	11	4		
25-34 years: Without PTB	156	85		
>= 35 years: With PTB	1	1		
>= 35 years: Without PTB	33	22		

Notes:

[26] - Number of participants analyzed in each row = 296.

Number of pregnancies analyzed in each row = 275.

[27] - Number of participants analyzed in each row = 152.

Number of pregnancies analyzed in each row = 137.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of pregnancies with preterm birth event stratified by pre-pregnancy body mass index (BMI), from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of pregnancies with preterm birth event stratified by pre-pregnancy body mass index (BMI), from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies ^[28]
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End point description:

The pre-pregnancy BMI categories assessed were < 30 kilogram per square meter (kg/m²), >=30 kg/m² and missing (no pre-pregnancy BMI data available).

Analysis was performed on the Full Analysis set (any pregnancy) - Maternal, which included any pregnancies that had an outcome of live birth and were conceived by the maternal participants within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by pre-pregnancy BMI) data available for the specified analysis during the specified period of any pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

[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 maternal participants.

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[29]	152 ^[30]		
Units: Pregnancies				
<30 kg/m ² : With PTB	10	2		
<30 kg/m ² : Without PTB	163	87		
>=30 kg/m ² : With PTB	1	3		

>=30 kg/m ² : Without PTB	38	10		
Missing: With PTB	12	2		
Missing: Without PTB	51	33		

Notes:

[29] - Number of participants analyzed in each row = 296.

Number of pregnancies analyzed in each row = 275.

[30] - Number of participants analyzed in each row = 152.

Number of pregnancies analyzed in each row = 137.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of pregnancies with preterm birth event stratified by race, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of pregnancies with preterm birth event stratified by race, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies ^[31]
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End point description:

The races assessed were American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, Multiple, Not reported and Unknown.

Analysis was performed on the Full Analysis set (any pregnancy) - Maternal, which included any pregnancies that had an outcome of live birth and were conceived by the maternal participants within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by race) data available for the specified analysis during the specified period of any pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

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

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

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[32]	152 ^[33]		
Units: Pregnancies				
American Indian/Alaska Native: With PTB	0	1		
American Indian/Alaska Native: Without PTB	5	8		
Asian: With PTB	6	0		
Asian: Without PTB	33	20		
Black/African American: With PTB	1	1		
Black/African American: Without PTB	14	6		
Native Hawaiian/Other Pacific Islander: With PTB	0	0		
Native Hawaiian/Other Pacific Islander: Without PTB	3	1		
White: With PTB	10	4		
White: Without PTB	178	88		
Multiple: With PTB	3	0		
Multiple: Without PTB	10	5		

Not reported: With PTB	0	1		
Not reported: Without PTB	2	0		
Unknown: With PTB	3	0		
Unknown: Without PTB	7	2		

Notes:

[32] - Number of participants analyzed in each row = 296.

Number of pregnancies analyzed in each row = 275.

[33] - Number of participants analyzed in each row = 152.

Number of pregnancies analyzed in each row = 137.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of pregnancies with preterm birth event stratified by multiple gestation pregnancy, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of pregnancies with preterm birth event stratified by multiple gestation pregnancy, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies ^[34]
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End point description:

The multiple gestation pregnancy assessed were one gestation, two gestations and three gestations. Analysis was performed on the Full Analysis set (any pregnancy) - Maternal, which included any pregnancies that had an outcome of live birth and were conceived by the maternal participants within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by multiple gestation pregnancy) data available for the specified analysis during the specified period of any pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

[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 maternal participants.

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[35]	152 ^[36]		
Units: Pregnancies				
One gestation: With PTB	22	7		
One gestation: Without PTB	242	125		
Two gestations: With PTB	1	0		
Two gestations: Without PTB	8	5		
Three gestations: With PTB	0	0		
Three gestations: Without PTB	2	0		

Notes:

[35] - Number of participants analyzed in each row = 296.

Number of pregnancies analyzed in each row = 275.

[36] - Number of participants analyzed in each row = 152.

Number of pregnancies analyzed in each row = 137.

Statistical analyses

Secondary: Number of pregnancies with preterm birth event stratified by geographic region, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of pregnancies with preterm birth event stratified by geographic region, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies ^[37]
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End point description:

The geographic regions assessed were Europe, Australasia, North America, Latin America and Africa. Analysis was performed on the Full Analysis set (any pregnancy) - Maternal, which included any pregnancies that had an outcome of live birth and were conceived by the maternal participants within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by geographic region) data available for the specified analysis during the specified period of any pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

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

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

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[38]	152 ^[39]		
Units: Pregnancies				
Europe: With PTB	6	3		
Europe: Without PTB	93	51		
Australasia: With PTB	6	0		
Australasia: Without PTB	43	25		
North America: With PTB	4	1		
North America: Without PTB	72	31		
Latin America: With PTB	7	2		
Latin America: Without PTB	36	20		
Africa: With PTB	0	1		
Africa: Without PTB	8	3		

Notes:

[38] - Number of participants analyzed in each row = 296.

Number of pregnancies analyzed in each row = 275.

[39] - Number of participants analyzed in each row = 152.

