



## Clinical trial results:

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

### Summary

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

### Results information

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

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 209544 |
|-----------------------|--------|

#### Additional study identifiers

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

Notes:

### Sponsors

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

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

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

Notes:

## General information about the trial

Main objective of the trial:

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

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 05 November 2019 |
| Long term follow-up planned                               | No               |
| Independent data monitoring committee (IDMC) involvement? | Yes              |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Australia: 16      |
| Country: Number of subjects enrolled | Canada: 11         |
| Country: Number of subjects enrolled | Finland: 34        |
| Country: Number of subjects enrolled | France: 6          |
| Country: Number of subjects enrolled | New Zealand: 39    |
| Country: Number of subjects enrolled | Panama: 72         |
| Country: Number of subjects enrolled | South Africa: 13   |
| Country: Number of subjects enrolled | Spain: 59          |
| Country: Number of subjects enrolled | United States: 284 |
| Worldwide total number of subjects   | 534                |
| EEA total number of subjects         | 99                 |

Notes:

### Subjects enrolled per age group

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

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

## Subject disposition

### Recruitment

Recruitment details:

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

### Pre-assignment

Screening details:

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

### Period 1

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

Blinding implementation details:

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

### Arms

|                              |     |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

|                  |                         |
|------------------|-------------------------|
| <b>Arm title</b> | RSV MAT 60 Group-Mother |
|------------------|-------------------------|

Arm description:

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

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

Dosage and administration details:

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

|                  |                          |
|------------------|--------------------------|
| <b>Arm title</b> | RSV MAT 120 Group-Mother |
|------------------|--------------------------|

Arm description:

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

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

Dosage and administration details:

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

|                  |                      |
|------------------|----------------------|
| <b>Arm title</b> | Control Group-Mother |
|------------------|----------------------|

Arm description:

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

|  |                          |
|--|--------------------------|
| Arm type   | Placebo                  |
| Investigational medicinal product name   | Placebo                  |
| Investigational medicinal product code   |                          |
| Other name   |                          |
| Pharmaceutical forms   | Solution for injection   |
| Routes of administration   | Intramuscular use        |
| Dosage and administration details:   |                          |
| One single dose of placebo (NaCl solution) administered intramuscularly in the deltoid region of the non-dominant arm on Day 1.                          |                          |
| <b>Arm title</b>   | RSV MAT 60 Group-Infant  |
| Arm description:   |                          |
| This group consisted of infants born to mothers (from RSV MAT 60 Group-Mother) who received a single dose of RSV MAT (60 µg) vaccine during pregnancy.   |                          |
| Arm type   | No intervention          |
| No investigational medicinal product assigned in this arm  |                          |
| <b>Arm title</b>   | RSV MAT 120 Group-Infant |
| Arm description:   |                          |
| This group consisted of infants born to mothers (from RSV MAT 120 Group-Mother) who received a single dose of RSV MAT (120 µg) vaccine during pregnancy. |                          |
| Arm type   | No intervention          |
| No investigational medicinal product assigned in this arm  |                          |
| <b>Arm title</b>   | Control Group-Infant     |
| Arm description:   |                          |
| This group consisted of infants born to mothers (from Control Group-Mother) who received a single dose of placebo during pregnancy.                      |                          |
| Arm type   | No intervention          |
| No investigational medicinal product assigned in this arm  |                          |

| <b>Number of subjects in period 1<sup>[1]</sup></b> | RSV MAT 60 Group-Mother | RSV MAT 120 Group-Mother | Control Group-Mother |
|---|-------------------------|--------------------------|----------------------|
| Started   | 70                      | 75                       | 68                   |
| Completed   | 58                      | 70                       | 59                   |
| Not completed                                       | 12                      | 5                        | 9                    |
| Consent withdrawn by subject                        | 3                       | 2                        | 1                    |
| MIGRATED / MOVED FROM THE STUDY AREA                | -                       | 2                        | 1                    |
| Lost to follow-up                                   | 9                       | 1                        | 5                    |
| UNSPECIFIED   | -                       | -                        | 2                    |

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

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

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Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

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

## Baseline characteristics

### Reporting groups

|  |                          |
|--|--------------------------|
| Reporting group title  | RSV MAT 60 Group-Mother  |
| Reporting group description:<br>Maternal subjects randomized to RSV MAT 60 Group received a single dose of RSV MAT (60 µg) vaccine at Day 1, and were followed up until the study end.   |                          |
| Reporting group title  | RSV MAT 120 Group-Mother |
| Reporting group description:<br>Maternal subjects randomized to RSV MAT 120 group received a single dose of RSV MAT (120 µg) vaccine at Day 1, and were followed up until the study end. |                          |
| Reporting group title  | Control Group-Mother     |
| Reporting group description:<br>Maternal subjects randomized to the Control Group received a single dose of Placebo at Day 1, and were followed up until the study end.                  |                          |
| Reporting group title  | RSV MAT 60 Group-Infant  |
| Reporting group description:<br>This group consisted of infants born to mothers (from RSV MAT 60 Group-Mother) who received a single dose of RSV MAT (60 µg) vaccine during pregnancy.   |                          |
| Reporting group title  | RSV MAT 120 Group-Infant |
| Reporting group description:<br>This group consisted of infants born to mothers (from RSV MAT 120 Group-Mother) who received a single dose of RSV MAT (120 µg) vaccine during pregnancy. |                          |
| Reporting group title  | Control Group-Infant     |
| Reporting group description:<br>This group consisted of infants born to mothers (from Control Group-Mother) who received a single dose of placebo during pregnancy.                      |                          |

| Reporting group values                    | RSV MAT 60 Group-Mother | RSV MAT 120 Group-Mother | Control Group-Mother |
|---|-------------------------|--------------------------|----------------------|
| Number of subjects                        | 70                      | 75                       | 68                   |
| Age Categorical                           |                         |                          |                      |
| Units: Participants                       |                         |                          |                      |
| 0 to 1 years                              | 0                       | 0                        | 0                    |
| 18 < 35 years                             | 59                      | 62                       | 56                   |
| >= 35 years                               | 11                      | 13                       | 12                   |
| Sex: Female, Male                         |                         |                          |                      |
| Units: Participants                       |                         |                          |                      |
| Female                                    | 70                      | 75                       | 68                   |
| Male                                      | 0                       | 0                        | 0                    |
| Race/Ethnicity, Customized                |                         |                          |                      |
| Units: Subjects                           |                         |                          |                      |
| AMERICAN INDIAN OR ALASKA NATIVE          | 0                       | 2                        | 0                    |
| ASIAN                                     | 0                       | 0                        | 2                    |
| BLACK OR AFRICAN AMERICAN                 | 12                      | 12                       | 13                   |
| NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER | 3                       | 1                        | 0                    |
| OTHER                                     | 10                      | 10                       | 7                    |
| UNKNOWN                                   | 0                       | 2                        | 1                    |
| WHITE                                     | 45                      | 48                       | 45                   |

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

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



## End points

### End points reporting groups

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

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

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

Notes:

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of maternal subjects with any solicited systemic events

|                 |  |
|-----------------|--|
| End point title | Percentage of maternal subjects with any solicited systemic events <sup>[3]</sup> <sup>[4]</sup> |
|-----------------|--|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

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

Notes:

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

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Number of maternal subjects with any haematological laboratory abnormalities at Day 8 by baseline ranges <sup>[5][6]</sup> |
|-----------------|--|

End point description:

[4:07 PM] Cornelia Ungurean

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At Day 8

Notes:

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

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

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

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

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

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

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

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

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

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



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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Number of maternal subjects with any biochemical laboratory abnormalities at Day 8 by baseline ranges <sup>[7][8]</sup> |
|-----------------|---|

End point description:

[4:07 PM] Cornelia Ungurean

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At Day 8

Notes:

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

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

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Percentage of maternal subjects with any unsolicited adverse events (AEs) <sup>[9][10]</sup> |
|-----------------|--|

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**End point description:**

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

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|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

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**End point timeframe:**

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

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**Notes:**

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

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

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

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

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

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**Statistical analyses**

No statistical analyses for this end point

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

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|                 |  |
|-----------------|--|
| End point title | Percentage of maternal subjects with any serious adverse events (SAEs) <sup>[11][12]</sup> |
|-----------------|--|

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**End point description:**

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

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|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

