A PHASE IV SOLUTIONS CASE STUDY

Streamlining the literature surveillance process to improve market value communications

In the commercialization stage of clinical development, literature surveillance provides significant value communication for a pharmaceutical product. It not only tracks industry trends and change in literature over time, but also informs a sponsor of the latest publications in real-world evidence, which can be leveraged to more effectively communicate a product's key differentiators from competitors for maximum healthcare impact.

A multinational pharmaceutical company well known for its pharmaceutical active ingredients and finished care products wanted to update and enhance their current literature surveillance processes. The company enjoyed an existing successful relationship with Fortrea, having relied on our insights for the development of several consumer and medicinal products. The client also entrusted our team with a majority of postmarketing pharmacovigilance activities, from end-to-end individual case safety reporting (ICSR) standards to regulatory work across the EU and safety variations management. With their latest ask, the client relied on Fortrea's partnership to streamline literature surveillance for ICSR, aggregate reporting and signal management.

KEY TAKEAWAYS

Mapped current surveillance processes and implemented recommendations based on established regulatory guidelines

Classified surveillance issues by category and customized solutions to overcome them

Standardized best practices to ensure overall consistency and compliance to regulatory requirements

Initiating a phased transition approach

To address the sponsor's needs, Fortrea proposed a dual-phase transitional approach to analyze and implement changes as seamlessly as possible. This consisted of a two-in-a-box project management model with one functional expert and one operations expert. For phase one, replications of ongoing processes were instated. Phase two focused on in-depth gap analysis and process streamlining. Overall objectives from the project management team included:

- Training to understand and map current processes and compare them against good pharmacovigilance practices (GVP)
- Recommendations for implementation of the European Medicines Agency's GVP Module VI and other regulatory guidelines
- Issue classification under four categories: search related, review related, allied process related and concept related
- Performing gap and deficiency analyses to plug process loopholes in the literature surveillance and review process

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Taking corrective action in multiple categories

During gap analysis, the Fortrea team identified several opportunities to improve literature surveillance for the sponsor's assets. These included search-related, review-related, concept-related and allied-process-related issues.

For search-related issues, our team:

- Identified missing and erroneous molecules through cross-verification of entire regional product lists against literature molecule search lists
- Fixed incorrect search strings and time periods for the entire list of molecules requiring literature search
- Upgraded the sponsor's search database from PubMed to Embase for better indexing and output accuracy. The new database simplified tracking through separate searches per molecule that were ready to use for six-month data outputs for each molecule during signaling activity, instead of combined drug outputs

For review-related issues, our team recommended:

- Discontinuing the databasing of literature cases irrespective of causality. A communication with the U.S. Food and Drug Administration (FDA) was established to confirm the causality cause was required for literature cases. After FDA confirmation, the new process was implemented
- Discontinuing the practice of creating multiple clusters and summary cases from single literature articles. When this practice was stopped, it reduced noise in signaling activity and reduced burden in processing multiple duplicate cases by 10%, thereby improving the quality of safety data collected and sent to regulatory authorities

For concept-related issues, we:

- Stopped manual review and processing medical literature monitoring cases and instead initiated an automated download option. Strings were created in .json format so that only XML cases relevant to company products could be downloaded, imported and processed
- Created a Reportability Matrix to align best practices for every country and region within the sponsor's scope as a single point of reference. This included details regarding standard and internally decided timelines, formats, methods and local affiliate contacts for local submission, which did not exist previously

Finally, for allied-process-related issues, we corrected inconsistencies in the full-text article procurement process.

Accelerating clinical outcomes for our sponsor

By leveraging Fortrea's multistep strategy to enhance processes, the sponsor successfully transformed ineffective processes into a faster, streamlined workflow that standardized operations for regulatory compliance. With the implementation of our changes, the sponsor saw a 10% reduction in volumes of incorrect case processing and benefitted from significant savings in costs and turnaround time for their products.

Partnering with Fortrea helped the sponsor rectify specific weaknesses in their postmarketing strategies. Our expert insights and flexible solutions equipped the client with an audit-ready, efficient and regulatory-compliant process. With accelerated timelines and approval processes in place, the sponsor is now able to expedite commercialization of new medicines, delivering new hope to improve health and patients' lives worldwide.

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