

Your Trusted Partner for High-Quality Biosimilar Pharmacovigilance Services

In the rapidly evolving arena of **biosimilars**, ensuring patient safety and effective monitoring through meticulous pharmacovigilance is paramount. Our strategy embraces a comprehensive and proactive approach to pharmacovigilance, designed to not only comply with **regulatory standards** but also enhance patients and prescribers trust and increase the commercial uptake for your biosimilar portfolio. With our **tailored approach**, **cutting-edge technology**, and a **team of seasoned experts**, we not only monitor safety but also enhance the market adoption of your biosimilar offerings in an evolving market.

Tailored Solutions. Global Expertise. Proven Value.



One-Stop Global & Local PV Services: End-to-end pharmacovigilance solutions across clinical and post-marketing phases - ensuring consistency, scalability, and regulatory compliance for your biosimilar portfolio.



Signal Detection & Risk Assessment: Advanced analytics to detect safety signals tied to batch variability, long-term use, or complex patient populations - enabling faster, proactive response.



Regulatory Compliance Support: Expert guidance to meet global and local biosimilar regulations, with flexible support for ad hoc authority requests and insight into country-specific adoption drivers.



Tailored Medical Writing: Specialized writing to reflect biosimilar safety nuances, supporting differentiation and market positioning through evidence-based narratives.



Stakeholder Engagement: Centralized oversight of partners and SDEAs, strengthening collaborations with regulators, HCPs, and support programs to drive safer biosimilar adoption.

**End-to-End PV Support:**

Comprehensive global and local pharmacovigilance—from clinical trials to post-marketing.



Strategic Trial Planning: Faster approvals through proactive PV integration and flexible setup.

**Integrated PV Roadmaps:**

PVIntegrate™ connects safety, regulatory, and commercial strategy for market success.



Dedicated Biosimilar Unit: Specialized teams delivering streamlined processes and cost-effective service.



Medical Writing Expertise: Clear, compliant safety documentation to support regulatory engagement.



Flexible Monitoring Models: Adaptive safety solutions that evolve with your product and data.



Global Reach with Local Insight: In-country experts ensure regulatory alignment and market readiness.



Smart Investment: Scalable, cost-conscious delivery powered by automation, oversight, and efficiency.



Regulatory Partnership: Collaborative support throughout development, filings, and inspections.



Quality and Compliance: Ensuring compliant, high-quality safety deliverables for your biosimilars.

Why Choose PrimeVigilance?

Navigating the complex regulatory landscape of biosimilars requires specialized expertise.

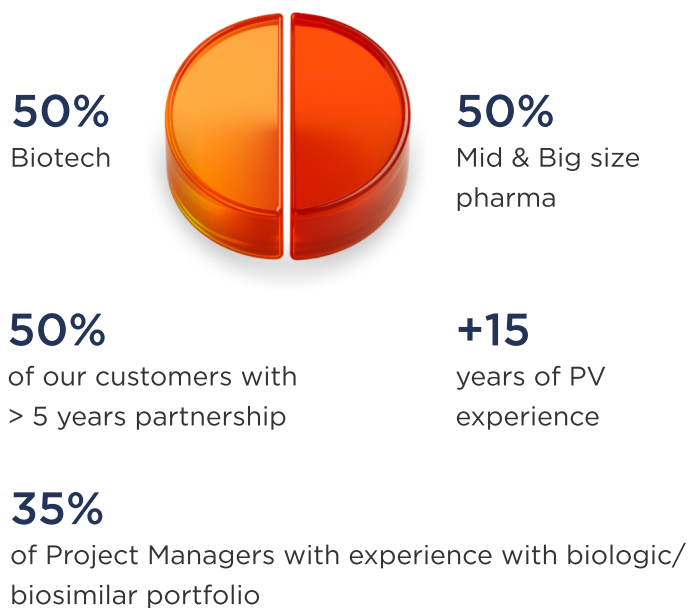
Selecting our services ensures that your biosimilar portfolio is safeguarded by industry-leading pharmacovigilance practices that prioritize patient safety while facilitating compliance and timely market penetration while controlling the investment costs.

Partnering with us means empowering your organization with the insights and tools necessary to navigate the complexities of biosimilar pharmacovigilance confidently.



PrimeVigilance is partner of choice to ensure the successful biosimilars portfolio management, achieving seamless compliance and market readiness.

Statistics



Therapeutic Area

Oncology
Hematology
Immunology
Cardiology
Endocrinology
Nephrology
Neurology
Rheumatology

Integrated. Efficient. Strategic.

We bring an unrivalled reputation in the sector, supported by a global network of Subject Matter Experts, including former regulators and experienced consultants, who understand the intricacies of biosimilar oversight.

Ready to Partner? Contact Us Today!



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