

Preserving Trust: Excellence in Generic Safety Monitoring

As the landscape of pharmaceuticals evolves, ensuring the safety and efficacy of generic medications is critical in maintaining public trust and compliance with regulatory standards.

With a **long-standing history of working with generic companies** we understand the need to adapt to the ever-changing regulatory landscape. Our pharmacovigilance strategy for generics is **designed to provide required safety oversight**, leveraging **state-of-the-art technology** and **comprehensive data analysis** to ensure cost effectiveness. We focus on providing services that ensure **rigorous safety standards** being met to **foster trust**, ultimately leading to greater acceptance and utilization while **enabling more affordable medication options**.

This way companies can successfully sustain market presence in a highly competitive market.

Full-Service Offerings



One stop shop - Building Confidence in Generics: Establishing comprehensive systems for efficiently collecting, analyzing, and reporting of safety data to ensure impeccable quality, compliance and transparency. An intelligent and mature legacy safety data migration strategy.



Risk Signal Detection and Assessment: Utilizing advanced methodologies to proactively identify and assess safety signals as they arise.



Regulatory Compliance Support: Delivering expert guidance on navigating the regulatory landscape where each country has its own drug approval process, making compliance resource-intensive, ensuring adherence to local and global pharmacovigilance requirements for generic medications to support increasing access to essential affordable medicines and consequently reducing healthcare costs. Building bespoke PV roadmaps to facilitate marketing authorization (MA) or transfer of MAs and lifecycle maintenance.



Training Programs: Making sure harmonised safety training programs are put in place and strongly monitored to overcome challenge of its mandatory compliance across multiple internal stakeholders.



Stakeholder Engagement and Communication: Implementing structured communication strategies, internal and external parties and safety agreements management that covers all safety data management & quality management system oversight and/or management (audits, inspections, deviations, ...). This strongly fosters collaboration between regulators, partners, healthcare professionals, and patients to enhance understanding and transparency regarding generic safety and efficacy.

Unique Benefits



Deep Expertise in Generics: A dedicated focus on the specific challenges and requirements of generic pharmaceuticals to ensure thorough and relevant pharmacovigilance practices. Impeccable track records in inspections support for our generic clients.



Proactive Safety Management: Our forward-looking approach anticipates potential safety issues, allowing for immediate response and adaptive risk mitigation strategies tailored to generics.



Real-Time Safety Monitoring: Utilizing cutting-edge technology and analytics for continuous safety data surveillance, providing timely insights to inform decision-making and enhance patient care.



Generic Business Unit: Tailored PV processes, reporting formats and insights that cater specifically to client needs, ensuring clarity and actionable intelligence. When managing full safety activities we can streamline processes, leverage resources more efficiently, simplify management, and have consistent high-quality deliverables which often translate to reducing the overall costs both from an outsourcing standpoint and for the customer resource needs, as less time is spent to manage a specialized PV provider.

Tailored Solutions



Bespoke Pharmacovigilance Systems

Designing customized pharmacovigilance frameworks that reflect the unique safety needs and operational realities of the generic industry. We pride ourselves on a relationship-focused approach.



Dynamic Risk Communication Plans

Crafting flexible strategies that adapt to evolving safety data and stakeholder concerns, fostering trust and proactive communication in managing safety risks increasing awareness that there is no difference in safety and efficacy of more affordable generic alternatives compared to the original brands.



Global Expertise with Local Considerations

Merging international best practices in pharmacovigilance with localized insights to ensure compliance with diverse regulatory frameworks relevant to generics.



Smart Investment

We offer balanced costs in ever-growing diverse global regulatory requirements and to ensure global compliance which tends to be resource intensive for companies. Working in partnership with us as trusted partner, we provide tailored solutions through economies of scale, simplified management, consistent quality, integrated data handling, scalability and access to expertise.

Why Choose PrimeVigilance?

Real-World Safety. Global Reach. Vaccine-Specific Precision.



Choosing our organization as your core global safety services provider guarantees a dedicated and experienced partner committed to upholding the highest standards of pharmacovigilance for your generic portfolio. Our technical teams are flexible and responsive, ensuring that we can meet your needs and work with you to build a strategy suitable to your own requirements. Quality and efficiency are our primary focus.

Our **unique blend of industry expertise, innovative technology, and proactive approaches** ensures not only compliance with regulatory demands but also fosters confidence among healthcare professionals and patients. By collaborating with us, you **gain access to a wealth of knowledge and tailored solutions** designed to navigate the complexities of generic drug safety - ultimately helping you to **protect your product integrity and enhance patient trust** in your offerings but still help reduce the financial burden on patients and healthcare systems.

Statistics

50%

Mid & Big size pharma

65%

of our customers with > 5 years
partnership

50%

of PMs with experience
with generic portfolio

15+

years of PV experience

Therapeutic Area

Cardiology
CNS
Anti-infectives
Gastroenterology
Endocrinology
Respiratory
Pain Management
Oncology
Urology
Dermatology

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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