CASE STUDY

Regulatory intelligence in action: Transforming compliance into strategy

A KEY QUESTION

How can proactive integration of regulatory intelligence into pharmacovigilance workflows transform post-marketing safety operations across global markets?

KEYWORDS Pharmacovigilance, Regulatory Intelligence, Safety

Operationalizing regulatory intelligence

Effective pharmacovigilance depends on steady access to the right regulatory knowledge. Regulatory intelligence, in turn, becomes action when it's embedded into daily safety operations, making it the cornerstone of ensuring drug safety and compliance within the pharmaceutical industry. Meaningful regulatory intelligence encompasses the systematic gathering, analysis and interpretation of regulatory information and updates pertaining to the development, marketing and post-marketing surveillance of medicinal products. For companies with global reach, that knowledge must move fast; it is indispensable support for maintaining the highest standards of pharmacovigilance and ensuring patient safety throughout the product life cycle.

Post-marketing surveillance often reveals what clinical trials miss—especially for breakthrough or accelerated therapies.[1] By embedding regulatory intelligence into workflows, organizations can swiftly adapt to changing requirements, ensure compliance and enhance risk management strategies. Fortrea's team brought that awareness into every step of this success story.

Background

A U.S.-based commercial-stage biopharmaceutical company had launched its product across a wide range of marketing regions around the world. Along with their business partners, this company had active clinical trials and early-access programs (EAPs), plus their product was recently approved for marketing across the United States, Canada, France, Germany, United Kingdom, Israel, Switzerland, Brunei, Singapore, Malaysia, Australia and New Zealand. The safety oversight needs were immediate, large and complex. This is where Fortrea stepped in.

Fortrea's pharmacovigilance work scope involved end-to-end individual case safety report (ICSR) processing (for pre-approval and post-approval activities), literature review and regulatory intelligence. The timeline: **12 weeks** to prepare everything ahead of go-live.

Fortrea

Challenges for project management

The safety environment surrounding this product was in constant motion. The client's clinical, early-access and commercial programs spanned continents, with different timelines, reporting obligations and regulatory nuances. Every safety input had to be tracked, triaged and reported correctly. Fortrea's team had to move fast while building a foundation that could flex with the client's growing pipeline:

- Short timeline to build and finalize all safety processes and documentation
- Multiple overlapping regulatory frameworks due to active trials, EAPs and post-approval launches
- Complex submission rules from global health authorities and local partners
- Expanded literature review needs, including local journals and multilingual sources
- Frequent queries and changes from the client, including study status updates, new approvals and pipeline expansion

Incorporating regulatory intelligence into project management

Reference documents and regulatory matrix:

- Fortrea's regulatory intelligence team built a master regulatory matrix. They pulled from a central repository, a global vendor database and added knowledge from experienced regional safety officers. They mapped out the requirements for clinical and post-marketing safety reporting, plus anything defined in the partnership agreements
- The team supplied the client with all the needed governing documents, from legislation to health authority guidance; reporting grids were built for each country to provide clear timelines, formats, destinations, prerequisites and cross-reporting needs
- When the regulatory text was unclear (e.g., some cross-reporting rules), Fortrea submitted queries directly to authorities for confirmation

Database reporting rule configuration:

- The regulatory matrix was used to define reporting requirements by ICSR type (clinical trial, EAP, post-marketing and business partner reports)
- Fortrea's intelligence team compiled these into a database configuration matrix
- All reporting rules were subjected to user testing to ensure accuracy and alignment with the relevant submission standards
- The process ensured **full coverage** of submission requirements across **all safety categories**

Literature review:

- Fortrea collaborated with the client's operations team to develop a globally compliant literature review process
- Regulatory requirements were mapped for both global and local literature surveillance in the United States, United Kingdom, Switzerland and Australia
- A literature matrix was created, laying out in detail each country's expectations for sources, frequency and formatting
- A unified global search string was developed to expedite the review of indexed literature
- Local safety teams completed regular reviews of region-specific journals to maintain compliance with local expectations

Support for process maintenance and ongoing process improvement

To keep the system responsive and compliant, Fortrea built processes that delivered continuous regulatory intelligence feedback. This included a monthly pharmacovigilance newsletter that covered important updates across all regions, along with real-time input on critical safety process changes. The team also provided structured impact assessments, including steps for change implementation. These covered updating of matrices and revising process documents, ensuring nothing fell through the cracks.

Lessons learned

This case study combined A) a proficient project management team specializing in pharmacovigilance (PV) services with B) a resilient, integrated, continuous regulatory intelligence support system. Fortrea gave this sponsor more than a safety system.
It gave them confidence:

- Processes were clear
- Communication was focused
- Submissions stayed on track
- System evolved in lockstep with the product's growth

Through this project, Fortrea has strengthened process setup by streamlining timelines, centralizing regulatory requirements and continuously monitoring updates to drive timely, compliant adaptations.

Conclusion

Pharmacovigilance is more critical than ever, and the challenges involved are only growing in complexity.[2] What worked five years ago won't hold up today. Fortrea's approach met the moment, and the sponsor moved forward: prepared, protected and fully supported.

If you're looking to elevate your pharmacovigilance operations with built-in regulatory intelligence, Fortrea is ready to help.

fortrea.com/contact

References

1. Trifirò G, Crusafulli S. A new era of pharmacovigilance: future challenges and opportunities *Frontiers in Drug Safety and Regulation.* Published 2022 February.

2. Sidharthan C. Why pharmacovigilance is more critical than ever. *Medical.net.* Published 2025.

Fortrea