

Industry Leading Pharmacovigilance and Clinical Safety Services



About Us

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



UNLOCKING THE POTENTIAL OF PHARMACOVIGILANCE

We augment our domain expertise by integrating medical and scientific knowledge with regulatory science in clinical settings and in everyday practice.

- **Partnership model of engagement**
- **Project execution excellence**
- **Automation expertise.**

Our Statistics

350k+

ICSRs/AEs processed per year across several therapeutic indications

1m+

Literature abstracts reviewed yearly

1.5k+

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

40k+

Medical Information inquiries per year

Why PrimeVigilance

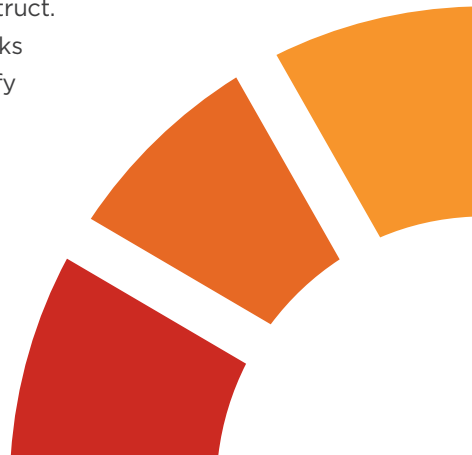
By galvanizing skilled resources and smart processes with proprietary technologies, our life sciences clients can advance discovery, manage drug and device development and deliver better solutions for patients.



FLEXIBLE BUSINESS MODELS THAT EMBRACE YOUR ASSETS

With over 1000 SMEs our operational teams:

- **Strategically align**
your corporate priorities through capacity management
- **Make data-driven decisions**
to assist you to strategically position your product on the market
- **Provide standardized quality**
and innovative technology solutions to maintain steady case flow and compliance
- **Offer efficiencies**
in communication, reporting and intelligence as well as budget construct. We compare processing benchmarks across our clients seeking to identify areas for potential efficiency gains.





Pharmacovigilance

A partner you can trust

PrimeVigilance's end-to-end services span clinical R&D, Review & Registration and Post-marketing phases from ICSR to Benefit-risk Management and from QPPV & PSMF to Signal Management.

SERVICES

- Case Processing
- Safety Reporting and Systems
- Medical Information
- GVP Audits/Inspections
- Benefit-Risk Management
- Literature Surveillance
- Safety Management Plan
- Medical Monitoring
- Local Contact Person for PV
- Signal Management
- QPPV & PSMF
- Safety and Medical Writing
- Project Management
- Pharmacoepidemiology





Technology-driven Solution Suite

From our world-class pool of experts and utilizing best-in-class technology, we connect our clients to the right safety solutions.

TO MATCH YOUR PRE- PERI- AND POST-MARKETING REQUIREMENTS

- **PVConsult™**

optimizes and streamlines PV operations and ensures regulatory compliance

- **PVTransition™**

allows for business continuity and regulatory compliance when switching service provider(s)

- **PVBridge™**

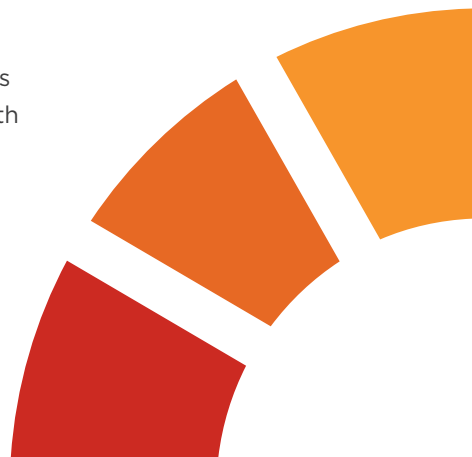
enables our long-standing clients to develop internal pharmacovigilance capabilities

- **PVIntegrate™**

brings harmonization in PV processes during expansion or changes in project scope

- **PVExpert™**

expedites access to KOLs and SMEs to strengthen your negotiations with regulators.



Product Expertise in Vigilance and Pharmacovigilance

Business Units provide safety monitoring of first-time exposure in the wider population. They have also supported management and reporting of medicines and devices in the pediatric and older people population.

TRANSITION FROM CLINICAL STAGE TO POST-MARKETING

- **‘One-stop shop’ Innovative/ Brand products Business Unit:**
serving not only your post-marketing PV commitments but overseeing clinical trials and share valuable intelligence across the board
- **Generics, Hybrids and Biosimilars (GHBs) Business Unit:**
has formulated processes and solutions across various therapeutic areas and agents in different jurisdictions
- **Clinical Safety Business Unit:**
enables consistent processing and safety reporting obligations to be streamlined across sponsors’ portfolios
- **Vaccines Business Unit:**
support any development campaign taking you from the thorny clinical realm all the way to the post-marketing maintenance stage.



Benefit-Risk Management

Through our signal management, medical monitoring, literature surveillance, safety management plan services, we 'inform' the benefit-risk profile of your product round the clock.



PHARMACOEPIDEMOLOGY 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





With over 300 clients, PrimeVigilance is dedicated to delivering high quality, fully compliant global life cycle management safety solutions.

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