Real-world evidence

Peri- and post-approval safety and real-world insights

To optimize the fulfillment of imposed and voluntary post-authorization safety obligations, we employ a unified, holistic approach that ensures a comprehensive understanding of the evidence needs. Our collaborative process ensures we identify the optimal study design to generate the necessary data, meeting stakeholder and regulatory requirements with the utmost rigor and efficiency. With our consultative approach, vast expertise across the product life cycle in all major therapeutic areas, and extensive experience interacting with regulatory authorities and delivering regulatory studies, we partner closely with clients to design custom study solutions.

Your challenges	Our solutions
Developing an appropriate strategy for the most scientifically rigorous and **efficient design/conduct of safety studies**, using existing data where possible	• Expert scientific team with extensive understanding of regulatory needs to **advise on the opportunities and limitations of data approaches and design options** to inform strategic recommendations
Achieving full integration and **regulatory strategy** alignment in the development and execution of new risk management plans (RMPs) and risk evaluation and mitigation strategies (REMS)	• In-house **expert team with dedicated representation from clinical safety, epidemiology, operations, and pharmacovigilance (PV)/risk management** to support RMP and REMS development, including risk minimization strategies, educational material development, and study delivery
Implementing innovative approaches to identify the right **data sources and/or data sets** tailored to a variety of potential safety study designs	• Deep understanding of the real-world data (RWD) landscape and **tailored data selection approach** that evaluates multiple secondary data sources (e.g., disease registries, EMR data) to support optimal study design and data selection • Unique integrated delivery network (IDN) relationships, allowing **access to large sample sizes in community-based settings**, and study designs that ensure integrity of study data • Access to **regulatory-grade data from proprietary disease-based registries** and experience fulfilling regulatory requirements by nesting marketing authorization holder-sponsored studies such as post-authorization safety studies within our independent registries • **Experience with linking multiple data sources**, including electronic medical records, claims and existing registries • Continuous surveillance of the **landscape of vendors** that are accessing and making available RWD for research purposes, to facilitate more comprehensive and real-time data inclusion
Reducing the patient burden associated with participation and **ensuring appropriate representation and patient diversity** in primary data collection safety studies	• **Decentralized, patient-centric study solutions** that broaden reach and enhance recruitment • **Virtual research coordination center** that aligns care coordinators with specific participants to optimize the patient experience and ensure protocol and schedule adherence • Established support and **training programs tailored to research-naïve healthcare providers,** expanding your study's reach in community-based settings
Timely capture and reporting of robust **adverse event data** across your safety studies	• Easy to use, **standardized electronic data collection (EDC) platform that integrates safety reporting processes and required data collection**, eliminating the need for multiple systems and improving efficiency in data management and data quality • Interface with your own or our PV department

What makes us different?

We can help you understand and manage your product's benefit-risk profile and create an evidence generation strategy that will not only meet regulatory requirements but help to identify other opportunities to maximize your asset's benefits relative to risk.

- **Global capabilities**, with country-specific understanding of safety requirements to deliver solutions across all post-authorization safety commitments
- **Dedicated professionals** in safety research, operational delivery, pharmacovigilance/risk management, pharmacoepidemiology, and decentralized study conduct
- **Strategic, insight-focused perspective** and deep experience with real-world evidence (RWE) study methodologies to optimize evidence generation and tailor study design to maximize efficiencies
- **Efficient engagement of experts** across scientific, operational, and technological domains (e.g., clinical, epidemiology, regulatory affairs, statistics, data science, patient-centered research, market access, study innovations) to provide a comprehensive solution
- Deep understanding of **evolving safety and risk management** challenges as well as regulatory and process requirements
- **Access to unique proprietary datasets and 20 years'** experience conducting secondary database studies and identification of fit-for-purpose data sources to optimize evidence generation

What we offer

Studies to meet regulatory authority obligations

- EMA post-authorization safety studies (PASS), including effectiveness of risk minimization measures (eRMM)
- FDA post-marketing requirements (PMRs) and post-marketing commitments (PMCs)
- Country-specific post-marketing requirements
- Pregnancy safety studies, including prospective exposure registries, healthcare database studies, descriptive studies, lactation studies and placental transfer studies
- Phase IIIb/IV and long-term safety studies
- Risk Evaluation and Mitigation Strategies (REMS), including design, implementation/management and assessment

PV and Pharmacoepidemiology (PE) consulting

- Product safety consulting across the life cycle
- Risk Management Plans (RMPs)
- Risk minimization program design and evaluation methods

Experience

- **720+** Staff dedicated to pharmacoepidemiology and real-world evidence globally
- **75+** Safety studies and programs performed in the past 5 years
- **40+** PASS studies designed and implemented in the past 5 years, including 12 nested PASS studies in independent registries
- **50+** Drugs/therapies supported in the past 5 years
- **50+** Pregnancy safety studies, including 20+ since 2019 FDA guidance
- **35+** REMS programs since 2010
- **Innovative approaches** in use of novel data sources and advanced analytics including machine learning, natural language processing and data visualization
- **Partnerships** that allow us to develop and offer full-scope virtual end-to-end studies

PPD CorEvitas clinical registry-based safety solutions

Unlock the benefits of over 20 years of unparalleled experience collecting and analyzing regulatory-grade, granular data from proprietary PPD™ CorEvitas™ Clinical Registries across rheumatology, dermatology, gastroenterology and neurology.

Our integrated scientific team supports documentation, protocol development, and revision of safety study analytic protocols nested within the disease registries, ensuring precision and reliability.

Efficiently fulfill global regulatory obligations and informational requirements for post-authorization safety studies nested within our exclusive registries:

Credibility with regulators

Independent, regulatory-grade approach accepted by the US Food and Drug Administration and European Medicines Agency to fulfill post-marketing safety requirements.

Efficient infrastructure

Existing registries can contribute drug-of-interest exposure data at launch without waiting for PASS protocol completion, speeding time to fulfillment of post-marketing obligations.

Science-led approach

Leading academic advisors provide clinical and scientific oversight of each registry and help customize data collection to ensure validity of clinical and safety measures collected.

Disease-based registries

Collection of standard-of-care therapies in addition to newly approved advanced therapies ensures the most relevant cohorts for comparative safety studies.

Actively assessed disease activity measures and safety outcomes

Investigator sites with expertise incorporating CorEvitas Clinical Registry research protocols in routine practice, conducting active assessments of disease activity and severity measures, treatment changes, and safety outcome monitoring, ensuring valid analytic results and thorough verification of safety events.

Customizable safety reporting

Tailored safety event reporting based on our robust safety monitoring, verification, and validation procedures to meet both internal standards and regulatory requirements.

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