

PHARMACOEPIDEMOLOGY & RISK MANAGEMENT

Strengthen the Value of Your Products Through Real World Evidence

Traditional data collection can only do so much for the success of your product. Real world evidence (RWE) brings credibility to your product's study results, as it satisfies the industry's ever growing need for more information on the real-life utilization of medicines and safety. The questions of benefits and risks have to be addressed in the real-world even more than in a controlled clinical trial setting.

That's why Ergomed and Primevigilance have come together to bring your study a unique set of services specifically tailored to the specialized needs of pharmacoepidemiology and RWE risk management.

The Tools of Real World Evidence Studies



Outcomes Research

- Complete services for peri-approval programs (e.g. PASS, PAES, registries)
- Protocol design: cover regulatory, scientific and commercial objectives
- Tailored operational strategy: address challenges of feasibility, enrolment, and retention in RWE studies
- Tailored risk-based monitoring solution, ensuring quality, compliance, and data accuracy



Epidemiology & Risk Management

- Risk management plan development and maintenance
- Risk analysis and benefit risk analysis
- Development of new approaches to risk minimization
- Decision analytics and preference choices
- Strategic consulting on observational study designs, including natural history studies, point prevalence etc.
- Societal, economic and humanistic burden of illness
- Systematic reviews, meta-analyses and disease modelling, including survival assessments

Drug Safety & Analytic Services



Pharmacovigilance

- Development and optimization of PV Systems
- Case processing
- Validated drug safety database
- Global Regulatory intelligence and submissions
- Qualified EEA QPPVs and NPRPs staff
- Global and non-indexed Literature Screening
- Aggregate report writing: (PBRERs, PADERs, DSURs)
- Risk management plan development and maintenance
- Signal management
- Quality Management System



Medical Information

- 24/7 Multilingual call centre
- Validated MI Database
- First and Second Line enquiries
- Receipt of Adverse Events and Product Quality Complaints
- Literature Searches
- Development & maintenance of standard response documents (SRDs)
- Global Value dossiers and reimbursement submissions

LEARN MORE ABOUT WHAT ERGOMED & PRIMEVIGILANCE
CAN DO FOR YOUR REAL WORLD EVIDENCE STUDY:

ergomedplc.com



primevigilance.com

ERGOMED

PRIMEVIGILANCE