

Strategic Pharmacovigilance for Biosimilars

Ensuring Safety, Compliance, and Market Success

Discover how PrimeVigilance helps biopharma companies navigate the complex biosimilar landscape with advanced pharmacovigilance solutions that ensure patient safety, regulatory compliance, and commercial success.

Global Biosimilar Market Growth and Opportunity

The biosimilar market is expanding rapidly — projected to exceed \$66 billion by 2030.

- ✓ Europe: Mature, cost-efficient market under a well-established regulatory framework.
- ✓ United States: Accelerating momentum as patent barriers fall and uptake grows.
- ✓ Asia-Pacific & Latin America: Emerging markets fueled by affordability initiatives and evolving regulations.

Success in biosimilars starts with a proactive safety and compliance strategy.

Why Biosimilars Require Specialized Pharmacovigilance

Unlike generics, biosimilars are highly complex biologics that demand tailored safety management. Variability in manufacturing can affect immunogenicity, efficacy, and perception — making specialized pharmacovigilance (PV) essential from launch to lifecycle management.

Key Safety Challenges:

- ✓ Continuous immunogenicity monitoring and long-term data collection.
- ✓ Signal differentiation between biosimilar and reference products.
- ✓ Managing interchangeability, perception, and education across markets.

Advanced Technology for Biosimilar Drug Safety

PrimeVigilance's ASaPPV platform enables efficient, technology-driven pharmacovigilance for biosimilars.

Core Capabilities:

- ✓ Centralized case intake – unifies global sources and minimizes missed reports.
- ✓ Automation and quality controls – ensure consistency and faster case handling.
- ✓ Scalable architecture – adapts to high-volume and multi-product portfolios.

Automation and AI-enhanced PV systems are transforming biosimilar safety management.

Building Trust Through Education and Real-World Evidence

Even with regulatory confidence, biosimilar adoption often depends on clinician and patient trust. PrimeVigilance partners with clients to design education strategies that build confidence and drive evidence-based adoption.

Our approach includes:

- ✓ Peer-to-peer medical engagement to strengthen clinical familiarity.
- ✓ Patient-focused communication with clear, empathetic information.
- ✓ Ongoing updates aligned with emerging real-world safety data.

Partner with PrimeVigilance for Biosimilar Pharmacovigilance Excellence

The biosimilar era offers huge opportunity – but only for those who manage safety, quality, and compliance with precision.

- ✓ Ensure global regulatory compliance.
- ✓ Strengthen signal detection and risk management.
- ✓ Enhance operational efficiency through automation.
- ✓ Build stakeholder confidence and trust.

Partner with PrimeVigilance — your trusted expert in global pharmacovigilance and biosimilar safety management.

Let's discuss how PrimeVigilance can support your biosimilar safety strategy.



Contact our team today at info@primevigilance.com

Learn more: www.primevigilance.com