



Clinical trial results:

A Phase 1, Open-Label, age-Descending, Dose-Finding Study to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus Prefusion F Subunit Vaccine (RSVpreF) in Children 2 to <18 Years of age

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2024-000422-17 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 29 February 2024 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 28 November 2024 |
| First version publication date | 28 November 2024 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | C3671016 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05900154 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Pfizer Inc. |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017 |
| Public contact | Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-002795-PIP02-21 |
| 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? | Yes |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 09 July 2024 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 29 February 2024 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To describe the safety and tolerability of RSVpreF at each dose level in children 5 to less than (<) 18 years of age and children 2 to <5 years of age.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 22 June 2023 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | United States: 127 |
| Worldwide total number of subjects | 127 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|---|----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 88 |
| Adolescents (12-17 years) | 39 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The study was conducted in United States only, from 22 June 2023 to 29 February 2024. A total of 127 participants were enrolled and in receipt of RSVpreF.

Pre-assignment

Screening details:

Participants were divided into 2 age groups: 5 to <18 years and 2 to < 5 years. All participants received single dose of RSVpreF vaccine.

Period 1

| | |
|------------------------------|------------------------------|
| Period 1 title | Period 1: Vaccination Period |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|--------------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Healthy RSVpreF 120 micrograms (mcg) |

Arm description:

Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| | |
|------------------|---------------------------|
| Arm title | High Risk RSVpreF 120 mcg |
|------------------|---------------------------|

Arm description:

High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| | |
|------------------|--------------------------------|
| Arm title | 2 to < 5 Years RSVpreF 120 mcg |
|------------------|--------------------------------|

Arm description:

Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|-------------------|
| Investigational medicinal product name | RSVpreF |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| | |
|------------------|------------------------|
| Arm title | Healthy RSVpreF 60 mcg |
|------------------|------------------------|

Arm description:

Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| | |
|------------------|--------------------------|
| Arm title | High Risk RSVpreF 60 mcg |
|------------------|--------------------------|

Arm description:

High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| | |
|------------------|-------------------------------|
| Arm title | 2 to < 5 Years RSVpreF 60 mcg |
|------------------|-------------------------------|

Arm description:

Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| Number of subjects in period 1 | Healthy RSVpreF 120 micrograms (mcg) | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg |
|--------------------------------|--|------------------------------|-----------------------------------|
| | Started | 25 | 23 |
| Completed | 25 | 23 | 24 |

| Number of subjects in period 1 | Healthy RSVpreF 60 mcg | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg |
|--------------------------------|---------------------------|-----------------------------|----------------------------------|
| | Started | 17 | 18 |
| Completed | 17 | 18 | 20 |

Period 2

| | |
|------------------------------|----------------------------|
| Period 2 title | Period 2: Follow-Up Period |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|-------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Healthy RSVpreF 120 mcg |

Arm description:

Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| | |
|------------------|---------------------------|
| Arm title | High Risk RSVpreF 120 mcg |
|------------------|---------------------------|

Arm description:

High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| | |
|------------------|--------------------------------|
| Arm title | 2 to < 5 Years RSVpreF 120 mcg |
|------------------|--------------------------------|

Arm description:

Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level

intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| | |
|------------------|------------------------|
| Arm title | Healthy RSVpreF 60 mcg |
|------------------|------------------------|

Arm description:

Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| | |
|------------------|--------------------------|
| Arm title | High Risk RSVpreF 60 mcg |
|------------------|--------------------------|

Arm description:

High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| | |
|------------------|-------------------------------|
| Arm title | 2 to < 5 Years RSVpreF 60 mcg |
|------------------|-------------------------------|

Arm description:

Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

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

Dosage and administration details:

60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

| Number of subjects in period 2 | Healthy RSVpreF 120 mcg | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg |
|---------------------------------------|----------------------------|------------------------------|-----------------------------------|
| Started | 25 | 23 | 24 |
| Completed | 24 | 21 | 23 |
| Not completed | 1 | 2 | 1 |
| Lost to follow-up | 1 | 2 | 1 |

| Number of subjects in period 2 | Healthy RSVpreF 60 mcg | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg |
|---------------------------------------|---------------------------|-----------------------------|----------------------------------|
| Started | 17 | 18 | 20 |
| Completed | 17 | 17 | 19 |
| Not completed | 0 | 1 | 1 |
| Lost to follow-up | - | 1 | 1 |

Baseline characteristics

Reporting groups

| | |
|---|--------------------------------------|
| Reporting group title | Healthy RSVpreF 120 micrograms (mcg) |
| Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | High Risk RSVpreF 120 mcg |
| Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | 2 to < 5 Years RSVpreF 120 mcg |
| Reporting group description: Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | Healthy RSVpreF 60 mcg |
| Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | High Risk RSVpreF 60 mcg |
| Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | 2 to < 5 Years RSVpreF 60 mcg |
| Reporting group description: Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |

| Reporting group values | Healthy RSVpreF 120 micrograms (mcg) | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg |
|---|--|------------------------------|-----------------------------------|
| Number of subjects | 25 | 23 | 24 |
| Age Categorical Units: Participants | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 9 | 11 | 24 |
| Adolescents (12-17 years) | 16 | 12 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous Units: years | | | |
| arithmetic mean | 12.56 | 11.04 | 3.00 |
| standard deviation | ± 4.55 | ± 3.50 | ± 0.78 |
| Gender Categorical Units: Participants | | | |
| Female | 15 | 11 | 13 |

| | | | |
|------|----|----|----|
| Male | 10 | 12 | 11 |
|------|----|----|----|

| | | | |
|----------------------------------|----|----|----|
| Race Units: Subjects | | | |
| White | 16 | 17 | 17 |
| Black or African American | 7 | 6 | 3 |
| Asian | 2 | 0 | 0 |
| American Indian or Alaska Native | 0 | 0 | 1 |
| Multiracial | 0 | 0 | 3 |
| Ethnicity Units: Subjects | | | |
| Hispanic/Latino | 5 | 0 | 1 |
| Non-Hispanic/non-Latino | 20 | 23 | 22 |
| Not reported | 0 | 0 | 1 |

| Reporting group values | Healthy RSVpreF 60 mcg | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg |
|--|------------------------|--------------------------|-------------------------------|
| Number of subjects | 17 | 18 | 20 |
| Age Categorical Units: Participants | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 12 | 12 | 20 |
| Adolescents (12-17 years) | 5 | 6 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous Units: years | | | |
| arithmetic mean | 9.53 | 9.61 | 3.20 |
| standard deviation | ± 3.57 | ± 3.40 | ± 0.77 |
| Gender Categorical Units: Participants | | | |
| Female | 5 | 7 | 7 |
| Male | 12 | 11 | 13 |
| Race Units: Subjects | | | |
| White | 13 | 9 | 15 |
| Black or African American | 2 | 6 | 4 |
| Asian | 0 | 0 | 0 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Multiracial | 2 | 3 | 1 |
| Ethnicity Units: Subjects | | | |
| Hispanic/Latino | 3 | 4 | 5 |
| Non-Hispanic/non-Latino | 14 | 13 | 15 |
| Not reported | 0 | 1 | 0 |

| Reporting group values | Total | | |
|---|-------|--|--|
| Number of subjects | 127 | | |
| Age Categorical | | | |
| Units: Participants | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | | |
| Newborns (0-27 days) | 0 | | |
| Infants and toddlers (28 days-23 months) | 0 | | |
| Children (2-11 years) | 88 | | |
| Adolescents (12-17 years) | 39 | | |
| Adults (18-64 years) | 0 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Gender Categorical | | | |
| Units: Participants | | | |
| Female | 58 | | |
| Male | 69 | | |
| Race | | | |
| Units: Subjects | | | |
| White | 87 | | |
| Black or African American | 28 | | |
| Asian | 2 | | |
| American Indian or Alaska Native | 1 | | |
| Multiracial | 9 | | |
| Ethnicity | | | |
| Units: Subjects | | | |
| Hispanic/Latino | 18 | | |
| Non-Hispanic/non-Latino | 107 | | |
| Not reported | 2 | | |

End points

End points reporting groups

| | |
|---|--------------------------------------|
| Reporting group title | Healthy RSVpreF 120 micrograms (mcg) |
| Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | High Risk RSVpreF 120 mcg |
| Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | 2 to < 5 Years RSVpreF 120 mcg |
| Reporting group description: Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | Healthy RSVpreF 60 mcg |
| Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | High Risk RSVpreF 60 mcg |
| Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | 2 to < 5 Years RSVpreF 60 mcg |
| Reporting group description: Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | Healthy RSVpreF 120 mcg |
| Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | High Risk RSVpreF 120 mcg |
| Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | 2 to < 5 Years RSVpreF 120 mcg |
| Reporting group description: Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | Healthy RSVpreF 60 mcg |
| Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | High Risk RSVpreF 60 mcg |
| Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |
| Reporting group title | 2 to < 5 Years RSVpreF 60 mcg |
| Reporting group description: Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1. | |

Primary: Percentage of Participants With Local Reactions Within 7 Days After Vaccination

| | |
|-----------------|--|
| End point title | Percentage of Participants With Local Reactions Within 7 Days After Vaccination ^[1] |
|-----------------|--|

End point description:

Local reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after vaccination. Local reactions included redness, swelling and pain at injection site. For participants greater than or equal to (\geq) 2 years to <12 years of age, redness and swelling were graded as mild: 0.5 to 2.0 centimeter (cm), moderate: >2.0 to 7.0 cm, and severe: > 7 cm; for participants \geq 12 years of age, mild: > 2.0 to 5.0 cm, moderate: >5.0 to 10.0 cm, and severe: >10 cm. Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), and severe (prevented daily activity). Percentage of participants reporting local reactions at injection site and associated 2-sided 95% confidence interval (CI) based on Clopper and Pearson method was presented in this endpoint. Safety population included all enrolled participants who received study intervention.

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

End point timeframe:

Within 7 days after Vaccination

Notes:

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

Justification: Only descriptive data was planned to be analyzed

| End point values | Healthy RSVpreF 120 micrograms (mcg) | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg | Healthy RSVpreF 60 mcg |
|-----------------------------------|--------------------------------------|---------------------------|--------------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 23 | 24 | 17 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Pain at injection site: Mild | 36.0 (18.0 to 57.5) | 39.1 (19.7 to 61.5) | 8.3 (1.0 to 27.0) | 35.3 (14.2 to 61.7) |
| Pain at injection site: Moderate | 8.0 (1.0 to 26.0) | 8.7 (1.1 to 28.0) | 0 (0.0 to 14.2) | 5.9 (0.1 to 28.7) |
| Pain at injection site: Severe | 4.0 (0.1 to 20.4) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Redness: Mild | 12.0 (2.5 to 31.2) | 4.3 (0.1 to 21.9) | 12.5 (2.7 to 32.4) | 0 (0.0 to 19.5) |
| Redness: Moderate | 12.0 (2.5 to 31.2) | 4.3 (0.1 to 21.9) | 0 (0.0 to 14.2) | 5.9 (0.1 to 28.7) |
| Redness: Severe | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Swelling: Mild | 4.0 (0.1 to 20.4) | 0 (0.0 to 14.8) | 4.2 (0.1 to 21.1) | 0 (0.0 to 19.5) |
| Swelling: Moderate | 8.0 (1.0 to 26.0) | 8.7 (1.1 to 28.0) | 0 (0.0 to 14.2) | 5.9 (0.1 to 28.7) |
| Swelling: Severe | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |

| End point values | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg | | |
|-----------------------------------|--------------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 20 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Pain at injection site: Mild | 33.3 (13.3 to 59.0) | 15.0 (3.2 to 37.9) | | |

| | | | | |
|----------------------------------|--------------------|-------------------|--|--|
| Pain at injection site: Moderate | 22.2 (6.4 to 47.6) | 0 (0.0 to 16.8) | | |
| Pain at injection site: Severe | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |
| Redness: Mild | 11.1 (1.4 to 34.7) | 5.0 (0.1 to 24.9) | | |
| Redness: Moderate | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |
| Redness: Severe | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |
| Swelling: Mild | 11.1 (1.4 to 34.7) | 0 (0.0 to 16.8) | | |
| Swelling: Moderate | 11.1 (1.4 to 34.7) | 5.0 (0.1 to 24.9) | | |
| Swelling: Severe | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Systemic Events Within 7 Days After Vaccination

| | |
|-----------------|--|
| End point title | Percentage of Participants With Systemic Events Within 7 Days After Vaccination ^[2] |
|-----------------|--|

End point description:

Systemic events included fever, fatigue, headache, vomiting, diarrhea, muscle pain and joint pain and were recorded by participants using e-diary. Fever: oral temperature ≥ 38.0 degree Celsius (deg C) and categorised as ≥ 38.0 to 38.4 deg C (mild), >38.4 to 38.9 deg C (moderate), and >38.9 to 40.0 deg C (severe). Fatigue, headache, muscle pain and joint pain were graded as mild (did not interfere with activity), moderate (some interference with activity), and severe (prevented daily routine activity). Vomiting was graded mild: 1-2 times in 24 hours (h), moderate: >2 times in 24h, and severe: required intravenous hydration. Diarrhea was graded mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h and severe: 6 or more loose stools in 24h. Percentage of participants with systemic events within 7 days after vaccination and associated 2-sided 95% CI based on Clopper and Pearson method was presented. Safety population = all enrolled participants who received study intervention.

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

End point timeframe:

Within 7 days after Vaccination

Notes:

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

Justification: Only descriptive data was planned to be analyzed

| End point values | Healthy RSVpreF 120 micrograms (mcg) | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg | Healthy RSVpreF 60 mcg |
|-----------------------------------|--------------------------------------|---------------------------|--------------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 23 | 24 | 17 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: Mild | 0 (0.0 to 13.7) | 4.3 (0.1 to 21.9) | 4.2 (0.1 to 21.1) | 0 (0.0 to 19.5) |
| Fever: Moderate | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Fever: Severe | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 5.9 (0.1 to 28.7) |
| Fatigue: Mild | 20.0 (6.8 to 40.7) | 21.7 (7.5 to 43.7) | 20.8 (7.1 to 42.2) | 41.2 (18.4 to 67.1) |

