Clinical trial results:
A Phase 2/3, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-COV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of age and Older

Summary

EudraCT number	2020-005444-35
Trial protocol	ES
Global end of trial date	22 July 2022

Results information

Result version number	v2 (current)
This version publication date	11 July 2024
First version publication date	30 July 2023
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	C4591015

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04754594
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	BioNTech SE
Sponsor organisation address	An der Goldgrube 12, Mainz, Germany, 55131
Public contact	BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de
Scientific contact	BioNTech SE, BioNTech clinical trials patient information, +49 6131 90840, patients@biontech.de

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	29 March 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 July 2022
Global end of trial reached?	Yes
Global end of trial date	22 July 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety and tolerability of prophylactic BNT162b2 when administered to maternal subjects 18 years of age or older vaccinated at 24 to 34 weeks' gestation.
To describe the immune response to prophylactic BNT162b2 in maternal subjects 18 years of age or older vaccinated at 24 to 34 weeks' gestation and reference to the immune response in nonpregnant women 18 years of age or older from the C4591001 study without evidence of past SARS-CoV-2 infection.
To describe the immune response to prophylactic BNT162b2 in maternal subjects 18 years of age or older vaccinated at 24 to 34 weeks' gestation and reference to the immune response in nonpregnant women 18 years of age or older from the C4591001 study with and without evidence of prior SARS-CoV-2 infection.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 February 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Brazil: 95
Country: Number of subjects enrolled	South Africa: 192
Country: Number of subjects enrolled	Spain: 75
Country: Number of subjects enrolled	United Kingdom: 28
Country: Number of subjects enrolled	United States: 336
Worldwide total number of subjects	726
EEA total number of subjects	75

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	10

Newborns (0-27 days)	325
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	391
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted in 2 periods-Blinded Period (from Day 1 to 1 month post-delivery) and Unblinded Period (1 to 6 Months Post-Delivery for those maternal subjects who initially received BNT162b2 and first dose of BNT162b2 to 1 month after second dose of BNT162b2 for those maternal subjects who initially received placebo).

Pre-assignment

Screening details:

A total of 726 subjects were enrolled in this study. 391 were maternal subjects who signed informed consent form and were enrolled out of which 41 were screen failures and 2 subjects were not randomised. Eventually 348 maternal subjects were randomised to receive treatment. 335 were infants born to maternal subjects.

Period 1

Period 1 title	Baseline Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Maternal Subjects: BNT162b2 30 mcg

Arm description:

Maternal subjects received two doses of BNT162b2 30 micrograms (mcg) as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. Subjects were followed-up until 6 months post-delivery.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 30 mcg of BNT162b2 as an intramuscular injection.

Arm title	Maternal Subjects: Placebo then BNT162b2 30 mcg

Arm description:

Maternal subjects received two doses of placebo as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. After unblinding at 1 month post-delivery, subjects were administered 2 doses of BNT162b2 vaccine as an intramuscular injection separated by 21 days. Subjects were followed-up until 1 month after last dose of vaccination.

Arm type	Placebo
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 30 mcg of BNT162b2 as an intramuscular injection.

Arm title	Infant Subjects: BNT162b2 30 mcg

Arm description:

Infant subjects who were born to maternal subjects vaccinated with BNT162b2 30 mcg during pregnancy were included. Infant subjects were followed up to 6 months of age.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Infant Subject: Placebo

Arm description:

Infant subjects who were born to maternal subjects vaccinated with placebo during pregnancy were included. Infant subjects were followed up to 6 months of age.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1[1]	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg	Infant Subjects: BNT162b2 30 mcg
Started	173	173	167
Completed	173	173	167

Number of subjects in period 1[1]	Infant Subject: Placebo
Started	168
Completed	168

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: A total of 726 subjects were enrolled in this study. 391 were maternal subjects who signed informed consent form and were enrolled out of which 41 were screen failures and 2 subjects were not randomized. Eventually 348 maternal subjects were randomized to receive treatment. 335 were infants born to maternal subjects

Period 2

Period 2 title	Blinded Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Maternal Subjects: BNT162b2 30 mcg

Arm description:

Maternal subjects received two doses of BNT162b2 30 micrograms (mcg) as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. Subjects were followed-up until 6 months post-delivery.

Arm type	Experimental

Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 30 mcg of BNT162b2 as an intramuscular injection.

Arm title	Maternal Subjects: Placebo then BNT162b2 30 mcg

Arm description:

Maternal subjects received two doses of placebo as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. After unblinding at 1 month post-delivery, subjects were administered 2 doses of BNT162b2 vaccine as an intramuscular injection separated by 21 days. Subjects were followed-up until 1 month after last dose of vaccination.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received placebo (normal saline) as an intramuscular injection.

Number of subjects in period 2[2]	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg
Started	173	173
Vaccination 1	173	173
Vaccination 2	170	170
Completed	167	162
Not completed	6	11
Consent withdrawn by subject	4	9
Lost to follow-up	1	1
Protocol deviation	1	1

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: No maternal subjects received vaccination during the unblinded phase.

Period 3

Period 3 title	Unblinded Period
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes

Arm title	Maternal Subjects: BNT162b2 30 mcg

Arm description:

Maternal subjects received two doses of BNT162b2 30 micrograms (mcg) as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. Subjects were followed-up until 6 months post-delivery.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Maternal Subjects: Placebo then BNT162b2 30 mcg

Arm description:

Maternal subjects received two doses of placebo as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. After unblinding at 1 month post-delivery, subjects were administered 2 doses of BNT162b2 vaccine as an intramuscular injection separated by 21 days. Subjects were followed-up until 1 month after last dose of vaccination.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 30 mcg of BNT162b2 as an intramuscular injection.

Number of subjects in period 3	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg
Started	167	162
Vaccination 3	0 [3]	152
Vaccination 4	0 [4]	148
Completed	151	147
Not completed	16	15
Consent withdrawn by subject	6	8
Unspecified	3	-
Lost to follow-up	5	3
Protocol deviation	2	4

Notes:

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: No maternal subjects received vaccination during the unblinded phase.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: For blinded period, only maternal subjects were included.

Period 4

Period 4 title	Infant Subjects
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	No
Arm title	Infant Subjects: BNT162b2 30 mcg

Arm description:

Infant subjects who were born to maternal subjects vaccinated with BNT162b2 30 mcg during pregnancy were included. Infant subjects were followed up to 6 months of age.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Infant Subjects: Placebo

Arm description:

Infant subjects who were born to maternal subjects vaccinated with placebo during pregnancy were included. Infant subjects were followed up to 6 months of age.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 4	Infant Subjects: BNT162b2 30 mcg	Infant Subjects: Placebo
Started	167	168
Completed	152	139
Not completed	15	29
Death	1	1
Unspecified	1	1
Lost to follow-up	4	10
Withdrawal by parent/guardian	9	17

Baseline characteristics

Reporting groups	
Reporting group title	Maternal Subjects: BNT162b2 30 mcg
Reporting group description:	
Maternal subjects received two doses of BNT162b2 30 micrograms (mcg) as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. Subjects were followed-up until 6 months post-delivery.	
Reporting group title	Maternal Subjects: Placebo then BNT162b2 30 mcg
Reporting group description:	
Maternal subjects received two doses of placebo as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. After unblinding at 1 month post-delivery, subjects were administered 2 doses of BNT162b2 vaccine as an intramuscular injection separated by 21 days. Subjects were followed-up until 1 month after last dose of vaccination.	
Reporting group title	Infant Subjects: BNT162b2 30 mcg
Reporting group description:	
Infant subjects who were born to maternal subjects vaccinated with BNT162b2 30 mcg during pregnancy were included. Infant subjects were followed up to 6 months of age.	
Reporting group title	Infant Subject: Placebo
Reporting group description:	
Infant subjects who were born to maternal subjects vaccinated with placebo during pregnancy were included. Infant subjects were followed up to 6 months of age.	

Reporting group values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg	Infant Subjects: BNT162b2 30 mcg
Number of subjects	173	173	167
Age Categorical Units: Subjects			
Less than (<) 18 years	0	0	167
Greater than or equal to (>=) 18 and <= 45 years	173	173	0
Sex: Female, Male Units: Subjects			
Female	173	173	85
Male	0	0	82
Race Units: Subjects			
American Indian or Alaska Native	1	1	1
Asian	5	9	3
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	47	43	40
White	117	118	115
More than one race	1	0	0
Unknown or Not Reported	2	1	8
Ethnicity Units: Subjects			
Hispanic or Latino	70	63	65
Not Hispanic or Latino	103	110	98
Unknown or Not Reported	0	0	4

Reporting group values	Infant Subject: Placebo	Total	
Number of subjects	168	681	
Age Categorical Units: Subjects			
Less than (<) 18 years	168	335	
Greater than or equal to (>=) 18 and <= 45 years	0	346	
Sex: Female, Male Units: Subjects			
Female	73	504	
Male	95	177	
Race Units: Subjects			
American Indian or Alaska Native	2	5	
Asian	7	24	
Native Hawaiian or Other Pacific Islander	0	1	
Black or African American	40	170	
White	104	454	
More than one race	6	7	
Unknown or Not Reported	9	20	
Ethnicity Units: Subjects			
Hispanic or Latino	60	258	
Not Hispanic or Latino	104	415	
Unknown or Not Reported	4	8	

End points

End points reporting groups

Reporting group title	Maternal Subjects: BNT162b2 30 mcg

Reporting group description:

Maternal subjects received two doses of BNT162b2 30 micrograms (mcg) as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. Subjects were followed-up until 6 months post-delivery.

