Pregnancy and Lactation Real-World Studies

We are uniquely positioned to offer a comprehensive array of RWE solutions tailored for pregnancy and lactation

- Pregnancy exposure registry solutions
- Healthcare database pregnancy studies
- Descriptive pregnancy safety studies
- Lactation safety studies
- Pregnancy and lactation studies beyond safety, including efficacy studies, HEOR, accessibility to healthcare, and patient preference

Pregnancy Exposure Registry Solutions:

- Bespoke pregnancy exposure registries
- Various fit-for-purpose multi-product pregnancy exposure registry solutions that efficiently consolidate resources and share costs, tools, and processes

Program Delivery Solutions:

- Incorporating a programmatic approach for the delivery of two or more studies for the same asset

75+
Safety studies and programs performed in the past 5 years

14
Lactation studies (Ph I-IV) performed in the past 5 years

50+
Pregnancy safety studies
including pregnancy exposure registries and complementary database studies
performed in the past 5 years

270+
Publications and presentations by our team of pregnancy experts

23
Pregnancy exposure registries in the past 5 years, **4** being **multi-product** pregnancy exposure registries

720+
RWE professionals, including dedicated pregnancy and lactation team

100+
Registries
Deep expertise in primary data collection studies

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Unparalleled pregnancy and lactation studies (PaLS) suite of solutions led by our Center of Excellence

PaLS SUITE

Descriptive Pregnancy Safety Studies

Multi-product Pregnancy Exposure Registries – Multiple Solutions

Single Product Exposure Registries

Pregnancy & Lactation Beyond Safety Studies

30+ years
of expertise for **program oversight, support and knowledge sharing**

Healthcare Database Pregnancy Studies

Lactation Studies

Strategic and operational excellence delivering **innovative solutions for recruitment and retention**

Industry thought leaders and invited consultants to FDA, WHO and CDC

CENTER OF EXCELLENCE

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Core Members, Pregnancy and Lactation Center of Excellence

Anne Delaney, MBA, BSc (Hons)
VP, Real World Evidence

Barbara Hawkins
VP, Non-Interventional Studies

Susan Oliveria, ScD, MPH, FISPE
VP, Global Head of Epidemiology and Scientific Affairs

Diego Wyszynski, MD, MHS, PhD
VP, Pregnancy and Lactation Studies

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Various prospective **pregnancy exposure registry** offerings to efficiently meet FDA post-marketing requirements

Single Product/ Single Protocol

A decentralized methodology using innovative technologies and patient-centric approaches to reduce burden, improve retention rates, enhance data quality, and streamline longitudinal data collection

Multi-Product/ Multi-Protocol Consortium

Maintain individuality of a single product/protocol while enabling **collaborative opportunities between sponsors (e.g., sharing comparator data)** with consistency across protocols, SAPs, DCFs, etc.

Multi-Product/ Single Protocol

Enhance efficiency in meeting PMC/ PMRs by utilizing **shared resources, such as comparators, tools, and processes** through an integrated registry under a single protocol

Proprietary Data

A solution that enables individual or multi-product sponsors to **extract data from registries** to efficiently fulfill individual post-authorization safety studies

Abbreviations: SAP: statistical analysis plan; DCF=data collection form; PMC=post-marketing commitment; PMR=post-marketing requirement

We are uniquely positioned to identify and facilitate collaborations for single and multi-product registries that satisfy regulatory obligations while fostering study and operational efficiencies

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