A FORTREA FSPx® CASE STUDY

Serving as an extended safety partner for an emerging biotech's vaccine studies.

An emerging biotech was developing an influenza vaccine and turned to the Functional Service Provider (FSPx®) team at Fortrea to handle their clinical and post-marketing safety data. This case study outlines how the team supported the sponsor's needs—and handled unexpected volume surges—to meet regulatory compliance and serve as more than a partner.

Understanding the challenge

The biotech sponsor had been focused on the clinical and regulatory aspects of their vaccine development and recognized the need for an experienced, external partner to support pharmacovigilance during the clinical phase. They chose the Fortrea FSPx team to host their safety database, provide end-to-end case processing and support their regulatory submissions across Latin America.

The sponsor tasked the FSPx team to manage a certain number of cases each month and the work started to progress as forecasted. But after six months, the sponsor's case volume suddenly increased by more than 1200% percent.

KEY TAKEAWAYS

- Set up the sponsor's safety database, quality management system and regulatory submissions for end-to-end pharmacovigilance services in a vaccine study
- Managed an unexpected, 12x surge in case volume
- Created strategic processes to increase resources and meet the study's unique requirements
- Delivered a full suite of integrated solutions to support pharmacovigilance and clinical safety in a global trial

Responding to volume surges with strategic operational management

With the unexpected increase in cases to manage, the FSPx team quickly worked to access their existing "buffer" pool of resources on stand-by, cross-train their existing resources as well as hire new resources. High-priority reports were handled first while the sponsor and the FSPx team continued to have regular meetings to discuss operational decisions and ensure that they were aligned with the service level agreement (SLA) and key performance indicator (KPI) metrics.

As a result of these operational strategies to rapidly increase the team size and respond to the sponsor's needs, the FSPx team was able to successfully manage the new case load within four months.

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Looking ahead to empower end-to-end safety for the sponsor

Based on the FSPx team's performance and success supporting safety monitoring for their influenza vaccine, the sponsor asked Fortrea FSPx to provide clinical and post-marketing safety services for their COVID-19 vaccine. By using the same FSPx partner for both pre- and post-marketing safety, the sponsor can expect streamlined operations as the FSPx team leverages its cumulative knowledge of the sponsor's expectations and the study's unique requirements. The existing safety database for pre-marketing safety can be quickly configured for post-marketing safety. No transition will be required for the pre-marketing safety data.

The FSPx team has also been asked to take on additional regions as the sponsor expands its global trial. They are now supporting the sponsor with medical monitoring in Japan and Latin American as well as providing a Qualified Person Responsible for Pharmacovigilance (QPPV) in the EU.

From setting up the safety database to facilitating regulatory communications, creating robust processes and developing quality management systems, the Fortrea FSPx team has proven its role as an extended safety partner for emerging biotechs as they work together to improve health and lives around the world.

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