

Excellence in pharmacovigilance solutions: How Fortrea's market-leading safety support enabled global operations for a leading pharmaceutical company

A KEY QUESTION



How can leading pharmaceutical sponsors find the global scale and localized expertise needed to solve complex pharmacovigilance challenges across multiple regulatory environments?

KEYWORDS

Pharmacovigilance Solutions, Pharmaceutical Company, Safety Solutions, Pharmacovigilance Partner



Executive summary

Fortrea has been recognized as a “Leader” for pharmacovigilance operations by Everest Group in its annual Pharmacovigilance Operations PEAK Matrix® Assessment 2025, with top position recognition in both pre-and post-approval pharmacovigilance (PV) operations.¹ This industry recognition validates our ability to deliver comprehensive, patient-centric safety solutions for global pharmaceutical companies.

A leading global pharmaceutical company operating across six continents partnered with Fortrea to solve complex pharmacovigilance challenges across multiple regulatory environments. The collaboration exceeded initial objectives and expanded to include additional services, proof of the strategic value we deliver.

The collaboration shows how Fortrea created measurable business outcomes for pharmaceutical sponsors seeking reliable, scalable safety solutions.

Client profile

The client operates a global pharmaceutical business with significant presence across Africa, Asia Pacific, Canada, Europe, Latin America and the Middle East. With products spanning multiple therapeutic areas and six continents of operation, they represent the complex challenges that today's leading pharmaceutical companies face in managing worldwide safety operations.

The challenge

Managing global pharmacovigilance operations across multiple regulatory environments requires deep expertise in region-specific requirements while maintaining consistent global standards. Each market brings unique reporting obligations, timelines and regulatory expectations that demand both flexibility and precision.

The company needed comprehensive safety solutions spanning the entire product life cycle, from clinical development through post-marketing surveillance. The challenge? Finding a provider that could deliver both global scale and localized expertise while maintaining top-tier regulatory compliance.

Their requirements included true end-to-end solutions that seamlessly integrate clinical and post-marketing safety activities:

- Complete Individual Case Safety Report (ICSR) case processing and expert medical review
- Safety writing, compliance support and audit preparation
- Regulatory-grade consistency across all therapeutic areas
- Customized solutions at competitive pricing without compromising quality

Beyond technical capabilities, they needed a collaborator with the agility to adapt to evolving project needs and the strategic insight to optimize operations continuously.



Fortrea's "One Safety" solution comprehensive service portfolio

We deployed our complete pharmacovigilance suite to tackle this client's complex global safety requirements. This integrated approach reflects Fortrea's "dual-strength PV capabilities, offering comprehensive clinical-stage safety services built on deep domain knowledge across 60+ therapeutic areas, alongside robust post-marketing operations."¹

Our team combined industry-standard safety systems with proprietary automation to drive efficiencies while meeting country-specific requirements across the client's six-continent operation. This approach stays ahead of global pharmacovigilance trends, such as those outlined by the European Medicines Agency (EMA) to emphasize the importance of digitalization and real-world data to enhance safety operations.²

Navigating complexities with agility:

We established frameworks that enable quick transitions and swift adaptation to client and regulatory requirements. Flexible workflows and strategic decision-making processes allowed us to manage complex safety operations efficiently while maintaining high service standards across all regions.

Continuous optimization: Data drives everything we do. Through systematic efficiency improvements and process refinements, we maximize accuracy and productivity while optimizing resource use. These were critical factors in this client's decision to expand our collaboration.

Seamless delivery: We don't just collaborate; we deliver on time and on budget. Innovation and reliability guarantee smooth project execution. Close client relationships combined with rigorous quality control produce consistent, high-value results that go beyond expectations.

Strategic contract management

Beyond core pharmacovigilance services, we provided dedicated contract manager support at various locations and workstreams. This approach ensured continuous client support for daily operations, helping maintain requirements, optimize contract execution and proactively address operational challenges.

Results and project success

The project's success stems from our track record of delivering high-quality solutions with exceptional consistency. Our ability to work seamlessly, adapt to evolving project needs and provide customized solutions—while maintaining competitive pricing—created significant value for global operations.

Fortrea's "first-time-right approach (FTR)" that "prioritizes the needs of patients, physicians and regulatory authorities" delivered measurable results:¹

- Improved regulatory compliance across all markets
- Streamlined safety processes and enhanced operational efficiency
- Organic growth with additional services added post-contract
- Contract managers deployed at two additional locations

Most significantly, this expansion demonstrates both client satisfaction and the strategic value proposition we deliver through comprehensive safety solutions.

Fortrea's **processing of over one million ICSRs annually with approximately 99.5% regulatory compliance** over the past five years demonstrates the depth of our commitment.³

Industry recognition

Fortrea's recognition as a "Leader" in Everest Group's 2025 Pharmacovigilance Operations PEAK Matrix Assessment is a welcome confirmation of our industry leadership position.¹ Out of 29 PV operations providers evaluated, we earned top recognition in both pre-and post-approval pharmacovigilance operations.

“Fortrea stands out with its dual-strength PV capabilities, offering comprehensive clinical-stage safety services built on deep domain expertise across 60+ therapeutic areas, alongside robust post-marketing operations supported by global Qualified Person Responsible for Pharmacovigilance (QPPV) coverage and technology-led innovation.”¹

Everest Group

What sets us apart? Our multidisciplinary collaboration model, flexible delivery frameworks and ongoing investment in cutting-edge technology and strategic collaborations. Clients consistently recognize Fortrea's strengths in scientific depth, scalability and global reach. These were the exact capabilities this global pharmaceutical company needed to succeed across six continents.



Key takeaways

This collaboration demonstrates the strategic value of working with an industry-recognized leader in pharmacovigilance operations. Essential success factors included:

- Adapting to unique client needs while maintaining uncompromising quality and compliance standards
- Proven ability to create measurable business value through the right pharmacovigilance approach
- Market-leading position with proven track record and strong patient-centric focus
- Delivering consistent results while adapting to developing industry demands

For pharmaceutical companies operating in today's complex global regulatory environment, choosing the right pharmacovigilance collaborator is paramount for patient safety AND business success.

Ready to explore how Fortrea's award-winning pharmacovigilance solutions can support your global safety operations?

Contact our team to discuss your specific requirements and discover why leading pharmaceutical companies trust Fortrea as their strategic safety collaborator.

LEARN MORE at fortrea.com

References

1. Fortrea, Fortrea named a leader in Everest Group's pharmacovigilance operations PEAK Matrix® assessment 2025: recognized in both pre-and post-approval pharmacovigilance operations. *GlobeNewswire*. Published 2025 May 1.
2. EMA regulatory science to 2025: strategic reflection. *EMA.Europa.EU*. Published 2020.
3. Safety. *Fortrea Website*. Accessed 2025 June 10.