| | | | | |
|-----------------------|--------------------|---------------------|-------------------|---------------------|
| Fatigue: Moderate | 12.0 (2.5 to 31.2) | 21.7 (7.5 to 43.7) | 8.3 (1.0 to 27.0) | 5.9 (0.1 to 28.7) |
| Fatigue: Severe | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Headache: Mild | 16.0 (4.5 to 36.1) | 26.1 (10.2 to 48.4) | 0 (0.0 to 14.2) | 29.4 (10.3 to 56.0) |
| Headache: Moderate | 12.0 (2.5 to 31.2) | 8.7 (1.1 to 28.0) | 4.2 (0.1 to 21.1) | 11.8 (1.5 to 36.4) |
| Headache: Severe | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Muscle pain: Mild | 16.0 (4.5 to 36.1) | 21.7 (7.5 to 43.7) | 0 (0.0 to 14.2) | 23.5 (6.8 to 49.9) |
| Muscle pain: Moderate | 4.0 (0.1 to 20.4) | 17.4 (5.0 to 38.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Muscle pain: Severe | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Joint pain: Mild | 4.0 (0.1 to 20.4) | 4.3 (0.1 to 21.9) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Joint pain: Moderate | 4.0 (0.1 to 20.4) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Joint pain: Severe | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Vomiting: Mild | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 5.9 (0.1 to 28.7) |
| Vomiting: Moderate | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Vomiting: Severe | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |
| Diarrhea: Mild | 4.0 (0.1 to 20.4) | 8.7 (1.1 to 28.0) | 4.2 (0.1 to 21.1) | 0 (0.0 to 19.5) |
| Diarrhea: Moderate | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 8.3 (1.0 to 27.0) | 0 (0.0 to 19.5) |
| Diarrhea: Severe | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |

| End point values | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg | | |
|-----------------------------------|--------------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 20 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: Mild | 0 (0.0 to 18.5) | 5.0 (0.1 to 24.9) | | |
| Fever: Moderate | 5.6 (0.1 to 27.3) | 0 (0.0 to 16.8) | | |
| Fever: Severe | 5.6 (0.1 to 27.3) | 0 (0.0 to 16.8) | | |
| Fatigue: Mild | 16.7 (3.6 to 41.4) | 30.0 (11.9 to 54.3) | | |
| Fatigue: Moderate | 33.3 (13.3 to 59.0) | 5.0 (0.1 to 24.9) | | |
| Fatigue: Severe | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |
| Headache: Mild | 16.7 (3.6 to 41.4) | 0 (0.0 to 16.8) | | |
| Headache: Moderate | 16.7 (3.6 to 41.4) | 0 (0.0 to 16.8) | | |
| Headache: Severe | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |
| Muscle pain: Mild | 33.3 (13.3 to 59.0) | 0 (0.0 to 16.8) | | |
| Muscle pain: Moderate | 5.6 (0.1 to 27.3) | 0 (0.0 to 16.8) | | |
| Muscle pain: Severe | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |

| | | | | |
|----------------------|--------------------|--------------------|--|--|
| Joint pain: Mild | 11.1 (1.4 to 34.7) | 0 (0.0 to 16.8) | | |
| Joint pain: Moderate | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |
| Joint pain: Severe | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |
| Vomiting: Mild | 5.6 (0.1 to 27.3) | 10.0 (1.2 to 31.7) | | |
| Vomiting: Moderate | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |
| Vomiting: Severe | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |
| Diarrhea: Mild | 5.6 (0.1 to 27.3) | 0 (0.0 to 16.8) | | |
| Diarrhea: Moderate | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |
| Diarrhea: Severe | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Adverse Events (AEs) Within 1 Month After Vaccination

| | |
|-----------------|--|
| End point title | Percentage of Participants With Adverse Events (AEs) Within 1 Month After Vaccination ^[3] |
|-----------------|--|

End point description:

AE was defined as any untoward medical occurrence in clinical study participant, temporally associated with use of study intervention, whether or not considered related to study intervention. AEs included serious and non-serious AE. Serious AEs (SAEs) were defined as AE that, at any dose: resulted in death; life-threatening; required inpatient hospitalisation/prolongation of existing hospitalisation; resulted in persistent disability/incapacity; was congenital anomaly/birth defect; was suspected transmission via Pfizer product of infectious agent, pathogenic or nonpathogenic or was considered to be important medical event. Percentage of participants reporting AEs within 1 month after Vaccination were reported. Exact 2-sided CI was calculated using Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported. Safety population included all enrolled participants who received study intervention.

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

End point timeframe:

Within 1 month after Vaccination

Notes:

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

Justification: Only descriptive data was planned to be analyzed

| End point values | Healthy RSVpreF 120 micrograms (mcg) | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg | Healthy RSVpreF 60 mcg |
|-----------------------------------|--------------------------------------|---------------------------|--------------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 23 | 24 | 17 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0.0 to 13.7) | 17.4 (5.0 to 38.8) | 12.5 (2.7 to 32.4) | 0 (0.0 to 19.5) |

| End point values | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg | | |
|------------------|--------------------------|-------------------------------|--|--|
| | | | | |

| | | | | |
|-----------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 20 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 27.8 (9.7 to 53.5) | 15.0 (3.2 to 37.9) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Serious Adverse Events (SAEs) Throughout the Study

| | |
|-----------------|---|
| End point title | Percentage of Participants With Serious Adverse Events (SAEs) Throughout the Study ^[4] |
|-----------------|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. SAEs were defined as an AE that, at any dose: resulted in death; was life-threatening; required inpatient hospitalisation or prolongation of existing hospitalisation; resulted in persistent disability/incapacity; was a congenital anomaly/birth defect; was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or nonpathogenic or that was considered to be an important medical event. Percentage of participants with SAEs and the associated 2-sided 95% CI based on the Clopper and Pearson method was presented. Percentage of participants reporting SAEs within 1 month after Vaccination were reported in this endpoint. Safety population included all enrolled participants who received study intervention.

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

End point timeframe:

From Day 1 up to 6-month follow-up visit after Day 1

Notes:

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

Justification: Only descriptive data was planned to be analyzed

| End point values | Healthy RSVpreF 120 micrograms (mcg) | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg | Healthy RSVpreF 60 mcg |
|-----------------------------------|--------------------------------------|---------------------------|--------------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 23 | 24 | 17 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0.0 to 13.7) | 4.3 (0.1 to 21.9) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |

| End point values | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg | | |
|-----------------------------------|--------------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 20 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 5.6 (0.1 to 27.3) | 0 (0.0 to 16.8) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Newly Diagnosed Chronic Medical Condition (NDCMCs) Throughout the Study

| | |
|-----------------|---|
| End point title | Percentage of Participants Reporting Newly Diagnosed Chronic Medical Condition (NDCMCs) Throughout the Study ^[5] |
|-----------------|---|

End point description:

An NDCMC was defined as a disease or medical condition, which was not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. Percentage of participants reporting NDCMC throughout the study was reported in this endpoint. Safety population included all enrolled participants who received study intervention.

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

End point timeframe:

From Day 1 up to 6-month follow-up visit after Day 1

Notes:

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

Justification: Only descriptive data was planned to be analyzed

| End point values | Healthy RSVpreF 120 micrograms (mcg) | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg | Healthy RSVpreF 60 mcg |
|-----------------------------------|--------------------------------------|---------------------------|--------------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 23 | 24 | 17 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0.0 to 13.7) | 0 (0.0 to 14.8) | 0 (0.0 to 14.2) | 0 (0.0 to 19.5) |

| End point values | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg | | |
|-----------------------------------|--------------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 20 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0.0 to 18.5) | 0 (0.0 to 16.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer of the Neutralising Titers for RSV A and RSV B

Before Vaccination and 1 Month After Vaccination

| | |
|-----------------|--|
| End point title | Geometric Mean Titer of the Neutralising Titers for RSV A and RSV B Before Vaccination and 1 Month After Vaccination |
|-----------------|--|

End point description:

Geometric mean titer (GMT) of neutralising titers of respiratory syncytial virus subgroup A and respiratory syncytial virus subgroup B (RSV A and RSV B) before vaccination and 1 month (M) after vaccination were reported in this endpoint. Assay results below the lower limit of quantification (LLOQ) were set to 0.5*LLOQ. The LLOQ for each neutralisation titer were: RSV A 50% = 242, RSV B 50% = 99. GMTs and corresponding 2-sided CIs were calculated by exponentiating mean logarithm of titers and corresponding CIs (based on Student's t distribution). Evaluable immunogenicity population (EIP) included all eligible participants who received the study intervention; had 1-month postvaccination blood collection 27 through 42 days after vaccination; had at least 1 valid and determinate assay result 1 month after vaccination; had no major protocol violations from vaccination through the 1-month postvaccination blood draw. Here, 'n' signifies participants evaluable for the specified rows.

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

End point timeframe:

Before vaccination and 1 month after vaccination

| End point values | Healthy RSVpreF 120 mcg | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg | Healthy RSVpreF 60 mcg |
|---|-------------------------|---------------------------|--------------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 24 | 21 | 24 | 15 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| RSV A: Before vaccination (n=24,20,24,15,18,20) | 1168 (706 to 1932) | 2003 (1421 to 2823) | 529 (335 to 835) | 916 (653 to 1285) |
| RSV A: 1 M after vaccination (n=24,21,24,15,18,20) | 27862 (21493 to 36119) | 35503 (26876 to 46900) | 26146 (13301 to 51396) | 25341 (15394 to 41715) |
| RSV B: Before vaccination (n=24,20,24,15,18,20) | 1206 (717 to 2027) | 1905 (1238 to 2930) | 391 (231 to 661) | 965 (668 to 1393) |
| RSV B: 1 M after vaccination (n=24,21,24,15,18,20) | 30251 (21607 to 42355) | 29019 (18786 to 44827) | 16504 (8267 to 32948) | 33351 (23565 to 47202) |
| RSVA/RSVB: Before vaccination (n=24,20,24,15,18,20) | 1187 (741 to 1900) | 1953 (1353 to 2820) | 455 (285 to 727) | 940 (698 to 1268) |
| A/B: 1 M after vaccination (n=24,21,24,15,18,20) | 29032 (22267 to 37853) | 32098 (23148 to 44509) | 20773 (10644 to 40543) | 29071 (19691 to 42920) |

| End point values | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg | | |
|--|--------------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 20 | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| RSV A: Before vaccination (n=24,20,24,15,18,20) | 1667 (1035 to 2684) | 561 (309 to 1016) | | |
| RSV A: 1 M after vaccination (n=24,21,24,15,18,20) | 24053 (17440 to 33173) | 11004 (4287 to 28245) | | |
| RSV B: Before vaccination (n=24,20,24,15,18,20) | 1760 (947 to 3272) | 499 (258 to 967) | | |

| | | | | |
|--|------------------------|-----------------------|--|--|
| RSV B:1 M after vaccination(n=24,21,24,15,18,20) | 31174 (21756 to 44668) | 10659 (3526 to 32228) | | |
| RSVA/RSVB: Before vaccination(n=24,20,24,15,18,20) | 1713 (1017 to 2884) | 529 (295 to 950) | | |
| A/B: 1 M after vaccination (n=24,21,24,15,18,20) | 27383 (20364 to 36820) | 10830 (3928 to 29860) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) of the NTs for RSV A and RSV B From Before Vaccination to 1 Month After Vaccination

| | |
|-----------------|---|
| End point title | Geometric Mean Fold Rise (GMFR) of the NTs for RSV A and RSV B From Before Vaccination to 1 Month After Vaccination |
|-----------------|---|

End point description:

GMFR of neutralising titers of RSV A and RSV B from before vaccination to 1 month after vaccination were reported in this endpoint. GMFR and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the fold rises and the corresponding CIs (based on the Student's t distribution). Evaluable immunogenicity population included all eligible participants who received the study intervention; had 1-month postvaccination blood collection 27 through 42 days after vaccination; had at least 1 valid and determinate assay result 1 month after vaccination; had no major protocol violations from vaccination through the 1-month postvaccination blood draw.

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

End point timeframe:

From before vaccination to 1 month after vaccination

| End point values | Healthy RSVpreF 120 micrograms (mcg) | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg | Healthy RSVpreF 60 mcg |
|--|--------------------------------------|---------------------------|--------------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 24 | 20 | 24 | 15 |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| RSV A | 21.9 (14.46 to 33.08) | 18.6 (13.03 to 26.55) | 42.8 (23.41 to 78.16) | 27.7 (17.81 to 42.93) |
| RSV B | 24.4 (15.53 to 38.26) | 16.3 (9.91 to 26.83) | 39.8 (22.96 to 69.08) | 34.6 (21.63 to 55.23) |
| RSV A/ RSV B | 23.1 (15.17 to 35.16) | 17.4 (11.73 to 25.85) | 41.3 (23.49 to 72.51) | 30.9 (19.99 to 47.81) |

| End point values | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg | | |
|-------------------------------------|--------------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 20 | | |
| Units: Fold rise | | | | |
| geometric mean (confidence interval | | | | |

| | | | | |
|--------------|----------------------|-----------------------|--|--|
| 95%) | | | | |
| RSV A | 13.9 (8.75 to 22.03) | 17.7 (9.02 to 34.67) | | |
| RSV B | 17.0 (9.25 to 31.40) | 20.6 (10.00 to 42.50) | | |
| RSV A/ RSV B | 15.4 (9.12 to 25.94) | 19.1 (9.61 to 37.96) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Median Frequencies of RSV F Antigen-Specific Cluster of Differentiation 4 (CD4+) Thymus-Derived Lymphocytes (T) Cells Expressing Interferon (IFN) Gamma and Interleukin-4 (IL-4) Before Vaccination and 1 Month After Vaccination

| | |
|-----------------|---|
| End point title | Median Frequencies of RSV F Antigen-Specific Cluster of Differentiation 4 (CD4+) Thymus-Derived Lymphocytes (T) Cells Expressing Interferon (IFN) Gamma and Interleukin-4 (IL-4) Before Vaccination and 1 Month After Vaccination |
|-----------------|---|

End point description:

Median frequencies of RSV F antigen-specific CD4+ T cells expressing IFN gamma and IL-4 before vaccination (vax) and 1M after vax were reported in this endpoint. RSV F enzyme-linked immune absorbent spot assay (ELISpot) limit of detection (LOD) values were IFN gamma=20 spot forming cell (SFC) per million peripheral blood mononuclear cell (PBMCs) and IL-4= 4 SFC/million PBMCs. Assay results below LOD=0.5*LOD for analysis, with exception of calculating fold-rise when before vax assay value was below LOD but corresponding after vax assay value was at LOD or above, where LOD was set for before vaccination. EIP= all eligible participants who received intervention; had 1-M postvaccination blood collection 27 to 42 days after vax; had at least 1 valid, determinate assay result 1 M after vax; had no major protocol violations from vax through 1M postvaccination blood draw. 'Number of Subjects Analysed'=participants evaluable for this endpoint and 'n'=participants evaluable for specified rows.

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

End point timeframe:

Before vaccination and 1 Month after vaccination

| End point values | Healthy RSVpreF 120 micrograms (mcg) | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 120 mcg | Healthy RSVpreF 60 mcg |
|--|--------------------------------------|---------------------------|--------------------------------|------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 23 | 21 | 22 | 15 |
| Units: SFC/million PBMCs | | | | |
| median (full range (min-max)) | | | | |
| INF gamma before vax (n=23, 19, 22, 14, 17, 17) | 47 (10 to 241) | 60 (10 to 193) | 10 (10 to 67) | 53 (10 to 277) |
| INF gamma 1 month after vax (n=22,21,21,15,18,17) | 255 (10 to 829) | 293 (10 to 1339) | 61 (10 to 257) | 244 (23 to 1027) |
| IL-4 before vax (n=23, 19, 22, 14, 17, 17) | 2 (2 to 2) | 2 (2 to 11) | 2 (2 to 2) | 2 (2 to 4) |
| IL-4 1 month after vax (n= 22, 21, 21, 15, 18, 17) | 2 (2 to 16) | 4 (2 to 28) | 2 (2 to 7) | 2 (2 to 24) |

| End point values | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 60 mcg | | |
|--|--------------------------------|-------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 17 | | |
| Units: SFC/million PBMCs | | | | |
| median (full range (min-max)) | | | | |
| INF gamma before vax (n=23, 19, 22, 14, 17, 17) | 41 (10 to 336) | 10 (10 to 79) | | |
| INF gamma 1 month after vax (n=22,21,21,15,18,17) | 187 (10 to 780) | 45 (10 to 184) | | |
| IL-4 before vax (n=23, 19, 22, 14, 17, 17) | 2 (2 to 5) | 2 (2 to 4) | | |
| IL-4 1 month after vax (n= 22, 21, 21, 15, 18, 17) | 2 (2 to 15) | 2 (2 to 13) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Local reactions and systemic events: Within 7 days after vaccination. SAEs and other AEs: up to 6-month follow-up visit after Day 1

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE but what is presented are distinct events. An event may be categorised as serious in one participant and nonserious in another participant or one participant may have experienced both serious and non-serious event. Safety population included all enrolled participants who received study intervention.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 26.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------------------|
| Reporting group title | Healthy RSVpreF 120 mcg |
|-----------------------|-------------------------|

Reporting group description:

Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

| | |
|-----------------------|---------------------------|
| Reporting group title | High Risk RSVpreF 120 mcg |
|-----------------------|---------------------------|

Reporting group description:

High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

| | |
|-----------------------|-------------------------------|
| Reporting group title | 2 to < 5 Years RSVpreF 60 mcg |
|-----------------------|-------------------------------|

Reporting group description:

Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

| | |
|-----------------------|------------------------|
| Reporting group title | Healthy RSVpreF 60 mcg |
|-----------------------|------------------------|

Reporting group description:

Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

| | |
|-----------------------|--------------------------|
| Reporting group title | High Risk RSVpreF 60 mcg |
|-----------------------|--------------------------|

Reporting group description:

High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

| | |
|-----------------------|--------------------------------|
| Reporting group title | 2 to < 5 Years RSVpreF 120 mcg |
|-----------------------|--------------------------------|

Reporting group description:

Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

| Serious adverse events | Healthy RSVpreF 120 mcg | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 60 mcg |
|---|----------------------------|------------------------------|----------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 1 / 23 (4.35%) | 0 / 20 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Immune system disorders | | | |
| Food allergy | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 25 (0.00%) | 1 / 23 (4.35%) | 0 / 20 (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 | | | |
| Asthma | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 23 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Healthy RSVpreF 60 mcg | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 120 mcg |
|--|------------------------|--------------------------|--------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 18 (5.56%) | 0 / 24 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Immune system disorders | | | |
| Food allergy | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 18 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |
| Asthma | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 18 (5.56%) | 0 / 24 (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: 5 %

| Non-serious adverse events | Healthy RSVpreF 120 mcg | High Risk RSVpreF 120 mcg | 2 to < 5 Years RSVpreF 60 mcg |
|--|-------------------------|---------------------------|-------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 17 / 25 (68.00%) | 15 / 23 (65.22%) | 13 / 20 (65.00%) |
| Injury, poisoning and procedural complications | | | |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 23 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |

| | | | |
|---|------------------------|------------------------|----------------------|
| Headache (HEADACHE) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 7 / 25 (28.00%) 7 | 8 / 23 (34.78%) 8 | 0 / 20 (0.00%) 0 |
| Syncope subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| General disorders and administration site conditions | | | |
| Axillary pain subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Fatigue subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 2 / 23 (8.70%) 2 | 0 / 20 (0.00%) 0 |
| Fatigue (FATIGUE) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 8 / 25 (32.00%) 8 | 10 / 23 (43.48%) 10 | 7 / 20 (35.00%) 7 |
| Injection site erythema subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 2 / 23 (8.70%) 2 | 0 / 20 (0.00%) 0 |
| Injection site pain subjects affected / exposed occurrences (all) | 2 / 25 (8.00%) 2 | 3 / 23 (13.04%) 3 | 0 / 20 (0.00%) 0 |
| Injection site pain (PAIN AT INJECTION SITE) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 12 / 25 (48.00%) 12 | 11 / 23 (47.83%) 11 | 3 / 20 (15.00%) 3 |
| Injection site swelling subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| Pyrexia (FEVER) | | | |

| | | | |
|--|----------------------|---------------------|----------------------|
| alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 1 / 23 (4.35%) 1 | 1 / 20 (5.00%) 1 |
| Swelling (SWELLING) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 3 / 25 (12.00%) 3 | 2 / 23 (8.70%) 2 | 1 / 20 (5.00%) 1 |
| Immune system disorders Food allergy subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Diarrhoea (DIARRHEA) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 1 / 25 (4.00%) 1 | 2 / 23 (8.70%) 2 | 0 / 20 (0.00%) 0 |
| Vomiting (VOMITING) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 2 / 20 (10.00%) 2 |
| Skin and subcutaneous tissue disorders Erythema (REDNESS) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 6 / 25 (24.00%) 6 | 2 / 23 (8.70%) 2 | 1 / 20 (5.00%) 1 |
| Musculoskeletal and connective tissue disorders Arthralgia (JOINT PAIN) alternative assessment type: Systematic subjects affected / exposed occurrences (all) | 2 / 25 (8.00%) 2 | 1 / 23 (4.35%) 1 | 0 / 20 (0.00%) 0 |
| Myalgia | | | |

| | | | |
|---|----------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Myalgia (MUSCLE PAIN) alternative assessment type: Systematic | | | |
| subjects affected / exposed occurrences (all) | 5 / 25 (20.00%) 5 | 9 / 23 (39.13%) 9 | 0 / 20 (0.00%) 0 |
| Infections and infestations | | | |
| Gastroenteritis viral | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| COVID-19 | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Viral infection | | | |
| subjects affected / exposed occurrences (all) | 0 / 25 (0.00%) 0 | 0 / 23 (0.00%) 0 | 1 / 20 (5.00%) 1 |

| Non-serious adverse events | Healthy RSVpreF 60 mcg | High Risk RSVpreF 60 mcg | 2 to < 5 Years RSVpreF 120 mcg |
|---|------------------------|--------------------------|--------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 12 / 17 (70.59%) | 14 / 18 (77.78%) | 9 / 24 (37.50%) |
| Injury, poisoning and procedural complications | | | |
| Skin laceration | | | |
| subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 1 / 18 (5.56%) 1 | 0 / 24 (0.00%) 0 |
| Nervous system disorders | | | |
| Headache (HEADACHE) alternative assessment type: Systematic | | | |
| subjects affected / exposed occurrences (all) | 7 / 17 (41.18%) 7 | 6 / 18 (33.33%) 6 | 1 / 24 (4.17%) 1 |
| Syncope | | | |
| subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 1 / 18 (5.56%) 1 | 0 / 24 (0.00%) 0 |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 1 / 18 (5.56%) 1 | 0 / 24 (0.00%) 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| Fatigue | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 18 (5.56%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 8 / 17 (47.06%) | 9 / 18 (50.00%) | 7 / 24 (29.17%) |
| occurrences (all) | 8 | 9 | 7 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 18 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 18 (5.56%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Injection site pain (PAIN AT INJECTION SITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 7 / 17 (41.18%) | 10 / 18 (55.56%) | 2 / 24 (8.33%) |
| occurrences (all) | 7 | 10 | 2 |
| Injection site swelling | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 18 (5.56%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 18 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 2 / 18 (11.11%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 2 | 1 |
| Swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 4 / 18 (22.22%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 4 | 1 |
| Immune system disorders | | | |
| Food allergy | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 18 (5.56%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 18 (5.56%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Diarrhoea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 18 (5.56%) | 3 / 24 (12.50%) |
| occurrences (all) | 0 | 1 | 3 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 18 (5.56%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 2 / 18 (11.11%) | 3 / 24 (12.50%) |
| occurrences (all) | 1 | 2 | 3 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 18 (11.11%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 18 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 17 (23.53%) | 7 / 18 (38.89%) | 0 / 24 (0.00%) |
| occurrences (all) | 4 | 7 | 0 |
| Infections and infestations | | | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 18 (5.56%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 18 (5.56%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---------------------|---------------------|---------------------|
| Viral infection subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 1 / 18 (5.56%) 1 | 1 / 24 (4.17%) 1 |
|---|---------------------|---------------------|---------------------|

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 09 February 2024 | Added the clinicaltrials.gov reference and sponsor legal address to the title page. Removed Phase 2/3 content. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date | Interruption | Restart date |
|--------------|---|----------------|
| 28 July 2023 | The study was interrupted due to reports of study intervention dosing errors at some investigational sites. The study was resumed after the site staff were retrained in preparation of study intervention. | 08 August 2023 |

Notes:

Limitations and caveats

None reported