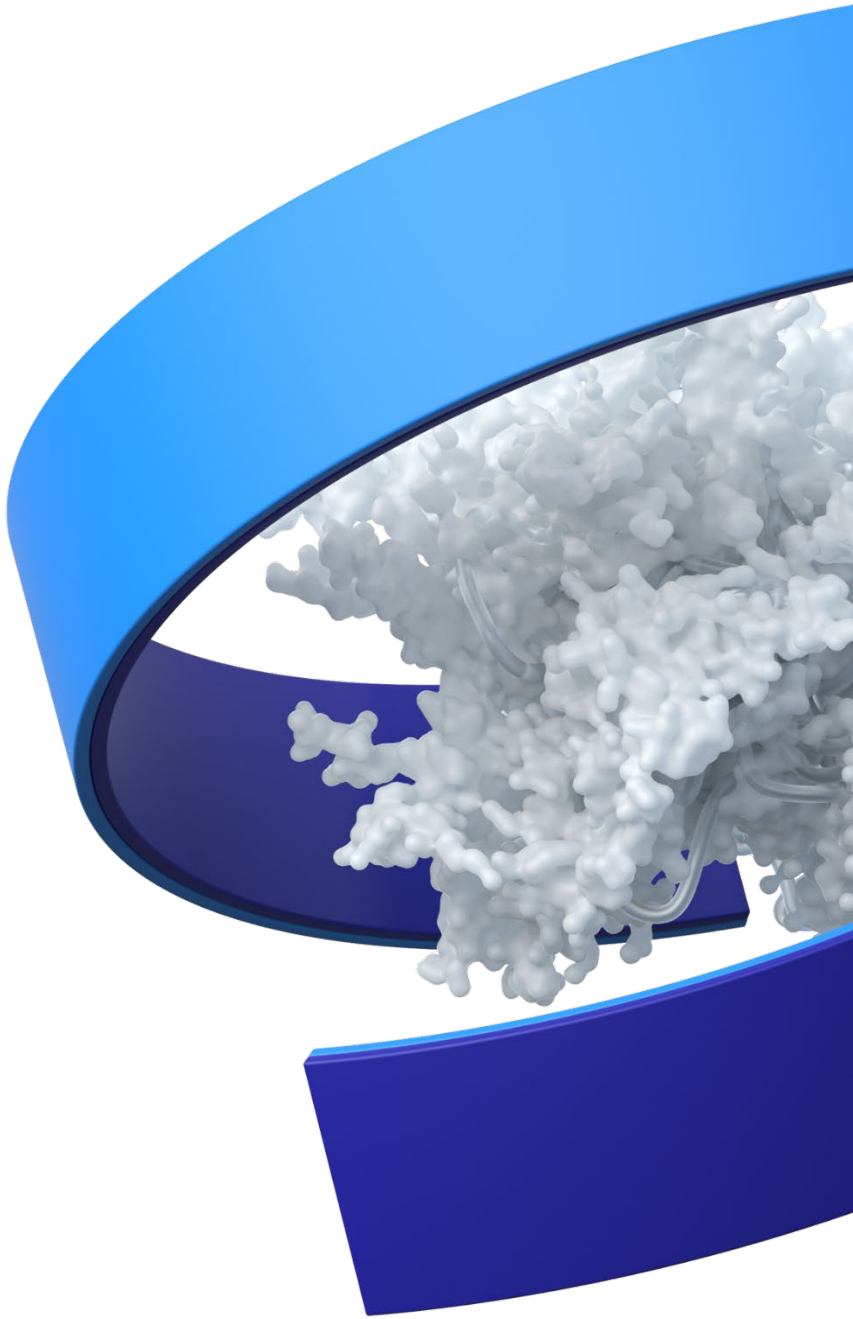
# Safety and Efficacy of Bivalent RSV Prefusion F Vaccine in Vaccinated Mothers and their Infants

Iona Munjal, MD

Senior Director, Vaccine Research and Development



# Bivalent RSV Prefusion F Vaccine

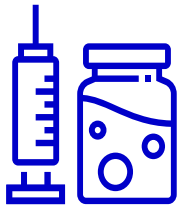
## Proposed Indication:

**Prevention of lower respiratory tract disease and severe lower respiratory tract disease caused by respiratory syncytial virus (RSV)**

**Infants from birth through 6 months of age by active immunization of pregnant individuals**

**DOSE LEVEL**

- **120 µg without an adjuvant**
- **Dose contains 60 µg dose of each prefusion protein antigen, in a 0.5 mL injection**



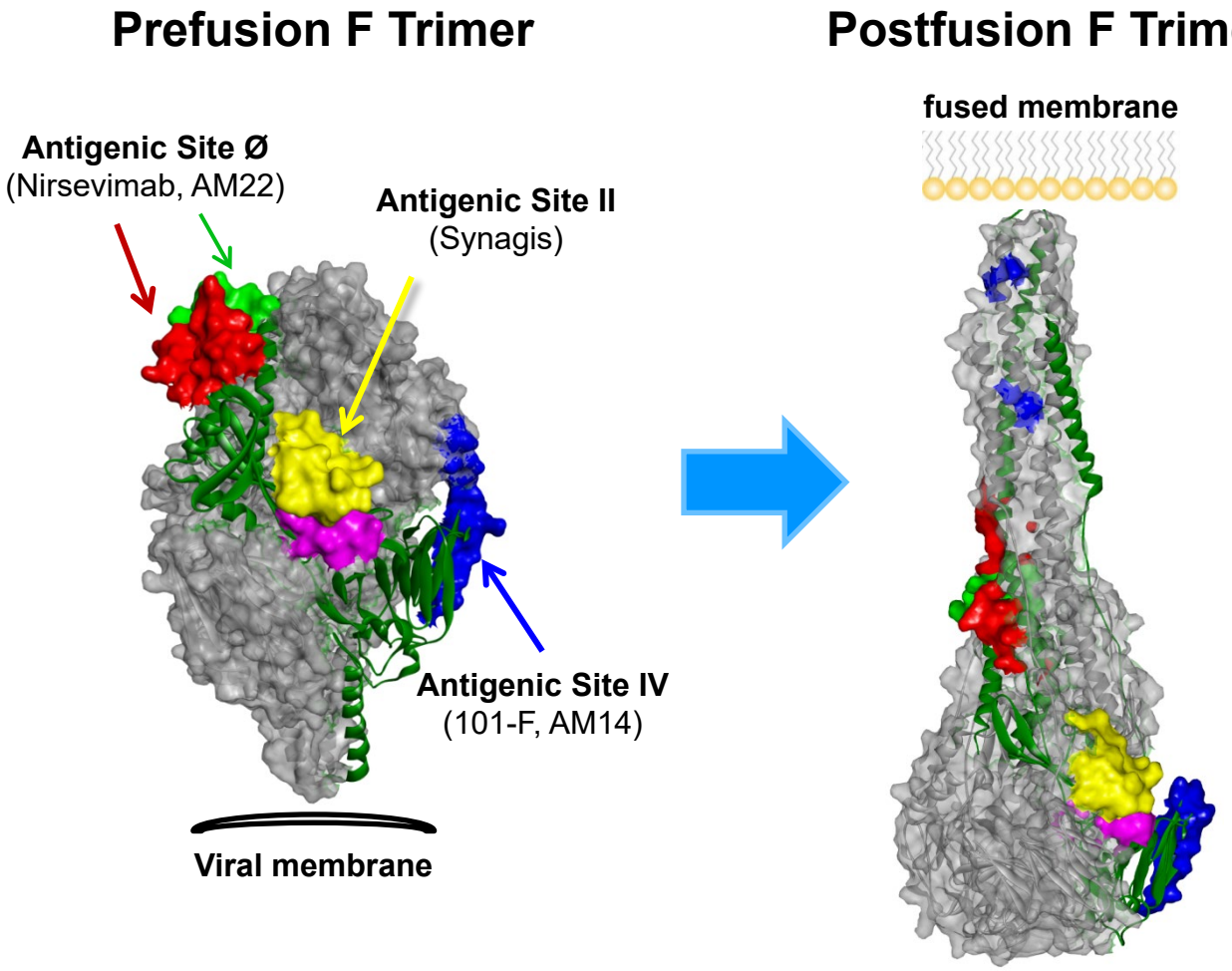
**PRESENTATION**

- **Single dose 2 mL vial**
- **1 mL Pre-filled syringe**
- **Vial adaptor**

**STORAGE**

- **Refrigeration at 2°C to 8°C**

# Groundbreaking Structural Work by NIH Elucidated that RSV F on the Virus Exists as an Unstable Prefusion Form




**Only prefusion F can bind host cells for RSV to infect**

**Antibodies specific to the prefusion form are most effective at blocking virus infection**



McLellan et al. *Science*, Nov 2013

# Pfizer's RSVpreF Maternal Immunization Clinical Development Program

| | | 2018 | 2019 | 2020 | 2021 | 2022+ |
|---|---|---|---|---|---|---|
| **Phase 1/2 First-in-Human**[1] | Adults 18-85y<br>Dose Ranging<br>+/- $Al(OH)_3$ +/- Influenza | | | | | |
| **Phase 2b**[2] | **Pregnant Women** 18–49y<br>Safety and Immunogenicity<br>Early Efficacy | SAVVY | | | | |
| **Phase 2b**[3] | Nonpregnant Women 18–49y<br>Concomitant Tdap | | | | | |
| **Phase 3**[4] | Adults 18-49y<br>Lot Consistency Study | | | | | |
| **Phase 3**[5] | **Pregnant Women** ≤49y<br>Pivotal Efficacy | Matisse | | | | |

