



An Ergomed company

Global Life Cycle Management Services





About Us

PrimeVigilance, an Ergomed plc company, provides global, top quality, cost-effective, innovative Life Cycle Management Services to enable emerging and established life sciences companies to meet their regulatory obligations and to maximise product value.

- Leading full-service safety specialist provider
- Global leader in QPPV services
- 24/7 multilingual call center
- Flexible resourcing strategies
- Automation in pharmacovigilance expertise
- Choice of leading drug safety databases
- Regulatory experts and key opinion 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

2.5k+

Number of products covered by Medical Information

Pharmacovigilance

A partner you can trust

With over 12 years 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 and opinion leaders.



OPERATIONAL SERVICES

- EU Qualified Persons Responsible for Pharmacovigilance (QPPV)
- Local QPPV network
- Development of SOPs / PSMF / SDEAs
- Individual case safety reports (ICSR) and adverse event (AE) processing and submission
- Aggregate reports
- Literature monitoring
- Signalling (detection, validation, prioritisation and evaluation)
- Risk Management Plans (RMPs)
- EudraVigilance and XEVMPD management.





Medical Information

Together we enhance patient care

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 30+ 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, customised 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 optimising drug benefit-risk profiles

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



PHARMACOEPIDEMOLOGY AND BENEFIT-RISK MANAGEMENT SERVICES

- Strategic consulting
- Human data research services
- Systematic literature reviews & meta-analyses
- Benefit-risk management training
- Risk management system design and execution
- Post-authorisation safety and efficacy studies
- Benefit-risk analyses
- Design and set-up of registries.



Audit & Inspection

We pride ourselves on quality

Routinely reviewing the quality management system is an activity for of any pharmaceutical company. 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.



SUPPORT SERVICES OUTSOURCING

- Independent pharmacovigilance auditing (through our independent auditing team)
- Quality management system development (procedures, training, compliance, and quality)
- Strategic and tactical audit planning and risk assessment
- Audit and inspection preparation
- Inspection readiness.



Regulatory Science

Understanding today's needs

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

- Strong team of regulatory experts and ex-regulators
- Scientific advice and referrals
- Regulatory consulting
- Regulatory affairs services
- Medical writing
- Training.





With over 200 clients, PrimeVigilance is dedicated to delivering high quality, fully compliant global life cycle management solutions to support products in partnership with our client companies globally.

Contact Us

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