Number of pregnancies analyzed in each row = 137.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of pregnancies with preterm birth event stratified by economic region, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of pregnancies with preterm birth event stratified by
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economic region, from Day 1 until Day 42 post-delivery of any pregnancy conceived by maternal participants within 2 years post-vaccination received in prior RSV MAT studies^[40]

End point description:

The economic regions assessed were low and middle-income countries (LMIC) and high-income countries (HIC).

Analysis was performed on the Full Analysis set (any pregnancy) - Maternal, which included any pregnancies that had an outcome of live birth and were conceived by the maternal participants within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by economic region) data available for the specified analysis during the specified period of any pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of any pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

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 participants.

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296 ^[41]	152 ^[42]		
Units: Pregnancies				
LMIC: With PTB	13	3		
LMIC: Without PTB	66	38		
HIC: With PTB	10	4		
HIC: Without PTB	186	92		

Notes:

[41] - Number of participants analyzed in each row = 296.

Number of pregnancies analyzed in each row = 275.

[42] - Number of participants analyzed in each row = 152.

Number of pregnancies analyzed in each row = 137.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with preterm birth event stratified by selected risk factors, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of maternal participants with preterm birth event stratified by selected risk factors, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies ^[43]
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End point description:

The selected risk factors assessed were prior preterm delivery, pregnancy complications, gestational diabetes mellitus, chorioamnionitis during pregnancy, hypertensive disorders of pregnancy, pre-existing hypertension, pre-existing diabetes, vaginal bleeding during pregnancy, polyhydramnios or oligohydramnios during pregnancy and fetal growth restriction.

Analysis was performed on the Full Analysis set (first pregnancy) - Maternal, which included all maternal participants with first pregnancy that had an outcome of live birth and was conceived within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by selected risk factors) data available for the specified analysis during the specified period of the first pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination

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 maternal participants.

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	266 ^[44]	133 ^[45]		
Units: Participants				
Prior preterm delivery with PTB	5	1		
Pregnancy complications with PTB	4	0		
Gestational diabetes mellitus with PTB	0	0		
Chorioamnionitis during pregnancy with PTB	0	0		
Hypertensive disorders of preg.with PTB	0	0		
Pre-existing hypertension with PTB	1	0		
Pre-existing diabetes with PTB	1	0		
Vaginal bleeding during pregnancy with PTB	1	0		
Polyhydramnios/oligohydramnios with PTB	1	0		
Fetal growth restriction with PTB	0	0		
Prior preterm delivery without PTB	2	3		
Pregnancy complications without PTB	27	15		
Gestational diabetes mellitus without PTB	13	7		
Chorioamnionitis during pregnancy without PTB	2	0		
Hypertensive disorders of preg. without PTB	0	0		
Pre-existing hypertension without PTB	1	2		
Pre-existing diabetes without PTB	0	0		
Vaginal bleeding during pregnancy without PTB	5	2		
Polyhydramnios/oligohydramnios without PTB	3	1		
Fetal growth restriction without PTB	3	3		
No prior preterm delivery with PTB	17	6		
No pregnancy complications with PTB	18	7		
No gestational diabetes mellitus with PTB	22	7		
No chorioamnionitis during pregnancy with PTB	22	7		
No hypertensive disorders of preg. with PTB	22	7		
No pre-existing hypertension with PTB	21	7		
No pre-existing diabetes with PTB	21	7		
No vaginal bleeding during pregnancy with PTB	21	7		
No Polyhydramnios/oligohydramnios with PTB	21	7		
No fetal growth restriction with PTB	22	7		
No prior preterm delivery without PTB	242	123		
No pregnancy complications without PTB	217	111		

No gestational diabetes mellitus without PTB	231	119		
No chorioamnionitis during pregnancy without PTB	242	126		
No hypertensive disorders of preg. without PTB	244	126		
No pre-existing hypertension without PTB	243	124		
No pre-existing diabetes without PTB	244	126		
No vaginal bleeding during pregnancy without PTB	239	124		
No polyhydramnios/oligohydramnios without PTB	241	125		
No fetal growth restriction without PTB	241	123		

Notes:

[44] - Number of participants analyzed in each row = 266.

[45] - Number of participants analyzed in each row = 133.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with preterm birth event stratified by age group at vaccination, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of maternal participants with preterm birth event stratified by age group at vaccination, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies ^[46]
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End point description:

The age groups at vaccination assessed were <18 years, 18-24 years, 25-34 years and ≥35 years. Analysis was performed on the Full Analysis set (first pregnancy) - Maternal, which included all maternal participants with first pregnancy that had an outcome of live birth and was conceived within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by age group at vaccination) data available for the specified analysis during the specified period of the first pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

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 maternal participants.

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	266 ^[47]	133 ^[48]		
Units: Participants				
<18 years: With PTB	0	0		
<18 years: Without PTB	2	0		
18-24 years: With PTB	11	2		
18-24 years: Without PTB	61	22		
25-34 years: With PTB	10	4		
25-34 years: Without IPTB	149	83		

>= 35 years: With PTB	1	1		
>= 35 years: Without PTB	32	21		

Notes:

[47] - Number of participants analyzed in each row = 266.