Reporting group title	Maternal Subjects: Placebo then BNT162b2 30 mcg

Reporting group description:

Maternal subjects received two doses of placebo as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. After unblinding at 1 month post-delivery, subjects were administered 2 doses of BNT162b2 vaccine as an intramuscular injection separated by 21 days. Subjects were followed-up until 1 month after last dose of vaccination.

Reporting group title	Infant Subjects: BNT162b2 30 mcg

Reporting group description:

Infant subjects who were born to maternal subjects vaccinated with BNT162b2 30 mcg during pregnancy were included. Infant subjects were followed up to 6 months of age.

Reporting group title	Infant Subject: Placebo

Reporting group description:

Infant subjects who were born to maternal subjects vaccinated with placebo during pregnancy were included. Infant subjects were followed up to 6 months of age.

Reporting group title	Maternal Subjects: BNT162b2 30 mcg

Reporting group description:

Maternal subjects received two doses of BNT162b2 30 micrograms (mcg) as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. Subjects were followed-up until 6 months post-delivery.

Reporting group title	Maternal Subjects: Placebo then BNT162b2 30 mcg

Reporting group description:

Maternal subjects received two doses of placebo as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. After unblinding at 1 month post-delivery, subjects were administered 2 doses of BNT162b2 vaccine as an intramuscular injection separated by 21 days. Subjects were followed-up until 1 month after last dose of vaccination.

Reporting group title	Maternal Subjects: BNT162b2 30 mcg

Reporting group description:

Maternal subjects received two doses of BNT162b2 30 micrograms (mcg) as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. Subjects were followed-up until 6 months post-delivery.

Reporting group title	Maternal Subjects: Placebo then BNT162b2 30 mcg

Reporting group description:

Maternal subjects received two doses of placebo as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. After unblinding at 1 month post-delivery, subjects were administered 2 doses of BNT162b2 vaccine as an intramuscular injection separated by 21 days. Subjects were followed-up until 1 month after last dose of vaccination.

Reporting group title	Infant Subjects: BNT162b2 30 mcg

Reporting group description:

Infant subjects who were born to maternal subjects vaccinated with BNT162b2 30 mcg during pregnancy were included. Infant subjects were followed up to 6 months of age.

Reporting group title	Infant Subjects: Placebo

Reporting group description:

Infant subjects who were born to maternal subjects vaccinated with placebo during pregnancy were included. Infant subjects were followed up to 6 months of age.

Subject analysis set title	Non-Pregnant Subjects: Study C4591001
Subject analysis set type	Per protocol

Subject analysis set description:

Non-pregnant subjects who received two doses of BNT162b2 30 mcg as an intramuscular injection

separated by 21 days in study C4591001 (NCT04368728).

Primary: Percentage of Maternal Subjects Reporting Local Reactions Within 7 Days After Dose 1

End point title	Percentage of Maternal Subjects Reporting Local Reactions Within 7 Days After Dose 1[1]

End point description:

Local reactions recorded by subjects in electronic diary (e-diary). Redness & swelling recorded in measuring device units (mdu, range 1 to 21) & converted to cm. 1 mdu=0.5 cm & graded mild: > 2.0-5.0 cm, moderate: >5.0-10.0 cm, severe: >10.0 cm, grade 4: necrosis/exfoliative dermatitis (redness) & necrosis (swelling). Pain at injection site graded mild: did not interfere with daily activity, moderate: interfered with daily activity, severe: prevented daily activity & grade 4: emergency room visit/hospitalisation for severe pain. Grade 4 classified by investigator/medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Exact 2-sided 95% CI based on Clopper & Pearson method. Safety population=all randomised subjects receiving at least 1 dose of study intervention. N=subjects evaluable for this endpoint. HIV positive subjects excluded as pre-specified in statistical analysis plan (SAP).

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after dose 1

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: Only descriptive data was planned to be analysed.

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	161	163		
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Mild	2.5 (0.7 to 6.2)	0.6 (0.0 to 3.4)		
Redness: Moderate	0.6 (0.0 to 3.4)	0 (0.0 to 2.2)		
Redness: Severe	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Redness: Grade 4	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Swelling: Mild	4.3 (1.8 to 8.8)	0 (0.0 to 2.2)		
Swelling: Moderate	0.6 (0.0 to 3.4)	0 (0.0 to 2.2)		
Swelling: Severe	0.6 (0.0 to 3.4)	0 (0.0 to 2.2)		
Swelling: Grade 4	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Pain at the injection site: Mild	59.0 (51.0 to 66.7)	9.8 (5.7 to 15.5)		
Pain at the injection site: Moderate	23.6 (17.3 to 30.9)	0 (0.0 to 2.2)		
Pain at the injection site: Severe	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Pain at the injection site: Grade 4	0 (0.0 to 2.3)	0 (0.0 to 2.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects Reporting Local Reactions Within 7 Days After Dose 2

End point title	Percentage of Maternal Subjects Reporting Local Reactions Within 7 Days After Dose 2[2]

End point description:

Local reactions recorded by subjects in e-diary. Redness & swelling recorded in mdu (range 1 to 21) & converted to cm. 1 mdu=0.5 cm & graded mild: > 2.0-5.0 cm, moderate: >5.0-10.0 cm, severe: >10.0 cm, grade 4: necrosis/exfoliative dermatitis (redness) & necrosis (swelling). Pain at injection site graded mild: did not interfere with daily activity, moderate: interfered with daily activity, severe: prevented daily activity & grade 4: emergency room visit/hospitalisation for severe pain. Grade 4 classified by investigator/medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Exact 2-sided 95% CI based on Clopper & Pearson method. Safety population=all randomised subjects receiving at least 1 dose of study intervention. N=subjects evaluable for this endpoint. HIV positive subjects excluded as pre-specified in SAP.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after dose 2

Notes:

[2] - 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: Only descriptive data was planned to be analysed.

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	148	146		
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Mild	3.4 (1.1 to 7.7)	0 (0.0 to 2.5)		
Redness: Moderate	2.0 (0.4 to 5.8)	0 (0.0 to 2.5)		
Redness: Severe	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Redness: Grade 4	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Swelling: Mild	4.1 (1.5 to 8.6)	0.7 (0.0 to 3.8)		
Swelling: Moderate	2.7 (0.7 to 6.8)	0 (0.0 to 2.5)		
Swelling: Severe	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Swelling: Grade 4	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Pain at the injection site: Mild	54.7 (46.3 to 62.9)	12.3 (7.5 to 18.8)		
Pain at the injection site: Moderate	19.6 (13.5 to 26.9)	4.1 (1.5 to 8.7)		
Pain at the injection site: Severe	0.7 (0.0 to 3.7)	0 (0.0 to 2.5)		
Pain at the injection site: Grade 4	0 (0.0 to 2.5)	0 (0.0 to 2.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects Reporting Systemic Events Within 7 Days After Dose 1

End point title	Percentage of Maternal Subjects Reporting Systemic Events Within 7 Days After Dose 1[3]

End point description:

Systemic events recorded by subject in e-diary. Fever: oral temperature ≥38 °C & categorised as ≥38.0-38.4°C, >38.4-38.9°C, >38.9-40.0°C & >40.0°C. Fatigue, headache, chills, new/worsened muscle pain & new/worsened joint pain: mild: did not interfere with activity, moderate: some interference with activity & severe: prevented daily routine activity. Vomiting: mild: 1-2 times in 24h, moderate: >2 times in 24h & severe: required IV hydration. Diarrhea: mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h & severe: 6 or more loose stools in 24h. Except fever, Grade 4= emergency room visit/hospitalisation. Grade 4 events classified by investigator/medically qualified person. Systemic events reported as AEs in CRF within 7 days of vaccination also included. Exact 95% CI based on Clopper & Pearson method. Safety population=all randomised subjects receiving at least 1 dose. N=subjects evaluable for this endpoint. HIV positive subjects excluded as pre-specified in SAP.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after dose 1

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed.

