

PRODUCT EXPERTISE IN BIOSIMILARS

Expanding Into a Biosimilar Portfolio

Impact on the Global PV System for a Generic Company

Navigating the complex regulatory landscape of biosimilars requires specialized expertise. PrimeVigilance partnered with a global generic leader to ensure the successful integration of biosimilars into their portfolio, achieving seamless compliance and market readiness.



Client Portfolio Overview

+100 INNs
(traditional generics) in EU, USA, Australia & Mena region

PrimeVigilance provided global case processing, global and local literature screening, partner management, local contact persons for pharmacovigilance (LCPPVs) in EU, benefit risk management and medical writing services.

Client planned expansion of portfolio with four monoclonal antibodies (oncology and immunology) requiring safety support for EU and US marketing approvals and the incorporation of biosimilars into the existing pharmacovigilance framework.

Main Challenges



Expertise & Regulatory Timelines

The client faced challenges due to a lack of experienced Regulatory Affairs (RA) team members with biosimilar-specific knowledge. This gap made it difficult to navigate the distinct and complex regulatory frameworks in the EU and US. Regulatory requirements for biosimilars vary significantly between these regions, necessitating tailored strategies for submissions, comparative studies, and post-market obligations. Limited internal resources and tight timelines further compounded these challenges, making the development of Risk Management Plans (RMPs) and signal management methodologies particularly demanding. These factors underscored the critical need for specialized expertise and meticulous attention to detail.



Integration of Biosimilars into PV Systems

Biosimilars can differ in safety profiles from their reference products, unlike generics, necessitating adaptations to existing pharmacovigilance (PV) systems. Tailored PV activities, a robust risk management plan, post-marketing surveillance, and detailed immunogenicity assessment are essential for compliance and successful biosimilar expansion.



Market Competition and Price Sensitivity

The competitive biosimilar market requires pricing strategies that ensure profitability while offering cost savings compared to reference biologics.

Approach Taken & Outcome



Expertise & Regulatory Timelines

PrimeVigilance initiated a comprehensive gap analysis leveraging its global regulatory intelligence to assess compliance needs across regions. This analysis informed tailored strategies for each biosimilar, factoring in unique development timelines and regulatory expectations.

Key actions included:

- Drafting safety-related application sections, including analytical data, extrapolation of indications, and detailed RMPs.
- Addressing safety queries from the FDA and EMA/CHMP during BLA and MAA review stages.
- Customizing RMPs to highlight critical PV measures, immunogenicity risks, and tailored risk management strategies.
- Suggested key RMMS included:
 - Educational materials for healthcare professionals.
 - Patient alert cards for informed treatment decisions.
 - Controlled distribution lists to ensure traceability.
 - Patient registries for cohort monitoring.
- Developing a bespoke signal management framework adaptable for post-approval safety maintenance.

Outcome: Regulatory Success

PrimeVigilance's strategic support enabled the client to achieve impressive regulatory milestones:

- **US Approvals:** Applicable approvals for biosimilars received approval within 10 months of BLA submissions.
- **EU Approvals:** Applicable marketing authorizations were successfully obtained within 16 months of MAA submissions.

These timelines were achieved despite the rigorous demands of regulatory bodies and the inherent complexity of biosimilar development, reflecting the effectiveness of the tailored strategies implemented by PrimeVigilance.



Integration of Biosimilars into PV Systems

PrimeVigilance adapted the client's PV system through targeted updates to case processing, benefit-risk analysis, and medical writing workflows.

These included:

- Enhanced data collection and event monitoring tailored to biosimilars.
- Development of focused follow-up questionnaires and signal methodologies.
- Strengthened oversight of product quality complaints.
- Establishing global literature search protocols and updated LCPPV coverage in the EU.
- Revising existing Safety Data Exchange Agreements (SDEAs) and creating nine new SDEAs to align with biosimilar requirements.

Outcome: PV System Integration

The client's global pharmacovigilance infrastructure was transformed into a robust, biosimilar-ready system:

- Compliance with EU, US, and global biosimilar safety requirements was achieved seamlessly.
- Tailored risk management measures, including patient registries, educational materials, and controlled distribution systems, were implemented to enhance safety monitoring.
- The newly developed signal management methodology proved effective and required no major adjustments during the post-approval phase, ensuring long-term operational efficiency.



Market Competition and Price Sensitivity

To support the client's cost-efficiency goals, PrimeVigilance optimized contract structures and operational workflows to accommodate expanded service volumes with minimal cost increases. Efficiencies were achieved through process innovation, technology implementation, and extending contract durations from three to five years.

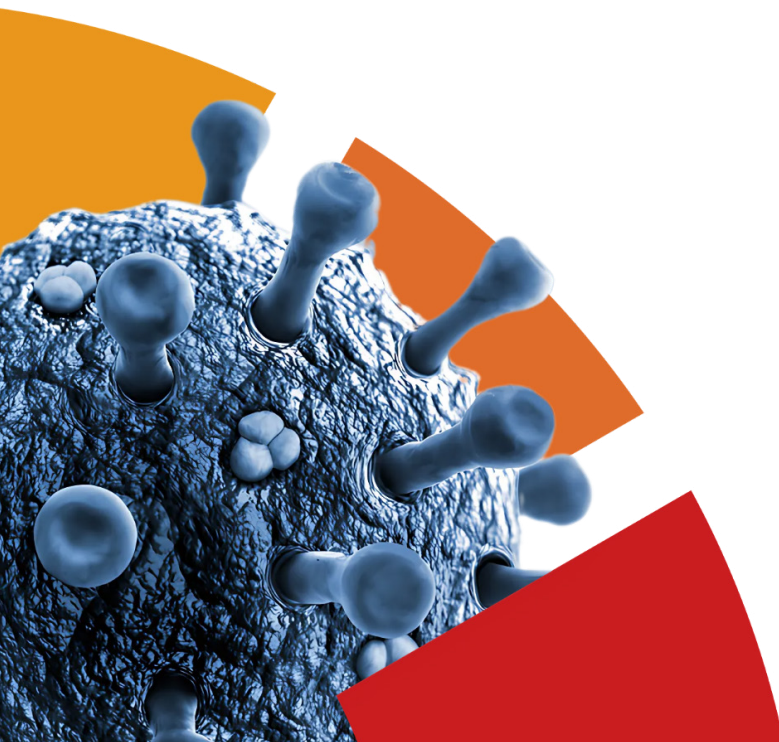
Outcome: Market Competitiveness

- **Expanded Service Scope:** The client successfully increased the scope of services without a significant rise in annual costs, maximizing value without compromising quality.
- **Enhanced Operational Efficiency:** Streamlined processes and innovative solutions ensured sustained profitability in the highly competitive biosimilar market.
- **Long-Term Collaboration:** A strategic contract extension solidified a trusted partnership, fostering deeper alignment and reinforcing a shared commitment to excellence.

Conclusion

This collaboration demonstrates the power of strategic pharmacovigilance in enabling seamless biosimilar market entry. PrimeVigilance's expertise in regulatory compliance, risk management, and operational efficiency empowered the client to:

- Successfully navigate regulatory complexities.
- Implement tailored pharmacovigilance strategies.
- Achieve sustained market competitiveness through cost-efficient, high-quality safety monitoring.



By acting as an extension of the client's team, PrimeVigilance fostered trust, innovation, and operational excellence, positioning both parties for long-term success in the evolving biosimilar landscape.