

CASE STUDY

Providing rapid staffing and flexibility during the pandemic



An FSP® case study for pharmacovigilance and patient safety

A global pharmaceutical sponsor was developing a COVID-19 vaccine and needed a CRO partner to rapidly support their global launch. Based on a longstanding relationship in supporting pharmacovigilance and patient safety in their other product portfolios, they selected Fortrea Functional Service Provider (FSP) as their partner. This case study outlines the unique challenges faced in order to deliver flexible services during the pandemic and the team's innovative solutions to help ensure that pharmacovigilance and patient safety protocols were upheld.

Understanding the challenge to uphold patient safety

Every day counted to ensure a rapid release of the sponsor's COVID-19 vaccine and reach global populations. When the sponsor was ready to launch their vaccine, they needed pharmacovigilance and patient safety staff across multiple global locations. In a process that typically requires 4-6 weeks, they asked Fortrea FSP to complete startup in just two weeks. Fortrea had just three months to hire, onboard and train all teams to align with the vaccine's release.

Delivering to meet demands

Working urgently to meet the sponsor's expectations, Fortrea FSP allocated 15% of their staff from in-house resources that had previous experience supporting the sponsor. For the new hires, they used a "train the trainer" model where remote training sessions could quickly disseminate knowledge and ensure understanding of the necessary systems. Given the pandemic required fully remote staff, the initiative consisted of additional logistical challenges with the delivery of pre-configured laptops. This challenge was overcome with the creation of focused sub-teams activated to meet the committed timelines.

Creating a flexible staffing model for key functions

With three global hubs activated, Fortrea FSP provided nearly 1,000 team members, which included staff skilled in translating reports. With a “hub and spoke” model, regional translation activities were performed at sites in the EU, Asia Pacific and South America. After the review of call center data, three FSP-staffed centralized delivery teams in India provided case processing support and data entry. Data safety documents were uploaded for case processing. Fortrea FSP then provided medical review, a task that required a significant number of physicians and highly specialized expertise.

Adjusting to evolving requirements and supporting patient safety

After reaching a steady state of operations, the sponsor reevaluated its work volume. Fortrea FSP then adjusted the partnership to provide approximately 800 additional staff based on the detailed evaluation to date, as well as an estimate of future volumes. Fortrea FSP also provided flexibility when the sponsor needed specific resources to help process adverse events (AEs) to ensure careful focus on these cases. After Fortrea quickly formed a team of medical reviewers dedicated to AEs, the sponsor was able to extend their expertise through FSP.

Now that the partnership has been in a steady state in all global regions, Fortrea FSP is working with the sponsor to extend automation capabilities and incorporate process efficiencies, which will help achieve ongoing regulatory compliance. As efforts to stop the spread of COVID-19 evolve, Fortrea FSP will provide ongoing, flexible support, serving as the sponsor’s source for pharmacovigilance and patient safety.

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