



An **ERGOMED** company

Global Life Cycle Management Services





About Us

PrimeVigilance, an Ergomed 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.

- Full-service safety provider with 500+ professionals
- Global leader in QPPV services
- Competitive right-shoring solutions
- Robotics and automation expertise
- Choice of leading drug safety databases
- Regulatory experts and key opinion leaders.

Our Statistics

150,000

ICSRs/AEs processed per year

500+
professionals

Plus a network of EEA
& Domestic QPPVs

1000+

PBRERs, PADERs, DSURs, ACOs
and RMPs written per year

40,000

Medical Information enquiries
received per year



Pharmacovigilance

A partner you can trust

With 10 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
- Individual case safety reports (ICSR) processing and submission
- Aggregate reports
- Literature monitoring
- Signalling (detection, validation, prioritisation and evaluation)
- 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 healthcare professionals providing Medical Information.



MEDICAL INFORMATION QUERY INTAKE AND QUALITY MANAGEMENT

- 24/7 multilingual call centre
- Experienced team of pharmacists
- 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

Essential component of any pharmaceutical company's quality management system, auditing provides an unbiased opinion of operational performance of the pharmacovigilance system, and ensuring that the system itself remains compliant with the regulations.



SUPPORT SERVICES OUTSOURCING

- Pharmacovigilance auditing
- Quality management system (procedures, training, compliance, and quality)
- Strategic and tactical audit planning
- 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

- Full-service regulatory science provider
- Strong team of regulatory experts and ex-regulators
- Scientific advice and referrals
- Regulatory consulting.





With over 100 clients globally, PrimeVigilance is dedicated to delivering high quality, fully compliant global life cycle management solutions to support products in partnership with our client companies.

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