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	161	163		
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: >=38.0 to 38.4 deg C	0.6 (0.0 to 3.4)	1.2 (0.1 to 4.4)		
Fever: >38.4 to 38.9 deg C	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Fever: >38.9 to 40.0 deg C	0.6 (0.0 to 3.4)	0.6 (0.0 to 3.4)		
Fever: >40 deg C	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Fatigue/tiredness: Mild	26.1 (19.5 to 33.6)	20.9 (14.9 to 27.9)		
Fatigue/tiredness: Moderate	23.0 (16.7 to 30.3)	21.5 (15.4 to 28.6)		
Fatigue/tiredness: Severe	0.6 (0.0 to 3.4)	0.6 (0.0 to 3.4)		
Fatigue/tiredness: Grade 4	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Headache: Mild	20.5 (14.5 to 27.6)	22.1 (16.0 to 29.2)		
Headache: Moderate	11.8 (7.3 to 17.8)	12.9 (8.2 to 19.0)		
Headache: Severe	1.9 (0.4 to 5.3)	0.6 (0.0 to 3.4)		
Headache: Grade 4	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Chills: Mild	5.0 (2.2 to 9.6)	5.5 (2.6 to 10.2)		
Chills: Moderate	1.9 (0.4 to 5.3)	0 (0.0 to 2.2)		
Chills: Severe	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Chills: Grade 4	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Vomiting: Mild	5.0 (2.2 to 9.6)	6.1 (3.0 to 11.0)		
Vomiting: Moderate	0 (0.0 to 2.3)	3.1 (1.0 to 7.0)		
Vomiting: Severe	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Vomiting: Grade 4	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
Diarrhea: Mild	11.2 (6.8 to 17.1)	7.4 (3.9 to 12.5)		
Diarrhea: Moderate	0.6 (0.0 to 3.4)	1.2 (0.1 to 4.4)		
Diarrhea: Severe	0 (0.0 to 2.3)	0 (0.0 to 2.2)		

Diarrhea: Grade 4	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
New or worsened muscle pain: Mild	6.8 (3.5 to 11.9)	6.1 (3.0 to 11.0)		
New or worsened muscle pain: Moderate	5.6 (2.6 to 10.3)	5.5 (2.6 to 10.2)		
New or worsened muscle pain: Severe	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
New or worsened muscle pain: Grade 4	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
New or worsened joint pain: Mild	1.2 (0.2 to 4.4)	2.5 (0.7 to 6.2)		
New or worsened joint pain: Moderate	1.9 (0.4 to 5.3)	2.5 (0.7 to 6.2)		
New or worsened joint pain: Severe	0 (0.0 to 2.3)	0 (0.0 to 2.2)		
New or worsened joint pain: Grade 4	0 (0.0 to 2.3)	0 (0.0 to 2.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects Reporting Systemic Events Within 7 Days After Dose 2

End point title	Percentage of Maternal Subjects Reporting Systemic Events Within 7 Days After Dose 2[4]

End point description:

Systemic events recorded by subjects in e-diary. Fever: oral temperature ≥38 °C & categorised as ≥38.0-38.4°C, >38.4-38.9°C, >38.9-40.0°C & >40.0°C. Fatigue, headache, chills, new/worsened muscle pain & new/worsened joint pain: mild: did not interfere with activity, moderate: some interference with activity & severe: prevented daily routine activity. Vomiting: mild: 1-2 times in 24h, moderate: >2 times in 24h & severe: required IV hydration. Diarrhea: mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h & severe: 6 or more loose stools in 24h. Except fever, Grade 4= emergency room visit/hospitalisation. Grade 4 events classified by investigator/medically qualified person. Systemic events reported as AEs in CRF within 7 days of vaccination also included. Exact 95% CI based on Clopper & Pearson method. Safety population=all randomised subjects receiving at least 1 dose. N=subjects evaluable for this endpoint. HIV positive subjects excluded as pre-specified in SAP.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after dose 2

Notes:

[4] - 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: Only descriptive data was planned to be analysed.

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	148	146		
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: >=38.0 to 38.4 deg C	1.4 (0.2 to 4.8)	0.7 (0.0 to 3.8)		
Fever: >38.4 to 38.9 deg C	0.7 (0.0 to 3.7)	0 (0.0 to 2.5)		
Fever: >38.9 to 40.0 deg C	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Fever: >40 deg C	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Fatigue/tiredness: Mild	15.5 (10.1 to 22.4)	15.8 (10.3 to 22.7)		

Fatigue/tiredness: Moderate	32.4 (25.0 to 40.6)	18.5 (12.6 to 25.8)		
Fatigue/tiredness: Severe	2.0 (0.4 to 5.8)	0 (0.0 to 2.5)		
Fatigue/tiredness: Grade 4	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Headache: Mild	25.0 (18.3 to 32.8)	13.7 (8.6 to 20.4)		
Headache: Moderate	14.9 (9.6 to 21.6)	10.3 (5.9 to 16.4)		
Headache: Severe	1.4 (0.2 to 4.8)	0 (0.0 to 2.5)		
Headache: Grade 4	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Chills: Mild	4.7 (1.9 to 9.5)	0.7 (0.0 to 3.8)		
Chills: Moderate	7.4 (3.8 to 12.9)	0 (0.0 to 2.5)		
Chills: Severe	0.7 (0.0 to 3.7)	0 (0.0 to 2.5)		
Chills: Grade 4	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Vomiting: Mild	8.8 (4.8 to 14.6)	2.1 (0.4 to 5.9)		
Vomiting: Moderate	0 (0.0 to 2.5)	1.4 (0.2 to 4.9)		
Vomiting: Severe	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Vomiting: Grade 4	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Diarrhea: Mild	6.1 (2.8 to 11.2)	4.1 (1.5 to 8.7)		
Diarrhea: Moderate	0 (0.0 to 2.5)	1.4 (0.2 to 4.9)		
Diarrhea: Severe	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Diarrhea: Grade 4	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
New or worsened muscle pain: Mild	13.5 (8.5 to 20.1)	4.8 (1.9 to 9.6)		
New or worsened muscle pain: Moderate	12.8 (7.9 to 19.3)	2.1 (0.4 to 5.9)		
New or worsened muscle pain: Severe	0.7 (0.0 to 3.7)	0 (0.0 to 2.5)		
New or worsened muscle pain: Grade 4	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
New or worsened joint pain: Mild	7.4 (3.8 to 12.9)	4.8 (1.9 to 9.6)		
New or worsened joint pain: Moderate	6.1 (2.8 to 11.2)	1.4 (0.2 to 4.9)		
New or worsened joint pain: Severe	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
New or worsened joint pain: Grade 4	0 (0.0 to 2.5)	0 (0.0 to 2.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects With Adverse Events (AEs) From Dose 1 Through 1 Month After Dose 2 - Blinded Follow-up Period

End point title	Percentage of Maternal Subjects With Adverse Events (AEs) From Dose 1 Through 1 Month After Dose 2 - Blinded Follow-up Period[5]

End point description:

An AE was any untoward medical occurrence in a subject temporally associated with the use of study intervention, whether or not considered related to the study intervention. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population (maternal) included all randomised subjects who received at least 1 dose of the study intervention. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint. HIV positive subjects were excluded from analysis as pre-specified in the SAP.

End point type	Primary

End point timeframe:

From dose 1 on Day 1 through 1 month after dose 2 (approximately 2 months)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed.

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	161	163		
Units: Percentage of subjects				
number (confidence interval 95%)	23.6 (17.3 to 30.9)	22.7 (16.5 to 29.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects Reporting Serious Adverse Events (SAEs) From Dose 1 Through 1 Month After Delivery - Blinded Follow-up Period

End point title	Percentage of Maternal Subjects Reporting Serious Adverse Events (SAEs) From Dose 1 Through 1 Month After Delivery - Blinded Follow-up Period[6]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population (maternal) included all randomised subjects who received at least 1 dose of the study intervention. Here, "Number of Subjects Analysed (N)" signifies subjects evaluable for this endpoint. HIV positive subjects were excluded from analysis as pre-specified in the SAP.

End point type	Primary

End point timeframe:

From dose 1 on Day 1 through 1 month after delivery

Notes:

[6] - 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: Only descriptive data was planned to be analysed.

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	161	163		
Units: Percentage of subjects				
number (confidence interval 95%)	13.0 (8.3 to 19.2)	14.1 (9.2 to 20.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Ratio (GMR) of the SARS-CoV-2 Neutralising Titers in Pregnant Women to Those in Nonpregnant Women From Study C4591001 (NCT04368728) for Evaluable Immunogenicity Population Without Evidence of Prior SARS-CoV-2 Infection

End point title	Geometric Mean Ratio (GMR) of the SARS-CoV-2 Neutralising Titers in Pregnant Women to Those in Nonpregnant Women From Study C4591001 (NCT04368728) for Evaluable Immunogenicity Population Without Evidence of Prior SARS-CoV-2 Infection

End point description:

GMR of SARS-CoV-2 neutralizing titers in pregnant women to those in nonpregnant women from study C4591001(NCT04368728)for evaluable immunogenicity population(eip)without evidence of prior SARS-CoV-2 infection upto 1month after Dose2 was reported.Geometric mean titer(GMT),2-sided 95% CIs were calculated by exponentiating mean logarithm of titers,corresponding CIs(student t distribution),was reported in descriptive section.GMR was reported in statistical analysis section.EIP:subjects eligible,randomised,received 2 doses vaccine to which they were randomised,with Dose2 received in predefined window(19-42 days,inclusive,after Dose1);had at least 1 valid immunogenicity result in appropriate window 1 month after Dose2(28-42 days,inclusive,after Dose2);had no important protocol deviations as determined by clinician.EIP without evidence of SARS-CoV2 infection upto 1 month after Dose2 was analysed."N"=subjects evaluable for this endpoint.HIV positive subjects excluded as pre-specified in SAP.

End point type	Primary

End point timeframe:

1 Month after Dose 2

End point values	Maternal Subjects: BNT162b2 30 mcg	Non-Pregnant Subjects: Study C4591001		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	58	107		
Units: Titer				
geometric mean (confidence interval 95%)	1109.2 (849.2 to 1448.9)	1663.7 (1411.5 to 1960.8)		

Statistical analyses

Statistical analysis title	Maternal:BNT 30 mcg vs Non-Pregnant:Study C4591001

Statistical analysis description:

GMRs and 2-sided 95% CIs was calculated by exponentiating the mean difference of the logarithms of the assay and the corresponding CIs.

