Clinical studies

# Pregnancy safety studies

Medications can affect pregnant women differently than other populations, and this can result in fear of taking necessary treatments while pregnant. Pregnancy safety studies track women exposed to products during pregnancy to identify possible effects on pregnancies and infants. These studies are required by regulators to assess the risk of adverse outcomes and inform decision making. In 2019, the US Food and Drug Administration (FDA) drafted a new guidance that increased the rigor of post-marketing pregnancy safety studies. Since then, there has been a rise in the number of products with post-marketing requirements/commitments for these studies.

Per the guidance, products commonly used in women of childbearing potential may require parallel, complementary studies of different designs to assess pregnancy safety:

- Prospective pregnancy exposure registry
- Retrospective database study (or case control study)

For products expected to have rare pregnancy exposures, a descriptive study that collects prospective and retrospective data (commonly referred to as a pregnancy surveillance program) may be required.

We offer best-in-class pregnancy solutions with a Pregnancy Center of Excellence. With diverse backgrounds and a deep understanding of women's health, our experts are thought leaders in pregnancy and safety and bring extensive operational study expertise and an innovative mindset to provide vision and insight to overcome challenges and move your product forward.

## We deliver tailored solutions by:

- Partnering with you to understand your specific research needs and goals
- Providing proactive and flexible strategies and customized study designs
- Leveraging our global expertise and operational capabilities
- Continuously assessing data quality and methods to deliver 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 and presentations by our team of pregnancy experts

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# Study types

## Retrospective Database Study

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

### Challenge:

These studies rely on extraction and analysis of existing data, which can often be messy and incomplete, resulting in a multitude of potential challenges, such as 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 encourage flexible study designs so data from additional databases can be leveraged to meet sample size targets, if needed.
- We use validated algorithms to estimate date of conception.
- We can refine the definition of exposure to minimize misclassification of exposure.

## Prospective pregnancy exposure registry

An observational, multi-cohort study that compares the maternal, fetal and infant outcomes of women exposed to the product during pregnancy to an unexposed control (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 greatest challenge with these studies is recruiting eligible patients and retaining them during the study period.

### Our solutions:

#### Recruitment

- We create customized, multi-pronged awareness plans and encourage the use of online advertising to target eligible pregnant women.
- Our patient-centric, virtual site approach enables enrollment regardless of proximity to research site.

#### Retention

- We streamline data collection forms and allow multiple methods for data submission via our virtual research coordination center.
- We leverage skilled research coordinators to engage participants in the reporting process.
- We provide compensation to data reporters.

## Pregnancy surveillance program

A worldwide, observational, single-cohort, descriptive study that collects both prospective and retrospective data to assess pregnancy and infant outcomes in women 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 extremely rare exposures.

### Our solutions:

- 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.
- We encourage flexible study designs to allow for study expansion to include sites in other countries, if needed.

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