Full Global Pharmacovigilance Services
About Us

PrimeVigilance, an Ergomed plc company, is a leading provider of global, high quality, and innovative pharmacovigilance services.

- Partnership model of engagement
- Project execution excellence
- Automation expertise
- Regulatory experts and PV thought leaders.

Our Statistics

- 300k+ ICSRs/AEs processed per year across several therapeutic indications
- 900k+ Literature abstracts reviewed yearly
- 1.5k+ PBRERs, PADERs, DSURs, ACOs and RMPs written per year
- 40k+ Medical Information inquiries per year
Dedicated to providing pharmacovigilance services, PrimeVigilance covers the entire product life cycle, assisting clients with the effective management of their drug safety information, and offering expert consulting services from former regulators, inspectors and PV opinion leaders.

**OPERATIONAL SERVICES**

- EU Qualified Persons Responsible for Pharmacovigilance (QPPV)
- Local QPPV network
- Pharmacovigilance system set-up and maintenance
- Clinical and post-marketing case processing
- Safety Data Exchange Agreements (SDEA)
- Aggregate reports
- Literature monitoring global and local
- Risk Management - benefit-risk and signal management
- Pharmacovigilance audits and inspection.
PrimeVigilance is a quality resource for concise, timely and accurate communication with highly trained, industry experienced professionals providing Medical Information in all therapeutic areas across 35+ countries.

**MEDICAL INFORMATION QUERY INTAKE AND QUALITY MANAGEMENT**

- Multilingual team of experienced professionals
- 24/7 availability of experts to answer your customer’s most urgent queries
- Adverse events and complaints intake
- Validated, customized query and document management
- Capability to create and maintain standard responses to FAQs
- Reconciliation, quality and compliance reporting
- ArisGlobal LifeSphere® MI Database
- Samsung automatic call distribution telephone system.
Pharmacoepidemiology & Benefit-Risk Management

Proactively optimizing drug benefit-risk profiles

Offering optimal approaches to life cycle benefit-risk management by providing systematic risk minimization and faster insights into the safety and effectiveness of drugs.

PHARMACOEPIDEMIOLOGY AND BENEFIT-RISK MANAGEMENT SERVICES

- Strategic consulting
- Human data research services
- Systematic literature reviews and meta-analyses
- Benefit-risk management training
- Risk management system design and execution
- Post-authorization safety and efficacy studies
- Benefit-risk analyses
- Design and set-up of registries.
Audit & Inspection
We pride ourselves on quality

We are audit ready at all times. Auditing provides an unbiased and independent opinion of operational performance of the pharmacovigilance system, and ensures that the system itself remains compliant with the regulations. Our audit track record is testimony to the quality we deliver.

SUPPORT SERVICES OUTSOURCING

- Independent gap analysis audit
- Quality management system development procedures, training, compliance and quality
- Strategic and tactical audit planning and risk assessment
- Audit and inspection preparation
- Inspection readiness.
Providing regulatory services and clinical development consultancy throughout the entire lifecycle of medicinal products with an international team of highly skilled and qualified regulatory experts.

REGULATORY SCIENCE SERVICES

- World-renowned global regulatory experts, ex-regulators and inspectors
- Scientific advice and referrals
- Regulatory consulting
- Marketing authorization and license maintenance
- Medical writing
- Local Contact Person in Pharmacovigilance (LCPPV).
With over 300 clients, PrimeVigilance is dedicated to delivering high quality, fully compliant global life cycle management safety solutions.