

# 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

# 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

Healthcare Database Pregnancy Studies



Strategic and operational excellence delivering innovative solutions for recruitment and retention

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

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



Lactation Studies



**CENTER OF EXCELLENCE**

# Core Members, Pregnancy and Lactation Center of Excellence

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



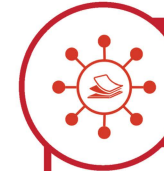
## Single Product/ Single Protocol

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**