Comparison groups	Maternal Subjects: BNT162b2 30 mcg v Non-Pregnant Subjects: Study C4591001
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	0.9

Primary: GMR of SARS-CoV-2 Neutralising Titers in Pregnant Women to Those in Nonpregnant Women From Study C4591001 (NCT04368728) for Evaluable Immunogenicity Population With and Without Evidence of Prior SARS-CoV-2 Infection

End point title	GMR of SARS-CoV-2 Neutralising Titers in Pregnant Women to Those in Nonpregnant Women From Study C4591001 (NCT04368728) for Evaluable Immunogenicity Population With and Without Evidence of Prior SARS-CoV-2 Infection

End point description:

GMR of SARS-CoV-2 neutralizing titers in pregnant women to those in nonpregnant women from study C4591001 (NCT04368728) for EIP with and without evidence of prior SARS-CoV-2 infection was reported. GMT and 2-sided 95% CIs were calculated by exponentiating mean logarithm of titers and corresponding CIs (student t distribution) and was reported in descriptive section. GMR was reported in statistical analysis section. EIP: all subjects who were eligible and randomised, received 2 doses of vaccine to which they were randomised, with Dose 2 received within predefined window (19-42 days, inclusive, after Dose 1); had at least 1 valid immunogenicity result within an appropriate window 1 month after Dose 2 (28-42 days, inclusive, after Dose 2); had no other important protocol deviations as determined by clinician. EIP was analysed. Here, "N" signifies subjects evaluable for this endpoint. HIV positive subjects were excluded from analysis as pre-specified in SAP.

End point type	Primary

End point timeframe:

1 Month after Dose 2

End point values	Maternal Subjects: BNT162b2 30 mcg	Non-Pregnant Subjects: Study C4591001		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	100	114		
Units: Titer				
geometric mean (confidence interval 95%)	2198.7 (1618.5 to 2987.0)	1732.0 (1469.4 to 2041.5)		

Statistical analyses

Statistical analysis title	Maternal:BNT 30 mcg vs Non-Pregnant:Study C4591001

Statistical analysis description:

GMRs and 2-sided 95% CIs was calculated by exponentiating the mean difference of the logarithms of the assay and the corresponding CIs.

Comparison groups	Maternal Subjects: BNT162b2 30 mcg v Non-Pregnant Subjects: Study C4591001
Number of subjects included in analysis	214
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.3

Statistical analysis title	Maternal:BNT 30 mcg vs Non-Pregnant:Study C4591001

Statistical analysis description:

GMRs and 2-sided 95% CIs was calculated by exponentiating the mean difference of the logarithms of the assay and the corresponding CIs.

Comparison groups	Maternal Subjects: BNT162b2 30 mcg v Non-Pregnant Subjects: Study C4591001
Number of subjects included in analysis	214
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.77

Secondary: Number of Subjects With COVID-19 Incidence per 100 Person-Years of Blinded Follow-Up in Evaluable Maternal Subjects With or Without Evidence of Prior SARS-CoV-2 Infection

End point title	Number of Subjects With COVID-19 Incidence per 100 Person-Years of Blinded Follow-Up in Evaluable Maternal Subjects With or Without Evidence of Prior SARS-CoV-2 Infection

End point description:

Number of subjects with COVID-19 incidence per 100 person-years of blinded follow-up in evaluable maternal subjects with or without evidence of prior SARS-CoV-2 infection was reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccinations as randomised, with Dose 2 received within predefined window (within 19-42 days after Dose 1) and had no other important protocol deviations as determined by clinician on or before 7 days after Dose 2. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint. HIV positive subjects were excluded from analysis as pre-specified in SAP.

End point type	Secondary

End point timeframe:

From 7 days after Dose 2 up to 1 month after delivery (Surveillance time [100 person-year]: BNT162b2-0.270, Placebo- 0.263)

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	149		
Units: Subjects	2	3		

Statistical analyses

Statistical analysis title	BNT162b2 30 mcg vs Placebo then BNT162b2 30 mcg

Statistical analysis description:

Vaccine efficacy was estimated by 100*(1 – IRR), where IRR=calculated ratio of confirmed COVID-19 illness per 1000 person-years of blinded follow-up in the active vaccine group to the corresponding illness rate in the placebo group.

Comparison groups	Maternal Subjects: BNT162b2 30 mcg v Maternal Subjects: Placebo then BNT162b2 30 mcg
Number of subjects included in analysis	294
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Vaccine efficacy
Point estimate	35.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-466.5
upper limit	94.6

Secondary: Number of Subjects With COVID-19 Occurrence per 100 Person-Years of Blinded Follow-Up in Evaluable Maternal Subjects Without Evidence of Prior SARS-CoV-2 Infection

End point title	Number of Subjects With COVID-19 Occurrence per 100 Person-Years of Blinded Follow-Up in Evaluable Maternal Subjects Without Evidence of Prior SARS-CoV-2 Infection

End point description:

Number of subjects COVID-19 occurrence per 100 person-years of blinded follow-up in evaluable maternal subjects without evidence of prior SARS-CoV-2 infection prior to 7 days after receipt of Dose 2 was reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccinations as randomised, with Dose 2 received within predefined window (within 19-42 days after Dose 1) and had no other important protocol deviations as determined by clinician on or before 7 days after Dose 2. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint. HIV positive subjects were excluded from analysis as pre-specified in SAP.

End point type	Secondary

End point timeframe:

From 7 days after Dose 2 up to 1 month after delivery (Surveillance time [100 person-year]: BNT162b2-0.155, Placebo- 0.149)

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	86	89		
Units: Subjects	2	2		

Statistical analyses

Statistical analysis title	BNT162b2 30 mcg vs Placebo then BNT162b2 30 mcg

Statistical analysis description:

Vaccine efficacy was estimated by 100*(1 – illness rate ratio [IRR]), where IRR=calculated ratio of confirmed COVID-19 illness per 1000 person-years of blinded follow-up in the active vaccine group to the corresponding illness rate in the placebo group.

Comparison groups	Maternal Subjects: BNT162b2 30 mcg v Maternal Subjects: Placebo then BNT162b2 30 mcg
Number of subjects included in analysis	175
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Vaccine efficacy
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1227.8
upper limit	93

Secondary: Number of Subjects With Asymptomatic Infection of SARS-CoV-2 Through 1 Month After Delivery in Evaluable Maternal Subjects Without Evidence of Prior SARS-CoV-2 Infection

End point title	Number of Subjects With Asymptomatic Infection of SARS-CoV-2 Through 1 Month After Delivery in Evaluable Maternal Subjects Without Evidence of Prior SARS-CoV-2 Infection

End point description:

Number of subjects with asymptomatic infection of SARS-CoV-2 through 1 month after delivery in evaluable maternal subjects without evidence of prior SARS-CoV-2 infection prior to the first post-dose 2 N-binding test without evidence of prior SARS-CoV-2 infection was reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccinations as randomised, with Dose 2 received within predefined window (within 19-42 days after Dose 1) and had no other important protocol deviations as determined by clinician on or before 7 days after Dose 2. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint. HIV positive subjects were excluded from analysis as pre-specified in SAP.

End point type	Secondary

End point timeframe:

Up to 1 month after delivery (Surveillance time [100 person-year]: BNT162b2- 0.099, Placebo- 0.147)

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	89		
Units: Subjects	4	10		

Statistical analyses

Statistical analysis title	NT162b2 30 mcg vs Placebo then BNT162b2 30 mcg

Statistical analysis description:

Vaccine efficacy was estimated by 100*(1 – IRR), where IRR=calculated ratio of confirmed COVID-19 illness per 1000 person-years of blinded follow-up in the active vaccine group to the corresponding illness rate in the placebo group.

Comparison groups	Maternal Subjects: BNT162b2 30 mcg v Maternal Subjects: Placebo then BNT162b2 30 mcg
Number of subjects included in analysis	173
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Vaccine efficacy
Point estimate	40.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-104.9
upper limit	86.5

Secondary: Geometric Mean Concentration (GMCs) of Full-Length S-Binding Immunoglobulin G (IgG) Levels in Evaluable Maternal Subjects

End point title	Geometric Mean Concentration (GMCs) of Full-Length S-Binding Immunoglobulin G (IgG) Levels in Evaluable Maternal Subjects

End point description:

GMCs & 2-sided 95% CIs were calculated by exponentiating mean logarithm of concentrations & corresponding CIs (student t distribution).Assay results below LLOQ=0.5*LLOQ.GMCs of full-length S-binding IgG levels in evaluable maternal subjects at baseline,2 weeks after Dose 2,1 month after Dose 2,at delivery,6 months after delivery was reported.Evaluable immunogenicity population:all subjects who were eligible,randomised,received 2 doses of vaccine to which they were randomised,with Dose 2 received within predefined window(19-42 days, inclusive,after Dose 1);had at least 1 valid immunogenicity result within appropriate window 1 month after Dose 2(28-42 days,inclusive,after Dose 2);had no other important protocol deviations as determined by clinician.Here, "N"=subjects evaluable for this endpoint and 'n'=subjects evaluable for specified rows.HIV positive subjects were excluded from analysis as pre-specified in SAP.Here,99999 suggests that no subject was evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (before Dose 1), 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65	59		
Units: Units/milliliter (U/mL)				
geometric mean (confidence interval 95%)				
Before Dose 1 (n=65, 59)	2.4 (1.6 to 3.7)	2.0 (1.4 to 2.8)		
2 weeks after Dose 2 (n=41, 35)	7802.0 (6273.3 to 9703.2)	1.8 (1.1 to 3.1)		
1 month after Dose 2 (n=36, 31)	4281.0 (3234.7 to 5665.7)	1.8 (1.1 to 2.9)		
At delivery (n=39, 29)	2747.6 (2144.7 to 3520.0)	1.7 (1.0 to 3.0)		
6 months after delivery (n=20, 0)	1639.4 (780.1 to 3445.4)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer (GMTs) of SARS-CoV-2 Neutralising Titers in Evaluable Maternal Subjects

