



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 | |

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 $\geq 38^{\circ}\text{C}$ & categorised as $\geq 38.0-38.4^{\circ}\text{C}$, $>38.4-38.9^{\circ}\text{C}$, $>38.9-40.0^{\circ}\text{C}$ & $>40.0^{\circ}\text{C}$. 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°C | 0.6 (0.0 to 3.4) | 1.2 (0.1 to 4.4) | | |
| Fever: >38.4 to 38.9°C | 0 (0.0 to 2.3) | 0 (0.0 to 2.2) | | |
| Fever: >38.9 to 40.0°C | 0.6 (0.0 to 3.4) | 0.6 (0.0 to 3.4) | | |
| Fever: $>40^{\circ}\text{C}$ | 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 $\geq 38^{\circ}\text{C}$ & categorised as ≥ 38.0 - 38.4°C , >38.4 - 38.9°C , >38.9 - 40.0°C & $>40.0^{\circ}\text{C}$. 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°C | 1.4 (0.2 to 4.8) | 0.7 (0.0 to 3.8) | | |
| Fever: >38.4 to 38.9°C | 0.7 (0.0 to 3.7) | 0 (0.0 to 2.5) | | |
| Fever: >38.9 to 40.0°C | 0 (0.0 to 2.5) | 0 (0.0 to 2.5) | | |
| Fever: $>40^{\circ}\text{C}$ | 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 $100 \times (1 - \text{IRR})$, 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 $100 \times (1 - \text{illness rate ratio [IRR]})$, 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 $100 \times (1 - \text{IRR})$, where $\text{IRR} = \text{calculated ratio of confirmed COVID-19 illness per 1000 person-years of blinded follow-up in the active vaccine group to the corresponding illness rate in the placebo group.}$ | |
| 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 |

| | | | |
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| 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 occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 159 (0.00%) 0 / 0 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Coagulopathy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 159 (0.63%) 0 / 1 0 / 0 | | |
| Thrombocytopenia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 159 (0.63%) 0 / 1 0 / 0 | | |
| Anemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 159 (0.00%) 0 / 0 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal wall haematoma subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 159 (0.00%) 0 / 0 0 / 0 | | |
| Allergic colitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 159 (0.00%) 0 / 0 0 / 0 | | |
| Allergic gastroenteritis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 159 (0.00%) 0 / 0 0 / 0 | | |
| Dysphagia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 159 (0.63%) 0 / 1 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 occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 13 / 144 (9.03%) 18 |
| Reproductive system and breast disorders | | | |
| Vaginal hemorrhage subjects affected / exposed occurrences (all) | 1 / 161 (0.62%) 1 | 2 / 163 (1.23%) 2 | 0 / 144 (0.00%) 0 |
| Vaginal discharge subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Investigations | | | |
| Streptococcus test positive subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 2 / 163 (1.23%) 2 | 0 / 144 (0.00%) 0 |
| Cardiac murmur subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Apgar score low subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Skin laceration subjects affected / exposed occurrences (all) | 2 / 161 (1.24%) 2 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Exposure to communicable disease subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Congenital, familial and genetic disorders | | | |

| | | | |
|---|--------------------------|-------------------------|----------------------|
| Ankyloglossia congenital subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Congenital naevus subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Hydrocele subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Polydactyly subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Cardiac disorders Tachycardia subjects affected / exposed occurrences (all) | 2 / 161 (1.24%) 2 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Nervous system disorders Headache (HEADACHE) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 85 / 161 (52.80%) 116 | 72 / 163 (44.17%) 93 | 0 / 144 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 2 / 161 (1.24%) 2 | 2 / 163 (1.23%) 2 | 7 / 144 (4.86%) 9 |
| Hypotonia subjects affected / exposed occurrences (all) | 0 / 161 (0.00%) 0 | 0 / 163 (0.00%) 0 | 0 / 144 (0.00%) 0 |
| Blood and lymphatic system disorders Anemia subjects affected / exposed occurrences (all) | 4 / 161 (2.48%) 4 | 2 / 163 (1.23%) 2 | 0 / 144 (0.00%) 0 |
| Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) | 3 / 161 (1.86%) 3 | 3 / 163 (1.84%) 3 | 0 / 144 (0.00%) 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 WORSENERD 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 WORSENER 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 occurrences (all) | 0 / 156 (0.00%) 0 | 1 / 8 (12.50%) 1 | 0 / 12 (0.00%) 0 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 1 / 8 (12.50%) 1 | 0 / 12 (0.00%) 0 |
| Investigations Streptococcus test positive subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 8 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Cardiac murmur subjects affected / exposed occurrences (all) | 2 / 156 (1.28%) 2 | 0 / 8 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Apgar score low subjects affected / exposed occurrences (all) | 4 / 156 (2.56%) 4 | 0 / 8 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Injury, poisoning and procedural complications Skin laceration subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 8 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Exposure to communicable disease subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 8 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Congenital, familial and genetic disorders Ankyloglossia congenital subjects affected / exposed occurrences (all) | 1 / 156 (0.64%) 1 | 0 / 8 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Congenital naevus subjects affected / exposed occurrences (all) | 3 / 156 (1.92%) 3 | 0 / 8 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Hydrocele subjects affected / exposed occurrences (all) | 2 / 156 (1.28%) 2 | 0 / 8 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Polydactyly subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 8 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Cardiac disorders | | | |

