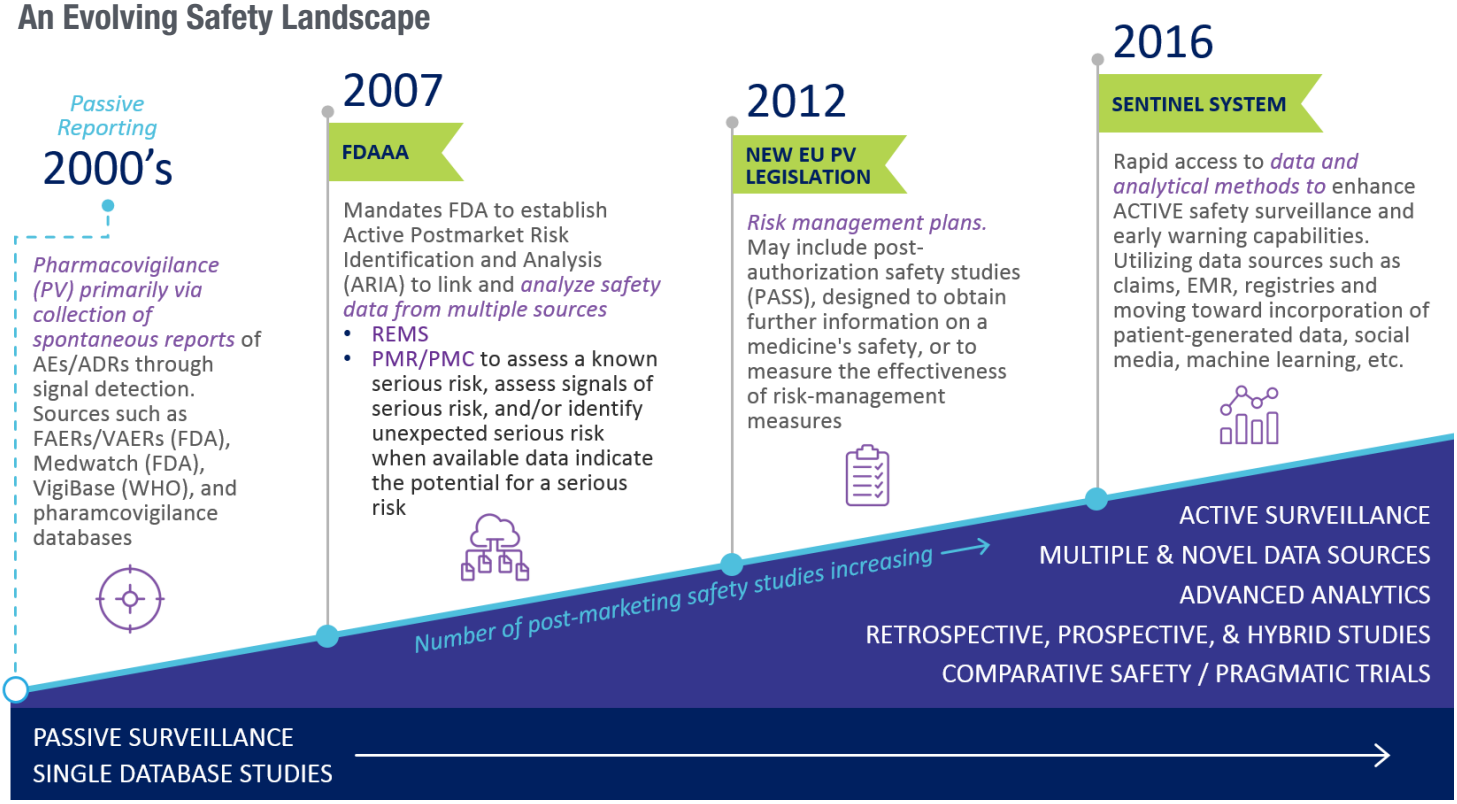
Peri- and Post-Approval Safety Solutions

Ensuring the safety of regulated medical products to protect public health has always been a key focus of regulators. Recent advances in science, technology, and the availability and integrability of real-world data sources, combined with an increased focus on safety by patients, advocates, health professionals, researchers, and other stakeholders, have resulted in an enhanced regulatory and methodological framework to improve risk assessment and management, surveillance, and the safe use of regulated medical products. A science of safety has emerged that aims to capitalize on scientific advances and real-world evidence to reduce adverse events by improved patient targeting of specific medical products to maximize benefits relative to risks. This new science applies advances in study design and pharmacoepidemiological analysis of a growing array of data sources, combined with enhanced understanding of disease and treatments at the molecular level, to generate and confirm hypotheses regarding safety problems and their causes, and to delineate factors that underlie risk.

Evidera, PPD's peri- and post-approval business unit, has deep expertise in designing, delivering, and communicating safety studies and programs to help ensure safe and appropriate product use.

An Evolving Safety Landscape



Why Evidera?

- Experienced safety team with full global operational capacity aligned with regulatory and pharmacoepidemiology experts
- Thought leaders with a proven track record of success
- Comprehensive understanding of safety evidence needs across all stages of product lifecycle
- Global operational capabilities for prospective post-approval safety requirements and commitments
- Innovative approaches in use of novel data sources and advanced analytics including machine learning, natural language processing, and data visualization
- Ability to engage experts in basic sciences, clinical care, pharmacology, regulatory affairs, pharmacovigilance, statistics, epidemiology, and data science
- Expertise in both interventional and observational real-world studies, as well as database analytics and hybrid studies

U.S. +1 301 654 9729 EUR +44 (0) 208 576 5000 info@evidera.com evidera.com

Peri- and Post-Approval Safety Offerings

Our global multi-disciplinary safety team of scientific and operational experts work with clients to create reliable study designs and on-time study execution utilizing primary and/or secondary data. Our safety offerings are aligned with regulatory frameworks in the U.S. and Europe and can be customized to help you satisfy post-marketing requirements.

- Risk Evaluation and Mitigation Strategies (REMS)
- Risk Management Plans (RMPs)
- Post-authorization safety studies (PASS)
- Pregnancy and lactation studies
- Phase IIIb/IV and long-term safety studies
- Pharmacoepidemiology post-approval safety studies (database, chart reviews, etc.)
- Interventional studies and pragmatic trials
- Comparative safety studies
- Consulting on medical product safety across the life-cycle
- Literature reviews and meta-analyses
- Epidemiology studies (e.g., background risk assessment)
- Surveys and other methodologies to evaluate effectiveness of risk mitigation or minimization efforts
- Drug utilization studies
- Registries
- Patient preferences
- Quantitative risk benefit analysis

Our Team and EXPERIENCE

— 70+ —

Staff dedicated to pharmacoepidemiology and real-world evidence across Europe, North America, and Asia

— 70+ —

Safety studies and programs performed in the past 5 years

— 50+ —

Drugs/Therapies supported in the past 5 years

— Data Sources —

Unsurpassed knowledge of and access to a vast array of real-world data sources (claims, EMR, registries, etc.)

— Therapeutic Areas —

Experience in most therapeutic areas, extensive experience pain/opioids, oncology, cardiovascular outcomes, and ophthalmology

Our Commitment to EXCELLENCE

— Our Customized — Approach

Experienced with changing regulatory demands and with deep expertise in both primary and secondary data collection, we provide tailored solutions to small and large companies that efficiently and effectively address safety concerns

— Innovators —

Leading the field in methods for health analytics of novel or atypical data sources (e.g., mining social media for conditional mapping, machine learning for event prediction and predictor discovery)

— Global Reach —

As a part of PPD, our experience, operational excellence, and global infrastructure enable us to manage large, prospective safety studies, multi-country PASS, REMS, peri- and post-approval trials, and long-term safety studies