[48] - Number of participants analyzed in each row = 133.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with preterm birth event stratified by pre-pregnancy BMI group, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of maternal participants with preterm birth event stratified by pre-pregnancy BMI group, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies ^[49]
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End point description:

The pre-pregnancy BMI categories assessed were < 30 kilogram per square meter (kg/m²), >=30 kg/m² and missing (no pre-pregnancy BMI data available).

Analysis was performed on the Full Analysis set (first pregnancy) - Maternal, which included all maternal participants with first pregnancy that had an outcome of live birth and was conceived within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by pre-pregnancy BMI group) data available for the specified analysis during the specified period of the first pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

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 maternal participants.

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	266 ^[50]	133 ^[51]		
Units: Participants				
<30 kg/m ² : With PTB	10	2		
<30 kg/m ² : Without PTB	161	87		
>=30 kg/m ² : With PTB	1	3		
>=30 kg/m ² : Without PTB	38	10		
Missing: With PTB	11	2		
Missing: Without PTB	45	29		

Notes:

[50] - Number of participants analyzed in each row = 266.

[51] - Number of participants analyzed in each row = 133.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with preterm birth event stratified by

race, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of maternal participants with preterm birth event stratified by race, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies ^[52]
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End point description:

The races assessed were American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, Multiple, Not reported and Unknown. Analysis was performed on the Full Analysis set (first pregnancy) - Maternal, which included all maternal participants with first pregnancy that had an outcome of live birth and was conceived within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by race) data available for the specified analysis during the specified period of the first pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

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

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

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	266 ^[53]	133 ^[54]		
Units: Participants				
American Indian/Alaska Native: With PTB	0	1		
American Indian/Alaska Native: Without PTB	5	8		
Asian: With PTB	6	0		
Asian: Without PTB	33	20		
Black/African American: With PTB	1	1		
Black/African American: Without PTB	14	6		
Native Hawaiian/Other Pacific Islander: With PTB	0	0		
Native Hawaiian/Other Pacific Islander: Without PTB	3	1		
White: With PTB	9	4		
White: Without PTB	170	84		
Multiple: With PTB	3	0		
Multiple: Without PTB	10	5		
Not reported: With PTB	0	1		
Not reported: Without PTB	2	0		
Unknown: With PTB	3	0		
Unknown: Without PTB	7	2		

Notes:

[53] - Number of participants analyzed in each row = 266.

[54] - Number of participants analyzed in each row = 133.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with preterm birth event stratified by

multiple gestation pregnancy, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of maternal participants with preterm birth event stratified by multiple gestation pregnancy, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies ^[55]
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End point description:

The multiple gestation pregnancy assessed were one gestation and two gestations. Analysis was performed on the Full Analysis set (first pregnancy) - Maternal, which included all maternal participants with first pregnancy that had an outcome of live birth and was conceived within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by multiple gestation pregnancy) data available for the specified analysis during the specified period of the first pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

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

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

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	266 ^[56]	133 ^[57]		
Units: Participants				
One gestation: With PTB	22	7		
One gestation: Without PTB	242	125		
Two gestations: With PTB	0	0		
Two gestations: Without PTB	2	1		

Notes:

[56] - Number of participants analyzed in each row = 266.

[57] - Number of participants analyzed in each row = 133.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with preterm birth event stratified by geographic region, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of maternal participants with preterm birth event stratified by geographic region, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies ^[58]
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End point description:

The geographic regions assessed were Europe, Australasia, North America, Latin America and Africa. Analysis was performed on the Full Analysis set (first pregnancy) - Maternal, which included all maternal participants with first pregnancy that had an outcome of live birth and was conceived within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by geographic region) data available for the specified analysis during the specified period of the first pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination

received in prior RSV MAT studies

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 maternal participants.

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	266 ^[59]	133 ^[60]		
Units: Participants				
Europe: With PTB	5	3		
Europe: Without PTB	90	50		
Australasia: With PTB	6	0		
Australasia: Without PTB	42	25		
North America: With PTB	4	1		
North America: Without PTB	68	28		
Latin America: With PTB	7	2		
Latin America: Without PTB	36	20		
Africa: With PTB	0	1		
Africa: Without PTB	8	3		

Notes:

[59] - Number of participants analyzed in each row = 266.

[60] - Number of participants analyzed in each row = 133.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with preterm birth event stratified by economic region, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

End point title	Number of maternal participants with preterm birth event stratified by economic region, from Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies ^[61]
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End point description:

The economic regions assessed were LMIC and HIC.

Analysis was performed on the Full Analysis set (first pregnancy) - Maternal, which included all maternal participants with first pregnancy that had an outcome of live birth and was conceived within 2 years post-vaccination received in prior RSV MAT studies and with preterm birth (PTB) event (stratified by economic region) data available for the specified analysis during the specified period of the first pregnancy.

End point type	Secondary
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End point timeframe:

From Day 1 until Day 42 post-delivery of the first pregnancy conceived within 2 years post-vaccination received in prior RSV MAT studies

Notes:

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

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

End point values	RSV MAT Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	266 ^[62]	133 ^[63]		
Units: Participants				
LMIC: With PTB	13	3		
LMIC: Without PTB	66	38		
HIC: With PTB	9	4		
HIC: Without PTB	178	88		

Notes:

[62] - Number of participants analyzed in each row = 266.

[63] - Number of participants analyzed in each row = 133.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Maternal groups: All-cause mortality, AESIs, and SAEs: From conception to Day 42 post-delivery of any pregnancy. Infant groups: All-cause mortality, AESIs, and SAEs: From birth to Day 42 post-birth of any pregnancy.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

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

Maternal participants who received the RSVPreF3 vaccine during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-009, RSV MAT-010, RSV MAT-011, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study.

Reporting group title	Control Group - Infant
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Reporting group description:

This group consisted of infants live-born to maternal participants in the Control Group - Mother.

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

This group consisted of infants live-born to maternal participants in the RSV MAT Group - Mother.

Reporting group title	Control Group - Mother
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Reporting group description:

Maternal participants who received any control (placebo, Tdap or influenza vaccine) during the prior RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-009, RSV MAT-010, RSV MAT-011, RSV MAT-012 and RSV MAT-039) according to the vaccination schedule specific to each study.

Serious adverse events	RSV MAT Group - Mother	Control Group - Infant	RSV MAT Group - Infant
Total subjects affected by serious adverse events			
subjects affected / exposed	60 / 296 (20.27%)	17 / 136 (12.50%)	39 / 275 (14.18%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign hydatidiform mole			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Surgical and medical procedures			
Medically induced preterm birth			
subjects affected / exposed	3 / 296 (1.01%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labour induction			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (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
Abortion induced			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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			
Abortion spontaneous			
subjects affected / exposed	28 / 296 (9.46%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	1 / 31	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous incomplete			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (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
Abortion threatened			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Anembryonic gestation			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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

Brow presentation			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breech presentation			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (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
Asynclitic presentation			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Ectopic pregnancy			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal disorder			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal distress syndrome			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage in pregnancy			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth restriction			

subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperemesis gravidarum			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oligohydramnios			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (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 / 296 (0.00%)	3 / 136 (2.21%)	6 / 275 (2.18%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice neonatal			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	2 / 275 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placenta praevia			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Postpartum haemorrhage			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Premature labour			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			

subjects affected / exposed	0 / 296 (0.00%)	3 / 136 (2.21%)	10 / 275 (3.64%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pre-eclampsia			
subjects affected / exposed	4 / 296 (1.35%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Prolonged labour			
subjects affected / exposed	3 / 296 (1.01%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Term baby			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superimposed pre-eclampsia			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Stillbirth			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Small for dates baby			

subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	2 / 275 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged rupture of membranes			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Threatened labour			
subjects affected / exposed	4 / 296 (1.35%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine hypertonus			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (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			
Death neonatal			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (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
Immune system disorders			
ABO incompatibility			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			

subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
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 asphyxia			
subjects affected / exposed	0 / 296 (0.00%)	3 / 136 (2.21%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal pneumothorax			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
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 distress			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	2 / 275 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	6 / 275 (2.18%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary haemorrhage			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (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
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 296 (0.00%)	2 / 136 (1.47%)	2 / 275 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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			
Medical observation			

subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
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			
Fall			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
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, familial and genetic disorders			
Congenital abdominal hernia			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
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 hydronephrosis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial septal defect			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital megaureter			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aorta hypoplasia			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (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 syphilis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constricted ear deformity			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (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
Haemangioma congenital			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ebstein's anomaly			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DiGeorge's syndrome			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Developmental hip dysplasia			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart disease congenital			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (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
Microcephaly			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	2 / 275 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tethered oral tissue			
subjects affected / exposed	0 / 296 (0.00%)	3 / 136 (2.21%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polydactyly			

subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycystic liver disease			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penoscrotal fusion			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberous sclerosis complex			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
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			
Bradycardia foetal			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal heart rate deceleration abnormality			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (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			
Encephalopathy neonatal			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (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
Paresis			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (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

Blood and lymphatic system disorders			
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (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
Anaemia			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (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			
Diarrhoea			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
COVID-19			

subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholin's abscess			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Dengue fever			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (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
Enterovirus infection			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	2 / 275 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (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 pneumonia			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	2 / 275 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genitourinary tract infection			

subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Puerperal pyrexia			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (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
Staphylococcal infection			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis neonatal			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (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 syncytial virus bronchiolitis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (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
Wound infection			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (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
Metabolism and nutrition disorders			
Weight gain poor			

subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Control Group - Mother		
Total subjects affected by serious adverse events			
subjects affected / exposed	37 / 152 (24.34%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign hydatidiform mole			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Medically induced preterm birth			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Labour induction			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abortion induced			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			

subjects affected / exposed	14 / 152 (9.21%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
Abortion spontaneous incomplete			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abortion threatened			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anembryonic gestation			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brow presentation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breech presentation			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asynclitic presentation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ectopic pregnancy			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foetal disorder			

subjects affected / exposed	0 / 152 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foetal distress syndrome				
subjects affected / exposed	2 / 152 (1.32%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haemorrhage in pregnancy				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gestational hypertension				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foetal growth restriction				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperemesis gravidarum				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oligohydramnios				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Low birth weight baby				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice neonatal				

subjects affected / exposed	0 / 152 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Placenta praevia				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postpartum haemorrhage				
subjects affected / exposed	3 / 152 (1.97%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Premature labour				
subjects affected / exposed	2 / 152 (1.32%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Premature baby				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pre-eclampsia				
subjects affected / exposed	3 / 152 (1.97%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Premature separation of placenta				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Preterm premature rupture of membranes				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prolonged labour				

subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Term baby			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Superimposed pre-eclampsia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stillbirth			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small for dates baby			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prolonged rupture of membranes			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Threatened labour			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine hypertonus			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death neonatal			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
ABO incompatibility			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal asphyxia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal pneumothorax			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal respiratory distress			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pulmonary haemorrhage			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Medical observation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Congenital abdominal hernia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital hydronephrosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial septal defect			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital megaureter			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aorta hypoplasia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital syphilis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constricted ear deformity			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemangioma congenital			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ebstein's anomaly			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
DiGeorge's syndrome			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Developmental hip dysplasia			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heart disease congenital			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Microcephaly			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tethered oral tissue			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polydactyly			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polycystic liver disease			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Penoscrotal fusion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tuberous sclerosis complex			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Bradycardia foetal			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal heart rate deceleration abnormality			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Encephalopathy neonatal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paresis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hyperbilirubinaemia neonatal			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary colic			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bartholin's abscess			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enterovirus infection			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal pneumonia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Genitourinary tract infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Puerperal pyrexia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis neonatal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus bronchiolitis			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Weight gain poor			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	RSV MAT Group - Mother	Control Group - Infant	RSV MAT Group - Infant
Total subjects affected by non-serious adverse events			
subjects affected / exposed	145 / 296 (48.99%)	42 / 136 (30.88%)	76 / 275 (27.64%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Melanocytic naevus			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Uterine leiomyoma			

subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Vascular disorders			
Thrombosis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Female sterilisation			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Medically induced preterm birth			
subjects affected / exposed	7 / 296 (2.36%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	7	0	0
Salpingectomy			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Sterilisation			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Caesarean section			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Pregnancy, puerperium and perinatal conditions			
Maternal pre-pregnancy obesity			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Abortion threatened			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Afterbirth pain			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Breech presentation			

subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Caput succedaneum			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Complication of delivery			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Foetal growth restriction			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Foetal malpresentation			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Gestational diabetes			
subjects affected / exposed	13 / 296 (4.39%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	13	0	0
Gestational hypertension			
subjects affected / exposed	9 / 296 (3.04%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	9	0	0
Gestational hyperthyroidism			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Haemorrhage in pregnancy			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Jaundice neonatal			
subjects affected / exposed	0 / 296 (0.00%)	2 / 136 (1.47%)	5 / 275 (1.82%)
occurrences (all)	0	2	5
Labour pain			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Large for dates baby			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (0.00%)
occurrences (all)	0	1	0
Low birth weight baby			

subjects affected / exposed	0 / 296 (0.00%)	4 / 136 (2.94%)	15 / 275 (5.45%)
occurrences (all)	0	4	15
Delayed delivery			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Abnormal cord insertion			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Morning sickness			
subjects affected / exposed	3 / 296 (1.01%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	3	0	0
Threatened labour			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Placenta praevia			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Placental insufficiency			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Polyhydramnios			
subjects affected / exposed	4 / 296 (1.35%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	4	0	0
Postpartum haemorrhage			
subjects affected / exposed	5 / 296 (1.69%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	5	0	0
Pre-eclampsia			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Premature baby			
subjects affected / exposed	0 / 296 (0.00%)	5 / 136 (3.68%)	14 / 275 (5.09%)
occurrences (all)	0	5	14
Premature labour			
subjects affected / exposed	12 / 296 (4.05%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	12	0	0
Premature rupture of membranes			

subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Premature separation of placenta			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Preterm premature rupture of membranes			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Prolonged labour			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Prolonged rupture of membranes			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Retained placenta or membranes			
subjects affected / exposed	3 / 296 (1.01%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	3	0	0
Shoulder dystocia			
subjects affected / exposed	2 / 296 (0.68%)	1 / 136 (0.74%)	0 / 275 (0.00%)
occurrences (all)	2	1	0
Small for dates baby			
subjects affected / exposed	0 / 296 (0.00%)	13 / 136 (9.56%)	19 / 275 (6.91%)
occurrences (all)	0	13	19
Oligohydramnios			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Uterine atony			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Uterine hypotonus			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Uterine contractions during pregnancy			

subjects affected / exposed occurrences (all)	2 / 296 (0.68%) 2	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Disturbance of thermoregulation of newborn			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Macrosomia			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (0.00%)
occurrences (all)	0	1	0
Unevaluable event			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Rhesus incompatibility			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
ABO incompatibility			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			

Genital ulceration subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Dysmenorrhoea subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Pelvic organ prolapse subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	5 / 296 (1.69%) 5	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Uterine pain subjects affected / exposed occurrences (all)	2 / 296 (0.68%) 2	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	2 / 296 (0.68%) 2	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Varicose veins vulval subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Vulvovaginal discomfort subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Shortened cervix subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Asthma subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Catarrh subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Dyspnoea			

subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Irregular breathing			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Neonatal respiratory distress			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	2 / 275 (0.73%)
occurrences (all)	0	1	2
Oropharyngeal pain			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Tachypnoea			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Fear of pregnancy			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	3 / 296 (1.01%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	3	0	0
Perinatal depression			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Postpartum anxiety			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1

Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Hyperbilirubinaemia			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Cholestasis of pregnancy			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Cholelithiasis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Investigations			
Weight increased			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	3 / 275 (1.09%)
occurrences (all)	0	1	3
Blood glucose decreased			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	3 / 275 (1.09%)
occurrences (all)	0	0	3
Blood iron decreased			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Cardiac murmur			
subjects affected / exposed	0 / 296 (0.00%)	2 / 136 (1.47%)	1 / 275 (0.36%)
occurrences (all)	0	2	1
Foetal heart rate indeterminate			

subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Haemoglobin decreased subjects affected / exposed occurrences (all)	2 / 296 (0.68%) 2	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Human rhinovirus test positive subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Oxygen saturation decreased subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	1 / 275 (0.36%) 1
Serum ferritin decreased subjects affected / exposed occurrences (all)	2 / 296 (0.68%) 2	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Streptococcus test positive subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Urine analysis abnormal subjects affected / exposed occurrences (all)	2 / 296 (0.68%) 2	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	2 / 275 (0.73%) 2
Injury, poisoning and procedural complications			
Vulvovaginal injury subjects affected / exposed occurrences (all)	8 / 296 (2.70%) 8	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Arthropod bite subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Tooth fracture subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Procedural pain			

subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Perineal injury			
subjects affected / exposed	15 / 296 (5.07%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	15	0	0
Ligament sprain			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Genital injury			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Fall			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Electric shock			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Congenital choroid plexus cyst			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Atrial septal defect			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	1 / 275 (0.36%)
occurrences (all)	0	1	1
Congenital naevus			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	3 / 275 (1.09%)
occurrences (all)	0	1	3
Tethered oral tissue			
subjects affected / exposed	0 / 296 (0.00%)	6 / 136 (4.41%)	4 / 275 (1.45%)
occurrences (all)	0	6	4
Single umbilical artery			

subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (0.00%)
occurrences (all)	0	1	0
Thalassaemia alpha			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Bradycardia foetal			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Foetal heart rate deceleration abnormality			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	1	0	1
Pericarditis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Bell's palsy			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Headache			
subjects affected / exposed	3 / 296 (1.01%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	3	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Intracranial haematoma			

subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	1 / 275 (0.36%) 1
Somnolence subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	1 / 275 (0.36%) 1
Syncope subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia of pregnancy subjects affected / exposed occurrences (all)	4 / 296 (1.35%) 4	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Antiphospholipid syndrome subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	15 / 296 (5.07%) 15	0 / 136 (0.00%) 0	1 / 275 (0.36%) 1
Blood loss anaemia subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Hypochromic anaemia subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Iron deficiency anaemia subjects affected / exposed occurrences (all)	8 / 296 (2.70%) 8	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Ear and labyrinth disorders			
Vertigo subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Eye disorders			
Eye discharge subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	1 / 275 (0.36%) 1
Dacryostenosis acquired			

subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Chalazion			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Abdominal pain			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	3	0	0
Dyspepsia			
subjects affected / exposed	4 / 296 (1.35%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	4	0	0
Dyschezia			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	5 / 296 (1.69%)	1 / 136 (0.74%)	1 / 275 (0.36%)
occurrences (all)	5	1	1
Abdominal pain upper			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	0 / 275 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	7 / 296 (2.36%)	2 / 136 (1.47%)	2 / 275 (0.73%)
occurrences (all)	7	2	2
Gastritis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0

Frequent bowel movements subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Palatal oedema subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	16 / 296 (5.41%) 16	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Mouth ulceration subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Infantile colic subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	1 / 136 (0.74%) 1	0 / 275 (0.00%) 0
Haemorrhoids subjects affected / exposed occurrences (all)	3 / 296 (1.01%) 3	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Vomiting projectile subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	1 / 275 (0.36%) 1
Vomiting subjects affected / exposed occurrences (all)	6 / 296 (2.03%) 6	1 / 136 (0.74%) 1	2 / 275 (0.73%) 2
Skin and subcutaneous tissue disorders			
Dermatitis atopic subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Dermatitis diaper subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	1 / 136 (0.74%) 1	2 / 275 (0.73%) 2
Pruritus			

subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Skin lesion subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Urticaria subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	1 / 136 (0.74%) 1	0 / 275 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Hydronephrosis subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	2 / 296 (0.68%) 2	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Pyelocaliectasis subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Urinary retention subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	3 / 296 (1.01%) 3	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Thyroid dysfunction in pregnancy			

subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Groin pain subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Ligament pain subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Axillary mass subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	2 / 296 (0.68%) 2	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Infections and infestations			
Asymptomatic bacteriuria subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Amniotic cavity infection subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Abscess oral subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Bacterial disease carrier			

subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 296 (0.00%)	1 / 136 (0.74%)	2 / 275 (0.73%)
occurrences (all)	0	1	2
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Candida infection			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	10 / 296 (3.38%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	10	0	1
Bronchitis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Bronchiolitis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Beta haemolytic streptococcal infection			
subjects affected / exposed	4 / 296 (1.35%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	4	0	0
Bacterial vulvovaginitis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Bacterial vaginosis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Endometritis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Gonorrhoea			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Chlamydial infection			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Oral candidiasis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Obstetric infection			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Nail infection			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Mastitis			
subjects affected / exposed	5 / 296 (1.69%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	5	0	0
Localised infection			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	1 / 275 (0.36%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0

Hordeolum			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Syphilis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Suspected COVID-19			
subjects affected / exposed	6 / 296 (2.03%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	6	0	0
Sinusitis			
subjects affected / exposed	4 / 296 (1.35%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	5	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 296 (0.34%)	2 / 136 (1.47%)	0 / 275 (0.00%)
occurrences (all)	1	2	0
Puerperal pyrexia			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0
Postoperative wound infection			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Post procedural infection			
subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Tonsillitis streptococcal			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0

Upper respiratory tract infection subjects affected / exposed occurrences (all)	10 / 296 (3.38%) 10	2 / 136 (1.47%) 2	3 / 275 (1.09%) 3
Urinary tract infection subjects affected / exposed occurrences (all)	18 / 296 (6.08%) 20	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Vaginal infection subjects affected / exposed occurrences (all)	2 / 296 (0.68%) 2	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Vulvovaginal candidiasis subjects affected / exposed occurrences (all)	5 / 296 (1.69%) 6	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Wound infection subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Tooth infection subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Metabolism and nutrition disorders			
Hypoglycaemia subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	2 / 136 (1.47%) 2	2 / 275 (0.73%) 2
Hypoglycaemia neonatal subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 136 (0.00%) 0	3 / 275 (1.09%) 3
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Iron deficiency subjects affected / exposed occurrences (all)	8 / 296 (2.70%) 8	0 / 136 (0.00%) 0	0 / 275 (0.00%) 0
Obesity			

subjects affected / exposed	2 / 296 (0.68%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	2	0	0
Poor feeding infant			
subjects affected / exposed	0 / 296 (0.00%)	0 / 136 (0.00%)	2 / 275 (0.73%)
occurrences (all)	0	0	2
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 296 (0.34%)	0 / 136 (0.00%)	0 / 275 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Control Group - Mother		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 152 (42.76%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Melanocytic naevus			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Uterine leiomyoma			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Vascular disorders			
Thrombosis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Hypertension			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Surgical and medical procedures			
Female sterilisation			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Medically induced preterm birth			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		

Salpingectomy			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Sterilisation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Caesarean section			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
Maternal pre-pregnancy obesity			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Abortion threatened			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Afterbirth pain			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Breech presentation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Caput succedaneum			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Complication of delivery			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Foetal growth restriction			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Foetal malpresentation			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Gestational diabetes			

subjects affected / exposed	8 / 152 (5.26%)		
occurrences (all)	8		
Gestational hypertension			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Gestational hyperthyroidism			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Haemorrhage in pregnancy			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Jaundice neonatal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Labour pain			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Large for dates baby			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Low birth weight baby			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Delayed delivery			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Abnormal cord insertion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Morning sickness			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Threatened labour			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Placenta praevia			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Placental insufficiency			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Polyhydramnios			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Postpartum haemorrhage			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	3		
Pre-eclampsia			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Premature baby			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Premature labour			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	4		
Premature rupture of membranes			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Premature separation of placenta			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Preterm premature rupture of membranes			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Prolonged labour			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Prolonged rupture of membranes			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Retained placenta or membranes subjects affected / exposed occurrences (all)	2 / 152 (1.32%) 2		
Shoulder dystocia subjects affected / exposed occurrences (all)	2 / 152 (1.32%) 2		
Small for dates baby subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Oligohydramnios subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Uterine atony subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Uterine hypotonus subjects affected / exposed occurrences (all)	1 / 152 (0.66%) 1		
Uterine contractions during pregnancy subjects affected / exposed occurrences (all)	2 / 152 (1.32%) 2		
General disorders and administration site conditions			
Fatigue subjects affected / exposed occurrences (all)	2 / 152 (1.32%) 2		
Disturbance of thermoregulation of newborn subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Influenza like illness subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Pyrexia subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Macrosomia			

subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Unevaluable event subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Immune system disorders			
Rhesus incompatibility subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Drug hypersensitivity subjects affected / exposed occurrences (all)	1 / 152 (0.66%) 1		
ABO incompatibility subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Reproductive system and breast disorders			
Genital ulceration subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Pelvic organ prolapse subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Vaginal haemorrhage subjects affected / exposed occurrences (all)	2 / 152 (1.32%) 2		
Uterine pain subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Vaginal discharge			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Varicose veins vulval			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Vulvovaginal discomfort			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Shortened cervix			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Catarrh			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Irregular breathing			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Neonatal respiratory distress			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Tachypnoea			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			

Agitation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Depressed mood			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Fear of pregnancy			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Insomnia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Perinatal depression			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Postpartum anxiety			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Restlessness			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hyperbilirubinaemia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Cholestasis of pregnancy			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Cholestasis			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Cholelithiasis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Investigations			
Weight increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Blood glucose decreased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Blood iron decreased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Cardiac murmur			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Foetal heart rate indeterminate			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Haemoglobin decreased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Human rhinovirus test positive			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Oxygen saturation decreased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Serum ferritin decreased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Streptococcus test positive subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Urine analysis abnormal subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Weight decreased subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Injury, poisoning and procedural complications			
Vulvovaginal injury subjects affected / exposed occurrences (all)	4 / 152 (2.63%) 4		
Arthropod bite subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Tooth fracture subjects affected / exposed occurrences (all)	1 / 152 (0.66%) 1		
Procedural pain subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Post lumbar puncture syndrome subjects affected / exposed occurrences (all)	1 / 152 (0.66%) 2		
Perineal injury subjects affected / exposed occurrences (all)	4 / 152 (2.63%) 4		
Ligament sprain subjects affected / exposed occurrences (all)	2 / 152 (1.32%) 2		
Genital injury subjects affected / exposed occurrences (all)	2 / 152 (1.32%) 2		
Fall			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Electric shock			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
Congenital choroid plexus cyst			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Atrial septal defect			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Congenital naevus			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Tethered oral tissue			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Single umbilical artery			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Thalassaemia alpha			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Bradycardia foetal			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Foetal heart rate deceleration abnormality			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Tachycardia			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pericarditis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Bell's palsy			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Hypoaesthesia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Intracranial haematoma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia of pregnancy			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Antiphospholipid syndrome			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Anaemia			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Blood loss anaemia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hypochromic anaemia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Iron deficiency anaemia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>13 / 152 (8.55%)</p> <p>13</p> <p>1 / 152 (0.66%)</p> <p>1</p> <p>1 / 152 (0.66%)</p> <p>1</p> <p>2 / 152 (1.32%)</p> <p>2</p>		
<p>Ear and labyrinth disorders</p> <p>Vertigo</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 152 (0.00%)</p> <p>0</p>		
<p>Eye disorders</p> <p>Eye discharge</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dacryostenosis acquired</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Chalazion</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 152 (0.00%)</p> <p>0</p> <p>0 / 152 (0.00%)</p> <p>0</p> <p>0 / 152 (0.00%)</p> <p>0</p>		
<p>Gastrointestinal disorders</p> <p>Abdominal pain lower</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Abdominal pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dyspepsia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dyschezia</p>	<p>1 / 152 (0.66%)</p> <p>2</p> <p>1 / 152 (0.66%)</p> <p>1</p> <p>0 / 152 (0.00%)</p> <p>0</p>		

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Abdominal pain upper			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	3		
Gastritis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Frequent bowel movements			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Palatal oedema			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	6 / 152 (3.95%)		
occurrences (all)	6		
Mouth ulceration			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Infantile colic			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Haemorrhoids			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Vomiting projectile			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Dermatitis diaper			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Skin lesion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Hydronephrosis			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Pyelocaliectasis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Urinary incontinence			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Urinary retention			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Thyroid dysfunction in pregnancy			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Musculoskeletal chest pain			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Ligament pain			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Arthralgia			

subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Axillary mass			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Amniotic cavity infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Abscess oral			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Bacterial disease carrier			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Candida infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	4 / 152 (2.63%)		
occurrences (all)	4		
Bronchitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Bronchiolitis				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences (all)	0			
Beta haemolytic streptococcal infection				
subjects affected / exposed	3 / 152 (1.97%)			
occurrences (all)	3			
Bacterial vulvovaginitis				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences (all)	0			
Bacterial vaginosis				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences (all)	0			
Ear infection				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences (all)	0			
Endometritis				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	2 / 152 (1.32%)			
occurrences (all)	2			
Gastrointestinal infection				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences (all)	1			
Genital herpes				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences (all)	0			
Gonorrhoea				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences (all)	0			
Chlamydial infection				
subjects affected / exposed	0 / 152 (0.00%)			
occurrences (all)	0			
Oral candidiasis				

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Obstetric infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	4		
Nail infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Mastitis			
subjects affected / exposed	4 / 152 (2.63%)		
occurrences (all)	4		
Localised infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Hordeolum			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Herpes zoster			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Syphilis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Suspected COVID-19			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	5		
Sinusitis			

subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Respiratory tract infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	2		
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Puerperal pyrexia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Postoperative wound infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Post procedural infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Tonsillitis streptococcal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	6 / 152 (3.95%)		
occurrences (all)	7		
Vaginal infection			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	3		
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	2		
Wound infection			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Tooth infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Iron deficiency			
subjects affected / exposed	4 / 152 (2.63%)		
occurrences (all)	4		
Obesity			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Poor feeding infant			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 June 2023	This amendment was done to include details pertaining to the exclusion criteria for women of nonchildbearing potential, the timeframe for the primary and secondary objectives and the Phase of the study (Phase 3b). It also includes updated information indicating that all the prior studies listed are collectively called 'prior RSV MAT studies' for both cohorts, to allow participants from any of the prior RSV MAT studies who are pregnant at enrollment to be enrolled in the prospective cohort. It further clarifies the method and source of data collection in the retrospective and prospective cohorts.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported