

PREHEVBRIO Pregnancy Outcomes Registry

NCT06097312

Status	RECRUITING
Sponsor	VBI Vaccines Inc.
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (4)

- Pregnant woman who received PREHEVBRIO® vaccine within 28 days prior to conception or at any time during pregnancy. The time of conception will be calculated as the most reliable estimated date of delivery (EDD) minus 38 weeks. For this registry, gestational weeks will be estimated from the EDD or as corrected EDD, if a more reliable EDD (e.g., by ultrasound) is provided. If the EDD is not available or never estimated, the first day of the last menstrual period (LMP) will be used to estimate gestational age and EDD.
- The subject provided consent prior to enrollment (for eligible subjects under 18 years old, consent must be obtained from the subject's legally authorized representative).
- The subject documents agreement with the release of medical information and contact with her healthcare providers (e.g., PCP, obstetrician, nurse midwife) and the infant's healthcare provider (e.g., pediatrician) for the purpose of collecting medical information.
- Reporter's (participant and/or healthcare provider) contact information is available to allow for follow up.

Exclusion (1)

- Subjects participating in another investigational device or drug study product within 28 days prior to conception or at any time during pregnancy.

Locations (1 total)

ProPharma, Recruiting Nationwide, Overland Park, Kansas, United States