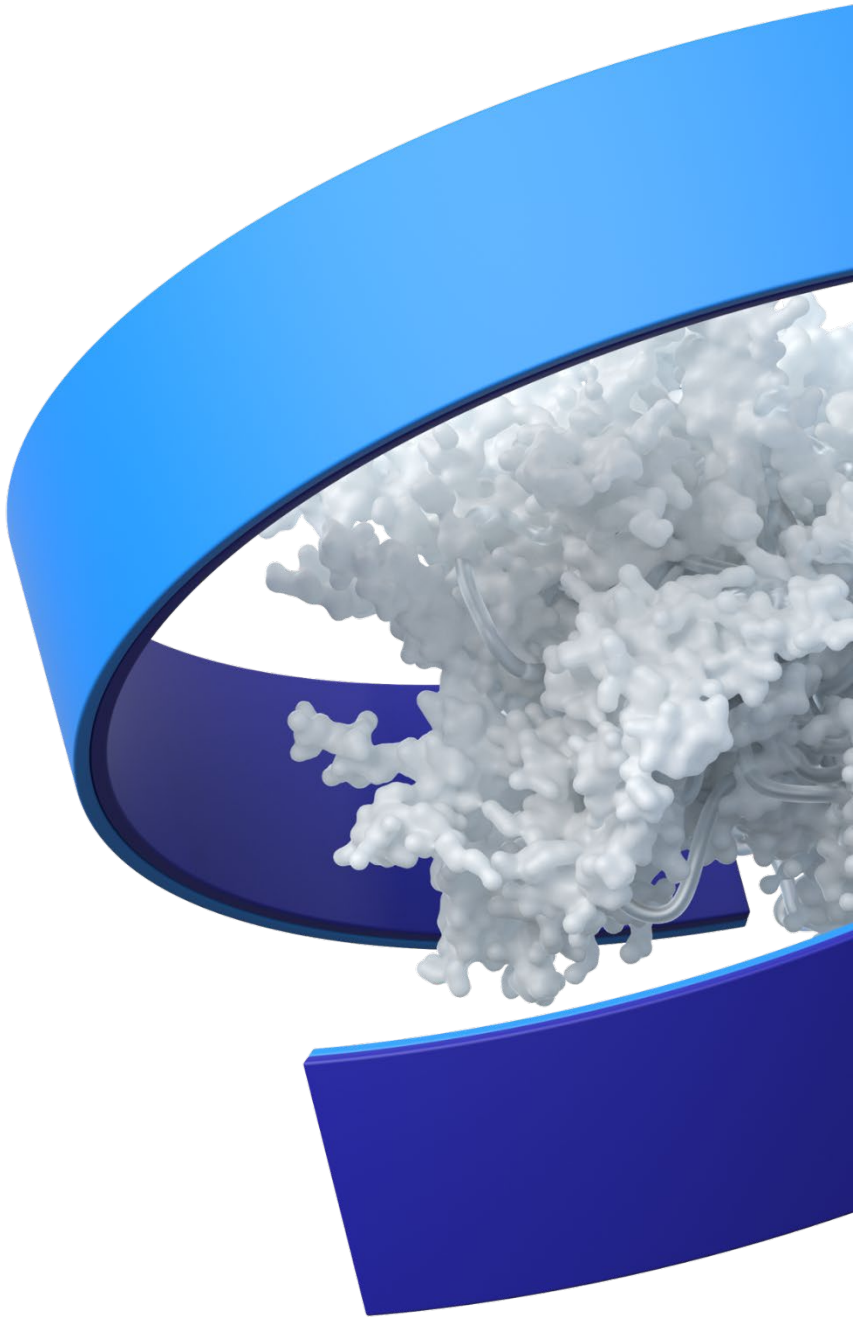
BEATRIX Study: Design of Pfizer's Phase 3 GBS Vaccine Study and Infant Safety Assessments



IABS Conference, Zurich

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David Radley

Pfizer

Group B Streptococcus 6-valent Polysaccharide Conjugate Vaccine (GBS6)

The 10 Group B Streptococcus CPS Serotypes

Ia	II	IV	VI	VIII
Ib	III	V	VII	IX

These 6 Serotypes Account for 98 % of Cases of Invasive Disease in Infants Worldwide[1]

Dose Level[2]

- 120µg/0.5mL (20µg/serotype)

Presentation[2]

- Pre-filled syringe*

Storage[2]

- 2 to 8°C (36 to 46°F)
- May be stored at ambient temperature (not to exceed 30°C (86°F)) for up to 4 hours

Proposed Indication[2]

- GBS6 is being developed for prevention of invasive disease caused by **6 GBS serotypes** (Ia, Ib, II, III, IV, and V) in infants by active immunization of pregnant individuals between 24–36 weeks gestation

CPS, capsular polysaccharide; GBS, Group B Streptococcus
*An MDV vial is also planned for WHO PQ.
1. Buurman ET, et al. J Infect Dis 2019; 220:105–15; 2. Pfizer Inc. Data on file.

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Phase 3 GBS6 Pivotal Trial: Overview of Plans[1,2]

BEATRIX group **B** str**E**ptococcus m**AT**e**R**nal and **I**nfant va**X** study

Healthy pregnant participants
Aged ≤49 years
Between ≥24 and ≤36 weeks' gestation

1:1

- **GBS6 20µg per serotype**
- **Placebo**

18 Countries

Representation from HICs and LMICs

Safety and Immunogenicity in maternal & infant participants

HIC, high income countries; LMIC, low-and-middle income countries.
1. Clinicaltrials.gov. NCT07160244. Available at: https://clinicaltrials.gov/study/NCT07160244. Accessed February 2026; 2. Pfizer Inc. Data on file.

Phase 3: Key Maternal Inclusion/Exclusion Criteria[1,2]

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Inclusion Criteria

- Healthy pregnant persons **≤49 years** of age who are **between 24 0/7 and 36 0/7 weeks of gestation** on the day of planned vaccination, with an uncomplicated, singleton pregnancy (including pregnant adolescents <18 where allowed), who are at no known increased risk for complications
- **Early dating ultrasound** (1st or early 2nd trimester) at <22 weeks of gestation
- Capable of giving signed informed consent for maternal and infant participants:
  - If a minor – parent(s)/legal guardian to sign, and obtain assent; [Note: Does not apply in Argentina]
  - If illiterate – thumbprint ICD; and signed/dated by an impartial witness
- Intention to **deliver at a hospital or birthing facility** where study procedures can be conducted

Exclusion Criteria

- History of microbiologically proven invasive disease caused by GBS in the current pregnancy
- Previous vaccination with any licensed or investigational GBS vaccine, or planned receipt during the participant's participation in the study

Country-specific modifications associated with the study eligibility criteria, including potential adjustments to the age range, are made in accordance with local ethics committee guidance and regulatory requirements

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1. Clinicaltrials.gov. NCT07160244. Available at: https://clinicaltrials.gov/study/NCT07160244. Accessed February 2026; 2. Pfizer Inc. Data on file.

Study Design – Maternal Participants

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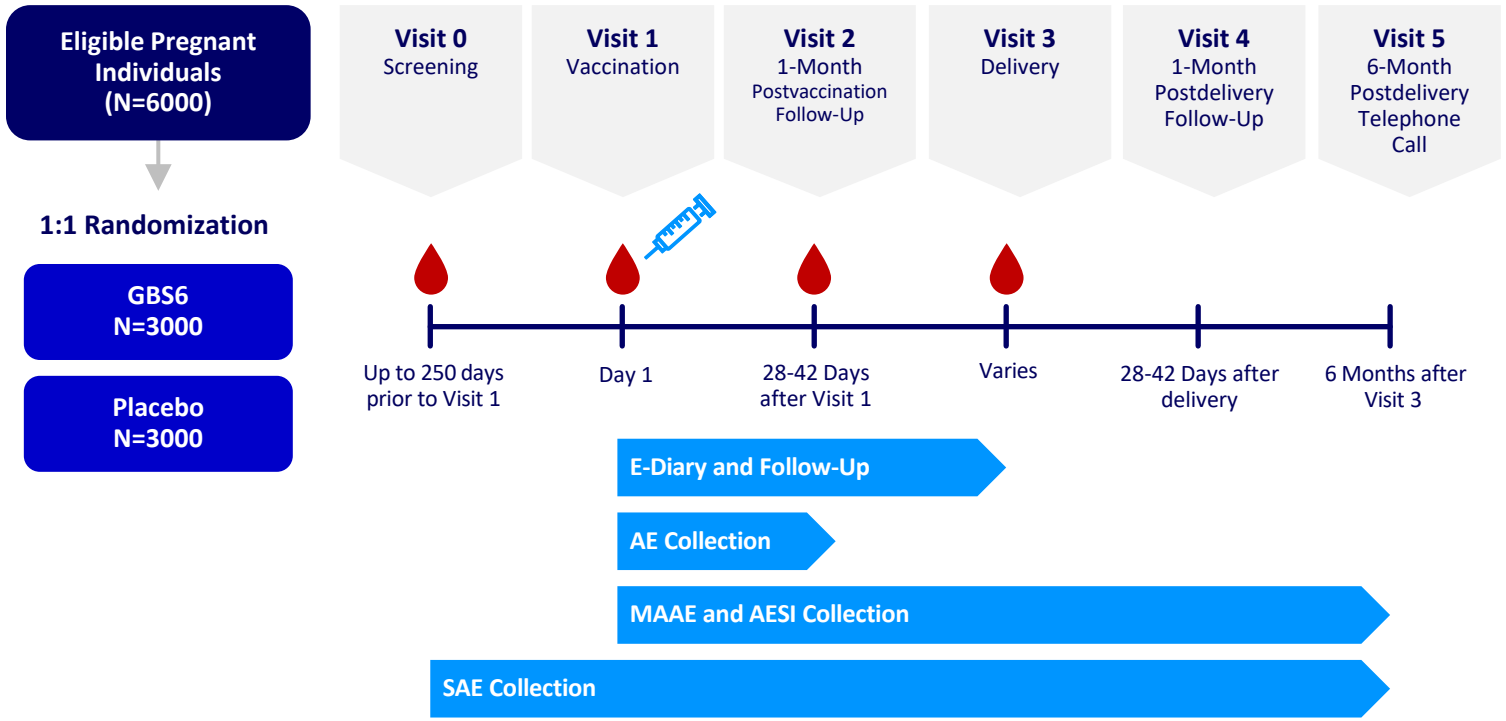

Study vaccination with either GBS6 or placebo at Visit 1

Blood draw

AE, adverse event; MAAE, medically attended adverse event; AESI, adverse event of special interest; SAE, serious adverse event.
Pfizer Inc. Data on file.

At Screening (Visit 0):

- Perform **a GA assessment ultrasound at <22 Wks** of GA
- Perform **a fetal anomaly ultrasound** examination **at ≥18 Wks** of GA, if not already done;
- Collect **blood** for HBV, HIV and syphilis testing if not done as part of prenatal care

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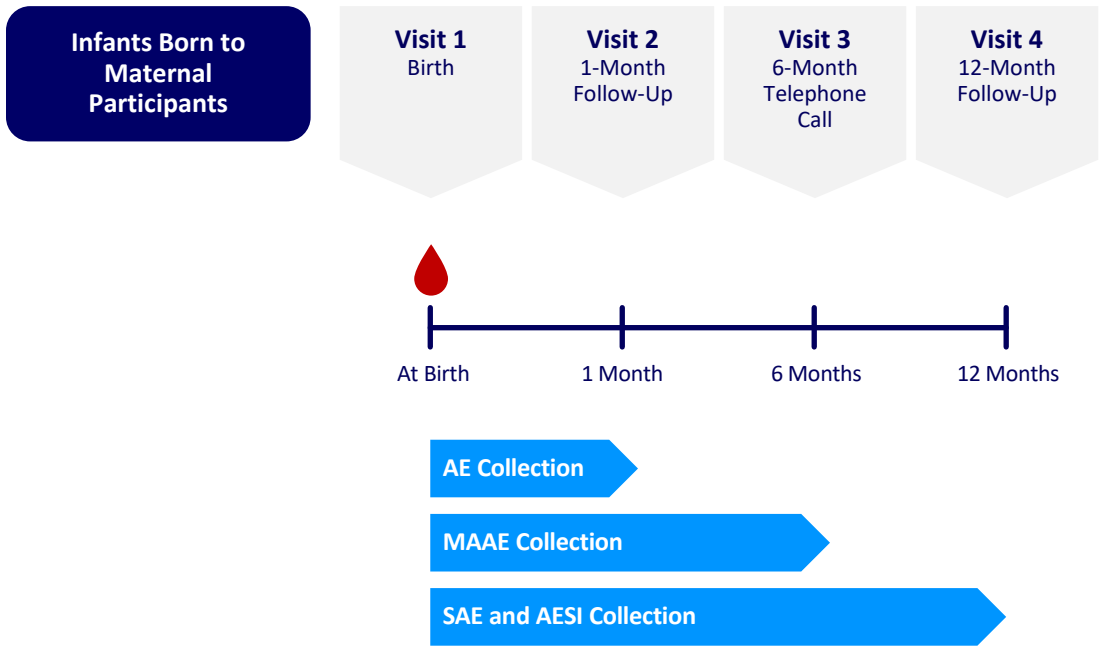
Study Design – Infant Participants



Cord blood

AE, adverse event; MAAE, medically attended adverse event; AESI, adverse event of special interest; SAE, serious adverse event.
Pfizer Inc. Data on file.

Cord blood to be collected for **immunogenicity analysis at delivery**

If cord blood is not available, a blood sample may be collected by venipuncture up to 72 hours after birth

Maternal Immunization Studies & Gestational Age at Vaccination Requirements:

GA dating has become more stringent in maternal trials; Beatrix will include most stringent dating

Study	Participant Requirements	GA Maximum Variability*
GBS6 Phase 2 (C1091002) Study 2019-2024	1st, 2nd,or 3rd trimester ultrasound	+/- 21 to 30 days
Matisse RSV Phase 3 Study 2020-2023	up to < 28 weeks	+/- 10 to 14 days
Morisot RSVpreF HIV Study 2024-2025	Early (first or early second trimester < 22 weeks) ultrasound	+/- 7 to 10 days
Beatrix GBS6 Phase3 Study 2025-2027	**Early (first or early second trimester < 22 weeks) ultrasound**	**+/- 7 to 10 days**

* If ultrasound was performed at the latest allowable gestation ages; earlier ultrasounds would have more accurate dating; LMIC dating has been historically later than HIC dating in practice and in clinical trials.

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BEATRIX Planned Global Footprint

Study Enrollment, Monitoring and DMC Oversight

- Adequate representation of HIC / non-HIC countries is planned
- External DMC reviews accumulating safety data, every 3 months
- Enrollment by GA at vaccination window proceeds carefully, with regular DMC reviews
- Aim for approximately equal representation across 24-36 weeks GA range, by end of study

Key Safety Outcomes Collected Throughout the Study

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Maternal Participants	Infant Participants
Preterm delivery (Gestational Age <37 weeks)	Preterm birth (Gestational Age<37 weeks)
Preterm labor	Low birth weight (1001 to 2500 g)
Hypertensive disorders of pregnancy (Gestational hypertension, Preeclampsia, HELLP syndrome, Superimposed preeclampsia, and Eclampsia)	Confirmed invasive GBS disease (isolation of GBS from sterile site)
	Developmental delay

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Outcome of Preterm Delivery & Data Collection

Preterm birth results from a variety of pathways ranging from idiopathic to spontaneous etiologies.

Pathways to preterm birth is a clinical syndrome characterized by any one or some combination of the following four pathways:

- **Preterm premature rupture of membranes (PPROM):** Membranes ruptured prior to 37 weeks.
- **Preterm Labor:** Regular contractions leading to cervical change before 37 weeks.
- **Provider-Initiated Preterm Birth:** Non-spontaneous, planned delivery before 37 weeks.
- **Insufficient Cervix**

▸ Vaccine. 2016 Dec 1;34(49):6093–6101. doi: 10.1016/j.vaccine.2016.03.054

Pathways to preterm birth: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data☆

Margo S Harrison [a], Linda O Eckert [b], Clare Cutland [c], Michael Gravett [d], Diane M Harper [e], Elizabeth M McClure [f], Anthony P Nunes [g], Suzette Lazo [h], Tamala Mallett Moore [i], Wendy Watson [j], Sonali Kochhar [k], Robert L Goldenberg [a]; The Brighton Collaboration Pathways to Preterm Birth Working Group[1,*]

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Conclusions

- Pfizer has designed the BEATRIX study taking account of experiences learned through the RSV vaccine maternal program
- Stringent entry criteria for GA assessment are implemented will increase confidence in safety findings
- Safety outcomes will be evaluated carefully, with frequent DMC reviews.
- Specified outcomes will be collected throughout the study in mothers and infants; including a prospective, standardized assessment of preterm pathways