

CASE STUDY

Growing a flexible FSP model to support biometrics.



An emerging biotech sponsor was developing a few compounds to target rare diseases and needed to extend their team with a functional service provider (FSP) model. They chose Fortrea FSP to support their short-term needs and design a long-term asset strategy for their portfolio.

This case study shares how Fortrea FSP has grown the relationship and served as their partner of choice for more than eight years. Learn how the team continues to support the sponsor's ongoing development through a flexible, regionalized model.

Designing an FSP model with core and flex teams

The partnership started with biometrics support and later expanded to include data management. In this model, the Fortrea FSP allocated a dedicated “core” full-time team of eight that were fully trained on the sponsor's molecules, processes and systems.

To address periods of increased demand, Fortrea FSP also provided access to a “flex” team, which could be used as needed. This team was also given access to the required systems and training to fully support the sponsor.

With this flexible structure, the sponsor could access technical experts to prepare for submissions, address workload variations in demanding phases of development and efficiently manage their budget.

Sharing risk management

Fortrea FSP and the sponsor worked together to define their priorities, review the sponsor's portfolio and track deliverables to share risk management. The FSP team also worked with the sponsor's selected CRO to form a productive tripartite relationship and promote consistent, high-quality delivery as the sponsor's needs evolved.

KEY TAKEAWAYS

Offered “core” and “flex” teams to meet demands for increased support for biometrics expertise

Formed a collaborative environment that shared risk management while developing a tripartite relationship with the sponsor's CRO

Grew the support from a team of 8 to a team of more than 175, including a large, regionalized percentage to provide cost-efficient resources

Provided an intense ramp-up of teams on multiple occasions to support high priority submissions

Played an integral role in helping the sponsor achieve successful submissions with the FDA, EMA and PMDA to make a difference for patients living with a rare disease

Adding regionalized resources to meet growing needs

Initially, the Fortrea FSP team was sourced from the US. As the sponsor's needs grew, Fortrea implemented a cost-effective resourcing structure of resources in India and Eastern Europe to create a 3:1 offshore to onshore ratio.

As the sponsor increased their pipeline in the following years, they required a high volume of Fortrea FSP subject matter experts, with a larger percentage from non-US regions. This global structure, which is supported with local leadership and management, has since grown to an FSP team of more than 175. Transparent practices and an employee retention plan have helped Fortrea FSP achieve a retention rate of more than 90%.

Recognizing the results

Throughout this long-term partnership, Fortrea FSP has become an integral part in supporting sponsor's needs. The team's expertise has helped reduce the sponsor's burden of maintaining resources and providing project management oversight. Under the sponsor's direction, the FSP team has focused on efficiency and quality to support numerous projects, such as:

- Incorporating acquired legacy data from the sponsor's numerous acquisitions
- Providing subject matter expertise to enhance the sponsor's analytics platform
- Advancing standards and process development

By delivering the right level of experience and scale at the right time, Fortrea FSP has helped the sponsor achieve successful submissions with the FDA, EMA and PMDA and provided significant cost savings through regionalization.

LEARN MORE about Fortrea FSP at:
fortrea.com/solutions/full-and-functional-service-provider-models