Peri- and Post-Approval Safety Solutions

Optimizing imposed and voluntary post-authorization safety obligations requires a unified, holistic approach to understand the core research need and identify the right study design to generate the right data for the right stakeholders in the most efficient manner possible. Evidera's consultative approach, combined with our comprehensive expertise across the product lifecycle in all major therapeutic areas, allows us to collaborate with clients to identify the best strategic approach for your product's safety needs.

Your Challenges	Evidera's Solutions
Complexity of pharmacovigilance (PV) processes; maintaining compliance across case processing, safety reporting and risk management	• Best practice benchmarking and process consultancy from a PV management team experienced in working across hundreds of different client PV systems • Proprietary workflow management software that optimizes internal processes and generates high-quality client reports • RPA-assisted follow-up and artificial intelligence-based case intake automation capability for improved efficiencies and quality • Signal detection supported by our real-time data analysis solution
Retaining the right internal PV subject matter experts to ensure globally compliant product safety planning, management and oversight	• Flexible and scalable expert resourcing solutions, including case management, literature and safety reporting specialists, safety writers, safety scientists, safety physicians and qualified persons for pharmacovigilance (QPPVs)
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 PV/risk management to support RMP and REMS development, including risk minimization strategies, educational material development, and study delivery
Reducing the burden of patient participation and ensuring appropriate representation and patient diversity in 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 quality adverse event data across your safety studies	• Easy to use standardized 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 PPD's PV department
Identifying and staying on the cutting edge of sources of participants and/or patient data tailored to a variety of potential safety study designs	• ClinicaLive™, our innovative data collection solution tapping into our global healthcare physician panel of 2.2m screened physicians • Unique integrated delivery network (IDN) relationships, allowing access to large sample sizes in community-based settings and designed to ensure integrity of study data • Access to and experience with many data sources, including electronic medical records, claims and existing registries • Continuous surveillance of the landscape of vendors that are accessing and making available real-world data (RWD) for research purposes to facilitate more comprehensive and real-time data inclusion

What Makes Evidera | PPD 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 expectations 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
- 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
- Strategic, insight-focused perspective to optimize evidence needs and provide a tailored study design strategy that maximizes efficiencies
- Deep understanding of evolving safety and risk management challenges as well as process requirements

What We Offer

Studies to meet regulatory authority obligations

- EMA post-authorisation 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 registries and lactation and placental transfer studies
- Phase IIIb/IV and long-term safety needs

PV and risk management

- Risk Management Plans (RMPs)
- Risk Evaluation and Mitigation Strategies (REMS)
- Qualified Person for Pharmacovigilance (QPPV)
- Pharmacovigilance System Master Files (PSMFs)
- Case processing
- Literature surveillance
- Safety reporting
- Aggregate report writing
- Signal detection

PV and PE consulting

- Product safety consulting across the lifecycle

Experience

- **70+** Staff dedicated to pharmacoepidemiology and real-world evidence globally
- **70+** Safety studies and programs performed in the past 5 years
- **50+** Drugs/therapies supported in the past 5 years
- **25+** REMS programs in 15+ indications since 2010
- **20+** Pregnancy registries in 10+ indications since 2010
- **40+** PASS studies designed and implemented in the past 5 years
- **500,000+** PV individual case safety reports (ICSRs) processed each year
- **20+** EU QPPV services provided for 18 marketing authorization holders and applicants
- **1400** PV staff
- **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

To learn more about Evidera, a PPD business, please visit evidera.com.