1. A Study to Describe the Safety and Immunogenicity of a RSV Vaccine in Healthy Adults. NCT03529773.
2. A Phase 2b Placebo-Controlled, Randomized Study of an RSV Vaccine in Pregnant Women. NCT04032093.
3. A Study of an RSV Vaccine When Given Together with Tdap in Healthy Nonpregnant Women Aged Between 18 to 49 Years. NCT04071158.
4. Clinical Lot Consistency for RSVpreF in a Population of Healthy Adults 18 to ≤49 Years of Age. NCT05096208.
5. A Trial to Evaluate the Efficacy and Safety of RSVpreF in Infants Born to Women Vaccinated During Pregnancy. NCT04424316.

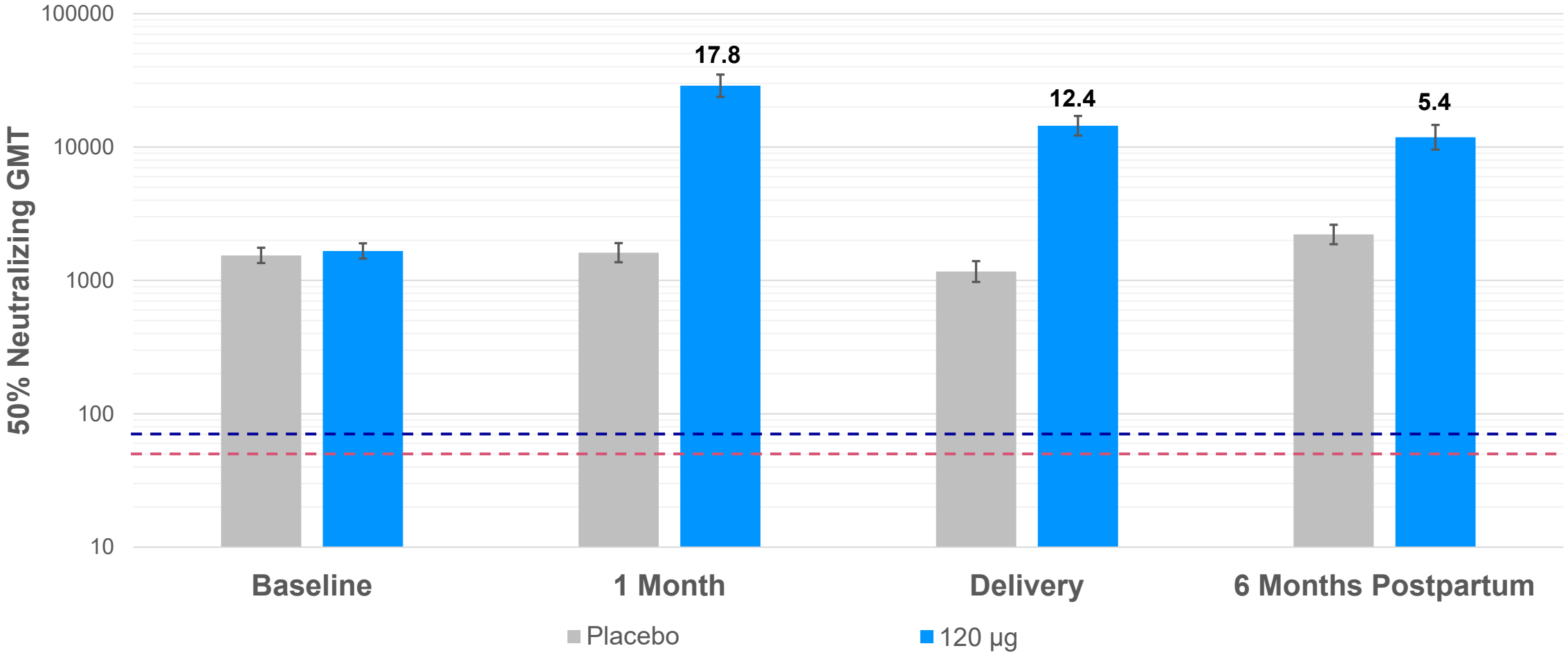
# Pfizer's RSVpreF Maternal Immunization Clinical Development Program

| | | 2018 | 2019 | 2020 | 2021 | 2022+ |
|---|---|---|---|---|---|---|
| Phase 1/2 First-in-Human[1] | Adults 18-85y<br>Dose Ranging<br>+/- $Al(OH)_3$ +/- Influenza | | | | | |
| **Phase 2b[2]** | **Pregnant Women** 18–49y<br>Safety and Immunogenicity<br>Early Efficacy | SAVVY | | | | |
| Phase 2b[3] | Nonpregnant Women 18-49y<br>Concomitant Tdap | | | | | |
| Phase 3[4] | Adults 18-49y<br>Lot Consistency Study | | | | | |
| **Phase 3[5]** | **Pregnant Women** ≤49y<br>Pivotal Efficacy | Matisse | | | | |

1. A Study to Describe the Safety and Immunogenicity of a RSV Vaccine in Healthy Adults. NCT03529773.
2. A Phase 2b Placebo-Controlled, Randomized Study of an RSV Vaccine in Pregnant Women. NCT04032093.
3. A Study of an RSV Vaccine When Given Together with Tdap in Healthy Nonpregnant Women Aged Between 18 to 49 Years. NCT04071158.
4. Clinical Lot Consistency for RSVpreF in a Population of Healthy Adults 18 to ≤49 Years of Age. NCT05096208.
5. A Trial to Evaluate the Efficacy and Safety of RSVpreF in Infants Born to Women Vaccinated During Pregnancy. NCT04424316.

# RSVpreF Elicits Maternal Neutralizing Titer with GMR >12 at Delivery*

**Phase 2b Combined A/B 50% Neutralization Geometric Mean Titers & Geometric Mean Ratio vs. Placebo – in Maternal Participants at Baseline (24-36 weeks GA), 1M (if Delivery had not Occurred), Delivery and Postpartum; All Evaluable (N=116 participants)**

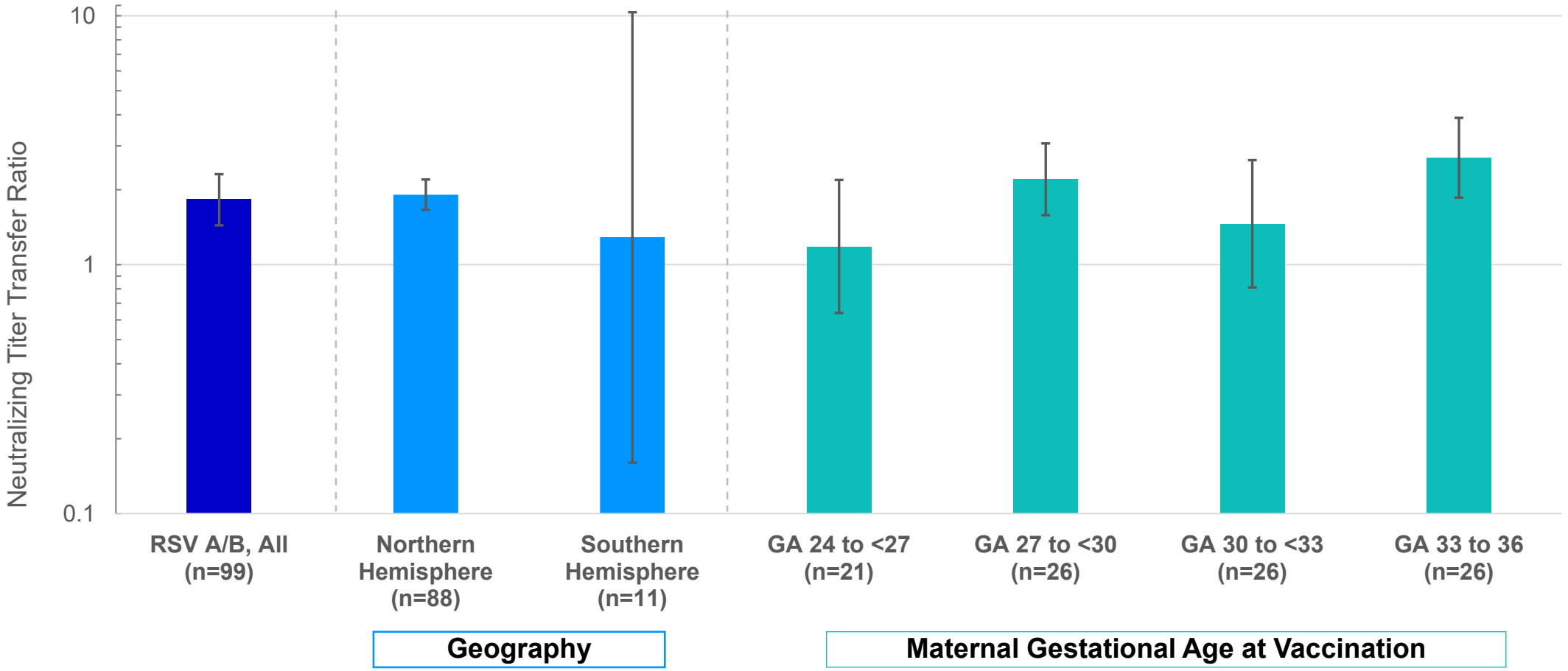



Lower Limit of Quantification (LLOQ), RSV A - - - - - LLOQ, RSV B - - - - -

**Mean time from vaccination to delivery, 61.4 days*

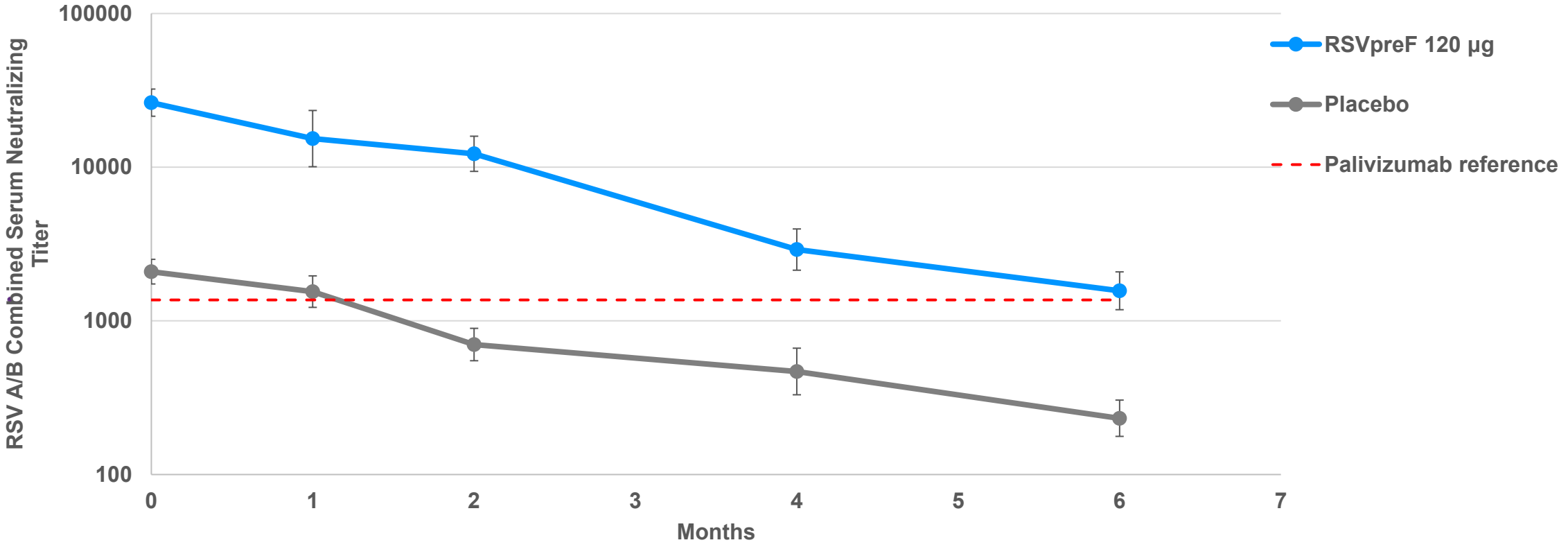
# Transplacental Transfer Ratios >1 Overall and by Geography and Gestational Age

## Combined RSV A/B 50% Neutralization Antibody Infant v. Maternal Ratio for Phase 3 selected dose Evaluable Population, RSVpreF Groups (N=99)



# Infant Neutralizing Titers Remain High Through 6 Months

RSV A/B Combined 50% Geometric Mean Neutralizing Titers by Month in Infants born to Mothers Vaccinated at 24-36 weeks




*Palivizumab reference line = 50% A/B neutralizing titer of a 100ug/mL palivizumab dose, demonstrated to be efficacious in preventing infant RSV-associated ICU admission (Forbes ML, Kumar VR, Yogev R, et al. Hum Vaccin Immunother 2014;10:2789-94.)*

# Pfizer's RSVpreF Maternal Immunization Clinical Development Program

| | | 2018 | 2019 | 2020 | 2021 | 2022+ |
|---|---|---|---|---|---|---|
| Phase 1/2 First-in-Human[1] | Adults 18-85y<br>Dose Ranging<br>+/- $Al(OH)_3$ +/- Influenza | | | | | |
| **Phase 2b[2]** | **Pregnant Women** 18–49y<br>Safety and Immunogenicity<br>Early Efficacy | SAVVY | | | | |
| Phase 2b[3] | Nonpregnant Women 18-49y<br>Concomitant Tdap | | | | | |
| Phase 3[4] | Adults 18-49y<br>Lot Consistency Study | | | | | |
| **Phase 3[5]** | **Pregnant Women** ≤49y<br>Pivotal Efficacy | Matisse | | | | |

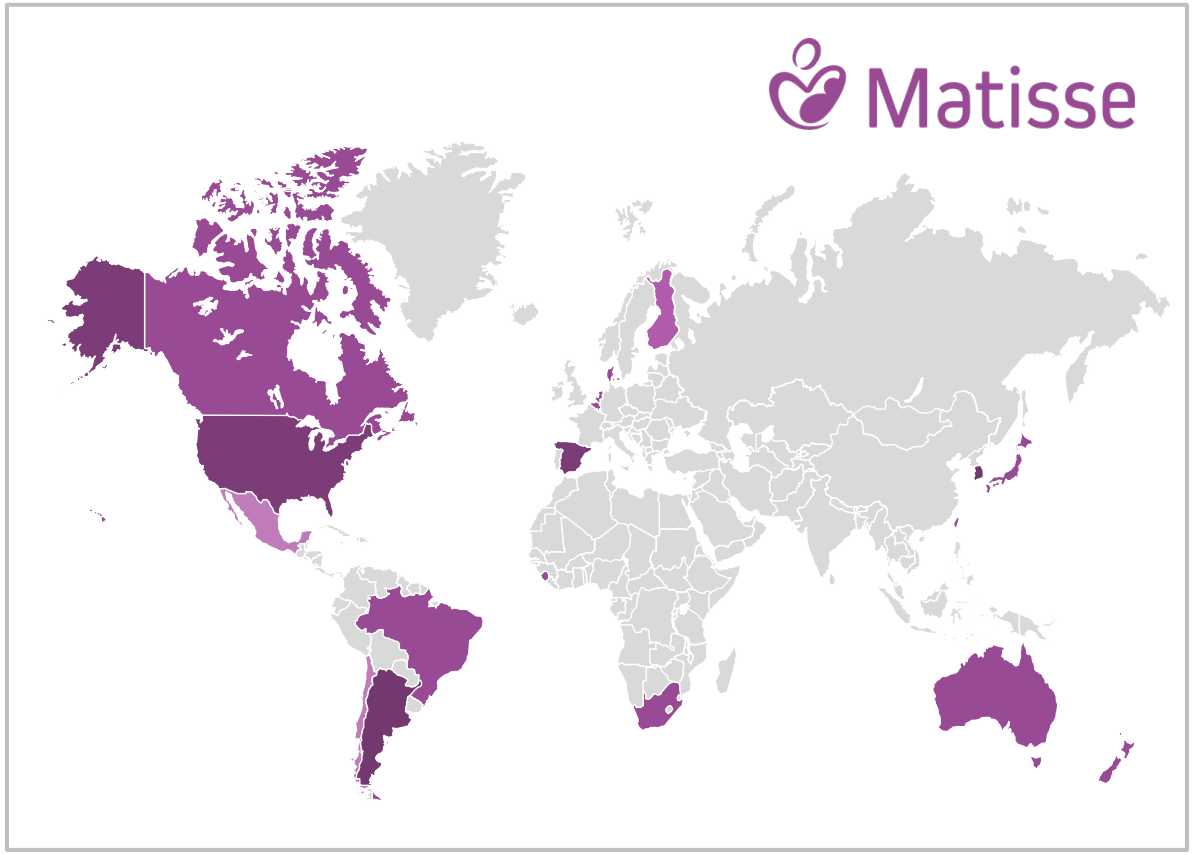
1. A Study to Describe the Safety and Immunogenicity of a RSV Vaccine in Healthy Adults. NCT03529773.
2. A Phase 2b Placebo-Controlled, Randomized Study of an RSV Vaccine in Pregnant Women. NCT04032093.
3. A Study of an RSV Vaccine When Given Together with Tdap in Healthy Nonpregnant Women Aged Between 18 to 49 Years. NCT04071158.
4. Clinical Lot Consistency for RSVpreF in a Population of Healthy Adults 18 to ≤49 Years of Age. NCT05096208.
5. A Trial to Evaluate the Efficacy and Safety of RSVpreF in Infants Born to Women Vaccinated During Pregnancy. NCT04424316.

# MATISSE: A Phase 3 Trial to Evaluate the Efficacy and Safety of RSVpreF in Infants Born to Women Vaccinated During Pregnancy

**7,392 Maternal Participants in 18 Countries**
**Randomized 1:1 RSVpreF 120µg or Placebo**

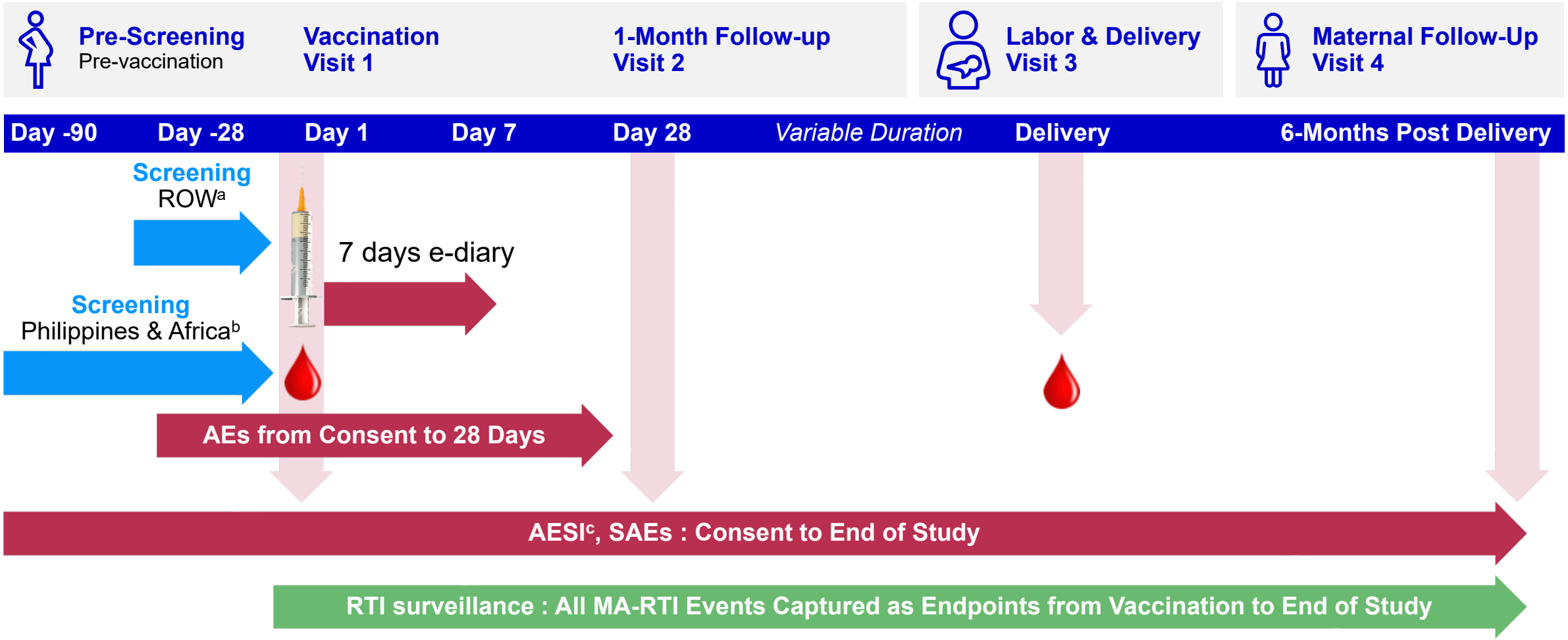
**Pregnant persons ≤49 years between ≥24 and ≤36 weeks gestation**

**7,128 Infants enrolled**




A Trial to Evaluate the Efficacy and Safety of RSVpreF in Infants Born to Women Vaccinated During Pregnancy. NCT04424316.

# Maternal Immunogenicity & Safety Assessment Timeline



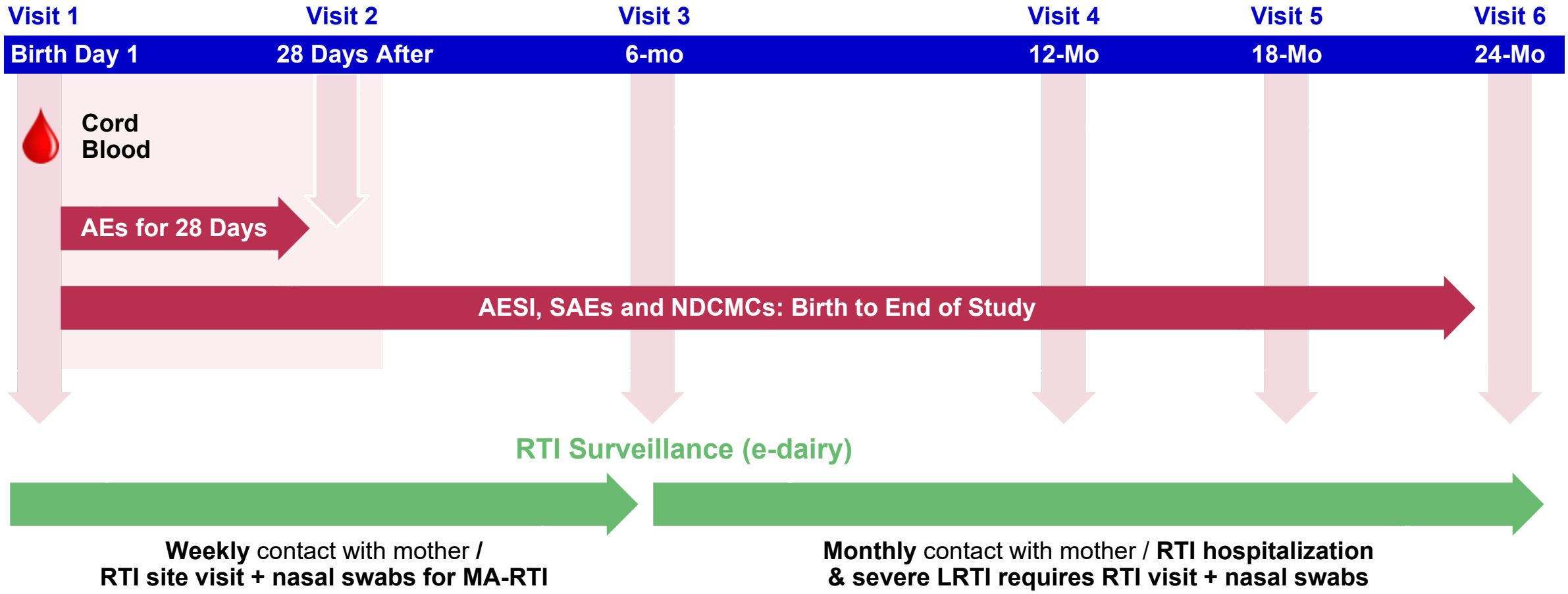

a. Screening bloods and fetal anomaly ultrasound (if not standard of care); ROW, Rest of World
b. Fetal dating and dating ultrasounds (if not standard of care).
c. AESI (AE of Special Interest including preterm delivery and asymptomatic SARS-CoV-2 test positive).

# Infant Efficacy, Immunogenicity & Safety Assessment Timeline

**Delivery & Infant RTI Surveillance Period***
*Starts 72 hours after delivery

**12-Mo Follow-up for All Infants**

**24-mo Follow-up for Infants Born in Study-year 1**




AESI (AE of Special Interest including preterm birth, low birth weight, developmental delay, and asymptomatic SARS-CoV-2 test positive)
SAE (Serious Adverse Event)
NDCMC (Newly Diagnosed Chronic Medical Condition)

# Demographic Characteristics
(Maternal Safety Population)

| | RSVpreF 120 µg (N[a]=3682); n (%) | Placebo (N[a]=3675); n (%) | Total (N[a]=7357); n (%) |
|---|---|---|---|
| **Race** | | | |
| White | 2383 (64.7) | 2365 (64.4) | 4748 (64.5) |
| Black or African American | 720 (19.6) | 723 (19.7) | 1443 (19.6) |
| Asian | 454 (12.3) | 464 (12.6) | 918 (12.5) |
| American Indian or Alaskan Native | 38 (1.0) | 37 (1.0) | 75 (1.0) |
| Native Hawaiian or Other Pacific Islander | 9 (0.2) | 12 (0.3) | 21 (0.3) |
| Multiracial | 30 (0.8) | 21 (0.6) | 51 (0.7) |
| **Ethnicity** | | | |
| Hispanic/Latino | 1049 (28.5) | 1075 (29.3) | 2124 (28.9) |

a. N = number of participants in the specified vaccine group. This value is the denominator for the percentage calculations.
b. n = Number of participants in the specified category.

# Demographic Characteristics (continued 2/2)
(Maternal Safety Population)

| | RSVpreF 120 µg (N[a]=3682); n (%) | Placebo (N[a]=3675); n (%) | Total (N[a]=7357); n (%) |
|---|---|---|---|
| **Age at Vaccination (years)** | | | |
| N | 3682 | 3675 | 7357 |
| Mean (SD) | 29.1 (5.64) | 29.0 (5.74) | 29.0 (5.69) |
| Median (Range) | 29.0 (16–45) | 29.0 (14–47) | 29.0 (14–47) |
| **Gestational Age (GA) at Vaccination*** | | | |
| ≥24 weeks to <28 weeks | 941 (25.6) | 909 (24.7) | 1850 (25.1) |
| ≥28 weeks to <32 weeks | 1085 (29.5) | 1128 (30.7) | 2213 (30.1) |
| ≥32 weeks to ≤36 weeks | 1653 (44.9) | 1632 (44.4) | 3285 (44.7) |
| >36 weeks | 3 (<0.1) | 6 (0.2) | 9 (0.1) |

*Average GA at vaccination = 30 weeks

Note: One participant is counted under ≥24 weeks to <28 weeks however actual age was 23 weeks 6 days.
a. N = number of participants in the specified vaccine group. This value is the denominator for the percentage calculations.
b. n = Number of participants in the specified category.

# Demographic Characteristics
(Infant Safety Population)

| | RSVpreF 120 µg (N[a]=3568); n (%) | Placebo (N[a]=3558); n (%) | Total (N[a]=7126); n (%) |
|---|---|---|---|
| **Sex** | | | |
| Male | 1816 (50.9) | 1793 (50.4) | 3609 (50.6) |
| Female | 1752 (49.1) | 1765 (49.6) | 3517 (49.4) |
| **Race** | | | |
| White | 2294 (64.3) | 2284 (64.2) | 4578 (64.2) |
| Black or African American | 687 (19.3) | 688 (19.3) | 1375 (19.3) |
| Asian | 420 (11.8) | 430 (12.1) | 850 (11.9) |
| American Indian or Alaskan Native | 42 (1.2) | 36 (1.0) | 78 (1.1) |
| Native Hawaiian or other Pacific Islander | 13 (0.4) | 11 (0.3) | 24 (0.3) |
| Multiracial | 65 (1.8) | 59 (1.7) | 124 (1.7) |
| **Ethnicity** | | | |
| Hispanic/Latino | 1033 (29.0) | 1039 (29.2) | 2072 (29.1) |

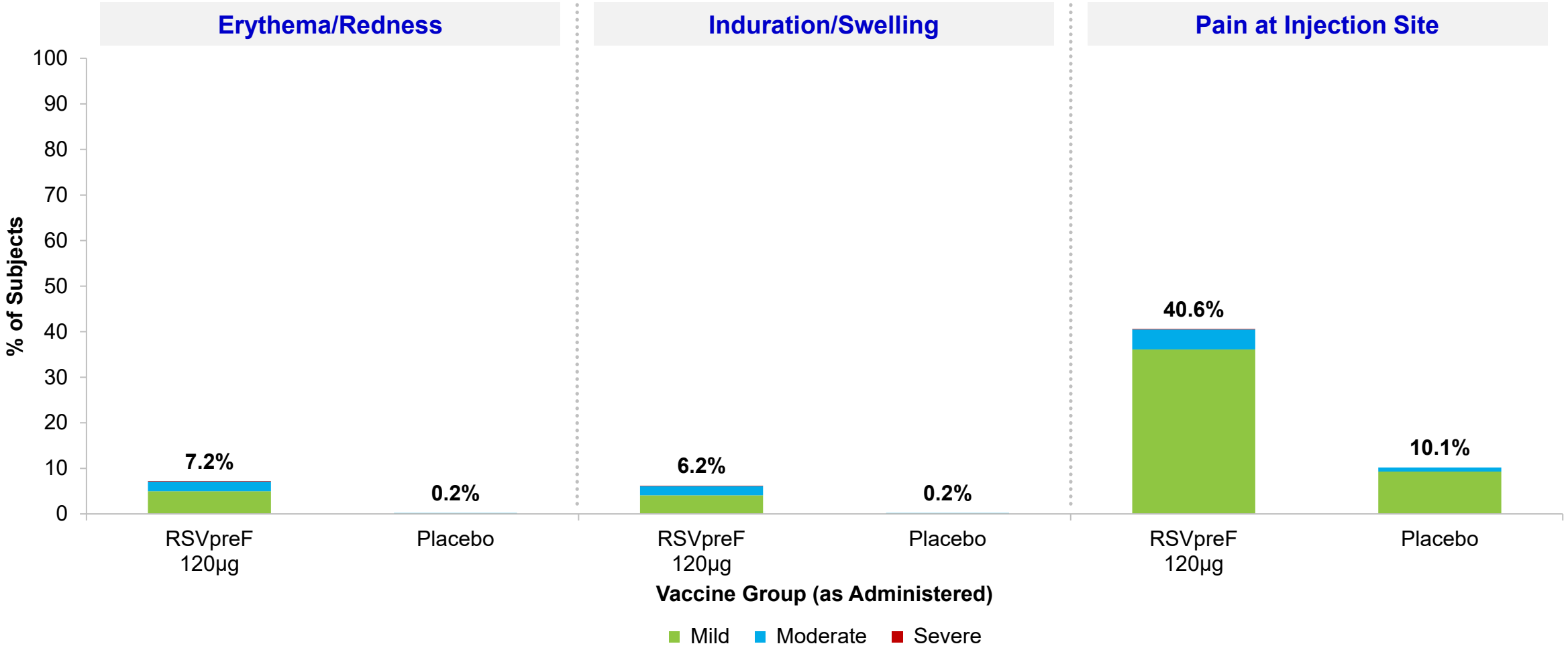
a. N = number of participants in the specified vaccine group. This value is the denominator for the percentage calculations.
b. n = Number of participants in the specified category.

# Phase 3 Study Objectives

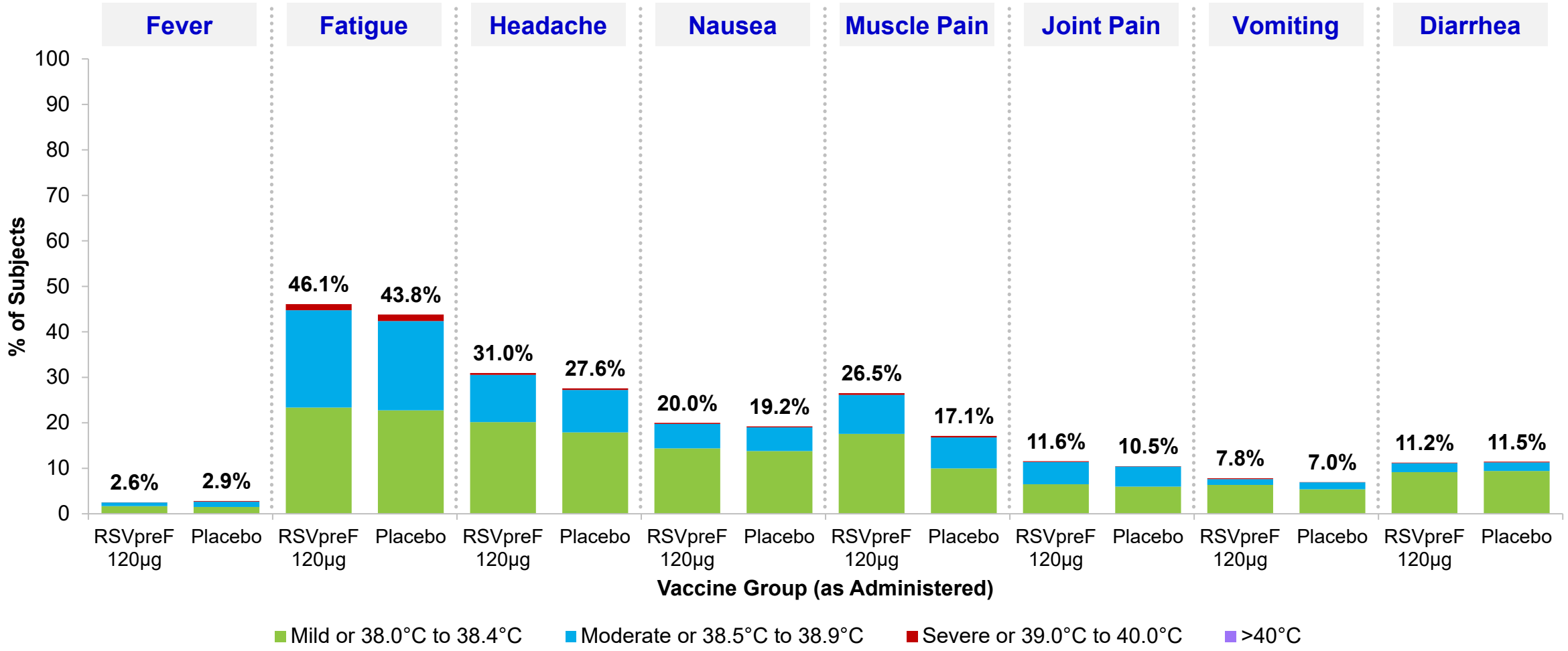
| | | |
|---|---|---|
| **Safety** | | • Describe the safety profile of RSVpreF<br>Local reactions and systemic events within 7 days post-vaccination<br>AEs through 1-month post-vaccination (Maternal)<br>AEs through 1-month after birth (Infant)<br>AESIs, SAEs (Maternal and Infant) and NDCMCs (Infant) throughout study |
| **Efficacy** | **Primary** | • Prevention of RSV MA-LRTI within 180 days after birth<br>• Prevention of RSV severe MA-LRTI within 180 days after birth |
| | **Secondary** | • Prevention of RSV MA-LRTIs within 360 days after birth<br>• Prevention of RSV hospitalization within 360 days after birth<br>• Prevention of MA-LRTIs due to any cause within 360 days after birth |

AE, adverse event; AESI, adverse event of special interest; NDCMC, newly diagnosed chronic medical condition; SAE, serious adverse event; MA, medically attended; LRTI, lower respiratory tract illness; RSV, respiratory syncytial virus

# Local Reactions, by Maximum Severity, within 7 Days After Vaccination Maternal Participants (n=7357)

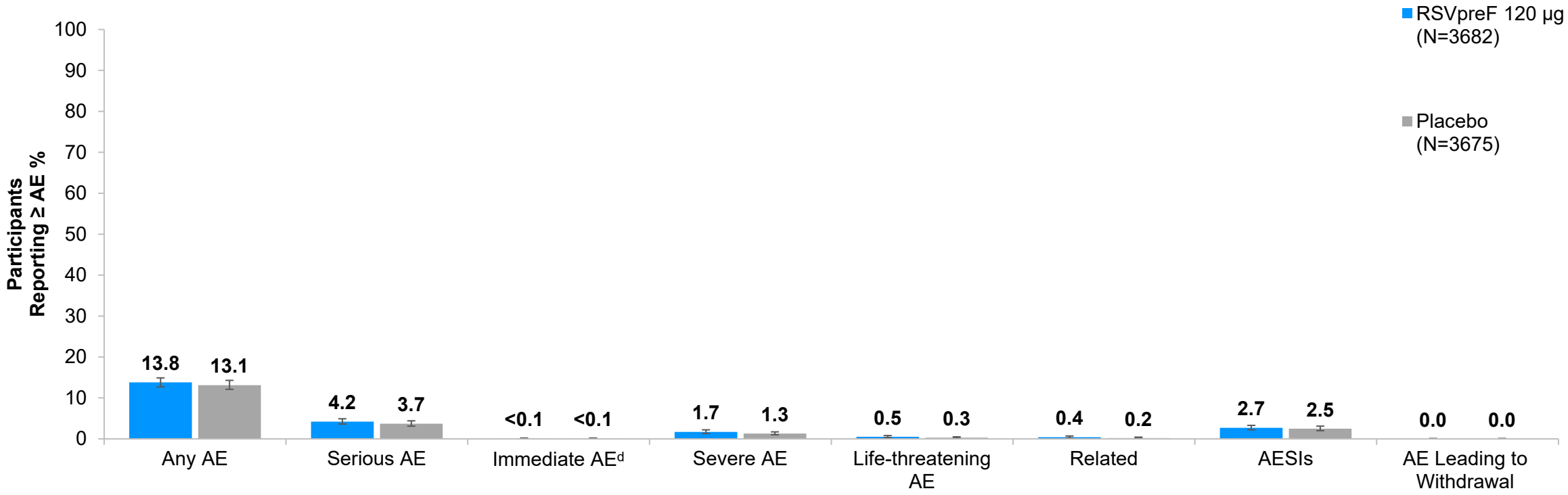


# Systemic Events, by Maximum Severity, Within 7 Days After Vaccination
## Maternal Participants (n=7357)



# Number (%) of Participants Reporting Adverse Events by Category Within 1 Month After Vaccination

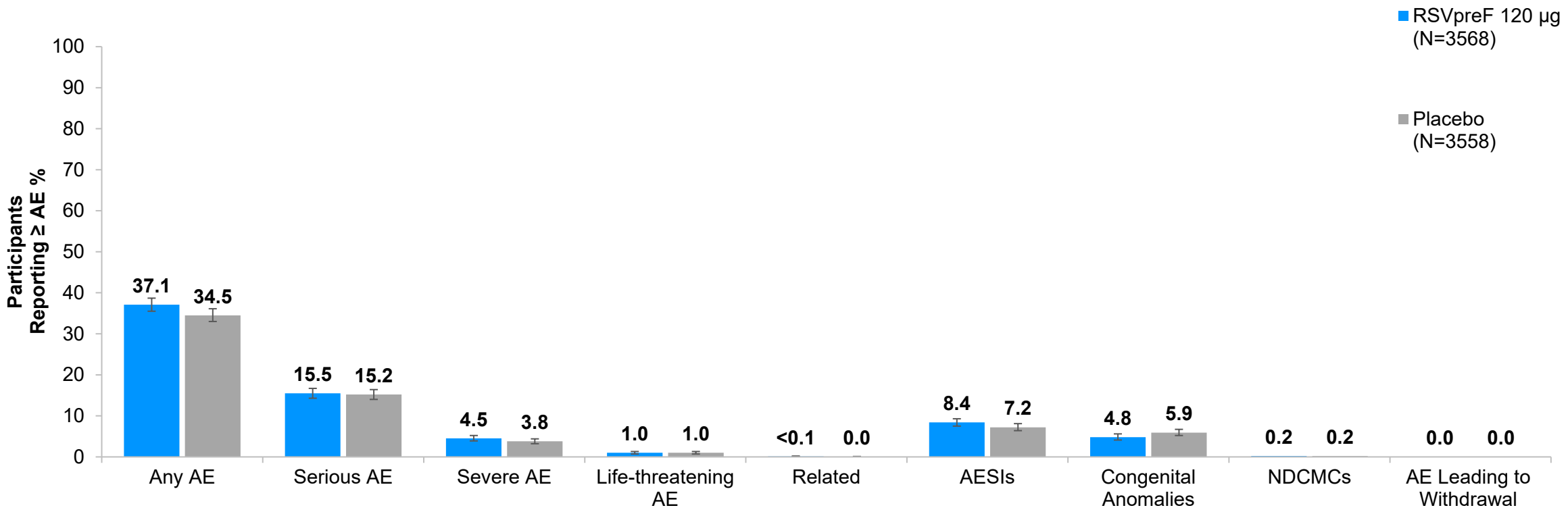
## Maternal Participants[a,b,c]




Abbreviations: AESIs = adverse events of special interest; NDCMCs = newly diagnosed chronic medical conditions.
Notes: The severity of the event is in the determination of the investigator. Per statistical analysis plan, 1 month after birth or 1 month after vaccination reflects a 30-day period. However, as per protocol, non-serious adverse events were only solicited through 28 days after birth/vaccination. AESIs and SAEs were solicited throughout the study for maternal participants.
a. N = number of participants in the specified vaccine group. This value is the denominator for the percentage calculations. b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event", n = number of participants reporting at least 1 occurrence of any adverse event. c. Exact 2-sided confidence interval (CI) calculated using the Clopper and Pearson method. d. An immediate AE is defined as any AE that occurred within the first 30 minutes after administration of the investigational product for maternal participants.

# Number (%) of Participants Reporting Adverse Events by Category Within 1 Month After Birth

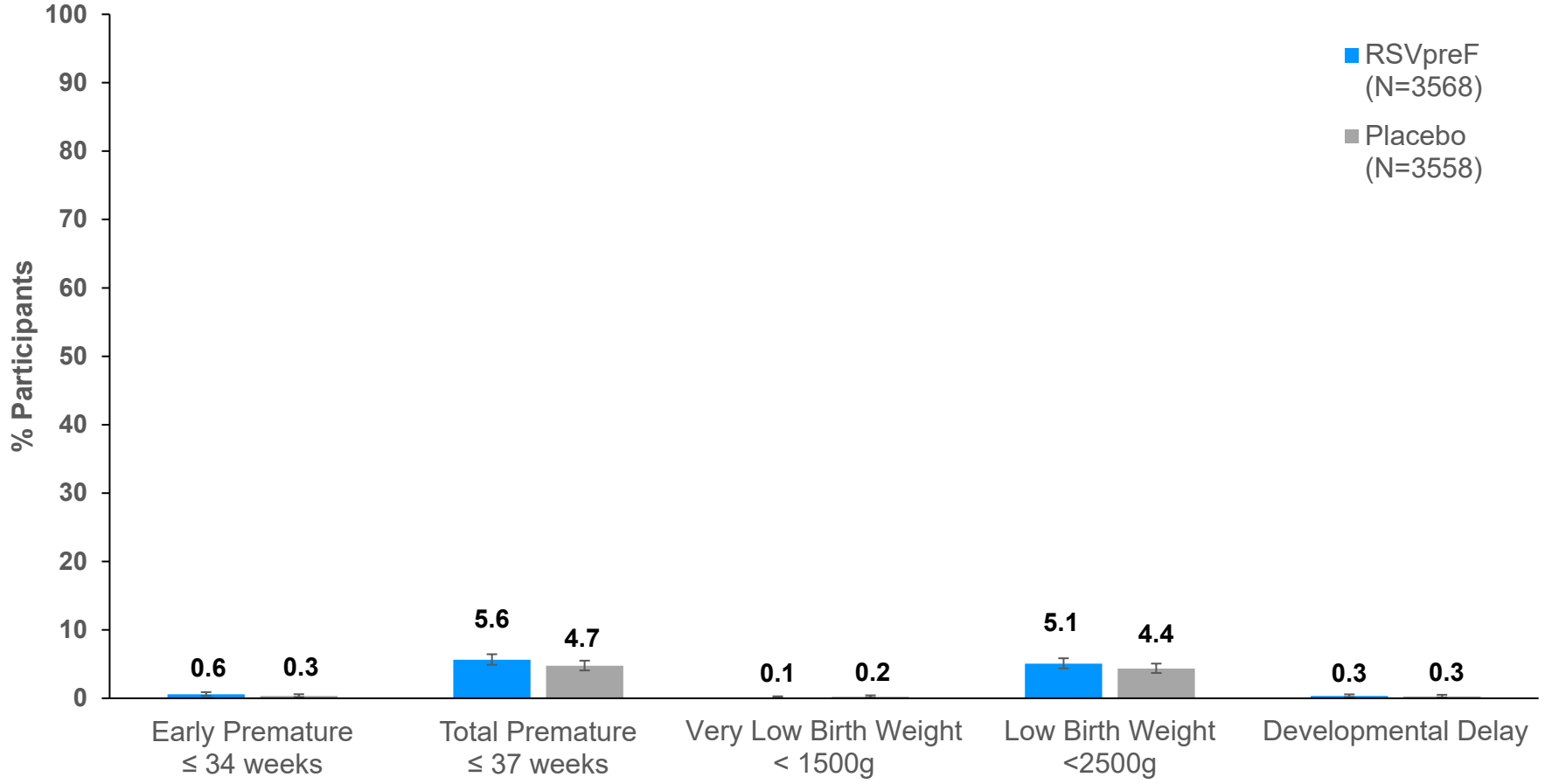
## Infant Participants[a,b,c]




Abbreviations: AESIs = adverse events of special interest; NDCMCs = newly diagnosed chronic medical conditions.
Notes: The severity of the event is in the determination of the investigator. Per statistical analysis plan, 1 month after birth or 1 month after vaccination reflects a 30-day period. However, as per protocol, non-serious adverse events were only solicited through 28 days after birth/vaccination. AESIs and SAEs were solicited throughout the study for maternal participants.
a. N = number of participants in the specified vaccine group. This value is the denominator for the percentage calculations. b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event", n = number of participants reporting at least 1 occurrence of any adverse event. c. Exact 2-sided confidence interval (CI) calculated using the Clopper and Pearson method. d. An immediate AE is defined as any AE that occurred within the first 30 minutes after administration of the investigational product for maternal participants.

# Birth Outcomes and Developmental Delay – Infant Participants

## Infant Participants with Prematurity, Low Birth Weight, or Developmental Delay (Adverse Events of Special Interest)



# Deaths and Fetal Losses Reported in the Trial (all unrelated)

| | Event Type | RSVpreF 120 µg (N=3682) | Placebo (N=3675) |
|---|---|---|---|
| **Maternal Death: n = 1** | | | |
| • 1 in a maternal participant who received RSVpreF | Maternal Death | 1 (<0.1%) | 0 |
| **Fetal Demise: n = 18** | | | |
| • 18 fetal demises in maternal participants who received Vaccine/Placebo | Fetal death or stillbirth | 10 (0.3%) | 8 (0.2%) |

| | Event Type | RSVpreF 120 µg (N=3568) | Placebo (N=3558) |
|---|---|---|---|
| **Infant Death: n = 17** | | | |
| • 16 due to various causes<br>• 1 infant adjudicated “Acute Respiratory Illness due to RSV” (placebo group) | Infant Death | 5 (0.1%) | 12 (0.3%) |

# *MATISSE*
## Infant Efficacy Endpoints

# Phase 3 Efficacy Endpoints Defined

**Weekly active surveillance for ARI symptoms**
Symptoms trigger nasal swab and possibly a visit

| Primary Endpoints | Criteria |
|---|---|
| **Medically attended RSV LRTI** | Medically attended visit **and ≥1**:<br>• tachypnea (RR ≥60 (<2 m [60 days]) or ≥50 (≥2 to 12 m)<br>• peripheral capillary oxygen saturation (SpO2) measured in room air <95%<br>• chest wall indrawing |
| **Medically attended severe RSV LRTI** | Medically attended visit **and ≥1**:<br>• tachypnea (RR ≥70 (<2 m [60 days]) or ≥60 (≥2 to 12 m)<br>• SpO2 measured in room air <93%<br>• high-flow nasal cannula or mechanical ventilation<br>• ICU admission for >4 hours; unresponsive/unconscious |

**Positive validated RT-PCR** in central laboratory

Medically attended visit: Infant participant taken to or seen by a healthcare provider (e.g. outpatient or inpatient visit, emergency room, urgent care, or home visit)

LRTI: Lower respiratory tract illness; SpO2: peripheral capillary oxygen saturation

C3671008: https://clinicaltrials.gov/ct2/show/NCT04424316?term=C3671008&draw=2&rank=1

# Primary Endpoints:

Vaccine Efficacy by Cumulative Days after Birth for Two Primary Endpoints

| | Maternal Vaccine Group (as Randomized) | | |
|---|---|---|---|
| **RSV-Positive Severe MA-LRTI** | RSVpreF 120 µg (N[a]=3495) | Placebo (N[a]=3480) | |
| Time Interval | **Number of Cases (%)** | **Number of Cases (%)** | **Vaccine Efficacy[b] (%) (CI*)** |
| 90 Days after birth | 6 (0.2) | 33 (0.9) | 81.8 (40.6, 96.3) |
| 120 Days after birth | 12 (0.3) | 46 (1.3) | 73.9 (45.6, 88.8) |
| 150 Days after birth | 16 (0.5) | 55 (1.6) | 70.9 (44.5, 85.9) |
| 180 Days after birth | 19 (0.5) | 62 (1.8) | 69.4 (44.3, 84.1) |
| **RSV-Positive MA-LRTI** | | | |
| Time Interval | **Number of Cases (%)** | **Number of Cases (%)** | **Vaccine Efficacy[b] (%) (CI*)** |
| 90 Days after birth | 24 (0.7) | 56 (1.6) | 57.1 (14.7, 79.8) |
| 120 Days after birth | 35 (1.0) | 81 (2.3) | 56.8 (31.2, 73.5) |
| 150 Days after birth | 47 (1.3) | 99 (2.8) | 52.5 (28.7, 68.9) |
| 180 Days after birth | 57 (1.6) | 117 (3.4) | 51.3 (29.4, 66.8) |

*99.5% CI for 90 days, 97.58% CI for 120/150/180 days. CI LB >20% for all time points.

Abbreviations: RSV = respiratory syncytial virus. a. N = number of participants (at risk) in the specified group. These values are used as the denominators for the percentage calculations. b. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results.

# Secondary Endpoint: RSV-Positive MA-LRTIs within 360 Days After Birth

## RSV-Positive MA-LRTIs Occurring Within 360 Days After Birth Met Statistical Criteria for Success (CI LB>0%)

| | Maternal Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | RSVpreF 120 µg (N[a]=3495) | Placebo (N[a]=3480) | |
| **Time Interval** | **Number of Cases (%)** | **Number of Cases (%)** | **Vaccine Efficacy[b] (%) (99.17% CI)** |
| 210 Days after birth | 70 (2.0) | 127 (3.6) | 44.9 (17.9, 63.5) |
| 240 Days after birth | 76 (2.2) | 133 (3.8) | 42.9 (16.1, 61.6) |
| 270 Days after birth | 82 (2.3) | 137 (3.9) | 40.1 (13.0, 59.2) |
| 360 Days after birth | 92 (2.6) | 156 (4.5) | 41.0 (16.2, 58.9) |

Abbreviations: MA-LRTI = medically attended lower respiratory tract illness; RSV = respiratory syncytial virus.
a. N = number of participants (at risk) in the specified group. These values are used as the denominators for the percentage calculations.
b. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results.

# Secondary Endpoint: Hospitalizations Due to RSV within 360 Days After Birth

## Hospitalizations Due to RSV through 180 days Met Statistical Criteria for Success (CI LB>0%)

| | Maternal Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | RSVpreF 120 µg (N[a]=3495) | Placebo (N[a]=3480) | |
| **Time Interval** | **Number of Cases (%)** | **Number of Cases (%)** | **Vaccine Efficacy[b] (%) (99.17% CI)** |
| 90 Days after birth | 10 (0.3) | 31 (0.9) | 67.7 (15.9, 89.5) |
| 180 Days after birth | 19 (0.5) | 44 (1.3) | 56.8 (10.1, 80.7) |
| 360 Days after birth | 38 (1.1) | 57 (1.6) | 33.3 (-17.6, 62.9) |

Abbreviations: EAC = endpoint adjudication committee; RSV = respiratory syncytial virus.
a. N = number of participants (at risk) in the specified group. These values are used as the denominators for the percentage calculations.
b. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results.

# Exploratory Endpoint: RSV-Positive MA-RTIs (EAC confirmed) within 180 Days After Birth

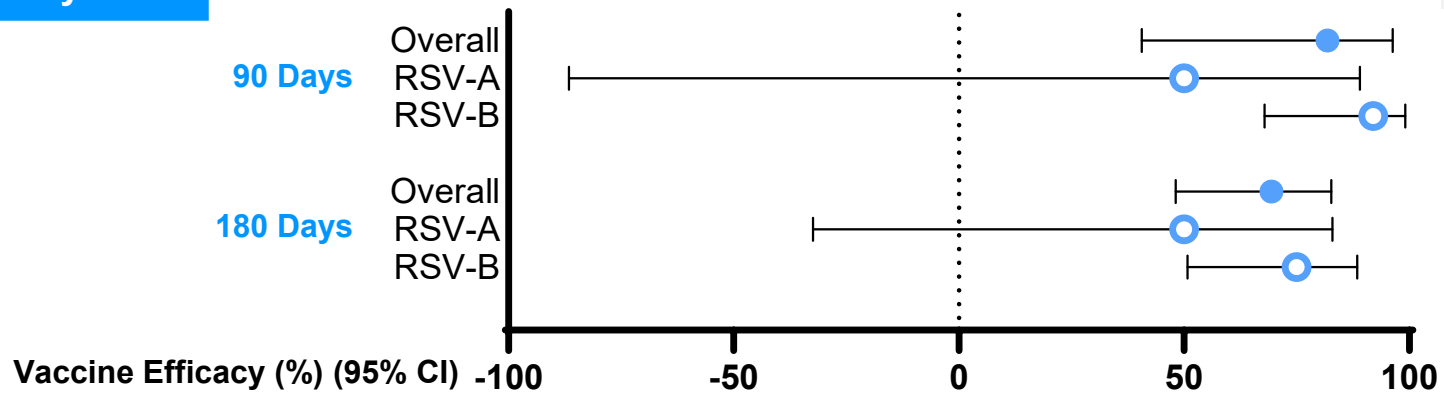
## RSV-Positive MA-RTIs through 180 Days After Birth

| | Maternal Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | RSVpreF 120 µg (N[a]=3495) | Placebo (N[a]=3480) | |
| **Time Interval** | **Number of Cases (%)** | **Number of Cases (%)** | **Vaccine Efficacy[b] (%) (95% CI)** |
| 90 Days after birth | 67 (1.9) | 110 (3.2) | 39.1 (16.7, 55.7) |
| 180 Days after birth | 157 (4.5) | 253 (7.3) | 37.9 (24.0, 49.5) |

Abbreviations: EAC = endpoint adjudication committee; MA-RTI = medically attended respiratory tract illness; RSV = respiratory syncytial virus.
a. N = number of participants (at risk) in the specified group. These values are used as the denominators for the percentage calculations.
b. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases.

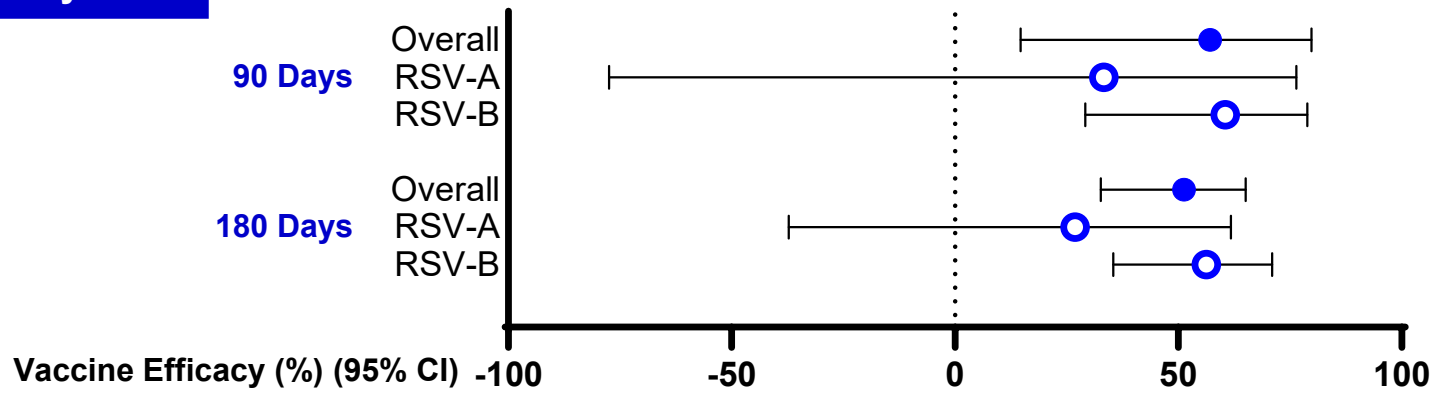
# Consistent efficacy Was Observed Across RSV Subgroup A and B*

**RSV Severe MA-LRTI 90, 180 Days**




| | Case Split (RSVpreF/Placebo) | VE |
|---|---|---|
| 90 Days Overall | 6:33 | 81.8% |
| 90 Days RSV-A | 4:8 | 50.0% |
| 90 Days RSV-B | 2:25 | 92.0% |
| 180 Days Overall | 19:62 | 69.4% |
| 180 Days RSV-A | 7:14 | 50.0% |
| 180 Days RSV-B | 11:44 | 75.0% |

**RSV MA-LRTI 90, 180 Days**




| | Case Split (RSVpreF/Placebo) | VE |
|---|---|---|
| 90 Days Overall | 24:56 | 57.1% |
| 90 Days RSV-A | 8:12 | 33.3% |
| 90 Days RSV-B | 17:43 | 60.5% |
| 180 Days Overall | 57:117 | 51.3% |
| 180 Days RSV-A | 19:26 | 26.9% |
| 180 Days RSV-B | 38:87 | 56.3% |

* Exploratory Endpoint – no prespecified criterion for RSV A and B

# RSVpreF Efficacious Against Severe Infant MA-LRTI in Phase 3 with a Favorable Safety Profile

**Primary Endpoint: Severe MA-LRTI**

| Time Period | Vaccine Efficacy |
|---|---|
| First 90 days of life* | **81.8%** (CI: 40.6%, 96.3%) |
| Six-month follow-up* | **69.4%** (CI: 44.3%, 84.1%) |

**Primary Endpoint: MA-LRTI**

| Time Period | Vaccine Efficacy |
|---|---|
| First 90 days of life* | **57.1%** (CI: 14.7%, 79.8%) |
| Six-month follow-up* | **51.3%** (CI: 29.4%, 66.8%) |

*Confidence intervals are 99.5% CI at 90 days and 97.58% CI at later intervals.

RSVpreF investigational vaccine was well-tolerated with a favorable benefit-risk profile for the maternal populations and their newborns.

*RSV = Respiratory Syncytial Virus; IA: Interim Analysis; MATISSE: **MAT**ernal **I**mmunization **S**tudy for **S**afety and **E**fficacy; MA-LRTI: Medically Attended Lower Respiratory Tract Illness; CI: Confidence Interval; DMC: Data Monitoring Committee; BLA: Biologics License Application; FDA: Food and Drug Administration*

*Source: Pfizer Press release, Oct 31, 2022*

# Thanks to

- The participants and their families
- The study investigators, nurses, coordinators, and laboratory personnel
- Pfizer essential colleagues and our vendors