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**End point timeframe:**

From Day 1 to Day 43 post-delivery

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**Notes:**

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Percentage of maternal subjects with AEs leading to study withdrawal <sup>[13][14]</sup> |
|-----------------|--|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 1 to Day 43 post-delivery

Notes:

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Percentage of maternal subjects with any medically attended AEs (MAE) <sup>[15][16]</sup> |
|-----------------|---|

End point description:

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

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 1 to Day 43 post-delivery

Notes:

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of maternal subjects with pregnancy outcomes

|                 |  |
|-----------------|--|
| End point title | Percentage of maternal subjects with pregnancy |
|-----------------|--|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 1 to Day 43 post-delivery

Notes:

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

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

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

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



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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Percentage of maternal subjects with pregnancy-related Adverse Events of Special Interest (AESIs) <sup>[19][20]</sup> |
|-----------------|---|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 1 to Day 43 post-delivery

Notes:

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

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of infant subjects with neonatal AESIs

|                 |   |
|-----------------|---|
| End point title | Percentage of infant subjects with neonatal AESIs <sup>[21]</sup> <sup>[22]</sup> |
|-----------------|---|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From birth to Day 43 post-birth

Notes:

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

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of infant subjects with any SAEs

|                 |   |
|-----------------|---|
| End point title | Percentage of infant subjects with any SAEs <sup>[23]</sup> <sup>[24]</sup> |
|-----------------|---|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From birth to Day 43 post-birth

Notes:

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Percentage of infant subjects with AEs leading to study withdrawal <sup>[25]</sup> <sup>[26]</sup> |
|-----------------|--|

**End point description:**

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

**End point timeframe:**

From birth to Day 43 post-birth

**Notes:**

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

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

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

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

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

**Statistical analyses**

No statistical analyses for this end point

**Primary: Percentage of infant subjects with any MAEs**

|                 |   |
|-----------------|---|
| End point title | Percentage of infant subjects with any MAEs <sup>[27]</sup> <sup>[28]</sup> |
|-----------------|---|

**End point description:**

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

**End point timeframe:**

From birth to Day 43 post-birth

**Notes:**

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | RSV MAT Immunoglobulin G (IgG)-specific antibody concentrations in terms of Geometric Mean Concentrations (GMCs) in maternal subjects <sup>[29][30]</sup> |
|-----------------|---|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

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

Notes:

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | RSV-A neutralizing antibody Geometric Mean Titers (GMTs) in maternal subjects <sup>[31][32]</sup> |
|-----------------|---|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

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

Notes:

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

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

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

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

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

### Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | RSV MAT IgG antibody GMCs in infants born to maternal subjects <sup>[33][34]</sup> |
|-----------------|--|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At delivery or within 3 days after birth

Notes:

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | RSV-A neutralizing antibody GMTs in infants born to maternal subjects <sup>[35]</sup> <sup>[36]</sup> |
|-----------------|---|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At delivery or within 3 days after birth

Notes:

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

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Geometric Mean Ratio between cord blood and maternal RSV MAT IgG-specific antibody concentrations <sup>[37]</sup> |
|-----------------|---|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

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

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Percentage of maternal subjects with any SAE from Day 1 to Day 181 post delivery <sup>[38]</sup> |
|-----------------|--|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From Day 1 to Day 181 post-delivery



Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Percentage of maternal subjects with any MAE from Day 1 to Day 181 post delivery <sup>[39]</sup> |
|-----------------|--|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From Day 1 to Day 181 post-delivery

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Percentage of maternal subjects with AE leading to study withdrawal from Day 1 to Day 181 post delivery <sup>[40]</sup> |
|-----------------|---|

### End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

### End point timeframe:

From Day 1 to Day 181 post-delivery

### Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Percentage of infant subjects with any SAE from birth to Day 181 post-birth <sup>[41]</sup> |
|-----------------|---|

### End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

### End point timeframe:

From birth to Day 181 post-birth

### Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Percentage of infant subjects with AE leading to study withdrawal from birth to Day 181 post-birth <sup>[42]</sup> |
|-----------------|--|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From birth to Day 181 post-birth

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Percentage of infant subjects with any MAE from birth to Day 181 post-birth <sup>[43]</sup> |
|-----------------|---|

End point description:

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

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

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

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Percentage of infant subjects with any SAE from birth to Month 12 post-birth <sup>[44]</sup> |
|-----------------|--|

End point description:

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

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

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Percentage of infant subjects with any AE leading to study withdrawal from birth to Month 12 post-birth <sup>[45]</sup> |
|-----------------|---|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From birth to Month 12 post-birth

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Percentage of infant subjects with any MAE from birth to Month 12 post-birth <sup>[46]</sup> |
|-----------------|--|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From birth to Month 12 post-birth

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Percentage of maternal subjects with RSV-associated Medically Attended Respiratory Tract Illnesses (MA-RTI) <sup>[47]</sup> |
|-----------------|---|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From delivery to Day 181 post-delivery

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

## tract illness (LRTI)

|                 |  |
|-----------------|--|
| End point title | Percentage of infant subjects with RSV-associated Lower respiratory tract illness (LRTI) <sup>[48]</sup> |
|-----------------|--|

### End point description:

An RSV-associated LRTI is characterised by a history of cough or difficulty in breathing, a blood oxygen saturation by pulse oximetry (SpO<sub>2</sub>) lesser than (<) 95% or respiratory rate increase and a confirmed RSV infection.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

### End point timeframe:

From birth to Day 181 post-birth

### Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

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

### End point description:

A RSV-associated severe LRTI is characterised by a history of cough or difficulty in breathing, a SpO<sub>2</sub> < 93% or lower chest wall in-drawing and a confirmed RSV infection.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

### End point timeframe:

From birth to Day 181 post-birth

### Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Percentage of infant subjects with RSV-associated very severe LRTI <sup>[50]</sup> |
|-----------------|--|

End point description:

A RSV-associated very severe LRTI is characterised by a history of cough or difficulty in breathing, a SpO<sub>2</sub> < 90% or inability to feed or failure to respond/unconscious and a confirmed RSV infection.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From birth to Day 181 post-birth

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of infant subjects with RSV-associated hospitalisation

|                 |   |
|-----------------|---|
| End point title | Percentage of infant subjects with RSV-associated hospitalisation <sup>[51]</sup> |
|-----------------|---|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From birth to Day 181 post-birth

Notes:

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

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

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



## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | RSV MAT IgG antibody GMCs in maternal subjects, at day 43 post-delivery <sup>[52]</sup> |
|-----------------|---|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 43 post-delivery

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | RSV-A neutralizing antibody GMTs in maternal subjects, at day 43 post-delivery <sup>[53]</sup> |
|-----------------|--|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 43 post-delivery

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

## Secondary: RSV-B neutralizing antibody GMTs in maternal subjects

|                 |   |
|-----------------|---|
| End point title | RSV-B neutralizing antibody GMTs in maternal subjects <sup>[54]</sup> |
|-----------------|---|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 1 (before vaccination), Day 31, at delivery and Day 43 post-delivery

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | RSV MAT IgG antibody GMCs in infants born to maternal subjects, at Day 43 after birth <sup>[55]</sup> |
|-----------------|---|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 43 after birth

Notes:

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

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

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

### Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | RSV MAT IgG antibody GMCs in infants born to maternal subjects, at Day 121 after birth <sup>[56]</sup> |
|-----------------|--|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 121 after birth

Notes:

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

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

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

### Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | RSV MAT IgG antibody GMCs in infants born to maternal subjects, at Day 181 after birth <sup>[57]</sup> |
|-----------------|--|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 181 after birth

Notes:

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

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

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

### Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | RSV-A neutralizing antibody GMTs in infants born to maternal subjects, at Day 43 after birth <sup>[58]</sup> |
|-----------------|--|

End point description:

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

measure at the specified time point.

|                       |           |
|-----------------------|-----------|
| End point type        | Secondary |
| End point timeframe:  |           |
| At Day 43 after birth |           |

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | RSV-A neutralizing antibody GMTs in infants born to maternal subjects, at Day 121 after birth <sup>[59]</sup> |
|-----------------|---|

End point description:

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

|                        |           |
|------------------------|-----------|
| End point type         | Secondary |
| End point timeframe:   |           |
| At Day 121 after birth |           |

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

---

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

---

|                 |   |
|-----------------|---|
| End point title | RSV-A neutralizing antibody GMTs in infants born to maternal subjects, at Day 181 after birth <sup>[60]</sup> |
|-----------------|---|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 181 after birth

Notes:

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

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

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

---

**Statistical analyses**

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No statistical analyses for this end point

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

---

|                 |   |
|-----------------|---|
| End point title | RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at birth <sup>[61]</sup> |
|-----------------|---|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At delivery or within 3 days after birth

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at Day 43 after birth <sup>[62]</sup> |
|-----------------|--|

End point description:

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

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 43 after birth

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at Day 121 after birth <sup>[63]</sup> |
|-----------------|---|

End point description:

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

measure at the specified time point.

|                        |           |
|------------------------|-----------|
| End point type         | Secondary |
| End point timeframe:   |           |
| At Day 121 after birth |           |

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | RSV-B neutralizing antibody GMTs in infants born to maternal subjects, at Day 181 after birth <sup>[64]</sup> |
|-----------------|---|

End point description:

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

|                        |           |
|------------------------|-----------|
| End point type         | Secondary |
| End point timeframe:   |           |
| At Day 181 after birth |           |

Notes:

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

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

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

## Statistical analyses





## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

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

Adverse event reporting additional description:

Infants born to vaccinated mothers were only monitored for AESIs and MAEs. These results are presented in the outcome measures section. Post vaccination solicited and unsolicited AEs were not collected for infants, as they were not vaccinated in the study.

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 24.0 |
|--------------------|------|

### Reporting groups

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | RSV MAT 60 Group-Mother |
|-----------------------|-------------------------|

Reporting group description:

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

|                       |                          |
|-----------------------|--------------------------|
| Reporting group title | RSV MAT 120 Group-Mother |
|-----------------------|--------------------------|

Reporting group description:

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

|                       |                      |
|-----------------------|----------------------|
| Reporting group title | Control Group-Mother |
|-----------------------|----------------------|

Reporting group description:

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

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | RSV MAT 60 Group-Infant |
|-----------------------|-------------------------|

Reporting group description:

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

|                       |                          |
|-----------------------|--------------------------|
| Reporting group title | RSV MAT 120 Group-Infant |
|-----------------------|--------------------------|

Reporting group description:

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

|                       |                      |
|-----------------------|----------------------|
| Reporting group title | Control Group-Infant |
|-----------------------|----------------------|

Reporting group description:

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

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

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

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

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

|   |                |                |                |
|---|----------------|----------------|----------------|
| Meconium aspiration syndrome                    |                |                |                |
| subjects affected / exposed                     | 1 / 70 (1.43%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Choking   |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Neonatal aspiration                             |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Neonatal respiratory depression                 |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Neonatal respiratory distress syndrome          |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Neonatal respiratory failure                    |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Tachypnoea                                      |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Transient tachypnoea of the newborn             |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Investigations                                  |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Cardiac murmur                                  |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural complications  |                |                |                |
| Post lumbar puncture syndrome                   |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 1 / 75 (1.33%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Road traffic accident                           |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 1 / 75 (1.33%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Congenital, familial and genetic disorders      |                |                |                |
| Congenital naevus                               |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Ankyloglossia congenital                        |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Cryptorchism                                    |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hypospadias                                     |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Birth mark                                      |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Congenital acrochordon                          |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Congenital arterial malformation                |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Congenital foot malformation                    |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Congenital pneumonia                            |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Congenital skin dimples                         |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Congenital viral hepatitis                      |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hooded prepuce                                  |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Naevus flammeus                                 |                |                |                |



|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Patent ductus arteriosus                        |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Phimosis  |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Polydactyly                                     |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Preauricular cyst                               |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Supernumerary nipple                            |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Ventricular septal defect                       |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Cardiac disorders                               |                |                |                |
| Cardiomegaly                                    |                |                |                |
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Nervous system disorders                        |                |                |                |

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

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

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

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 70 (0.00%) | 0 / 75 (0.00%) | 0 / 68 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

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

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

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

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



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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

| <b>Non-serious adverse events</b>      | RSV MAT 60 Group-Infant | RSV MAT 120 Group-Infant | Control Group-Infant |
|--|-------------------------|--------------------------|----------------------|
| Total subjects affected by non-serious |                         |                          |                      |

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

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

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



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

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

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

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

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

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

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported