

# Pregnancy, Lactation, and Infant Follow-Up Studies

Evidera provides transformational services to enable our clients to better succeed in the fast-changing drug development and market access landscape. Our extensive experience conducting studies in a variety of maternal and child health indications allows us to bring an understanding of the complexities of executing these types of studies as well as proven strategies to ensure study goals are met in a timely and efficient manner.

We are a top global provider of pregnancy and infant follow-up studies, lactation studies, and other study methodologies to assess the safety of exposure to medicinal products during pregnancy and postpartum. We provide consultation, design, implementation, analysis, interpretation, and dissemination services for the following study types.

- Prospective pregnancy registries and infant follow-up studies, including: global pregnancy registries; disease pregnancy registries; multi-sponsor, multi-product pregnancy registries; multi-sponsor, single product (branded and generic) pregnancy registries; single sponsor, multi-product pregnancy registries
- Database studies (linked medication, obstetric, and pediatric data)
- Lactation and placental transfer studies

For each of these types of studies, we provide a wide range of services, including:

- Study design, protocol, and case report form development services
- Negotiations with regulatory agencies
- Establishment and facilitation of Advisory Committees
- Registry/study implementation and project management
- Recruitment and retention plans
- Endpoint evaluation, adjudication, and signal detection
- Study reports, scientific manuscripts, and abstracts
- Consulting services on the U.S. Food and Drug Administration's (FDA) new Pregnancy and Lactation Labeling Rule

## Proven Track Record

- 15+ years of experience working with clients to develop and implement pregnancy studies that meet global regulatory agency requirements
- Experienced, dedicated pregnancy registry staff
- Perinatal staff who have designed and implemented over 40 pregnancy and infant follow-up studies that met FDA and/or European Medicine's Agency (EMA) guidelines for monitoring pregnancy exposures
- Quick turn-around on pregnancy exposure registry protocols that met FDA and/or EMA requirements
- Thought leaders who have served as invited consultants to the World Health Organization, FDA, and the Centers for Disease Control; published over 50 papers in scientific literature, including authoring papers on best practices for conducting pregnancy registries; and, authored chapters on pregnancy registries for textbooks and the Agency for Healthcare Research and Quality (AHRQ)<sup>1,2</sup>

## Lactation Study: Case Study

### Challenges

- Sponsor engaged us to conduct two global post-marketing, Phase I clinical studies evaluating the placental transfer of a tumor necrosis factor alpha blocker in exposed pregnant women and concentration of this product in breast milk of exposed mothers.
- These studies could be off-putting for new mothers because they required blood samples from neonates within 24 hours of birth and at 4 and 8 weeks, as well as up to 9 breast milk samples within 28 days postpartum.

### Our Approach to Overcome Challenges

- Due to these potential barriers, we implemented a unique open enrollment approach combined with the traditional site-based approach to maximize enrollment of all eligible women.
- This approach, where approved by country regulatory authorities, allows Principal Investigators (PIs) the option to enroll and manage subjects treated at their site (i.e., traditional model) and/or to serve as a Central PI (i.e., enroll and manage subjects remotely via open enrollment model).
- Additionally, home healthcare nurses were used to collect samples in the home rather than requiring the mothers to make site visits.

### Value to Client

- Employing the open enrollment model boosted enrollment by 50%
- The use of home healthcare nurses to collect samples proved to be highly successful in subject retention, and sample and data collection
  - 100% of enrolled subjects completed study requirements
  - 100% of home visits were completed successfully with 99% completed "in window"
- Featured at a FDA sponsored workshop on successful lactation study approaches

## Global Prospective Pregnancy Registry: Case Study

### Background

- Sponsor engaged us to develop and manage a registry to address FDA and EU post-marketing commitment
- Goal of the registry was to evaluate birth outcomes, birth defects, and infant infections among pregnant women exposed to commercially supplied biologic agent

### Challenges

- Exposures to the biologic agent are not common
- Difficult to find sites that have access to women with pregnancy exposure to the biologic agent
- Regulatory/Ethics requirements vary by countries
- Research naïve sites

### Our Approach to Overcome Challenges

- Engaged with regulatory/ethics committees on study design and enrollment model
- Established single registry site in each country to allow 'open enrollment' of all eligible women
- Employed self-enrollment model whereby patients self-enroll
- Negotiated with regulatory/ethics committees to streamline consent procedures, using verbal consent when possible
- Established a contact center whereby our experienced registry specialists facilitated enrollment, data collection, and data entry – lessening burden on research naïve sites

### Value to Client

- Cost-efficient approach
- Allows Sponsor to meet post-marketing commitment with a limited number of sites
- Open-enrollment model maximizes enrollment by allowing all eligible women to enroll
- Streamlined consent and enrollment processes encourage recruitment
- Experienced registry specialists establish rapport with participants, which encourages retention

## References

1 Hernandez-Diaz S, Chambers C, Covington DL, Cragan J, Ephross S, Tassenari M. Registries for Evaluating Pregnancy Outcomes. In: Gliklich RE, Dreyer NA, eds. Registries for Evaluating Patient Outcomes: A User's Guide. 3rd ed. AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014.

2 Covington DL, Doi PA, Cunningham MC, Kennedy DL, Tilson HH. Pregnancy Registries. In: Hartzema AG, Tilson HH, Chan KA, eds. Pharmacoepidemiology and Therapeutic Risk Management. 1st ed. 2008:439-476.