End point title	Geometric Mean Titer (GMTs) of SARS-CoV-2 Neutralising Titers in Evaluable Maternal Subjects

End point description:

GMTs & 2-sided 95% CIs were calculated by exponentiating mean logarithm of titers & corresponding CIs (student t distribution).Assay results below LLOQ=0.5*LLOQ. GMTs of SARS-CoV-2 neutralizing titers in evaluable maternal subjects at baseline,2 weeks after Dose 2,1 month after Dose 2,at delivery,6 months after delivery was reported. Evaluable immunogenicity population:all subjects who were eligible,randomised,received 2 doses of vaccine to which they were randomised,with Dose 2 received within predefined window(19-42 days, inclusive,after Dose 1);had at least 1 valid immunogenicity result within appropriate window 1 month after Dose 2(28-42 days,inclusive,after Dose 2);had no other important protocol deviations as determined by clinician.Here, "N"=subjects evaluable for this endpoint and 'n'=subjects evaluable for specified rows.HIV positive subjects were excluded from analysis as pre-specified in SAP.Here, 99999 suggests that no subject was evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (before Dose 1), 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65	59		
Units: Titer				
geometric mean (confidence interval 95%)				
Before Dose 1 (n= 65, 59)	47.6 (41.6 to 54.4)	43.5 (43.5 to 43.5)		
2 weeks after Dose 2 (n= 41, 35)	1991.8 (1456.3 to 2724.1)	45.0 (42.0 to 48.3)		
1 month after Dose 2 (n= 36, 31)	1212.6 (855.2 to 1719.4)	43.5 (43.5 to 43.5)		
At delivery (n= 39, 29)	695.7 (500.6 to 966.8)	43.5 (43.5 to 43.5)		
6 months after delivery (n= 20, 0)	465.4 (168.6 to 1284.5)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) From Before Vaccination to Each Subsequent Time Point After Vaccination for SARS-CoV-2 Neutralising Titers in Evaluable Maternal Subjects

End point title	Geometric Mean Fold Rise (GMFR) From Before Vaccination to Each Subsequent Time Point After Vaccination for SARS-CoV-2 Neutralising Titers in Evaluable Maternal Subjects

End point description:

GMFRs and 2-sided 95% CIs were calculated by exponentiating mean logarithm of fold rises and corresponding CIs (based on student t distribution). Assay results below LLOQ were set to 0.5*LLOQ. Evaluable immunogenicity population: all subjects who were eligible, randomised, received 2 doses of vaccine to which they were randomised, with Dose 2 received within predefined window (19-42 days, inclusive, after Dose 1); had at least 1 valid immunogenicity result within appropriate window 1 month after Dose 2 (28-42 days, inclusive, after Dose 2); had no important protocol deviations as determined by clinician. "N"= subjects evaluable for this endpoint, 'n'= subjects evaluable for specified rows. HIV positive subjects were excluded from analysis as pre-specified in SAP. Here, 99999 suggests that no subject was evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (before Dose 1), 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	54		
Units: Fold rise				
geometric mean (confidence interval 95%)				
2 weeks after Dose 2 (n= 58, 54)	43.7 (33.9 to 56.4)	1.0 (1.0 to 1.1)		
1 month after Dose 2 (n= 50, 49)	25.3 (18.9 to 33.9)	1.0 (1.0 to 1.0)		
At delivery (n= 55, 47)	15.6 (12.1 to 20.1)	1.0 (1.0 to 1.0)		
6 months after delivery (n= 26, 0)	11.3 (5.0 to 25.4)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) From Before Vaccination to Each Subsequent Time Point After Vaccination for Full-Length S-Binding IgG Levels in Evaluable Maternal Subjects

End point title	Geometric Mean Fold Rise (GMFR) From Before Vaccination to Each Subsequent Time Point After Vaccination for Full-Length S-Binding IgG Levels in Evaluable Maternal Subjects

End point description:

GMFRs and 2-sided 95% CIs calculated by exponentiating mean logarithm of fold rises and corresponding CIs (based on student t distribution). Assay results below LLOQ were set to 0.5*LLOQ. Evaluable immunogenicity population: all subjects who were eligible, randomised, received 2 doses of vaccine to which they were randomised, with Dose 2 received within predefined window (19-42 days, inclusive, after Dose 1); had at least 1 valid immunogenicity result within appropriate window 1 month after Dose 2 (28-42 days, inclusive, after Dose 2); had no important protocol deviations as determined by clinician. "N"= subjects evaluable for this endpoint, 'n'=subjects evaluable for specified rows. HIV positive subjects were excluded from analysis as pre-specified in SAP. Here, 99999 suggests that no subject was evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (before Dose 1), 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery

End point values	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo then BNT162b2 30 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	54		
Units: Fold rise				
geometric mean (confidence interval 95%)				

2 weeks after Dose 2 (n= 58, 54)	3618.7 (2489.1 to 5260.7)	0.9 (0.8 to 1.1)		
1 month after Dose 2 (n= 50, 49)	2276.4 (1545.5 to 3352.9)	0.9 (0.8 to 1.1)		
At delivery (n= 55, 47)	1377.6 (948.6 to 2000.5)	0.8 (0.6 to 1.0)		
6 months after delivery (n= 26, 0)	650.3 (279.3 to 1514.3)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects Reporting Specific Birth Outcomes

End point title	Percentage of Infant Subjects Reporting Specific Birth Outcomes

End point description:

Percentage of infant subjects reporting specific birth outcomes (normal, congenital malformation/anomaly, other neonatal problems) were reported in this endpoint. Safety population for infant subjects included all infant subjects born to maternal subjects who received at least 1 dose of the study intervention. As this endpoint was measured at birth, HIV positive infant subjects were included in this endpoint.

End point type	Secondary

End point timeframe:

At birth

End point values	Infant Subjects: BNT162b2 30 mcg	Infant Subjects: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	167	168		
Units: Percentage of subjects				
number (confidence interval 95%)				
Normal	91.6 (86.3 to 95.3)	89.3 (83.6 to 93.5)		
Congenital malformation/anomaly	6.0 (2.9 to 10.7)	3.6 (1.3 to 7.6)		
Other neonatal problem	1.8 (0.4 to 5.2)	6.5 (3.3 to 11.4)		
Missing	0.6 (0.0 to 3.3)	0.6 (0.0 to 3.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects Reporting Serious Adverse Events (SAE)

From Birth Through 6 Months of age

End point title	Percentage of Infant Subjects Reporting Serious Adverse Events (SAE) From Birth Through 6 Months of age

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population for infant subjects included all infant subjects born to maternal subjects who received at least 1 dose of the study intervention. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint. HIV positive subjects were excluded from analysis as pre-specified in the SAP.

End point type	Secondary

End point timeframe:

From birth through 6 months of age

End point values	Infant Subjects: BNT162b2 30 mcg	Infant Subjects: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	159		
Units: Percentage of subjects				
number (confidence interval 95%)	13.5 (8.5 to 19.8)	15.1 (9.9 to 21.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects Reporting Adverse Events From Birth Through 1 Month of age

End point title	Percentage of Infant Subjects Reporting Adverse Events From Birth Through 1 Month of age

End point description:

An AE was any untoward medical occurrence in a subject temporally associated with the use of study intervention, whether or not considered related to the study intervention. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population for infant subjects included all infant subjects born to maternal subjects who received at least 1 dose of the study intervention. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint. HIV positive subjects were excluded from analysis as pre-specified in the SAP.

End point type	Secondary

End point timeframe:

From birth through 1 month of age

End point values	Infant Subjects: BNT162b2 30 mcg	Infant Subjects: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	159		
Units: Percentage of subjects				
number (confidence interval 95%)	35.3 (27.8 to 43.3)	37.1 (29.6 to 45.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects Reporting Adverse Event of Special Interest (AESI) From Birth Through 6 Months of age

End point title	Percentage of Infant Subjects Reporting Adverse Event of Special Interest (AESI) From Birth Through 6 Months of age

End point description:

Percentage of infant subjects who reported AESI including major congenital anomalies and developmental delay from birth through 6 months of age were reported in this endpoint. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population for infant subjects included all infant subjects born to maternal subjects who received at least 1 dose of the study intervention. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint. HIV positive subjects were excluded from analysis as pre-specified in the SAP.

End point type	Secondary

End point timeframe:

From birth through 6 months of age

End point values	Infant Subjects: BNT162b2 30 mcg	Infant Subjects: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	159		
Units: Percentage of subjects				
number (confidence interval 95%)	5.1 (2.2 to 9.9)	1.3 (0.2 to 4.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMCs of Full-Length S-Binding IgG Levels at Birth and 6 Months of age in Infant Subjects Born to Evaluable Maternal Subjects

End point title	GMCs of Full-Length S-Binding IgG Levels at Birth and 6 Months of age in Infant Subjects Born to Evaluable Maternal Subjects

End point description:

GMCs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. GMCs of full-length S-binding IgG levels at birth and 6 months of age in infant subjects born to evaluable maternal subjects was reported in this endpoint. All infant subjects born to evaluable immunogenicity maternal subjects and had no important protocol deviations as determined by the clinician. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint and 'n' signifies subjects evaluable for the specified rows. HIV positive subjects were excluded from analysis as pre-specified in the SAP.

End point type	Secondary

End point timeframe:

At birth and 6 months of age

End point values	Infant Subjects: BNT162b2 30 mcg	Infant Subjects: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	92		
Units: Units/milliliter (U/mL)				
geometric mean (confidence interval 95%)				
At Birth (n= 91, 92)	5576.4 (4246.2 to 7323.2)	19.4 (10.2 to 37.0)		
6 months of age (n= 83, 69)	311.1 (235.8 to 410.5)	22.0 (11.4 to 42.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR of Full-Length S-Binding IgG Levels From Birth to 6 Months of age in Infant Subjects Born to Evaluable Maternal Subjects

End point title	GMFR of Full-Length S-Binding IgG Levels From Birth to 6 Months of age in Infant Subjects Born to Evaluable Maternal Subjects

End point description:

GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. GMFR of full-length S-binding IgG levels from birth to 6 months of age in infant subjects born to evaluable maternal subjects was reported in this endpoint. All infant subjects born to evaluable immunogenicity maternal subjects and had no important protocol deviations as determined by the clinician. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint. HIV positive subjects were excluded from analysis as pre-specified in the SAP.

End point type	Secondary

End point timeframe:

From birth to 6 months of age

End point values	Infant Subjects: BNT162b2 30 mcg	Infant Subjects: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	65		
Units: Fold rise				
geometric mean (confidence interval 95%)	0.1 (0.0 to 0.1)	0.6 (0.3 to 1.3)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Local reactions/systemic events up to Day 7 after dose 1&2. AEs:up to 1 month (M) after each dose (from birth to 1 M for infants). SAEs:dose 1 to 6 M post-delivery/1 M post-delivery (placebo)/1 M after dose 4(placebo then BNT)/from birth to 6 M(infants)

Adverse event reporting additional description:

Same event may appear as non-SAE and SAE but are distinct events. Event may be an SAE in 1 subject and non-SAE in other, or subject may have both non-SAE and SAE. Safety population for maternal and infants was evaluated. Systematic events are local reactions and systemic events recorded in e-diary, non-systematic events are all other AEs.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Maternal Subjects: BNT162b2 30 mcg

Reporting group description:

Maternal subjects received two doses of BNT162b2 30 micrograms (mcg) as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. Subjects were followed-up until 6 months post-delivery. HIV positive maternal subjects were excluded.

Reporting group title	Maternal Subjects: Placebo

Reporting group description:

Maternal subjects received two doses of placebo as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. HIV positive maternal subjects were excluded.

Reporting group title	Maternal Subjects: Placebo then BNT162b2

Reporting group description:

Subjects who originally received 2 doses of blinded placebo were administered 2 doses of 30 mcg BNT162b2 vaccine as intramuscular injection separated by 21 days after unblinding at 1 month post-delivery. Subjects were followed-up until 1 month after last vaccination. HIV positive maternal subjects were excluded.

Reporting group title	Infant Subjects: BNT162b2 30 mcg

Reporting group description:

Infant subjects who were born to maternal subjects vaccinated with BNT162b2 30 mcg during pregnancy were included. Infant subjects were followed up to 6 months of age. HIV positive infant subjects born to HIV positive maternal subjects were excluded.

Reporting group title	HIV Positive Maternal Subjects: Placebo then BNT162b2

Reporting group description:

HIV positive maternal subjects who originally received 2 doses of blinded placebo were administered 2 doses of 30 mcg BNT162b2 vaccine as intramuscular injection separated by 21 days after unblinding at 1 month post-delivery. Subjects were followed-up until 1 month after last vaccination.

Reporting group title	HIV Positive Maternal Subjects: BNT162b2 30 mcg

Reporting group description:

Maternal subjects who were HIV positive received two doses of BNT162b2 30 micrograms (mcg) as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase. Subjects were followed-up until 6 months post-delivery.

Reporting group title	HIV Positive Maternal Subjects: Placebo

Reporting group description:

Maternal subjects who were HIV positive received two doses of placebo as an intramuscular injection separated by 21 days during their 24 to 34 weeks gestation in the blinded phase.

Reporting group title	HIV Positive Infant Subjects: BNT162b2 30 mcg

Reporting group description:

Infant subjects who were born to HIV positive maternal subjects vaccinated with BNT162b2 30 mcg during pregnancy were included. Infant subjects were followed up to 6 months of age.

Reporting group title	HIV Positive Infant Subjects: Placebo
Reporting group description:	
Infant subjects who were born to HIV positive maternal subjects vaccinated with placebo during pregnancy were included. Infant subjects were followed up to 6 months of age.	

Reporting group title	Infant Subjects: Placebo
Reporting group description:	
Infant subjects who were born to maternal subjects vaccinated with placebo during pregnancy were included. Infant subjects were followed up to 6 months of age. HIV positive infant subjects born to HIV positive maternal subjects were excluded.	

Serious adverse events	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo	Maternal Subjects: Placebo then BNT162b2
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 161 (13.04%)	23 / 163 (14.11%)	0 / 144 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Shock			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoperfusion			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (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
Subgaleal hemorrhage			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal			

conditions			
Arrested labor			
subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breech presentation			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (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
Fetal growth restriction			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (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
Fetal distress syndrome			
subjects affected / exposed	3 / 161 (1.86%)	2 / 163 (1.23%)	0 / 144 (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
Failed induction of labor			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalo-pelvic disproportion			
subjects affected / exposed	1 / 161 (0.62%)	3 / 163 (1.84%)	0 / 144 (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
Fetal hypokinesia			
subjects affected / exposed	1 / 161 (0.62%)	1 / 163 (0.61%)	0 / 144 (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
Gestational hypertension			
subjects affected / exposed	1 / 161 (0.62%)	1 / 163 (0.61%)	0 / 144 (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
Hemorrhage in pregnancy			

subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium in amniotic fluid			
subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium stain			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (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
Omphalorrhexis			
subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (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 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	0 / 161 (0.00%)	3 / 163 (1.84%)	0 / 144 (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
Pre-eclampsia			
subjects affected / exposed	4 / 161 (2.48%)	2 / 163 (1.23%)	0 / 144 (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
Postpartum hemorrhage			
subjects affected / exposed	0 / 161 (0.00%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			

subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged rupture of membranes			
subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (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
Retained placenta or membranes			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (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
Caput succedaneum			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice neonatal			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Low birth weight baby			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small for dates baby			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decrease neonatal			

subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed trial of labor			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fetal death			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Uterine disorder			
subjects affected / exposed	2 / 161 (1.24%)	0 / 163 (0.00%)	0 / 144 (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
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium aspiration syndrome			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 pneumothorax			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory failure			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 distress			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 failure			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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			
Fetal heart rate abnormal			
subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (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 fetal abnormal			
subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (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 murmur			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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			
Injury to brachial plexus due to birth trauma			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 procedural complication			
subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (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
Traumatic intracranial hemorrhage			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Ankyloglossia congenital			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial septal defect			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 rubella syndrome			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital skin dimples			

subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DiGeorge's syndrome			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcephaly			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucopolysaccharidosis			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polydactyly			

subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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			
Non reassuring fetal heart rate pattern			
subjects affected / exposed	0 / 161 (0.00%)	2 / 163 (1.23%)	0 / 144 (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
Bradycardia fetal			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Coma			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy neonatal			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischemic encephalopathy			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 disorder			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Superior sagittal sinus thrombosis			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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			
Coagulopathy			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anemia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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			
Abdominal wall haematoma			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (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
Allergic colitis			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic gastroenteritis			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium plug syndrome			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoperitoneum			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal tubular necrosis			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vesicoureteric reflux			

subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Lower respiratory tract infection			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (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
Endometritis			
subjects affected / exposed	1 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (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 / 161 (0.62%)	0 / 163 (0.00%)	0 / 144 (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
Urinary tract infection			
subjects affected / exposed	0 / 161 (0.00%)	1 / 163 (0.61%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neonatal pneumonia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 respiratory syncytial viral			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis neonatal			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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			
Hypoglycemia neonatal			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
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 Subjects: BNT162b2 30 mcg	HIV Positive Maternal Subjects: Placebo then BNT162b2	HIV Positive Maternal Subjects: BNT162b2 30 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 156 (13.46%)	0 / 8 (0.00%)	2 / 12 (16.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Shock			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoperfusion			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subgaleal hemorrhage			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Arrested labor			

subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breech presentation			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fetal growth restriction			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fetal distress syndrome			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed induction of labor			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalo-pelvic disproportion			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fetal hypokinesia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemorrhage in pregnancy			

subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium in amniotic fluid			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium stain			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Omphalorrhexis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placental insufficiency			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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 separation of placenta			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum hemorrhage			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			

subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged rupture of membranes			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retained placenta or membranes			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Caput succedaneum			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice neonatal			
subjects affected / exposed	7 / 156 (4.49%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Low birth weight baby			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small for dates baby			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Weight decrease neonatal			

subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed trial of labor			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fetal death			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
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 disorder			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium aspiration syndrome			
subjects affected / exposed	2 / 156 (1.28%)	0 / 8 (0.00%)	0 / 12 (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
Neonatal pneumothorax			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory failure			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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 distress			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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 failure			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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			
Fetal heart rate abnormal			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ultrasound fetal abnormal			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Injury, poisoning and procedural complications			
Injury to brachial plexus due to birth trauma			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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 procedural complication			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial hemorrhage			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Ankyloglossia congenital			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial septal defect			
subjects affected / exposed	3 / 156 (1.92%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital rubella syndrome			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital skin dimples			

subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DiGeorge's syndrome			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Microcephaly			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Mucopolysaccharidosis			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Patent ductus arteriosus			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Syndactyly			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Polydactyly			

subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Cardiac disorders			
Non reassuring fetal heart rate pattern			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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 fetal			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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			
Coma			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy neonatal			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischemic encephalopathy			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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 disorder			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Seizure			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Superior sagittal sinus thrombosis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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			
Coagulopathy			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anemia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal wall haematoma			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic colitis			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Allergic gastroenteritis			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Dysphagia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium plug syndrome			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoperitoneum			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal tubular necrosis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vesicoureteric reflux			

subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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			
Lower respiratory tract infection			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometritis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (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
Urinary tract infection			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	2 / 156 (1.28%)	0 / 8 (0.00%)	0 / 12 (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

Neonatal pneumonia			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis neonatal			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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			
Hypoglycemia neonatal			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
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	HIV Positive Maternal Subjects: Placebo	HIV Positive Infant Subjects: BNT162b2 30 mcg	HIV Positive Infant Subjects: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 10 (40.00%)	1 / 11 (9.09%)	2 / 9 (22.22%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Vascular disorders			
Shock			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoperfusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subgaleal hemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Arrested labor			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breech presentation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fetal growth restriction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fetal distress syndrome			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (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
Failed induction of labor			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalo-pelvic disproportion			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (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
Fetal hypokinesia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemorrhage in pregnancy			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium in amniotic fluid			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium stain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Omphalorrhexis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placental insufficiency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 separation of placenta			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum hemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged rupture of membranes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retained placenta or membranes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Caput succedaneum			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice neonatal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Low birth weight baby			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small for dates baby			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decrease neonatal			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed trial of labor			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (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
Fetal death			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Uterine disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium aspiration syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 pneumothorax			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 distress			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
Fetal heart rate abnormal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ultrasound fetal abnormal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
Injury to brachial plexus due to birth trauma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 procedural complication			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial hemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Ankyloglossia congenital			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial septal defect			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 rubella syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital skin dimples			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DiGeorge's syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcephaly			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucopolysaccharidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polydactyly			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
Non reassuring fetal heart rate pattern			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 fetal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
Coma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy neonatal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischemic encephalopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Superior sagittal sinus thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Coagulopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
Abdominal wall haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium plug syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoperitoneum			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal tubular necrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vesicoureteric reflux			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
Lower respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neonatal pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis neonatal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
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			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoglycemia neonatal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Infant Subjects: Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 159 (15.09%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Vascular disorders			
Shock			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypoperfusion			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subgaleal hemorrhage			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Arrested labor			

subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breech presentation				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fetal growth restriction				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fetal distress syndrome				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failed induction of labor				
subjects affected / exposed	0 / 159 (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 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fetal hypokinesia				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gestational hypertension				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hemorrhage in pregnancy				

subjects affected / exposed	0 / 159 (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	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meconium stain			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Omphalorrhexis			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Placental insufficiency			
subjects affected / exposed	0 / 159 (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 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pre-eclampsia			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postpartum hemorrhage			
subjects affected / exposed	0 / 159 (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 / 159 (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 / 159 (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 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Caput succedaneum				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Jaundice neonatal				
subjects affected / exposed	4 / 159 (2.52%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Low birth weight baby				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Premature baby				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small for dates baby				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Weight decrease neonatal				

subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Failed trial of labor				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fetal death				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Uterine disorder				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Hypoxia				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meconium aspiration syndrome				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal pneumothorax				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neonatal respiratory distress				
subjects affected / exposed	2 / 159 (1.26%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Pulmonary hypertension				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neonatal respiratory failure				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neonatal respiratory distress syndrome				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tachypnoea				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Investigations				
Fetal heart rate abnormal				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ultrasound fetal abnormal				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Cardiac murmur				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Injury to brachial plexus due to birth trauma				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract procedural complication				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic intracranial hemorrhage				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Ankyloglossia congenital				
subjects affected / exposed	2 / 159 (1.26%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Atrial septal defect				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Congenital rubella syndrome				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital skin dimples				

subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
DiGeorge's syndrome				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Microcephaly				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mucopolysaccharidosis				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Patent ductus arteriosus				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ventricular septal defect				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Trisomy 21				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syndactyly				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polydactyly				

subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Non reassuring fetal heart rate pattern			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bradycardia fetal			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Coma			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalopathy neonatal			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoxic-ischemic encephalopathy			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorder			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Superior sagittal sinus thrombosis			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Coagulopathy			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anemia			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal wall haematoma			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Allergic colitis			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Allergic gastroenteritis			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysphagia			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Intestinal perforation				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meconium plug syndrome				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumoperitoneum				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholelithiasis				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia neonatal				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Pruritus				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Renal tubular necrosis				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vesicoureteric reflux				

subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Lower respiratory tract infection			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometritis			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Neonatal pneumonia				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis neonatal				
subjects affected / exposed	2 / 159 (1.26%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 159 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Hypoglycemia neonatal				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolic acidosis				
subjects affected / exposed	1 / 159 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dehydration				

subjects affected / exposed	0 / 159 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Maternal Subjects: BNT162b2 30 mcg	Maternal Subjects: Placebo	Maternal Subjects: Placebo then BNT162b2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	143 / 161 (88.82%)	119 / 163 (73.01%)	21 / 144 (14.58%)
Surgical and medical procedures			
Episiotomy			
subjects affected / exposed	3 / 161 (1.86%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	3	0	0
Pregnancy, puerperium and perinatal conditions			
Fetal hypokinesia			
subjects affected / exposed	1 / 161 (0.62%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	1	2	0
Abnormal labor			
subjects affected / exposed	0 / 161 (0.00%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	0	2	0
Gestational diabetes			
subjects affected / exposed	1 / 161 (0.62%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	1	2	0
Gestational hypertension			
subjects affected / exposed	2 / 161 (1.24%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	2	0	0
Oligohydramnios			
subjects affected / exposed	1 / 161 (0.62%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	1	2	0
Pre-eclampsia			
subjects affected / exposed	2 / 161 (1.24%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	2	0	0
Premature delivery			

subjects affected / exposed	0 / 161 (0.00%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	0	2	0
Uterine contractions during pregnancy			
subjects affected / exposed	2 / 161 (1.24%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	2	0	0
Caput succedaneum			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Jaundice neonatal			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Low birth weight baby			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Large for dates baby			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Small for dates baby			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Umbilical cord around neck			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 161 (0.00%)	2 / 163 (1.23%)	3 / 144 (2.08%)
occurrences (all)	0	2	3
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 161 (6.83%)	1 / 163 (0.61%)	0 / 144 (0.00%)
occurrences (all)	13	1	0
Chills (CHILLS)			
alternative assessment type: Systematic			

subjects affected / exposed	28 / 161 (17.39%)	10 / 163 (6.13%)	0 / 144 (0.00%)
occurrences (all)	30	10	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	101 / 161 (62.73%)	82 / 163 (50.31%)	0 / 144 (0.00%)
occurrences (all)	154	120	0
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	17 / 161 (10.56%)	1 / 163 (0.61%)	0 / 144 (0.00%)
occurrences (all)	19	1	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 161 (3.73%)	4 / 163 (2.45%)	0 / 144 (0.00%)
occurrences (all)	6	4	0
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	138 / 161 (85.71%)	30 / 163 (18.40%)	0 / 144 (0.00%)
occurrences (all)	244	39	0
Injection site erythema			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	3 / 144 (2.08%)
occurrences (all)	0	0	3
Hypothermia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	3 / 144 (2.08%)
occurrences (all)	0	0	3
Pyrexia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	5 / 144 (3.47%)
occurrences (all)	0	0	5
Chills			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	2 / 144 (1.39%)
occurrences (all)	0	0	2
Injection site pain			

subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	13 / 144 (9.03%)
occurrences (all)	0	0	18
Reproductive system and breast disorders			
Vaginal hemorrhage			
subjects affected / exposed	1 / 161 (0.62%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	1	2	0
Vaginal discharge			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Investigations			
Streptococcus test positive			
subjects affected / exposed	0 / 161 (0.00%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	0	2	0
Cardiac murmur			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Apgar score low			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	2 / 161 (1.24%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	2	0	0
Exposure to communicable disease			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			

Ankyloglossia congenital			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Congenital naevus			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Polydactyly			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	2 / 161 (1.24%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	85 / 161 (52.80%)	72 / 163 (44.17%)	0 / 144 (0.00%)
occurrences (all)	116	93	0
Headache			
subjects affected / exposed	2 / 161 (1.24%)	2 / 163 (1.23%)	7 / 144 (4.86%)
occurrences (all)	2	2	9
Hypotonia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	4 / 161 (2.48%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	4	2	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 161 (1.86%)	3 / 163 (1.84%)	0 / 144 (0.00%)
occurrences (all)	3	3	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			

subjects affected / exposed	18 / 161 (11.18%)	16 / 163 (9.82%)	0 / 144 (0.00%)
occurrences (all)	21	20	0
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	24 / 161 (14.91%)	21 / 163 (12.88%)	0 / 144 (0.00%)
occurrences (all)	28	22	0
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 161 (0.62%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	1	2	0
Hemorrhoids			
subjects affected / exposed	1 / 161 (0.62%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	1	2	0
Constipation			
subjects affected / exposed	0 / 161 (0.00%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	0	2	0
Dyspepsia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinemia neonatal			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Leukocyturia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia (NEW OR WORSENED JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	22 / 161 (13.66%)	13 / 163 (7.98%)	0 / 144 (0.00%)
occurrences (all)	25	17	0
Back pain			

subjects affected / exposed	2 / 161 (1.24%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	2	0	0
Myalgia (NEW OR WORSENED MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	53 / 161 (32.92%)	26 / 163 (15.95%)	0 / 144 (0.00%)
occurrences (all)	60	29	0
Myalgia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	4 / 144 (2.78%)
occurrences (all)	0	0	4
Arthralgia			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	2 / 144 (1.39%)
occurrences (all)	0	0	2
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	0 / 161 (0.00%)	2 / 163 (1.23%)	0 / 144 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	4 / 161 (2.48%)	1 / 163 (0.61%)	0 / 144 (0.00%)
occurrences (all)	4	1	0
COVID-19			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	2 / 144 (1.39%)
occurrences (all)	0	0	2
Body tinea			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypoglycemia neonatal			
subjects affected / exposed	0 / 161 (0.00%)	0 / 163 (0.00%)	0 / 144 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Infant Subjects: BNT162b2 30 mcg	HIV Positive Maternal Subjects: Placebo then BNT162b2	HIV Positive Maternal Subjects: BNT162b2 30 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 156 (18.59%)	1 / 8 (12.50%)	12 / 12 (100.00%)
Surgical and medical procedures			

Episiotomy			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Fetal hypokinesia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abnormal labor			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gestational diabetes			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gestational hypertension			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oligohydramnios			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pre-eclampsia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Premature delivery			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Caput succedaneum			
subjects affected / exposed	3 / 156 (1.92%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Jaundice neonatal			
subjects affected / exposed	12 / 156 (7.69%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	12	0	0
Low birth weight baby			

subjects affected / exposed	2 / 156 (1.28%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Large for dates baby			
subjects affected / exposed	2 / 156 (1.28%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Small for dates baby			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Umbilical cord around neck			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	8 / 12 (66.67%)
occurrences (all)	0	0	15
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Pyrexia (FEVER)			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	12 / 12 (100.00%)
occurrences (all)	0	0	21
Injection site erythema			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vaginal hemorrhage			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			

subjects affected / exposed	0 / 156 (0.00%)	1 / 8 (12.50%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 156 (0.00%)	1 / 8 (12.50%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Investigations			
Streptococcus test positive			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	2 / 156 (1.28%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Apgar score low			
subjects affected / exposed	4 / 156 (2.56%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Exposure to communicable disease			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Ankyloglossia congenital			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Congenital naevus			
subjects affected / exposed	3 / 156 (1.92%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Hydrocele			
subjects affected / exposed	2 / 156 (1.28%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Polydactyly			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Tachycardia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	7 / 12 (58.33%)
occurrences (all)	0	0	10
Headache			
subjects affected / exposed	0 / 156 (0.00%)	1 / 8 (12.50%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypotonia			
subjects affected / exposed	2 / 156 (1.28%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	3 / 12 (25.00%)
occurrences (all)	0	0	4
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	3 / 12 (25.00%)
occurrences (all)	0	0	3
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hemorrhoids			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Constipation			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinemia neonatal			
subjects affected / exposed	1 / 156 (0.64%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Leukocyturia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia (NEW OR WORSENED JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Back pain			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia (NEW OR WORSENED MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	5 / 12 (41.67%)
occurrences (all)	0	0	8
Myalgia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthralgia			

subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypoglycemia neonatal			
subjects affected / exposed	0 / 156 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	HIV Positive Maternal Subjects: Placebo	HIV Positive Infant Subjects: BNT162b2 30 mcg	HIV Positive Infant Subjects: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	1 / 11 (9.09%)	3 / 9 (33.33%)
Surgical and medical procedures			
Episiotomy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Fetal hypokinesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abnormal labor			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gestational diabetes			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gestational hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oligohydramnios			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pre-eclampsia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Premature delivery			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Caput succedaneum			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Jaundice neonatal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Low birth weight baby			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Large for dates baby			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Small for dates baby			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Umbilical cord around neck			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 10 (80.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	11	0	0
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 10 (40.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	6	0	0
Injection site erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vaginal hemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Streptococcus test positive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Apgar score low			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Exposure to communicable disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
Ankyloglossia congenital			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Congenital naevus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Polydactyly			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 10 (70.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	10	0	0
Headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 10 (30.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	4	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hemorrhoids			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hyperbilirubinemia neonatal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			

Leukocyturia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia (NEW OR WORSENED JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 10 (50.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Back pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myalgia (NEW OR WORSENED MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 10 (30.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			

Hypoglycemia neonatal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Infant Subjects: Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 159 (20.75%)		
Surgical and medical procedures			
Episiotomy			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
Fetal hypokinesia			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Abnormal labor			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Gestational diabetes			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Gestational hypertension			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Oligohydramnios			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Pre-eclampsia			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Premature delivery			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		

Caput succedaneum			
subjects affected / exposed	3 / 159 (1.89%)		
occurrences (all)	3		
Jaundice neonatal			
subjects affected / exposed	13 / 159 (8.18%)		
occurrences (all)	13		
Low birth weight baby			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences (all)	1		
Large for dates baby			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Small for dates baby			
subjects affected / exposed	4 / 159 (2.52%)		
occurrences (all)	4		
Umbilical cord around neck			
subjects affected / exposed	5 / 159 (3.14%)		
occurrences (all)	5		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Swelling (SWELLING)			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Injection site erythema			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Hypothermia			
subjects affected / exposed	2 / 159 (1.26%)		
occurrences (all)	2		
Pain			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Vaginal hemorrhage			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Vaginal discharge			

subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Investigations			
Streptococcus test positive			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Cardiac murmur			
subjects affected / exposed	2 / 159 (1.26%)		
occurrences (all)	2		
Apgar score low			
subjects affected / exposed	2 / 159 (1.26%)		
occurrences (all)	2		
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Exposure to communicable disease			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
Ankyloglossia congenital			
subjects affected / exposed	2 / 159 (1.26%)		
occurrences (all)	2		
Congenital naevus			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences (all)	1		
Hydrocele			

subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Polydactyly			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Hypotonia			
subjects affected / exposed	1 / 159 (0.63%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		

Gastroesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 159 (0.00%) 0		
Hemorrhoids subjects affected / exposed occurrences (all)	0 / 159 (0.00%) 0		
Constipation subjects affected / exposed occurrences (all)	0 / 159 (0.00%) 0		
Dyspepsia subjects affected / exposed occurrences (all)	0 / 159 (0.00%) 0		
Hepatobiliary disorders Hyperbilirubinemia neonatal subjects affected / exposed occurrences (all)	4 / 159 (2.52%) 4		
Skin and subcutaneous tissue disorders Dermatitis allergic subjects affected / exposed occurrences (all)	0 / 159 (0.00%) 0		
Renal and urinary disorders Leukocyturia subjects affected / exposed occurrences (all)	0 / 159 (0.00%) 0		
Musculoskeletal and connective tissue disorders Arthralgia (NEW OR WORSENED JOINT PAIN) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 159 (0.00%) 0		
Back pain subjects affected / exposed occurrences (all)	0 / 159 (0.00%) 0		
Myalgia (NEW OR WORSENED MUSCLE PAIN) alternative assessment type: Systematic			

subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Body tinea			
subjects affected / exposed	0 / 159 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hypoglycemia neonatal			
subjects affected / exposed	2 / 159 (1.26%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 January 2021	Based on availability of BNT162b2 in high-risk pregnant women and evidence of safety in the real-world setting, the sentinel cohort of N=50 in Phase 2 was removed. Based on feedback from an external advisory board, inclusion criterion 10 was updated to allow enrollment of subjects with a pre pregnancy BMI of ≤40 kg/m2.
02 March 2021	Section 8.2.3: clarified that stopping rules are in place during Phase 2 only, with no overlap into Phase 3. Clarified that a study pause may not prevent administration of Dose 2 for enrolled subjects. Modified stopping rule 7 to include a trigger of preterm premature rupture of membranes. Stopping rule 4: removed assessment of laboratory abnormalities, as these data are not collected in this study. Section 8.11.1, Visit 1: removed the requirement of a repeat fetal scan to clarify that an earlier scan done at ≥18 weeks' GA can be used to confirm singleton pregnancy and rule out fetal anomalies.
14 May 2021	Reduced the study sample size based on regulatory feedback and evolving global availability of COVID-19 vaccines for pregnant women.
08 March 2022	Enrollment of study subjects was terminated with fewer study subjects enrolled than originally planned due to enrollment challenges into a placebo-controlled trial as a result of universal recommendations for COVID-19 vaccination of pregnant women and the increased global availability of COVID-19 vaccines.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported