

Safeguarding Global Health Through Vaccine-Centric Vigilance

Vaccines are transforming global health, requiring advanced and trustworthy safety systems. PrimeVigilance specializes in comprehensive **vaccine pharmacovigilance**, offering precise, rapid, and globally scalable safety monitoring across all age groups and vaccine types — from pediatric to pandemic-related immunizations. PrimeVigilance supports pharma, biotech, and NGOs with tailored, real-time solutions that leverage technology and real-world data. This ensures regulatory compliance, enhances public trust, and enables agile responses to emerging health threats like outbreaks and shifting immunization needs.

Full-Service Offerings



Geographical Coverage: PrimeVigilance supports a diverse client base across the vaccine development and marketing spectrum – from large pharmaceutical companies and emerging biotech's to NGOs dedicated to expanding vaccine access in underserved regions, all type of companies working in the vaccine drug development and marketing field including large pharma and well as NGOs and emerging biotech.

Leveraging our extensive global network, **we ensure vaccine safety oversight** where it matters most — including high-need geographies facing emerging infectious threats. **Our teams support travel vaccines**, region-specific products (e.g., dengue, cholera), and pandemic rollouts, ensuring timely and compliant reporting across five continents.

We serve pediatric, adult, and elderly populations — with a focus on areas where access is limited but urgency is high. Our capabilities span a broad range of vaccine types, including travel, seasonal, infectious disease, and pandemic vaccines. We understand and manage **vaccine-specific challenges** such as seasonality and surges in volume during pandemics, **delivering agile, effective pharmacovigilance solutions** tailored to the evolving global landscape.

With the support of PrimeVigilance's **large global network** in collaboration with its clients the population across the globe that needs vaccines the most is ensured-as an example monkey pox outbreak, infectious disease and AIDS.



Signal Detection and Risk Assessment combined with Initiative-taking Safety

Surveillance: Applying advanced analytics methods to identify and evaluate safety signals in real time, enabling immediate interventions and robust risk management tailored to vaccine safety. In addition, PrimeVigilance is establishing continuous global safety monitoring systems that capture, analyze, and report adverse events in real-time, ensuring immediate attention to any safety concerns associated with vaccines throughout the lifecycle - from clinical trials to mass distribution.



Regulatory Compliance and Support: Mastering the Global Regulatory Maze governing vaccine pharmacovigilance to ensure your products meet all local and global compliance requirements. Expert navigation through complex, country-specific vaccine safety regulations, including integration of lessons from COVID-19 and regulatory innovations around vaccine-targeted medical events



Education and Outreach Initiatives: Designing training that empowers frontline providers and public health leaders to act swiftly, report effectively, and protect with confidence. PrimeVigilance supports educational programs on the importance of vaccines and the impact on saving lives.



Stakeholder Communication and Engagement: Developing strategic frameworks for engaging with key stakeholders—including regulatory bodies, healthcare providers, and patients—to promote transparency and trust surrounding vaccine safety. Integrated Communication Management: Robust stakeholder engagement frameworks designed to deliver consistent and transparent safety communications to regulators, healthcare providers, and the public.

Unique Benefits



End-to-End Expertise in Vaccine Safety: From early-phase pediatric and travel vaccines to pandemic mass immunization, our team brings dedicated experience and scalable systems to meet each vaccine's unique safety and regulatory profile.



Population-Specific Safety Oversight: Tailored pharmacovigilance frameworks for pediatric, adult, and elderly populations — with age-appropriate monitoring strategies, communication, and stakeholder engagement.



Real-World Evidence Utilization: Leveraging real-world data to enhance safety monitoring, providing actionable insights to inform decisions and support proactive risk mitigation strategies. Post-COVID Frameworks and Agility: Integration of regulatory learnings from pandemic vaccine rollouts and management of high ICSR volumes during peak immunization phases.



Comprehensive Risk Management: A holistic approach that anticipates potential adverse events and equips stakeholders with strategies to minimize risks throughout the vaccine lifecycle. Rapid Signal Escalation & Risk Minimization: Dedicated vaccine-specific workflows that allow swift implementation of corrective actions and risk communication.



Customizable Reporting Solutions: Offering tailored reporting formats to meet the requirements of different stakeholders, ensuring clarity and effectiveness in the dissemination of safety information. Multilingual, Global Footprint: Seamless coordination of global PV operations with locally compliant implementation to address unique regulatory nuances in both high- and low-resource settings.



Specialist Talent Pool: Our pharmacovigilance experts offer extensive hands-on experience across the entire vaccine lifecycle - from clinical development to post-marketing. With a strong track record in seasonal, pediatric, travel-related, infectious disease and pandemic vaccines worldwide - we deliver tailored safety solutions for even the most complex portfolios on a global scale. Our subject matter experts are dedicated vaccine specialists - providing precise insight into regulatory expectations, evolving risk profiles, and crisis readiness.

Tailored Solutions



Bespoke Pharmacovigilance Frameworks: Designing tailored pharmacovigilance systems that reflect the specific safety needs and operational realities of individual vaccine products globally.



Adaptive Risk Communication Plans: Creating responsive communication strategies that evolve with emerging safety data, empowering stakeholders and patients with timely and relevant information. Adaptive outreach tailored to product lifecycle stage, media coverage, and evolving epidemiological context.



Patient and Provider Empowerment Programs: Implementing initiatives focused on educating patients and healthcare providers about the importance of reporting side effects, thereby promoting active participation in safety monitoring. PrimeVigilance also supports educational programs on the importance and lifesaving role of vaccines. Spreading knowledge on vaccine safety promotes higher vaccination rates and acceptance by patient communities.



Global Presence with Local Precision: The organization combines global best practices in vaccine pharmacovigilance with localized expertise to ensure regulatory compliance and cultural sensitivity. It provides integrated oversight across clinical and commercial phases, focusing on identifying and mitigating rare and serious adverse events through tailored risk strategies. We support vaccine programs through EU, US, and global public health collaborations — including delivery in underserved, urgent-need regions where access to immunization is most critical.

The approach includes adaptive, resource-conscious frameworks, culturally appropriate risk communication, and flexible reporting to build vaccine confidence and public health impact where it matters most.



Strategic Safety Partner in the Vaccine Era: Working in partnership with a company that operates as an integral extension of clients' systems, offers them the freedom to focus on research and development of new products. Tailored solutions are designed based on each client's needs thus ensuring cost effectiveness through rapid scalability, wealth of expertise; streamlined management, consistent a quality and integrated data handling.

As the world prepares for next-generation vaccines - from universal flu and RSV to personalized cancer vaccines - the stakes for pharmacovigilance have never been higher. PrimeVigilance stands ready to co-create agile, globally harmonized, and scientifically rigorous PV solutions that ensure safety, uphold public confidence, and contribute to the success of your vaccine innovation.

Why Choose PrimeVigilance?

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



Partnering with us as your core global safety services provider ensures you have a **dedicated team committed to excellence in vaccine pharmacovigilance**. Our **extensive industry experience**, combined with a **deep understanding of the unique challenges** surrounding vaccine safety, allows us to provide unmatched support and **innovative solutions**. With our focus on real-time data analysis, proactive risk management, and effective stakeholder communication, you can trust us to **enhance the safety profile of your vaccines** and **reinforce public confidence in vaccination programs**. Together, we strengthen global immunity - **one vaccine, one region, one life at a time**.

Statistics

Supporting all major vaccine categories: travel, pediatric, elderly, seasonal, pandemic, and region-specific infectious diseases

25%

of PMs with experience in Vaccine portfolio

20+

operations countries with regional regulatory insight

80%

of vaccine clients with multiyear partnerships

15+

years of vaccine PV experience

20+

vaccine products supported globally, including travel, pediatric, seasonal, infectious and pandemic portfolios

100%

compliance on audits and inspections related to vaccine portfolios in the last 5 years

Therapeutic Area

Infectious diseases:

Shigella, Smallpox & Monkeypox, Rabies, Cholera, Chikungunya, Encephalitis, Tick-borne Encephalitis, Lyme Disease, Ebola, RSV, Pneumococci, Pertussis, COVID-19

Flu vaccines for infants, adults and elderly over 65 years of age

Periodontitis vaccine

AIDS vaccine

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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