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

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

| | | | |
|--|----------------------|--------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 8 (0.00%) 0 | 0 / 12 (0.00%) 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 occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Chills subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Injection site pain subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Reproductive system and breast disorders Vaginal hemorrhage subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Vaginal discharge subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Investigations Streptococcus test positive subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Cardiac murmur subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Apgar score low subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 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 occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Vomiting (VOMITING) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 2 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Diarrhoea (DIARRHEA) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 3 / 10 (30.00%) 4 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Gastroesophageal reflux disease subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Hemorrhoids subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Constipation subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Dyspepsia subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Hepatobiliary disorders | | | |
| Hyperbilirubinemia neonatal subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis allergic subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 2 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 0 |
| Renal and urinary disorders | | | |

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

| | | | |
|---|---------------------|---------------------|--------------------|
| Hypoglycemia neonatal subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 11 (0.00%) 0 | 0 / 9 (0.00%) 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 occurrences (all) | 0 / 159 (0.00%) 0 | | |
| Pregnancy, puerperium and perinatal conditions Fetal hypokinesia subjects affected / exposed occurrences (all) Abnormal labor subjects affected / exposed occurrences (all) Gestational diabetes subjects affected / exposed occurrences (all) Gestational hypertension subjects affected / exposed occurrences (all) Oligohydramnios subjects affected / exposed occurrences (all) Pre-eclampsia subjects affected / exposed occurrences (all) Premature delivery subjects affected / exposed occurrences (all) Uterine contractions during pregnancy subjects affected / exposed occurrences (all) | 0 / 159 (0.00%) 0 0 / 159 (0.00%) 0 0 / 159 (0.00%) 0 0 / 159 (0.00%) 0 0 / 159 (0.00%) 0 0 / 159 (0.00%) 0 0 / 159 (0.00%) 0 0 / 159 (0.00%) 0 | | |

| | | | |
|--|------------------------|--|--|
| Caput succedaneum subjects affected / exposed occurrences (all) | 3 / 159 (1.89%) 3 | | |
| Jaundice neonatal subjects affected / exposed occurrences (all) | 13 / 159 (8.18%) 13 | | |
| Low birth weight baby subjects affected / exposed occurrences (all) | 1 / 159 (0.63%) 1 | | |
| Large for dates baby subjects affected / exposed occurrences (all) | 0 / 159 (0.00%) 0 | | |
| Small for dates baby subjects affected / exposed occurrences (all) | 4 / 159 (2.52%) 4 | | |
| Umbilical cord around neck subjects affected / exposed occurrences (all) | 5 / 159 (3.14%) 5 | | |
| General disorders and administration site conditions | | | |
| Fatigue subjects affected / exposed occurrences (all) | 0 / 159 (0.00%) 0 | | |
| Erythema (REDNESS) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 0 / 159 (0.00%) 0 | | |
| Chills (CHILLS) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 0 / 159 (0.00%) 0 | | |
| Fatigue (FATIGUE) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 0 / 159 (0.00%) 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 occurrences (all) | 0 / 159 (0.00%) 0 | | |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 159 (0.00%) 0 0 / 159 (0.00%) 0 | | |
| Investigations Streptococcus test positive subjects affected / exposed occurrences (all) Cardiac murmur subjects affected / exposed occurrences (all) Apgar score low subjects affected / exposed occurrences (all) | 0 / 159 (0.00%) 0 2 / 159 (1.26%) 2 2 / 159 (1.26%) 2 | | |
| Injury, poisoning and procedural complications Skin laceration subjects affected / exposed occurrences (all) Exposure to communicable disease subjects affected / exposed occurrences (all) | 0 / 159 (0.00%) 0 0 / 159 (0.00%) 0 | | |
| Congenital, familial and genetic disorders Ankyloglossia congenital subjects affected / exposed occurrences (all) Congenital naevus subjects affected / exposed occurrences (all) Hydrocele | 2 / 159 (1.26%) 2 1 / 159 (0.63%) 1 | | |

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

| | | | |
|--|----------------------|--|--|
| 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 WORSENERD 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 WORSENERD 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/m ² . |
| 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