Clinical trial results:
A Phase 3, Randomized, Observer-Blind, Placebo-Controlled, Group-Sequential Study to Determine the Immunogenicity and Safety of a Respiratory Syncytial Virus (RSV) F Nanoparticle Vaccine with Aluminum in Healthy Third-trimester Pregnant Women; and Safety and Efficacy of Maternally Transferred Antibodies in Preventing RSV Disease in their Infants

Summary

EudraCT number	2016-002302-39
Trial protocol	GB ES IT
Global end of trial date	12 July 2019

Results information

Result version number	v1 (current)
This version publication date	10 April 2020
First version publication date	10 April 2020

Trial information

Trial identification

Sponsor protocol code	RSV-M-301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02624947
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novavax, Inc.
Sponsor organisation address	21 Firstfield Road, Gaithersburg, United States, 20878
Public contact	Erika Trahan, Novavax, Inc. , +1 2402682000, etrahan@novavax.com
Scientific contact	Greg Glenn, Novavax, Inc. , +1 2402682000, gglenn@novavax.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	12 July 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 July 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the efficacy of maternal immunization with the RSV F vaccine against medically-significant RSV lower respiratory tract infection (LRTI) with EITHER hypoxemia (peripheral oxygen saturation [SpO2] < 95% at sea level or < 92% at altitudes > 1800 meters) OR tachypnea (≥ 70 bpm for infants 0 to 59 days of age or ≥ 60 bpm for infants ≥ 60 days of age) through the first 90 days of life in infants of maternal RSV F vaccinees as compared to placebo recipients. In the event that efficacy is shown through the first 90 days of life, a hierarchical sequence of hypothesis tests will be carried out to examine efficacy at 120, 150, and 180 days of life.

Protection of trial subjects:

The protocol (and amendments) were reviewed and approved by regulatory authorities in all countries; the protocol (and amendments) and consent were reviewed and approved by the ethical review committees with jurisdiction for all clinical sites. All maternal subjects gave written informed consent, and consent was obtained for infant subjects in accordance with applicable local regulatory requirements and laws. The study was conducted in accordance with the protocol, the Declaration of Helsinki (and amendments) and the International Conference on Harmonisation (ICH) Guidelines on Good Clinical Practice (GCP). An independent Data and Safety Monitoring Board monitored subject safety in a regularly scheduled and completely unblinded manner throughout active enrollment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 December 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1080
Country: Number of subjects enrolled	South Africa: 2419
Country: Number of subjects enrolled	New Zealand: 236
Country: Number of subjects enrolled	Australia: 113
Country: Number of subjects enrolled	Chile: 39
Country: Number of subjects enrolled	Argentina: 247
Country: Number of subjects enrolled	Mexico: 11
Country: Number of subjects enrolled	Philippines: 264
Country: Number of subjects enrolled	Bangladesh: 147
Country: Number of subjects enrolled	Spain: 38
Country: Number of subjects enrolled	United Kingdom: 32
Worldwide total number of subjects	4626
EEA total number of subjects	70

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	4626
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited and enrolled in 11 countries in both the Northern and Southern hemispheres from December 2015 to July 2018. Enrollment included 4636 women, of whom 10 were found to have defects in source documents and/or consent documentation and were thus not included in any summary or analysis.

Pre-assignment

Screening details:

Healthy women 18 to 40 years of age with low-risk singleton pregnancies were enrolled and treated between 28 and 36 weeks gestational age based on first or second trimester dating ultrasonography. Randomization was 1:1, active to placebo in year 1 (175 subjects) then 2:1 active to placebo thereafter, and was stratified on age on site.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Maternal participants - placebo

Arm description:

Pregnant women who received one injection of placebo

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in administration system
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5 mL dose of placebo (22 mM sodium phosphate, pH 6.2, with 150 mM NaCl, 1.0% histidine, and 0.03% PS-80) administered intramuscularly

Arm title	Maternal participants - RSV F Vaccine

Arm description:

Pregnant women who received one dose of RSV F Vaccine

Arm type	Experimental
Investigational medicinal product name	Adjuvanted RSV F 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:

0ne 0.5 mL dose of adjuvanted RSV F Vaccine (120 µg RSV F protein with 0.4 mg aluminum as the phosphate salt) administered intramuscularly

Number of subjects in period 1	Maternal participants - placebo	Maternal participants - RSV F Vaccine
Started	1581	3045
Completed	1510	2908
Not completed	71	137
Non-Compliance	5	8
Adverse Event	-	5
Other	11	17
Investigator Decision	3	5
Lost to follow-up	24	53
Sponsor Request	1	1
Voluntary Withdrawal Unrelated to AE	27	48

Baseline characteristics

Reporting groups	
Reporting group title	Maternal participants - placebo
Reporting group description:	
Pregnant women who received one injection of placebo	
Reporting group title	Maternal participants - RSV F Vaccine
Reporting group description:	
Pregnant women who received one dose of RSV F Vaccine	

Reporting group values	Maternal participants - placebo	Maternal participants - RSV F Vaccine	Total
Number of subjects	1581	3045	4626
Age categorical			
Units: Subjects			
Adults (18-64 years)	1581	3045	4626
Age continuous			
Units: years			
arithmetic mean	26	26	
standard deviation	± 5.2	± 5.3	-
Gender categorical			
Units: Subjects			
Female	1581	3045	4626
Male	0	0	0

Subject analysis sets	
Subject analysis set title	Per-protocol efficacy infant participants
Subject analysis set type	Per protocol
Subject analysis set description:	
All infant subjects who: a) are ≥ 37 weeks gestational age at birth, b) are born to maternal subjects who received a study injection as randomized and ≥ 2 weeks prior to delivery, c) have not received prophylactic treatment with palivizumab between birth and Day 180 after delivery, d) have at least one documented post-partum contact during which active and/or passive surveillance activities for RSV-suspect illness can occur, and e) have no major protocol deviations affecting the primary efficacy outcomes as determined and documented by Novavax prior to database lock and unblinding.	
Subject analysis set title	Infant safety population - placebo
Subject analysis set type	Safety analysis
Subject analysis set description:	
All infants born live to maternal subjects who received placebo	
Subject analysis set title	Infant safety population - RSV F Vaccine
Subject analysis set type	Safety analysis
Subject analysis set description:	
All infants born live to maternal subjects who received RSV F Vaccine	

Reporting group values	Per-protocol efficacy infant participants	Infant safety population - placebo	Infant safety population - RSV F Vaccine
Number of subjects	4195	1561	3008

Age categorical Units: Subjects			
Adults (18-64 years)	0	0	0
Age continuous Units: years			
arithmetic mean	0	0	0
standard deviation	± 0	± 0	± 0
Gender categorical Units: Subjects			
Female		762	1451
Male		799	1557

End points

End points reporting groups

Reporting group title	Maternal participants - placebo
Reporting group description:	
Pregnant women who received one injection of placebo	
Reporting group title	Maternal participants - RSV F Vaccine
Reporting group description:	
Pregnant women who received one dose of RSV F Vaccine	
Subject analysis set title	Per-protocol efficacy infant participants
Subject analysis set type	Per protocol
Subject analysis set description:	
All infant subjects who: a) are ≥ 37 weeks gestational age at birth, b) are born to maternal subjects who received a study injection as randomized and ≥ 2 weeks prior to delivery, c) have not received prophylactic treatment with palivizumab between birth and Day 180 after delivery, d) have at least one documented post-partum contact during which active and/or passive surveillance activities for RSV-suspect illness can occur, and e) have no major protocol deviations affecting the primary efficacy outcomes as determined and documented by Novavax prior to database lock and unblinding.	
Subject analysis set title	Infant safety population - placebo
Subject analysis set type	Safety analysis
Subject analysis set description:	
All infants born live to maternal subjects who received placebo	
Subject analysis set title	Infant safety population - RSV F Vaccine
Subject analysis set type	Safety analysis
Subject analysis set description:	
All infants born live to maternal subjects who received RSV F Vaccine	

Primary: Medically-significant RSV lower respiratory tract infection

End point title	Medically-significant RSV lower respiratory tract infection[1]
End point description:	
Percentages of infants with medically-significant RSV LRTI from delivery through 90, 120, 150, and 180 days of life, defined by: -The presence of RSV infection confirmed by detection of RSV genome by RT PCR on respiratory secretions; AND -At least one of the following: cough, nasal flaring, lower chest wall indrawing, subcostal retractions, stridor, rales, rhonchi, wheezing, crackles/crepitations, or observed apnea; AND -Evidence of medical significance as defined by the presence of: EITHER hypoxemia (peripheral oxygen saturation [SpO2] < 95% at sea level or < 92% at altitudes > 1800 meters) OR Tachypnea (≥ 70 breaths per minute [bpm] in infants 0 to 59 days of age and ≥ 60 bpm in infants ≥ 60 days of age) Data supporting the primary endpoint were obtained exclusively from observations of history and physical examination by trained study site staff, pulse oximetry with the sponsor-supplied device, and RSV detection by molecular diagnostics in the study central laboratory	
End point type	Primary
End point timeframe:	
From delivery through 90, 120, 150, and 180 days of life	

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 specified analysis of the primary endpoint was based on a 97.52% confidence interval (which was conditioned on the original group-sequential design), and exclusion of a specific target value (30%) at the lower bound. The 97.52% confidence interval about the point estimate of efficacy at 90 days was -1.0 to 63.7% and hence did not exclude values <30%. All subsequent analyses were descriptive

End point values	Per-protocol efficacy infant participants			
Subject group type	Subject analysis set			
Number of subjects analysed	4195			
Units: Efficacy (%)				
number (confidence interval 95%)				
0 - 90 Days	39.4 (5.3 to 61.2)			
0 - 120 Days	34.4 (1.7 to 56.2)			
0 - 150 Days	31.4 (-1.3 to 53.6)			
0 - 180 Days	26.6 (-7.8 to 50.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: RSV lower respiratory tract infection with hospitalization

End point title	RSV lower respiratory tract infection with hospitalization

End point description:

Percentages of infants with RSV LRTI with hospitalization from delivery through 90, 120, 150, and 180 days of life. An event is considered RSV LRTI hospitalization if all parameters outlined below are present during a continuous symptomatic illness episode:
- RSV infection as confirmed by detection of the RSV genome by RT-PCR, AND
- At least one manifestation of lower respiratory tract infection (LRTI) from among the following: cough, nasal flaring, lower chest wall indrawing, subcostal retractions, stridor, rales, rhonchi, wheezing, crackles/crepitations, or observed apnea, AND
- Documented hospitalization

Data supporting the secondary endpoints were obtained exclusively from observations of history and physical examination by trained study site staff, pulse oximetry with the sponsor-supplied device, and RSV detection by molecular diagnostics in the study central laboratory

End point type	Secondary

End point timeframe:

Delivery through 90, 120, 150, and 180 days of life

End point values	Per-protocol efficacy infant participants			
Subject group type	Subject analysis set			
Number of subjects analysed	4195			
Units: Efficacy (%)				
number (confidence interval 95%)				
0 - 90 Days	44.4 (19.6 to 61.5)			
0 - 120 Days	40.9 (15.9 to 58.5)			
0 - 150 Days	39.2 (14.0 to 57.0)			

0 - 180 Days	40.4 (16.0 to 57.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: RSV lower respiratory tract infection with sever hypoxemia

End point title	RSV lower respiratory tract infection with sever hypoxemia

End point description:

Percentages of infants with RSV LRTI with EITHER severe hypoxemia (SpO2 < 92% at sea level or < 87% at altitudes > 1800 meters) OR the documented use of oxygen by high flow nasal cannula OR a requirement for continuous positive airway pressure OR bilevel positive airway pressure OR Bubble CPAP OR bag-mask ventilation OR intubation with subsequent mechanical ventilation OR extracorporeal membrane oxygenation. An event was considered RSV LRTI with severe hypoxemia if specific parameters were present during a continuous symptomatic illness episode.

Data supporting the secondary endpoints were obtained exclusively from observations of history and physical examination by trained study site staff, pulse oximetry with the sponsor-supplied device, and RSV detection by molecular diagnostics in the study central laboratory

End point type	Secondary

End point timeframe:

Delivery through 90, 120, 150, and 180 days of life

End point values	Per-protocol efficacy infant participants			
Subject group type	Subject analysis set			
Number of subjects analysed	4195			
Units: Efficacy (%)				
number (confidence interval 95%)				
0 - 90 Days	48.3 (-8.2 to 75.3)			
0 - 120 Days	48.3 (-3.1 to 74.1)			
0 - 150 Days	48.3 (-1.0 to 73.5)			
0 - 180 Days	42.2 (-10.9 to 69.9)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Medically-significant RSV lower respiratory tract infection (expanded data)

End point title	Medically-significant RSV lower respiratory tract infection (expanded data)

End point description:

Percentages of infants with medically-significant RSV LRTI from delivery through 90, 120, 150, and 180 days of life as defined for the primary endpoint, with the exception that evidence of RSV infection, LRTI, hypoxemia, and/or tachypnea may be based on either or both of the observations of the clinical site staff using sponsor-supplied devices and diagnostic tests OR review and abstraction of medical records for infants undergoing hospitalization for a respiratory serious adverse event.

End point type	Other pre-specified

End point timeframe:

Delivery through 90, 120, 150 and 180 days of life

End point values	Per-protocol efficacy infant participants			
Subject group type	Subject analysis set			
Number of subjects analysed	4195			
Units: Efficacy (%)				
number (confidence interval 95%)				
0 - 90 Days	40.9 (15.9 to 58.5)			
0 - 120 Days	34.9 (9.7 to 53.1)			
0 - 150 Days	30.5 (4.6 to 49.4)			
0 - 180 Days	26.5 (-0.6 to 46.2)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: RSV lower respiratory tract infection with Hospitalization (expanded data)

End point title	RSV lower respiratory tract infection with Hospitalization (expanded data)

End point description:

Percentages of infants with RSV LRTI with hospitalization from delivery through 90, 120, 150, and 180 days of life, defined as for the secondary endpoint, with the exception that evidence of RSV infection and LRTI may be based on either or both of the observations of the clinical site staff using sponsor-supplied devices and diagnostic tests OR review and abstraction of medical records for infants undergoing hospitalization for a respiratory serious adverse event.

End point type	Other pre-specified

End point timeframe:

Delivery through 90, 120, 150 and 180 days of life

End point values	Per-protocol efficacy infant participants			
Subject group type	Subject analysis set			
Number of subjects analysed	4195			
Units: Efficacy (%)				
number (confidence interval 95%)				
0 - 90 Days	41.7 (16.7 to 59.2)			
0 - 120 Days	37.6 (12.1 to 55.7)			
0 - 150 Days	35.1 (9.2 to 53.6)			
0 - 180 Days	35.6 (10.3 to 53.7)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: RSV lower respiratory tract infection with Severe Hypoxemia (expanded data)

End point title	RSV lower respiratory tract infection with Severe Hypoxemia (expanded data)

End point description:

Percentages of infants with RSV LRTI with EITHER severe hypoxemia OR the documented use of oxygen by high flow nasal cannula OR a requirement for continuous positive airway pressure (CPAP) OR bilevel positive airway pressure (BiPAP) OR Bubble CPAP OR bag-mask ventilation OR intubation with subsequent mechanical (or manual) ventilation OR extracorporeal membrane oxygenation (ECMO) from delivery through 90, 120, 150, and 180 days of life, as defined for the corresponding secondary endpoint with the exception that evidence of RSV infection, LRTI, severe hypoxemia, and/or respiratory support may be based on either or both of the observations of the clinical site staff using sponsor-supplied devices and diagnostic tests OR review and abstraction of medical records for infants undergoing hospitalization for a respiratory serious adverse event.

End point type	Other pre-specified

End point timeframe:

Delivery through 90, 120, 150 and 180 days of life

End point values	Per-protocol efficacy infant participants			
Subject group type	Subject analysis set			
Number of subjects analysed	4195			
Units: Efficacy (%)				
number (confidence interval 95%)				
0 - 90 Days	59.6 (32.1 to 76.0)			
0 - 120 Days	57.4 (30.1 to 74.1)			
0 - 150 Days	54.2 (26.0 to 71.6)			
0 - 180 Days	51.2 (21.9 to 69.6)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

In maternal subjects, solicited AEs were collected for 7 days post-dosing and unsolicited AEs were collected through delivery and 180 days thereafter. In infant subjects, AEs were collected through 364 days of life.

Adverse event reporting additional description:

Adverse event collection included solicited adverse events typical of IM vaccine reactogenicity in mothers, all adverse events, medically-attended adverse events, adverse events of special interest concerning pregnancy and the puerperium (which were treated as serious adverse events regardless of fulfillment of the ICH criteria for seriousness), an

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups

Reporting group title	Maternal participants - placebo

Reporting group description:

Pregnant women who received one injection of placebo

Reporting group title	Maternal participants - RSV F Vaccine

Reporting group description:

Pregnant women who received one dose of RSV F Vaccine

Reporting group title	Infant Safety Population - placebo

Reporting group description:

All infants born live to maternal subjects who received placebo

Reporting group title	Infant Safety Population - RSV F Vaccine

Reporting group description:

All infants born live to maternal subjects who received RSV F Vaccine

Serious adverse events	Maternal participants - placebo	Maternal participants - RSV F Vaccine	Infant Safety Population - placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	455 / 1581 (28.78%)	906 / 3045 (29.75%)	724 / 1561 (46.38%)
number of deaths (all causes)	0	2	12
number of deaths resulting from adverse events	0	2	12
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cervix warts			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Papillary thyroid cancer			

subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Infantile haemangioma			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of skin			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Benign neoplasm of spinal cord			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Fibromatosis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma of liver			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Lipoma			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 1581 (0.38%)	11 / 3045 (0.36%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential hypertension			

subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Hypotension			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Hypovolaemic shock			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Shock			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Varicose vein			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Subgaleal haematoma			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Foetal distress syndrome			
subjects affected / exposed	97 / 1581 (6.14%)	200 / 3045 (6.57%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 97	0 / 200	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature delivery			

subjects affected / exposed	90 / 1581 (5.69%)	174 / 3045 (5.71%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 90	5 / 174	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	66 / 1581 (4.17%)	141 / 3045 (4.63%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 66	0 / 142	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged labour			
subjects affected / exposed	47 / 1581 (2.97%)	81 / 3045 (2.66%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 47	0 / 81	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	43 / 1581 (2.72%)	72 / 3045 (2.36%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 43	0 / 73	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalo-pelvic disproportion			
subjects affected / exposed	20 / 1581 (1.27%)	47 / 3045 (1.54%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 20	0 / 47	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum haemorrhage			
subjects affected / exposed	17 / 1581 (1.08%)	35 / 3045 (1.15%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 17	0 / 35	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes			
subjects affected / exposed	19 / 1581 (1.20%)	24 / 3045 (0.79%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 19	1 / 24	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed induction of labour			
subjects affected / exposed	11 / 1581 (0.70%)	28 / 3045 (0.92%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 28	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged pregnancy			

subjects affected / exposed	15 / 1581 (0.95%)	23 / 3045 (0.76%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 15	0 / 23	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged rupture of membranes			
subjects affected / exposed	14 / 1581 (0.89%)	17 / 3045 (0.56%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 17	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrested labour			
subjects affected / exposed	6 / 1581 (0.38%)	23 / 3045 (0.76%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 23	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breech presentation			
subjects affected / exposed	8 / 1581 (0.51%)	14 / 3045 (0.46%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 14	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium stain			
subjects affected / exposed	6 / 1581 (0.38%)	16 / 3045 (0.53%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 16	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stillbirth			
subjects affected / exposed	8 / 1581 (0.51%)	14 / 3045 (0.46%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 8	1 / 14	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage in pregnancy			
subjects affected / exposed	7 / 1581 (0.44%)	13 / 3045 (0.43%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 13	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			
subjects affected / exposed	7 / 1581 (0.44%)	12 / 3045 (0.39%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 9	2 / 13	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			

subjects affected / exposed	7 / 1581 (0.44%)	12 / 3045 (0.39%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	1 / 7	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	2 / 1581 (0.13%)	11 / 3045 (0.36%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eclampsia			
subjects affected / exposed	6 / 1581 (0.38%)	6 / 3045 (0.20%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal macrosomia			
subjects affected / exposed	1 / 1581 (0.06%)	9 / 3045 (0.30%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal hypokinesia			
subjects affected / exposed	4 / 1581 (0.25%)	5 / 3045 (0.16%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oligohydramnios			
subjects affected / exposed	4 / 1581 (0.25%)	5 / 3045 (0.16%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructed labour			
subjects affected / exposed	2 / 1581 (0.13%)	6 / 3045 (0.20%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational diabetes			
subjects affected / exposed	4 / 1581 (0.25%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine hyperstimulation			

subjects affected / exposed	3 / 1581 (0.19%)	3 / 3045 (0.10%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retained placenta or membranes			
subjects affected / exposed	1 / 1581 (0.06%)	4 / 3045 (0.13%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed trial of labour			
subjects affected / exposed	1 / 1581 (0.06%)	4 / 3045 (0.13%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Threatened labour			
subjects affected / exposed	3 / 1581 (0.19%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HELLP syndrome			
subjects affected / exposed	1 / 1581 (0.06%)	3 / 3045 (0.10%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium in amniotic fluid			
subjects affected / exposed	1 / 1581 (0.06%)	3 / 3045 (0.10%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripartum cardiomyopathy			
subjects affected / exposed	0 / 1581 (0.00%)	4 / 3045 (0.13%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Maternal distress during labour			
subjects affected / exposed	0 / 1581 (0.00%)	3 / 3045 (0.10%)	0 / 1561 (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
Placenta praevia			

subjects affected / exposed	0 / 1581 (0.00%)	3 / 3045 (0.10%)	0 / 1561 (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
Umbilical cord prolapse			
subjects affected / exposed	2 / 1581 (0.13%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face presentation			
subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal death			
subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Previous caesarean section			
subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retained products of conception			
subjects affected / exposed	2 / 1581 (0.13%)	0 / 3045 (0.00%)	0 / 1561 (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
Transverse presentation			
subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complication of pregnancy			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth abnormality			

subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth restriction			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	8 / 1561 (0.51%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
High risk pregnancy			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Hyperemesis gravidarum			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Induced labour			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Labour pain			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Large for dates baby			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placenta praevia haemorrhage			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Placental disorder			

subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Placental insufficiency			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Polyhydramnios			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Postmature baby			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Retroplacental haematoma			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Shoulder dystocia			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Uterine hypertonus			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Pyelonephritis			

subjects affected / exposed	1 / 1581 (0.06%)	5 / 3045 (0.16%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 1581 (0.06%)	5 / 3045 (0.16%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Funisitis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Low birth weight baby			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	98 / 1561 (6.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 98
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small for dates baby			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	72 / 1561 (4.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 72
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	52 / 1561 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 52
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalhaematoma			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decrease neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Caput succedaneum			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Poor weight gain neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical cord abnormality			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical granuloma			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 1581 (0.13%)	1 / 3045 (0.03%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Chest pain			

subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Complication associated with device			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Influenza like illness			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Developmental delay			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fever neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macrosomia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden infant death syndrome			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oedema peripheral			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Temperature regulation disorder			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Death neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Death			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Uterine atony			
subjects affected / exposed	1 / 1581 (0.06%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval haematoma			
subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shortened cervix			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Uterine pain			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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

Uterine prolapse			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Vaginal discharge			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Vaginal haemorrhage			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Varicose veins vulval			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Vulval oedema			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Vulvovaginal discomfort			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Vulvovaginal swelling			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Testicular retraction			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	5 / 1561 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acquired phimosis			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Enlarged clitoris			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 testicular torsion			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Penile adhesion			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Penis disorder			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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			
Pulmonary embolism			
subjects affected / exposed	3 / 1581 (0.19%)	4 / 3045 (0.13%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Asthma			
subjects affected / exposed	2 / 1581 (0.13%)	1 / 3045 (0.03%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			

subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Pleural effusion			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Status asthmaticus			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	36 / 1561 (2.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 36
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	9 / 1561 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal asphyxia			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	10 / 1561 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Meconium aspiration syndrome			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	6 / 1561 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchial obstruction			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile apnoea			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal hypoxia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rales			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal tachypnoea			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Pneumothorax			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyanosis neonatal			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal congestion			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 failure			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 failure			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory symptom			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachypnoea			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Apparent life threatening event			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Atelectasis			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Choking			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Cough			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Dysphonia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Grunting			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Lung infiltration			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory depression			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Pneumonia aspiration			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Pulmonary artery stenosis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Pulmonary hypertension			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Tracheal stenosis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 airway obstruction			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Use of accessory respiratory muscles			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Wheezing			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Perinatal depression			
subjects affected / exposed	2 / 1581 (0.13%)	3 / 3045 (0.10%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised anxiety disorder			

subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Anxiety disorder			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Sleep disorder			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Foetal monitoring abnormal			
subjects affected / exposed	3 / 1581 (0.19%)	5 / 3045 (0.16%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased			
subjects affected / exposed	2 / 1581 (0.13%)	3 / 3045 (0.10%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amniotic fluid index decreased			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Ejection fraction decreased			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal heart rate increased			

subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Seroconversion test positive			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Ultrasound Doppler abnormal			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac murmur			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	13 / 1561 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acoustic stimulation tests abnormal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apgar score low			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body height below normal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac murmur functional			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
HIV test positive			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Haemoglobin abnormal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Karyotype analysis abnormal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Opiates positive			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Oxygen saturation decreased			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Platelet count decreased			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Reflex test abnormal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular resistance pulmonary increased			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Perineal injury			
subjects affected / exposed	2 / 1581 (0.13%)	5 / 3045 (0.16%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal laceration			
subjects affected / exposed	1 / 1581 (0.06%)	4 / 3045 (0.13%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine cervical laceration			
subjects affected / exposed	3 / 1581 (0.19%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine rupture			
subjects affected / exposed	2 / 1581 (0.13%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed forceps delivery			
subjects affected / exposed	0 / 1581 (0.00%)	3 / 3045 (0.10%)	0 / 1561 (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
Post lumbar puncture syndrome			
subjects affected / exposed	2 / 1581 (0.13%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine dehiscence			

subjects affected / exposed	1 / 1581 (0.06%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention postoperative			
subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Fibula fracture			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Multiple injuries			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Procedural haemorrhage			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Spinal compression fracture			

subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal biophysical profile score abnormal			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Thermal burn			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Accidental overdose			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 to brachial plexus due to birth trauma			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Arterial injury			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Brachial plexus injury			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Concussion			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Craniocerebral injury			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Femur fracture			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Subdural haematoma			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound necrosis			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 naevus			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	177 / 1561 (11.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 183
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital umbilical hernia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	146 / 1561 (9.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 146
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Birth mark			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	96 / 1561 (6.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 99
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankyloglossia congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	19 / 1561 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	23 / 1561 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital skin dimples			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	14 / 1561 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcephaly			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	9 / 1561 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Naevus flammeus			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	5 / 1561 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital acrochordon			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	6 / 1561 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial septal defect			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	7 / 1561 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polydactyly			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	7 / 1561 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital melanocytic naevus			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accessory auricle			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngomalacia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	5 / 1561 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital melanosis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preauricular cyst			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	6 / 1561 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital pneumonia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital torticollis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	5 / 1561 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labial tie			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	5 / 1561 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supernumerary nipple			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	5 / 1561 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal palmar/plantar creases			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Developmental hip dysplasia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plagiocephaly			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clinodactyly			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryostenosis congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypospadias			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Talipes			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniosynostosis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macrocephaly			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear malformation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microtia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile torsion			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Persistent foetal circulation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Phimosis			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull malformation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Eyelid ptosis congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Micrognathia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patent ductus arteriosus			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sebaceous naevus			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABO haemolytic disease of newborn			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anomaly of external ear congenital			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Branchial cyst			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Camptodactyly congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral palsy			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Chordee			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cleft lip			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Cleft palate			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 hearing disorder			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 knee dislocation			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 pulmonary hypertension			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pectus excavatum			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Pulmonary artery stenosis congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Single umbilical artery			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Telangiectasia congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Trisomy 21			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accessory breast			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Anal atresia			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Anomalous pulmonary venous connection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Beckwith-Wiedemann syndrome			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Buried penis syndrome			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 septal defect			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Choledochal cyst			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Chondrodystrophy			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Chromosomal deletion			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Cleft uvula			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital aortic anomaly			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital cardiovascular anomaly			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Congenital central nervous system anomaly			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital cerebral cyst			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 choroid plexus cyst			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital claw toe			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital eye disorder			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital genital malformation female			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital hyperextension of knee			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 megacolon			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 mitral valve incompetence			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital nephrotic syndrome			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital nose malformation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 pulmonary artery anomaly			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital renal disorder			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital tracheomalacia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital tricuspid valve incompetence			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital varicella infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital vesicoureteric reflux			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Dermoid cyst			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Extrarenal pelvis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Galactosaemia			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Heart disease congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertelorism of orbit			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Interruption of aortic arch			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal malrotation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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 set ears			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Macroglossia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Mosaicism			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odontogenic cyst			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Persistent pupillary membrane			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scaphocephaly			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Syndactyly			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Thalassaemia alpha			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital Cleft Hand			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Nonreassuring foetal heart rate pattern			
subjects affected / exposed	10 / 1581 (0.63%)	24 / 3045 (0.79%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 24	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia foetal			

subjects affected / exposed	3 / 1581 (0.19%)	10 / 3045 (0.33%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	4 / 1581 (0.25%)	7 / 3045 (0.23%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia foetal			
subjects affected / exposed	5 / 1581 (0.32%)	6 / 3045 (0.20%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal heart rate deceleration abnormality			
subjects affected / exposed	2 / 1581 (0.13%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal heart rate disorder			
subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Lymphadenopathy			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Congestive cardiomyopathy			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Bradycardia neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 arrest			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cyanosis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Myocarditis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal tachycardia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Pericardial effusion			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Right atrial dilatation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Sinus bradycardia			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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			
False labour			
subjects affected / exposed	1 / 1581 (0.06%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	2 / 1581 (0.13%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complex partial seizures			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Dysarthria			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Epilepsy			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	7 / 1561 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Encephalopathy neonatal			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Seizure			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Convulsion neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Fine motor delay			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gross motor delay			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile spasms			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Lethargy			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Poor sucking reflex			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Reflexes abnormal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Tethered cord syndrome			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Benign intracranial hypertension			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	7 / 1581 (0.44%)	17 / 3045 (0.56%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 17	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	4 / 1581 (0.25%)	4 / 3045 (0.13%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia of pregnancy			
subjects affected / exposed	1 / 1581 (0.06%)	3 / 3045 (0.10%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	2 / 1581 (0.13%)	0 / 3045 (0.00%)	0 / 1561 (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
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Bicytopenia			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Iron deficiency anaemia			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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 neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Polycythaemia neonatorum			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemolytic anaemia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Lymphadenitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Neutropenia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Thrombocytopenia neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Conductive deafness			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Tympanic membrane perforation			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Visual impairment			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Dacryostenosis acquired			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Opsoclonus myoclonus			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Retinal haemorrhage			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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	2 / 1581 (0.13%)	2 / 3045 (0.07%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 1581 (0.00%)	3 / 3045 (0.10%)	0 / 1561 (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
Abdominal pain			
subjects affected / exposed	2 / 1581 (0.13%)	0 / 3045 (0.00%)	0 / 1561 (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
Vomiting			

subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Constipation			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Ileus			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Pancreatitis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Peptic ulcer			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Colitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Intussusception			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Tooth development disorder			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Abdominal distension			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile vomiting			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Intestinal obstruction			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Intestinal perforation			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising enterocolitis neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal intestinal dilatation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Volvulus			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Enterocolitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholestasis of pregnancy			
subjects affected / exposed	1 / 1581 (0.06%)	5 / 3045 (0.16%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	1 / 1581 (0.06%)	3 / 3045 (0.10%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Biliary colic			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Conversion disorder			
subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	11 / 1561 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	1 / 1561 (0.06%)
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 inguinal hernia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cafe au lait spots			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	12 / 1561 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macule			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin hypopigmentation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin hyperpigmentation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blister			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Dermal cyst			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis atopic			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Dermatosis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Eczema infantile			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Ephelides			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Erythema toxicum neonatorum			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Hair colour changes			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash erythematous			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin exfoliation			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin lesion			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	0 / 1581 (0.00%)	4 / 3045 (0.13%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			
subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Pelvi-ureteric obstruction			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Ureterolithiasis			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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 impairment			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Micturition frequency decreased			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal disorder			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure neonatal			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Sterile pyuria			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Thyroid mass			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Musculoskeletal and connective tissue disorders			
Symphysiolysis			
subjects affected / exposed	0 / 1581 (0.00%)	3 / 3045 (0.10%)	0 / 1561 (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
Back pain			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Neck pain			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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

Diastasis recti abdominis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cranial sutures widening			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Foot deformity			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Head deformity			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Joint laxity			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Tendinous contracture			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Positional Plagiocephaly			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	12 / 1581 (0.76%)	17 / 3045 (0.56%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 13	0 / 17	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	10 / 1581 (0.63%)	13 / 3045 (0.43%)	14 / 1561 (0.90%)
occurrences causally related to treatment / all	0 / 10	0 / 13	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometritis			
subjects affected / exposed	3 / 1581 (0.19%)	6 / 3045 (0.20%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum sepsis			
subjects affected / exposed	0 / 1581 (0.00%)	8 / 3045 (0.26%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	3 / 1581 (0.19%)	3 / 3045 (0.10%)	8 / 1561 (0.51%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 1581 (0.00%)	5 / 3045 (0.16%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Puerperal pyrexia			
subjects affected / exposed	1 / 1581 (0.06%)	4 / 3045 (0.13%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound sepsis			
subjects affected / exposed	5 / 1581 (0.32%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 1581 (0.06%)	3 / 3045 (0.10%)	32 / 1561 (2.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 34
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia			

subjects affected / exposed	2 / 1581 (0.13%)	2 / 3045 (0.07%)	70 / 1561 (4.48%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 74
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	3 / 1581 (0.19%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicitis			
subjects affected / exposed	0 / 1581 (0.00%)	3 / 3045 (0.10%)	0 / 1561 (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
HIV infection			
subjects affected / exposed	0 / 1581 (0.00%)	3 / 3045 (0.10%)	0 / 1561 (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
Abdominal sepsis			
subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	2 / 1581 (0.13%)	0 / 3045 (0.00%)	0 / 1561 (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
Kidney infection			
subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastitis			
subjects affected / exposed	0 / 1581 (0.00%)	2 / 3045 (0.07%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Bacteraemia			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Bronchitis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbuncle			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Cellulitis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Endometritis decidual			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Herpes simplex			

subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Influenza			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node tuberculosis			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Mastitis postpartum			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Perineal abscess			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Peritonitis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural sepsis			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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 tract infection			

subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Tooth abscess			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	0 / 1561 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal infection			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	49 / 1561 (3.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 52
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	29 / 1561 (1.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Neonatal pneumonia			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	9 / 1561 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	5 / 1561 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	6 / 1561 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmia neonatorum			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	4 / 1561 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash pustular			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis enteroviral			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Omphalitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Acarodermatitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Fungal sepsis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal infection			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nosocomial infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Oral candidiasis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Otitis media acute			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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 skin infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
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 enterococcal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Abscess jaw			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Amoebic dysentery			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest wall abscess			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Corona virus infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Cytomegalovirus infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Dengue fever			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysentery			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema infected			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Encephalitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Enterococcal infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Escherichia pyelonephritis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye infection bacterial			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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 viral infection			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Group B streptococcus neonatal sepsis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Listeria sepsis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Pertussis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Rhinitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Rocky mountain spotted fever			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Rotavirus infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic rash			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin candida			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Tonsillitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Tracheobronchitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Tuberculosis of intrathoracic lymph nodes			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical sepsis			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Varicella			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Viral rash			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (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
Hypokalaemia			
subjects affected / exposed	1 / 1581 (0.06%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	13 / 1561 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	8 / 1561 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	3 / 1561 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poor feeding infant			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	2 / 1561 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Hypovolaemia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Acidosis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	1 / 1561 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cow's milk intolerance			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Hyperinsulinaemia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Hyponatraemia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Lactose intolerance			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (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
Underweight			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	0 / 1561 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Infant Safety Population - RSV F Vaccine		
Total subjects affected by serious adverse events			
subjects affected / exposed	1337 / 3008 (44.45%)		
number of deaths (all causes)	17		
number of deaths resulting from adverse events	17		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cervix warts			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Papillary thyroid cancer			

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infantile haemangioma				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign neoplasm of skin				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign neoplasm of spinal cord				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fibromatosis				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemangioma of liver				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Lipoma				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Hypertension				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Essential hypertension				

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypovolaemic shock			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subgaleal haematoma			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Foetal distress syndrome			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Premature delivery			

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gestational hypertension			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prolonged labour			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pre-eclampsia			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cephalo-pelvic disproportion			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postpartum haemorrhage			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature rupture of membranes			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failed induction of labour			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prolonged pregnancy			

subjects affected / exposed	0 / 3008 (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 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arrested labour			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breech presentation			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meconium stain			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stillbirth			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage in pregnancy			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature labour			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature separation of placenta			

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Preterm premature rupture of membranes				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eclampsia				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foetal macrosomia				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foetal hypokinesia				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oligohydramnios				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstructed labour				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gestational diabetes				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine hyperstimulation				

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retained placenta or membranes			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failed trial of labour			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Threatened labour			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HELLP syndrome			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meconium in amniotic fluid			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Peripartum cardiomyopathy			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Maternal distress during labour			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Placenta praevia			

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical cord prolapse				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Face presentation				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foetal death				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Previous caesarean section				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retained products of conception				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transverse presentation				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Complication of pregnancy				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foetal growth abnormality				

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal growth restriction			
subjects affected / exposed	16 / 3008 (0.53%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 1		
High risk pregnancy			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperemesis gravidarum			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Induced labour			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Labour pain			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large for dates baby			
subjects affected / exposed	12 / 3008 (0.40%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Placenta praevia haemorrhage			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Placental disorder			

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Placental insufficiency			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polyhydramnios			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postmature baby			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retroplacental haematoma			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shoulder dystocia			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine hypertonus			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Funisitis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Low birth weight baby			
subjects affected / exposed	149 / 3008 (4.95%)		
occurrences causally related to treatment / all	0 / 149		
deaths causally related to treatment / all	0 / 0		
Small for dates baby			
subjects affected / exposed	151 / 3008 (5.02%)		
occurrences causally related to treatment / all	1 / 151		
deaths causally related to treatment / all	0 / 0		
Jaundice neonatal			
subjects affected / exposed	97 / 3008 (3.22%)		
occurrences causally related to treatment / all	0 / 98		
deaths causally related to treatment / all	0 / 0		
Cephalhaematoma			
subjects affected / exposed	4 / 3008 (0.13%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Weight decrease neonatal			
subjects affected / exposed	4 / 3008 (0.13%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Caput succedaneum			

subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Poor weight gain neonatal				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Premature baby				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical cord abnormality				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Umbilical granuloma				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Pyrexia				
subjects affected / exposed	5 / 3008 (0.17%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Peripheral swelling				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthenia				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chest pain				

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Complication associated with device				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza like illness				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Developmental delay				
subjects affected / exposed	6 / 3008 (0.20%)			
occurrences causally related to treatment / all	1 / 10			
deaths causally related to treatment / all	0 / 0			
Fever neonatal				
subjects affected / exposed	4 / 3008 (0.13%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Macrosomia				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Sudden infant death syndrome				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 3			
Oedema peripheral				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Temperature regulation disorder				

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Death neonatal			
subjects affected / exposed	3 / 3008 (0.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 3		
Death			
subjects affected / exposed	4 / 3008 (0.13%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 4		
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Uterine atony			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vulval haematoma			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shortened cervix			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine pain			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Uterine prolapse				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vaginal discharge				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vaginal haemorrhage				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Varicose veins vulval				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vulval oedema				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vulvovaginal discomfort				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vulvovaginal swelling				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Testicular retraction				
subjects affected / exposed	6 / 3008 (0.20%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Acquired phimosis				

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enlarged clitoris				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal testicular torsion				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Penile adhesion				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Penis disorder				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Pulmonary embolism				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Status asthmaticus				
subjects affected / exposed	0 / 3008 (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	62 / 3008 (2.06%)			
occurrences causally related to treatment / all	0 / 62			
deaths causally related to treatment / all	0 / 1			
Transient tachypnoea of the newborn				
subjects affected / exposed	19 / 3008 (0.63%)			
occurrences causally related to treatment / all	0 / 19			
deaths causally related to treatment / all	0 / 0			
Neonatal asphyxia				

subjects affected / exposed	15 / 3008 (0.50%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 1		
Meconium aspiration syndrome			
subjects affected / exposed	16 / 3008 (0.53%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 4		
Bronchial obstruction			
subjects affected / exposed	6 / 3008 (0.20%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Infantile apnoea			
subjects affected / exposed	4 / 3008 (0.13%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Neonatal hypoxia			
subjects affected / exposed	5 / 3008 (0.17%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Rales			
subjects affected / exposed	4 / 3008 (0.13%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Neonatal tachypnoea			
subjects affected / exposed	5 / 3008 (0.17%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cyanosis neonatal			

subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Obstructive airways disorder				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Acute respiratory distress syndrome				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nasal congestion				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neonatal respiratory failure				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				

subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory symptom			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stridor			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tachypnoea			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adenoidal hypertrophy			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Apnoea			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Apparent life threatening event			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspiration			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atelectasis			

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Choking			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cough			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysphonia			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Grunting			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal oedema			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung infiltration			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal respiratory depression			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary artery stenosis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary hypertension				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tracheal stenosis				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper airway obstruction				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Use of accessory respiratory muscles				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Wheezing				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Perinatal depression				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised anxiety disorder				

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety disorder				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sleep disorder				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Investigations				
Foetal monitoring abnormal				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood pressure increased				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Amniotic fluid index decreased				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ejection fraction decreased				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foetal heart rate increased				

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seroconversion test positive				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ultrasound Doppler abnormal				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac murmur				
subjects affected / exposed	23 / 3008 (0.76%)			
occurrences causally related to treatment / all	0 / 23			
deaths causally related to treatment / all	0 / 0			
Acoustic stimulation tests abnormal				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Apgar score low				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Body height below normal				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac murmur functional				

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
HIV test positive			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemoglobin abnormal			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Karyotype analysis abnormal			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Opiates positive			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oxygen saturation decreased			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Platelet count decreased			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reflex test abnormal			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular resistance pulmonary increased			

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Weight decreased				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Perineal injury				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vaginal laceration				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine cervical laceration				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine rupture				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failed forceps delivery				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post lumbar puncture syndrome				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine dehiscence				

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention postoperative			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fibula fracture			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple injuries			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural complication			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Procedural haemorrhage			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture			

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal biophysical profile score abnormal			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metapneumovirus infection			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	3 / 3008 (0.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	3 / 3008 (0.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Accidental overdose			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury to brachial plexus due to birth trauma			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arterial injury			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brachial plexus injury			

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Craniocerebral injury				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head injury				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull fracture				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound necrosis				

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laceration				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Congenital naevus				
subjects affected / exposed	307 / 3008 (10.21%)			
occurrences causally related to treatment / all	0 / 314			
deaths causally related to treatment / all	0 / 0			
Congenital umbilical hernia				
subjects affected / exposed	259 / 3008 (8.61%)			
occurrences causally related to treatment / all	0 / 261			
deaths causally related to treatment / all	0 / 0			
Birth mark				
subjects affected / exposed	195 / 3008 (6.48%)			
occurrences causally related to treatment / all	0 / 199			
deaths causally related to treatment / all	0 / 0			
Ankyloglossia congenital				
subjects affected / exposed	44 / 3008 (1.46%)			
occurrences causally related to treatment / all	0 / 45			
deaths causally related to treatment / all	0 / 0			
Haemangioma congenital				
subjects affected / exposed	24 / 3008 (0.80%)			
occurrences causally related to treatment / all	0 / 27			
deaths causally related to treatment / all	0 / 0			
Congenital skin dimples				
subjects affected / exposed	22 / 3008 (0.73%)			
occurrences causally related to treatment / all	0 / 22			
deaths causally related to treatment / all	0 / 0			
Microcephaly				

subjects affected / exposed	23 / 3008 (0.76%)		
occurrences causally related to treatment / all	0 / 24		
deaths causally related to treatment / all	0 / 0		
Hydrocele			
subjects affected / exposed	19 / 3008 (0.63%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 0		
Naevus flammeus			
subjects affected / exposed	17 / 3008 (0.57%)		
occurrences causally related to treatment / all	0 / 17		
deaths causally related to treatment / all	0 / 0		
Congenital acrochordon			
subjects affected / exposed	13 / 3008 (0.43%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Cryptorchism			
subjects affected / exposed	10 / 3008 (0.33%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Atrial septal defect			
subjects affected / exposed	7 / 3008 (0.23%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Polydactyly			
subjects affected / exposed	16 / 3008 (0.53%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
Congenital melanocytic naevus			
subjects affected / exposed	12 / 3008 (0.40%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Accessory auricle			

subjects affected / exposed	10 / 3008 (0.33%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Laryngomalacia			
subjects affected / exposed	6 / 3008 (0.20%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Congenital melanosis			
subjects affected / exposed	9 / 3008 (0.30%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Preauricular cyst			
subjects affected / exposed	5 / 3008 (0.17%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Congenital pneumonia			
subjects affected / exposed	7 / 3008 (0.23%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Congenital torticollis			
subjects affected / exposed	5 / 3008 (0.17%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Labial tie			
subjects affected / exposed	5 / 3008 (0.17%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Supernumerary nipple			
subjects affected / exposed	6 / 3008 (0.20%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Ventricular septal defect			

subjects affected / exposed	5 / 3008 (0.17%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Abnormal palmar/plantar creases			
subjects affected / exposed	6 / 3008 (0.20%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Developmental hip dysplasia			
subjects affected / exposed	4 / 3008 (0.13%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Plagiocephaly			
subjects affected / exposed	4 / 3008 (0.13%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Strabismus congenital			
subjects affected / exposed	7 / 3008 (0.23%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Clinodactyly			
subjects affected / exposed	6 / 3008 (0.20%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Dacryostenosis congenital			
subjects affected / exposed	4 / 3008 (0.13%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed	4 / 3008 (0.13%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Hypospadias			

subjects affected / exposed	5 / 3008 (0.17%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Talipes				
subjects affected / exposed	5 / 3008 (0.17%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Craniosynostosis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Macrocephaly				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear malformation				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Microtia				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Penile torsion				
subjects affected / exposed	4 / 3008 (0.13%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Persistent foetal circulation				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Phimosis				

subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Skull malformation				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Deafness congenital				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Eyelid ptosis congenital				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Micrognathia				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Patent ductus arteriosus				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sebaceous naevus				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
ABO haemolytic disease of newborn				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anomaly of external ear congenital				

subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Branchial cyst				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Camptodactyly congenital				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebral palsy				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chordee				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cleft lip				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cleft palate				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Congenital hearing disorder				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Congenital knee dislocation				

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital pulmonary hypertension			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pectus excavatum			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pulmonary artery stenosis congenital			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Single umbilical artery			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Telangiectasia congenital			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Trisomy 21			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accessory breast			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal atresia			

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anomalous pulmonary venous connection			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Beckwith-Wiedemann syndrome			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Buried penis syndrome			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac septal defect			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cataract congenital			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Choledochal cyst			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chondrodystrophy			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chromosomal deletion			

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cleft uvula			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital aortic anomaly			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital cardiovascular anomaly			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital central nervous system anomaly			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital cerebral cyst			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital choroid plexus cyst			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital claw toe			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital eye disorder			

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital genital malformation female			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital hydronephrosis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital hyperextension of knee			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital megacolon			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital mitral valve incompetence			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital nephrotic syndrome			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Congenital nose malformation			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital pulmonary artery anomaly			

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital renal disorder			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital tracheomalacia			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital tricuspid valve incompetence			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital varicella infection			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital vesicoureteric reflux			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermoid cyst			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Extrarenal pelvis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Galactosaemia			

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Heart disease congenital			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertelorism of orbit			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Interruption of aortic arch			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal malrotation			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Low set ears			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Macroglossia			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mosaicism			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Odontogenic cyst			

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Persistent pupillary membrane				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pilonidal cyst congenital				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scaphocephaly				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Syndactyly				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thalassaemia alpha				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Congenital Cleft Hand				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Nonreassuring foetal heart rate pattern				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradycardia foetal				

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tachycardia foetal			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal heart rate deceleration abnormality			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal heart rate disorder			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial thrombosis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congestive cardiomyopathy			

subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Bradycardia neonatal				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cyanosis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocarditis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neonatal tachycardia				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Right atrial dilatation				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinus bradycardia				

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
False labour			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Complex partial seizures			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysarthria			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	12 / 3008 (0.40%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 1		
Encephalopathy neonatal			

subjects affected / exposed	7 / 3008 (0.23%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 1			
Febrile convulsion				
subjects affected / exposed	4 / 3008 (0.13%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Cerebrospinal fluid leakage				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Convulsion neonatal				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial paresis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fine motor delay				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gross motor delay				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotonia				

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infantile spasms				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lethargy				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Poor sucking reflex				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Reflexes abnormal				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Status epilepticus				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tethered cord syndrome				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign intracranial hypertension				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				

subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia of pregnancy				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukocytosis				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia vitamin B12 deficiency				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bicytopenia				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Iron deficiency anaemia				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia neonatal				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Polycythaemia neonatorum				

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Disseminated intravascular coagulation				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolytic anaemia				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lymphadenitis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lymphadenopathy mediastinal				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia neonatal				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
Conductive deafness				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tympanic membrane perforation				

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Visual impairment			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dacryostenosis acquired			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Opsoclonus myoclonus			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal haemorrhage			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	17 / 3008 (0.57%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			

subjects affected / exposed	3 / 3008 (0.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	3 / 3008 (0.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			

subjects affected / exposed	3 / 3008 (0.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 3008 (0.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Intussusception			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tooth development disorder			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal distension			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal inflammation			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infantile vomiting			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Necrotising enterocolitis neonatal				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neonatal intestinal dilatation				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Volvulus				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholestasis of pregnancy				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bile duct stone				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary colic				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Conversion disorder				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia neonatal				
subjects affected / exposed	26 / 3008 (0.86%)			
occurrences causally related to treatment / all	0 / 26			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Dermatitis				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eczema				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital inguinal hernia				
subjects affected / exposed	5 / 3008 (0.17%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Cafe au lait spots				

subjects affected / exposed	28 / 3008 (0.93%)		
occurrences causally related to treatment / all	0 / 31		
deaths causally related to treatment / all	0 / 0		
Macule			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin hypopigmentation			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Skin hyperpigmentation			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blister			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermal cyst			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis atopic			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermatosis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eczema infantile			

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ephelides				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Erythema toxicum neonatorum				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hair colour changes				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash erythematous				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Seborrhoeic dermatitis				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin exfoliation				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin lesion				
subjects affected / exposed	0 / 3008 (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	3 / 3008 (0.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Proteinuria			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysuria			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvi-ureteric obstruction			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureterolithiasis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Micturition frequency decreased			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal disorder			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal failure neonatal			

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sterile pyuria			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroid mass			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Symphysiolysis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neck pain			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Diastasis recti abdominis				
subjects affected / exposed	5 / 3008 (0.17%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Cranial sutures widening				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foot deformity				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Head deformity				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Joint laxity				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tendinous contracture				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Positional Plagiocephaly				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Amniotic cavity infection				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				

subjects affected / exposed	15 / 3008 (0.50%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Endometritis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postpartum sepsis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	17 / 3008 (0.57%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 1		
Breast abscess			
subjects affected / exposed	3 / 3008 (0.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Puerperal pyrexia			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound sepsis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	50 / 3008 (1.66%)		
occurrences causally related to treatment / all	0 / 52		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	65 / 3008 (2.16%)		
occurrences causally related to treatment / all	0 / 72		
deaths causally related to treatment / all	0 / 2		
Postoperative wound infection			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervicitis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HIV infection			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal sepsis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kidney infection			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastitis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	6 / 3008 (0.20%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Carbuncle			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endometritis decidual			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes simplex			

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infectious pleural effusion			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	3 / 3008 (0.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Lymph node tuberculosis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastitis postpartum			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Perineal abscess			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural sepsis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			

subjects affected / exposed	5 / 3008 (0.17%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	0 / 3008 (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	12 / 3008 (0.40%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Vaginal infection			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
subjects affected / exposed	85 / 3008 (2.83%)		
occurrences causally related to treatment / all	0 / 94		
deaths causally related to treatment / all	0 / 0		
Sepsis neonatal			
subjects affected / exposed	43 / 3008 (1.43%)		
occurrences causally related to treatment / all	0 / 44		
deaths causally related to treatment / all	0 / 0		
Neonatal pneumonia			

subjects affected / exposed	11 / 3008 (0.37%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	8 / 3008 (0.27%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	8 / 3008 (0.27%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Ophthalmia neonatorum				
subjects affected / exposed	4 / 3008 (0.13%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				
subjects affected / exposed	4 / 3008 (0.13%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Rash pustular				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Bacterial infection				

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Croup infectious				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Enterovirus infection				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Meningitis enteroviral				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Omphalitis				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Otitis media				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	3 / 3008 (0.10%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 2			
Acarodermatitis				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Conjunctivitis bacterial			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Escherichia urinary tract infection			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Fungal sepsis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Klebsiella sepsis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Measles			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			
subjects affected / exposed	2 / 3008 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Neonatal infection			

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nosocomial infection				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Oral candidiasis				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Otitis media acute				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Staphylococcal skin infection				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection bacterial				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection enterococcal				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Viral upper respiratory tract infection				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Abscess jaw				

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess neck			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenovirus infection			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Amoebic dysentery			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest wall abscess			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Corona virus infection			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cytomegalovirus infection			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related sepsis			

subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysentery				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eczema infected				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterococcal infection				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia pyelonephritis				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye infection bacterial				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis adenovirus				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal viral infection				

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Group B streptococcus neonatal sepsis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Listeria sepsis			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis bacterial			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningitis neonatal			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningitis viral			

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pertussis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection viral				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rhinitis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rocky mountain spotted fever				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rotavirus infection				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic rash				

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin candida				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tracheobronchitis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tuberculosis of intrathoracic lymph nodes				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Umbilical sepsis				

subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Varicella				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Viral rash				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Hypoglycaemia				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia neonatal				
subjects affected / exposed	13 / 3008 (0.43%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	14 / 3008 (0.47%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				

subjects affected / exposed	5 / 3008 (0.17%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Poor feeding infant				
subjects affected / exposed	5 / 3008 (0.17%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Malnutrition				
subjects affected / exposed	4 / 3008 (0.13%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Metabolic acidosis				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Feeding intolerance				
subjects affected / exposed	1 / 3008 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypernatraemia				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypovolaemia				
subjects affected / exposed	2 / 3008 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Acidosis				
subjects affected / exposed	0 / 3008 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cow's milk intolerance				

subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperinsulinaemia			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lactose intolerance			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Underweight			
subjects affected / exposed	1 / 3008 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Maternal participants - placebo	Maternal participants - RSV F Vaccine	Infant Safety Population - placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	749 / 1581 (47.38%)	1595 / 3045 (52.38%)	571 / 1561 (36.58%)
Vascular disorders			
Hypertension			
subjects affected / exposed	48 / 1581 (3.04%)	80 / 3045 (2.63%)	0 / 1561 (0.00%)
occurrences (all)	58	91	0
Essential hypertension			
subjects affected / exposed	22 / 1581 (1.39%)	37 / 3045 (1.22%)	0 / 1561 (0.00%)
occurrences (all)	22	40	0
Pregnancy, puerperium and perinatal conditions			

Foetal distress syndrome			
subjects affected / exposed	6 / 1581 (0.38%)	6 / 3045 (0.20%)	0 / 1561 (0.00%)
occurrences (all)	6	6	0
Gestational hypertension			
subjects affected / exposed	1 / 1581 (0.06%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences (all)	1	1	0
Prolonged labour			
subjects affected / exposed	8 / 1581 (0.51%)	11 / 3045 (0.36%)	0 / 1561 (0.00%)
occurrences (all)	9	11	0
Postpartum haemorrhage			
subjects affected / exposed	17 / 1581 (1.08%)	32 / 3045 (1.05%)	0 / 1561 (0.00%)
occurrences (all)	17	32	0
Premature rupture of membranes			
subjects affected / exposed	9 / 1581 (0.57%)	22 / 3045 (0.72%)	0 / 1561 (0.00%)
occurrences (all)	9	22	0
Cephalo-pelvic disproportion			
subjects affected / exposed	0 / 1581 (0.00%)	1 / 3045 (0.03%)	0 / 1561 (0.00%)
occurrences (all)	0	1	0
Prolonged rupture of membranes			
subjects affected / exposed	12 / 1581 (0.76%)	21 / 3045 (0.69%)	0 / 1561 (0.00%)
occurrences (all)	12	21	0
Foetal hypokinesia			
subjects affected / exposed	17 / 1581 (1.08%)	30 / 3045 (0.99%)	0 / 1561 (0.00%)
occurrences (all)	25	34	0
Prolonged pregnancy			
subjects affected / exposed	7 / 1581 (0.44%)	10 / 3045 (0.33%)	0 / 1561 (0.00%)
occurrences (all)	7	10	0
Jaundice neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	102 / 1561 (6.53%)
occurrences (all)	0	0	105
Poor weight gain neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	20 / 1561 (1.28%)
occurrences (all)	0	0	20
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	15 / 1581 (0.95%)	29 / 3045 (0.95%)	0 / 1561 (0.00%)
occurrences (all)	19	34	0
Fever neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	173 / 1561 (11.08%)
occurrences (all)	0	0	226
Pyrexia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	30 / 1561 (1.92%)
occurrences (all)	0	0	36
Reproductive system and breast disorders			
Vaginal discharge			
subjects affected / exposed	13 / 1581 (0.82%)	47 / 3045 (1.54%)	0 / 1561 (0.00%)
occurrences (all)	13	49	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	106 / 1561 (6.79%)
occurrences (all)	0	0	120
Nasal congestion			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	65 / 1561 (4.16%)
occurrences (all)	0	0	72
Rhinorrhoea			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	49 / 1561 (3.14%)
occurrences (all)	0	0	52
Rhinitis allergic			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	14 / 1561 (0.90%)
occurrences (all)	0	0	19
Investigations			
Streptococcus test positive			
subjects affected / exposed	38 / 1581 (2.40%)	80 / 3045 (2.63%)	0 / 1561 (0.00%)
occurrences (all)	38	80	0
Blood pressure increased			
subjects affected / exposed	40 / 1581 (2.53%)	70 / 3045 (2.30%)	0 / 1561 (0.00%)
occurrences (all)	41	74	0
Blood pressure diastolic increased			

subjects affected / exposed	22 / 1581 (1.39%)	34 / 3045 (1.12%)	0 / 1561 (0.00%)
occurrences (all)	23	36	0
Pharyngitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	21 / 1561 (1.35%)
occurrences (all)	0	0	21
Cardiac murmur			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	24 / 1561 (1.54%)
occurrences (all)	0	0	26
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	18 / 1581 (1.14%)	34 / 3045 (1.12%)	0 / 1561 (0.00%)
occurrences (all)	23	47	0
Arthropod bite			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	24 / 1561 (1.54%)
occurrences (all)	0	0	28
Congenital, familial and genetic disorders			
Dacryostenosis congenital			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	18 / 1561 (1.15%)
occurrences (all)	0	0	19
Cardiac disorders			
Tachycardia			
subjects affected / exposed	14 / 1581 (0.89%)	40 / 3045 (1.31%)	0 / 1561 (0.00%)
occurrences (all)	16	43	0
Nervous system disorders			
Headache			
subjects affected / exposed	170 / 1581 (10.75%)	331 / 3045 (10.87%)	0 / 1561 (0.00%)
occurrences (all)	204	423	0
Dizziness			
subjects affected / exposed	24 / 1581 (1.52%)	45 / 3045 (1.48%)	0 / 1561 (0.00%)
occurrences (all)	26	49	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	16 / 1581 (1.01%)	7 / 3045 (0.23%)	0 / 1561 (0.00%)
occurrences (all)	16	17	0
Anaemia neonatal			

subjects affected / exposed	25 / 1581 (1.58%)	21 / 3045 (0.69%)	0 / 1561 (0.00%)
occurrences (all)	25	21	0
Eye disorders			
Eye discharge			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	17 / 1561 (1.09%)
occurrences (all)	0	0	17
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	26 / 1581 (1.64%)	73 / 3045 (2.40%)	82 / 1561 (5.25%)
occurrences (all)	29	81	92
Dyspepsia			
subjects affected / exposed	34 / 1581 (2.15%)	55 / 3045 (1.81%)	0 / 1561 (0.00%)
occurrences (all)	35	59	0
Abdominal pain			
subjects affected / exposed	29 / 1581 (1.83%)	56 / 3045 (1.84%)	29 / 1561 (1.86%)
occurrences (all)	31	61	29
Diarrhoea neonatal			
subjects affected / exposed	25 / 1581 (1.58%)	56 / 3045 (1.84%)	115 / 1561 (7.37%)
occurrences (all)	29	61	137
Nausea			
subjects affected / exposed	23 / 1581 (1.45%)	48 / 3045 (1.58%)	0 / 1561 (0.00%)
occurrences (all)	23	49	0
Constipation			
subjects affected / exposed	27 / 1581 (1.71%)	42 / 3045 (1.38%)	70 / 1561 (4.48%)
occurrences (all)	28	46	76
Abdominal pain lower			
subjects affected / exposed	13 / 1581 (0.82%)	43 / 3045 (1.41%)	0 / 1561 (0.00%)
occurrences (all)	13	48	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	63 / 1561 (4.04%)
occurrences (all)	0	0	63
Teething			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	47 / 1561 (3.01%)
occurrences (all)	0	0	50
Diarrhoea			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	33 / 1561 (2.11%)
occurrences (all)	0	0	30
Flatulence			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	20 / 1561 (1.28%)
occurrences (all)	0	0	22
Infantile colic			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	8 / 1561 (0.51%)
occurrences (all)	0	0	9
Hepatobiliary disorders			
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	14 / 1561 (0.90%)
occurrences (all)	0	0	14
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	205 / 1561 (13.13%)
occurrences (all)	0	0	240
Eczema infantile			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	126 / 1561 (8.07%)
occurrences (all)	0	0	137
Rash			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	135 / 1561 (8.65%)
occurrences (all)	0	0	152
Dermatitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	58 / 1561 (3.72%)
occurrences (all)	0	0	68
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	54 / 1561 (3.46%)
occurrences (all)	0	0	56
Dermatitis atopic			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	42 / 1561 (2.69%)
occurrences (all)	0	0	47
Dry skin			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	36 / 1561 (2.31%)
occurrences (all)	0	0	38
Eczema			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	19 / 1561 (1.22%)
occurrences (all)	0	0	21
Rash neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	22 / 1561 (1.41%)
occurrences (all)	0	0	22
Rash papular			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	17 / 1561 (1.09%)
occurrences (all)	0	0	17
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	52 / 1581 (3.29%)	100 / 3045 (3.28%)	0 / 1561 (0.00%)
occurrences (all)	58	121	0
Muscle spasms			
subjects affected / exposed	18 / 1581 (1.14%)	42 / 3045 (1.38%)	0 / 1561 (0.00%)
occurrences (all)	21	46	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	58 / 1581 (3.67%)	145 / 3045 (4.76%)	12 / 1561 (0.77%)
occurrences (all)	62	158	13
Mastitis			
subjects affected / exposed	25 / 1581 (1.58%)	52 / 3045 (1.71%)	0 / 1561 (0.00%)
occurrences (all)	28	62	0
Gastroenteritis			
subjects affected / exposed	19 / 1581 (1.20%)	39 / 3045 (1.28%)	77 / 1561 (4.93%)
occurrences (all)	19	41	88
Amniotic cavity infection			
subjects affected / exposed	6 / 1581 (0.38%)	10 / 3045 (0.33%)	0 / 1561 (0.00%)
occurrences (all)	7	12	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	198 / 1561 (12.68%)
occurrences (all)	0	0	264
Ophthalmia neonatorum			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	97 / 1561 (6.21%)
occurrences (all)	0	0	109
Otitis media			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	94 / 1561 (6.02%)
occurrences (all)	0	0	126
Pneumonia			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	22 / 1561 (1.41%)
occurrences (all)	0	0	39
Oral candidiasis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	74 / 1561 (4.74%)
occurrences (all)	0	0	92
Bronchiolitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	26 / 1561 (1.67%)
occurrences (all)	0	0	31
Fungal skin infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	46 / 1561 (2.95%)
occurrences (all)	0	0	48
Nasopharyngitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	39 / 1561 (2.50%)
occurrences (all)	0	0	49
Ear infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	53 / 1561 (3.40%)
occurrences (all)	0	0	54
Respiratory tract infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	37 / 1561 (2.37%)
occurrences (all)	0	0	41
Sepsis neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	8 / 1561 (0.51%)
occurrences (all)	0	0	8
Otitis media acute			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	28 / 1561 (1.79%)
occurrences (all)	0	0	38
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	26 / 1561 (1.67%)
occurrences (all)	0	0	42
Rhinitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	32 / 1561 (2.05%)
occurrences (all)	0	0	33
Viral upper respiratory tract infection			

subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	27 / 1561 (1.73%)
occurrences (all)	0	0	39
Candida infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	20 / 1561 (1.28%)
occurrences (all)	0	0	22
Conjunctivitis bacterial			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	27 / 1561 (1.73%)
occurrences (all)	0	0	28
Conjunctivitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	19 / 1561 (1.22%)
occurrences (all)	0	0	21
Lower respiratory tract infection			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	9 / 1561 (0.58%)
occurrences (all)	0	0	10
Acarodermatitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	16 / 1561 (1.02%)
occurrences (all)	0	0	20
Viral rash			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	20 / 1561 (1.28%)
occurrences (all)	0	0	21
Bronchitis			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	13 / 1561 (0.83%)
occurrences (all)	0	0	14
Impetigo			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	12 / 1561 (0.77%)
occurrences (all)	0	0	14
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	14 / 1561 (0.90%)
occurrences (all)	0	0	14
Metabolism and nutrition disorders			
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 1581 (0.00%)	0 / 3045 (0.00%)	11 / 1561 (0.70%)
occurrences (all)	0	0	11

Non-serious adverse events	Infant Safety Population - RSV F Vaccine		
Total subjects affected by non-serious			

adverse events subjects affected / exposed	1140 / 3008 (37.90%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Essential hypertension			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
Foetal distress syndrome			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Gestational hypertension			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Prolonged labour			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Postpartum haemorrhage			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Premature rupture of membranes			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Cephalo-pelvic disproportion			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Prolonged rupture of membranes			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Foetal hypokinesia			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Prolonged pregnancy			

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Jaundice neonatal			
subjects affected / exposed	178 / 3008 (5.92%)		
occurrences (all)	186		
Poor weight gain neonatal			
subjects affected / exposed	38 / 3008 (1.26%)		
occurrences (all)	39		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Fever neonatal			
subjects affected / exposed	400 / 3008 (13.30%)		
occurrences (all)	527		
Pyrexia			
subjects affected / exposed	80 / 3008 (2.66%)		
occurrences (all)	89		
Reproductive system and breast disorders			
Vaginal discharge			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	241 / 3008 (8.01%)		
occurrences (all)	288		
Nasal congestion			
subjects affected / exposed	127 / 3008 (4.22%)		
occurrences (all)	142		
Rhinorrhoea			
subjects affected / exposed	123 / 3008 (4.09%)		
occurrences (all)	140		
Rhinitis allergic			
subjects affected / exposed	41 / 3008 (1.36%)		
occurrences (all)	60		

Investigations			
Streptococcus test positive			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Blood pressure increased			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Blood pressure diastolic increased			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	36 / 3008 (1.20%)		
occurrences (all)	37		
Cardiac murmur			
subjects affected / exposed	22 / 3008 (0.73%)		
occurrences (all)	35		
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	57 / 3008 (1.89%)		
occurrences (all)	60		
Congenital, familial and genetic disorders			
Dacryostenosis congenital			
subjects affected / exposed	27 / 3008 (0.90%)		
occurrences (all)	31		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Dizziness			

subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Anaemia neonatal			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Eye disorders			
Eye discharge			
subjects affected / exposed	39 / 3008 (1.30%)		
occurrences (all)	41		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	169 / 3008 (5.62%)		
occurrences (all)	211		
Dyspepsia			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	49 / 3008 (1.63%)		
occurrences (all)	51		
Diarrhoea neonatal			
subjects affected / exposed	252 / 3008 (8.38%)		
occurrences (all)	312		
Nausea			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	124 / 3008 (4.12%)		
occurrences (all)	133		
Abdominal pain lower			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			

subjects affected / exposed	105 / 3008 (3.49%)		
occurrences (all)	116		
Teething			
subjects affected / exposed	99 / 3008 (3.29%)		
occurrences (all)	117		
Diarrhoea			
subjects affected / exposed	63 / 3008 (2.09%)		
occurrences (all)	56		
Flatulence			
subjects affected / exposed	31 / 3008 (1.03%)		
occurrences (all)	31		
Infantile colic			
subjects affected / exposed	43 / 3008 (1.43%)		
occurrences (all)	47		
Hepatobiliary disorders			
Hyperbilirubinaemia neonatal			
subjects affected / exposed	24 / 3008 (0.80%)		
occurrences (all)	24		
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	424 / 3008 (14.10%)		
occurrences (all)	520		
Eczema infantile			
subjects affected / exposed	230 / 3008 (7.65%)		
occurrences (all)	245		
Rash			
subjects affected / exposed	203 / 3008 (6.75%)		
occurrences (all)	246		
Dermatitis			
subjects affected / exposed	107 / 3008 (3.56%)		
occurrences (all)	118		
Seborrhoeic dermatitis			
subjects affected / exposed	93 / 3008 (3.09%)		
occurrences (all)	94		
Dermatitis atopic			

subjects affected / exposed	68 / 3008 (2.26%)		
occurrences (all)	75		
Dry skin			
subjects affected / exposed	65 / 3008 (2.16%)		
occurrences (all)	68		
Eczema			
subjects affected / exposed	52 / 3008 (1.73%)		
occurrences (all)	56		
Rash neonatal			
subjects affected / exposed	40 / 3008 (1.33%)		
occurrences (all)	40		
Rash papular			
subjects affected / exposed	36 / 3008 (1.20%)		
occurrences (all)	39		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	29 / 3008 (0.96%)		
occurrences (all)	30		
Mastitis			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	169 / 3008 (5.62%)		
occurrences (all)	211		
Amniotic cavity infection			
subjects affected / exposed	0 / 3008 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			

subjects affected / exposed	365 / 3008 (12.13%)			
occurrences (all)	477			
Ophthalmia neonatorum				
subjects affected / exposed	195 / 3008 (6.48%)			
occurrences (all)	213			
Otitis media				
subjects affected / exposed	158 / 3008 (5.25%)			
occurrences (all)	205			
Pneumonia				
subjects affected / exposed	69 / 3008 (2.29%)			
occurrences (all)	106			
Oral candidiasis				
subjects affected / exposed	158 / 3008 (5.25%)			
occurrences (all)	173			
Bronchiolitis				
subjects affected / exposed	52 / 3008 (1.73%)			
occurrences (all)	75			
Fungal skin infection				
subjects affected / exposed	99 / 3008 (3.29%)			
occurrences (all)	109			
Nasopharyngitis				
subjects affected / exposed	87 / 3008 (2.89%)			
occurrences (all)	116			
Ear infection				
subjects affected / exposed	72 / 3008 (2.39%)			
occurrences (all)	95			
Respiratory tract infection				
subjects affected / exposed	60 / 3008 (1.99%)			
occurrences (all)	76			
Sepsis neonatal				
subjects affected / exposed	21 / 3008 (0.70%)			
occurrences (all)	10			
Otitis media acute				
subjects affected / exposed	61 / 3008 (2.03%)			
occurrences (all)	76			

Respiratory syncytial virus infection				
subjects affected / exposed	49 / 3008 (1.63%)			
occurrences (all)	61			
Rhinitis				
subjects affected / exposed	52 / 3008 (1.73%)			
occurrences (all)	58			
Viral upper respiratory tract infection				
subjects affected / exposed	52 / 3008 (1.73%)			
occurrences (all)	76			
Candida infection				
subjects affected / exposed	49 / 3008 (1.63%)			
occurrences (all)	53			
Conjunctivitis bacterial				
subjects affected / exposed	38 / 3008 (1.26%)			
occurrences (all)	44			
Conjunctivitis				
subjects affected / exposed	40 / 3008 (1.33%)			
occurrences (all)	43			
Lower respiratory tract infection				
subjects affected / exposed	23 / 3008 (0.76%)			
occurrences (all)	26			
Acarodermatitis				
subjects affected / exposed	38 / 3008 (1.26%)			
occurrences (all)	44			
Viral rash				
subjects affected / exposed	33 / 3008 (1.10%)			
occurrences (all)	34			
Bronchitis				
subjects affected / exposed	31 / 3008 (1.03%)			
occurrences (all)	34			
Impetigo				
subjects affected / exposed	36 / 3008 (1.20%)			
occurrences (all)	37			
Hand-foot-and-mouth disease				
subjects affected / exposed	32 / 3008 (1.06%)			
occurrences (all)	32			

Metabolism and nutrition disorders Hypoglycaemia neonatal subjects affected / exposed occurrences (all)	 17 / 3008 (0.57%) 17		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 June 2015	-The planned number of third-trimester pregnant maternal subjects to be enrolled into the study was increased -The upper limit of the gestational age window for maternal immunization of third-trimester pregnant subjects was increased by 1 week -The calendar dates at which interim analyses will be performed to assess for futility and success at the conclusion of RSV seasons in the Northern and Southern hemispheres were specified. Justification for selection of these dates and the minimum amount of infant subject data required for each analysis was also provided. -The sentence "Ultrasound performed at ≤31 weeks estimated gestational age is acceptable" was removed. -The definition of RSV lower respiratory tract infection (LRTI) was further refined. -The omission of the SCR analysis for anti-F IgG was corrected. An additional means to assess for transplacental transfer of maternal antibodies was added -Table 8 (Simulation Scenarios and Operating Characteristics) was revised -Clarification was provided regarding how subjects with any SNMC or SAE that continues beyond the duration of the study are to be followed. -An interim evaluation of immunogenicity and transplacental antibody transfer will be performed by the DSMB statistician for the first global season analysis.
09 July 2015	-Inclusion and exclusion criteria were updated -The term "proportions" was changed to "percentages" throughout the document -Clarifications added around the informed consent requirements for pre-screening -Issuance of Study Identification Cards added -Changes to the active RSV surveillance -The number of hospitalizations and outpatient visits due to RSV among children <5 years of age was updated with new information from the Centers for Disease Control and Prevention (CDC)

08 January 2016	-The role of the independent biostatistics group (IBG), the data and safety monitoring board (DMSB) statistician, and the DSMB project manager was clarified. -Addition to the list of labor and delivery complications -Masking of syringes containing test article added -Additions and clarifications to the inclusion and exclusion criteria -Option added for postpartum study visits to be completed in clinic or at home -Clarified the study procedures for the screening visit -Clarified when maternal and infant subjects may participate in an unscheduled visit and the study procedures that may be performed -A new section for the "Ages & Stages Questionnaires®, Third Edition (ASQ-3™)" was created -Clarified that maternal and infant subjects with ongoing respiratory episodes at the D+180 visit will be followed weekly until symptoms have resolved or have returned to baseline -Changes to the toxicity grades used to assess for severity of clinical laboratory parameters -A toxicity grading scale to assess for severity of an abnormal fetal heart tone value was developed -Hospitalizations categorized as medically-attended events -Maternal/Fetal/Neonatal Adverse Events of Special Interest were updated -The procedure for SAE reporting was revised -Severity for all unsolicited events reported in infant subjects will be based on whether medical intervention/therapy is required
09 February 2016	-Clarifications to the inclusion and exclusion criteria -Option for Day 7 and 14 visits to be conducted as home visits. Pregnancy testing will be administered to all subjects at the D+180 visit -For applicable subjects who deliver prior to the Day 14 visit, the clinical safety laboratory assessment will be performed at the Delivery visit -Institutional Review Board/Independent Ethics Committee approval of telephone scripts is now designated "if applicable" -Every infant study visit will query to determine if other children < 5 years of age reside in the same household as the infant subject -The collection methods for sampling of upper respiratory secretions were expanded
09 May 2016	-The gestational age for immunization of pregnant women in the third trimester with the RSV F vaccine was widened at the lower end of the third trimester, from 31 weeks to 28 weeks -Clarification added for the primary efficacy objective and the first and second exploratory objectives -Updates to efficacy endpoints -The sample size was revised. The timing for maternal subject enrollment and study inclusion was clarified. After the first global season of enrollment, the randomization scheme will be changed to a 2:1 (active / placebo) ratio -Updated the description for the manufacture of the RSV F protein to reflect current processes. -Clarifications to exclusion criteria -Screening for hepatitis B (HBV) and C (HCV) viruses, syphilis, and HIV can be performed using the central or local laboratory if undocumented. -Specified that maternal subjects with a positive pregnancy result at the D+180 visit will be followed for safety through the time of delivery to determine the outcome of this pregnancy. -Clarified that RSV surveillance visits are not considered unscheduled visits. -Added text to allow for procedures and vaccinations associated with a baby-wellness visit to be performed at any infant post-partum study visit, if applicable. The Day 112 visit was changed to Day 120 -Clarified that all procedures associated with the RSV surveillance visits are performed only on symptomatic subjects. -Clarified that respiratory specimens will be processed and subjected to a commercially available multiplex RT-PCR for identification of a range of common viral pathogens in addition to RSV. -Clarified that abnormal fetal heart tone measures may be repeated, but any consistent abnormality should be reported as an AE -Statistical methods were updated and refined

15 July 2016	-The administration of any licensed vaccine recommended for pregnancy to occur within 14 days of the Day 0 vaccination was emphasized -Changed the screening visit window -The window for clinician evaluation and respiratory specimen collection of maternal and infant subjects with symptoms of RSV-suspected illness was extended -Telephone contact for the Day 28 safety follow-up will encompass short message service (SMS) -Specified that all procedures that are considered standard of care for a corresponding baby-wellness visit may be performed at any study visit, if applicable. -Infant subjects with a positive screen detected at both 6 and 12 months of age, or first appearing at 12 months of age, will be offered repeat developmental testing at 15 and 18 months of age as a follow-up procedure -As part of passive RSV surveillance, symptomatic maternal subjects and parents/guardians of symptomatic infant subjects should contact the study site directly within 3 days of the onset of symptoms -Clarified that the evaluation of maternal and infant subjects with RSV-suspected illness will occur within 7 days of symptom/s onset. -Addition to the list of trigger symptoms for symptomatic maternal subjects with an RSV-suspected illness. -Clarified the study completion procedures for maternal subjects who discontinue from the study prematurely -Clarified that template source documents will be used for Global Year 1, and the electronic source documentation for all subsequent years -Clarified that remote monitoring may be performed by independent clinical monitors designated by Novavax -Briefly updated the study files that will be maintained in the centralized filing system. -Definition provided for a symptomatic RSV infection in maternal subjects. -The gestational weeks for all visits occurring after Day 0 were updated
23 August 2016	-Clarified the permissive timing of maternal subject enrollment and immunization -Clarified the procedures for unblinding of subject treatment assignment in the event of a medical emergency -Updates to the inclusions and exclusion criteria -The assay descriptions for anti-F IgG and PCA ELISA have been reworded for clarity -The safety reporting requirements have been amended

21 July 2017	-A brief description of RSV epidemiology among the United States Native American pediatric population was provided. -A section was added to provide a brief discussion of RSV in children in India, Southeast Asia, and the Philippines. -The summary of clinical experience was updated to include Phase 2 safety data - The primary efficacy objective in infants was changed -The 2nd exploratory objective was updated -Target subject enrollment was updated -The description of the study design was updated -The description of the group-sequential design strategy was updated to reflect the updated primary objective of efficacy -The primary efficacy endpoint in infant subjects was changed -It was specified that the duration of the entire study is estimated to be approximately four years -Inclusion criteria updated -It was clarified that active surveillance for RSV-suspect illnesses will cease after D+180 -RSV surveillance rules were updated and new rules added -Additional procedures were outlined for the study staff to increase efficiency and completeness in capturing study endpoints during RSV surveillance. -New section added to provide additional direction for the study staff for follow-up of RSV-suspect illness among subjects -It has been specified that a respiratory specimen will be collected as soon as possible after onset of illness among subjects -Guidance regarding the safety reporting of ASQ abnormalities was added -Clarification on reporting of neonatal and infant deaths -Updated on how pregnancy will be captured -Clarification on how the DSMB will be composed -Study definition for RSV LRTI was changed throughout -Statistical considerations were updated -Text corrected to reflect that all unsolicited AEs for maternal subjects through 180 days post-delivery by severity and relatedness, will be captured The estimated enrollment projections per global season have been updated
02 October 2018	-The title of the study has been updated -The wording of two secondary objectives was updated -Two secondary objectives were recategorized as exploratory -Seven new exploratory endpoints were added -The study design description was updated and the approximate number of subjects in treatment groups added -The section on group sequential design was deleted -The description of all efficacy endpoints was amended -Two secondary endpoints were modified -Changes to correct the omission of the term “seroconversion rate” from prior versions and provide an expectation for the schedule of completion of microneutralization -The language used to describe the safety endpoints has been changed -Clarification on how the gestational age at birth will be determined -Changes have been applied to provide clarity on the functioning of the data and safety monitoring board (DSMB) -Clarification to the population definitions -Clarification to the source of data for the referenced endpoint -Section has been added to present information about the CEAC -Clarifications on on how the safety endpoints will be described -Updates to the statistical analysis -Clarification that “interim” analyses refer to futility and informational analyses
12 October 2018	-Change to the title of the study

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported