Real-world evidence

Pregnancy safety studies

Medications can affect pregnant individuals differently than other populations, often leading to apprehension about taking necessary treatments during pregnancy. Pregnancy safety studies track individuals exposed to products during this crucial period to identify possible effects on pregnancies and infants. These studies are mandated by regulatory agencies to assess the risk of adverse outcomes and inform decision making.

We provide best-in-class solutions for pregnancy study needs through our Pregnancy and Lactation Center of Excellence. Our team of experts boasts diverse backgrounds and a deep understanding of maternal and infant health. As recognized leaders in pregnancy safety, equipped with extensive operational study and data expertise and an innovative mindset, we offer valuable insights to produce results that move your product forward.

We partner with you to:

- Understand your specific research needs and objectives
- Advise what registry model aligns best with your requirements, whether in the US, Europe or globally
- Provide proactive, flexible strategies and customized study designs
- Leverage our global expertise and operational capabilities to optimize your success
- Continuously assess data quality and employ rigorous methods to ensure the highest quality results

Proven track record

We have successfully conducted studies for a variety of product types, such as drugs, biologics and vaccines, including:

Prospective registries | Retrospective database studies | Global surveillance programs | Long-term infant follow-up studies
Lactation studies | Placental transfer studies

50+ pregnancy studies

20+ studies in the past 4 years that meet the FDA's more rigorous standards introduced by the 2019 guidance

30+ years of experience in delivery of pregnancy safety studies

270+ publications and presentations by our team of pregnancy experts

Study types

RETROSPECTIVE DATABASE STUDY

A study that uses secondary data from claims or electronic health records to compare pregnancy and infant outcomes in people exposed to the product during pregnancy to an unexposed (treated or untreated) population.

Challenge:

These studies rely on extraction and analysis of existing data, which can often be messy and incomplete, leading to a range of potential challenges. These challenges may include potential bias due to comparator selection, low sample sizes, missing pregnancy dating data, and misclassification of exposure and outcomes.

Our solutions:

- We provide recommendations for comparator selection to minimize confounding by indication.
- We employ validated algorithms to accurately estimate date of conception.
- We can refine the definition of exposure to reduce the likelihood of exposure misclassification.
- We encourage flexible study designs that allow for the inclusion of data from additional databases to meet sample size targets, if needed.

PROSPECTIVE PREGNANCY EXPOSURE REGISTRY

An observational, multi-cohort study that compares the maternal, fetal and infant outcomes of individuals exposed to the product during pregnancy to an unexposed (treated or untreated) population. Enrolled participants and the healthcare providers involved in their care, or the care of their infants, provide data to the registry. Only data that are routinely collected as part of usual care are collected. Adverse outcomes are assessed throughout pregnancy and during the first year of life of the infant.

Challenge:

The primary challenge associated with these studies lies in recruiting an eligible and representative patient population and maintaining their participation throughout the study period.

Our solutions:

Recruitment

- We design customized, multi-pronged awareness plans and encourage the use of online advertising to specifically target eligible pregnant individuals.
- Our studies can be conducted in the US only, North America or globally, maximizing participant diversity and expediting enrollment, making studies faster and more cost-effective.
- Studies can be tailored to be independent or company-sponsored according to your specific need and goals.
- Our patient-centric, virtual site approach enables enrollment regardless of proximity to research site.

Retention

- We simplify data collection forms and offer multiple methods for data submission through our virtual research coordination center.
- Our skilled research coordinators actively engage with participants throughout the reporting process to enhance retention.
- We provide compensation to data reporters to further incentivize participation.

PREGNANCY SURVEILLANCE PROGRAM

A worldwide, observational, single-cohort, descriptive study that collects both prospective and retrospective data to assess pregnancy and infant outcomes in individuals exposed to the product during pregnancy and/or lactation. These programs are simple and streamlined, with reduced scientific rigor, but they are designed to capture as much information about the pregnancy/lactation exposures and outcomes as possible.

Challenge:

These studies require a global study design for very infrequent exposures.

Our solutions:

- We provide study design recommendations based on our extensive experience and comprehensive knowledge of global regulations and study operations. This includes guidance related to enrollment methods, data collection processes and analysis methods.
- We promote flexible study designs that allow for potential study expansion to include sites in various countries, ensuring that infrequent exposures are adequately captured. We provide study design recommendations based on our experience and knowledge of global regulations and study operations, including guidance related to enrollment methods, data collection processes and analysis methods.

Learn more at **ppd.com/rwe**