

ONCOLOGY FSP CASE STUDY

Transforming a long-term FSP partnership to enhance global oncology studies



Building trust in a Functional Service Provider (FSP) relationship starts with a collaborative relationship and the ability to respond with agility to evolving needs. This case study shares how Fortrea has swiftly adapted to change, flexibly adjusted its delivery services and enabled operational efficiencies for a sponsor.

Initiating the FSP model

In 2015, the sponsor sought a CRO with strong FSP services and trusted experience in several therapeutic areas, specifically oncology. They chose Fortrea (then operating under a legacy name) to deliver its FSP solutions based on demonstrated success as measured by key performance indicators (KPIs).

During the first five years, Fortrea FSP provided clinical data management, biostatistics and statistical programming to support Phase I–III studies spanning ophthalmology, cardiovascular and oncology therapeutic areas.

As part of this collaboration, the sponsor also relied on Fortrea FSP to handle its Integrated Summary of Safety (ISS) submissions, create standardized templates and guide their Clinical Data Interchange Standards Consortium (CDISC) standards development.

KEY HIGHLIGHTS

Over the last 10 years, a large global pharmaceutical sponsor has relied on Fortrea FSP to advance their clinical trials in North America, Europe and Asia Pacific. Fortrea's FSP team currently supports more than 20 early and late phase studies with:

- Clinical data management
- Biostatistics
- Statistical programming
- Electronic data capture programming and user access
- External data review
- Data archiving
- Risk-based quality management (RBQM)

The sponsor continues to benefit from a strong collaboration as Fortrea FSP applies its deep understanding of the sponsor's oncology portfolio and tailors services to meet specific delivery needs.



Focusing on oncology clinical research

With a rapidly growing oncology portfolio, the sponsor asked Fortrea FSP to support them in oncology standards development, and soon, the FSP team was solely focused on oncology. Serving as an extension of the sponsor's oncology team, Fortrea FSP partnered to:

- **Optimize study designs** to capture data effectively
- **Establish vendor transfer specifications** and schedules to efficiently reconcile and clean vendor data throughout the studies
- **Understand and identify Electronic Data Capture (EDC) data trends** to issue queries, clarify ambiguity and clean the data
- **Develop and incorporate tools and reports** to drive data cleaning activities from study start-up
- **Inform study teams** of risk assessments and decisions
- **Drive critical discussions** with the sponsor's study teams and make recommendations to support key timelines

To guide these processes, Fortrea FSP used its standard operating procedures (SOPs) and integrated the sponsor's SOPs as they were developed. This hybrid SOP approach supported current study needs and allowed the sponsor to adapt their standards and best practices over time.

While developing SOPs with the sponsor, Fortrea FSP also applied lessons learned to support problem-solving. For example, working internally and with the sponsor, Fortrea refined the LNR (lab normal range) process. By incorporating additional checks and balances in LNR analyses, they helped catch discrepancies, track source documentation and minimize risks to promote quality and consistency.





Establishing a flexible FSP partnership

Every FSP partnership is unique as Fortrea aligns with the sponsor's culture and continually adjusts its approach to meet their needs. Over the past 10 years, several notable milestones demonstrated Fortrea's ability to refine its delivery services and offer custom solutions for the sponsor. These included:

Incorporating new cost efficiencies with regionalization

To enhance cost efficiencies for the sponsor, Fortrea's FSP team strategically expanded to other global regions beyond North America. In addition to cost sustainability, this shift aligned with the sponsor's operational resources and addressed business needs.

Enabling a strong collaboration for a swift study database build

To achieve an unusually tight target for a study database build, Fortrea partnered with the sponsor's executive and operational leadership. They united resources and drove process efficiencies to ensure that the study database was ready for First Patient In (FPI).

Scaling resourcing to support priority deliverables

The sponsor's level of full-time employee (FTE) support through Fortrea FSP has steadily grown from approximately 40 team members in 2015 to more than 100 in 2025. In some years, the FSP team has expanded as required to more than 120 FTEs, highlighting flexibility and a commitment to quickly meet the sponsor's priority deliverables.


Enhancing commercial flexibility

The sponsor is exploring its options for converting from unitized support to a FTE contracting model. Fortrea FSP is guiding the discussion to help the sponsor achieve commercial flexibility, adjust its FSP model and align with the sponsor's current and future pipeline.

Expanding services to include risk-based quality management

Recognizing the team's ability to drive consistency and quality, the sponsor awarded Fortrea FSP "preferred vendor" status for biometrics and data management. They subsequently asked Fortrea FSP to incorporate its RBQM services and support for additional clinical data technology.

As part of this expansion, the sponsor is relying on Fortrea's SOPs and expertise to refine the sponsor's current risk-based approaches. Fortrea FSP is also piloting a metadata repository (MDR) implementation for Study Data Tabulation Model (SDTM) specifications to improve further efficiency and consistency in the clinical data submission process.





Reflecting on shared success and future delivery

Since engaging with Fortrea FSP, two of the sponsor's oncology compounds have achieved FDA approval. Fortrea FSP currently supports more than 20 early and late phase oncology studies and continues to serve as a trusted partner. The team has highlighted several ways it maintains strong collaboration, including:

- **Enabling transparency:** Fortrea FSP openly discusses concerns and issues with the sponsor and evaluates options to determine the appropriate resolution
- **Providing expertise:** The FSP team advises the sponsor on process and technology improvements, drives study team decision-making and shares recommendations
- **Strategically locating resources:** Many Fortrea FSP resources are co-located with sponsor leads in North America, Europe and Asia Pacific to maximize the overlap of working hours, promote efficient communication and enable cost-effectiveness
- **Anticipating risk:** With a deep understanding of the sponsor's processes and oncology portfolio, Fortrea FSP works to proactively identify and mitigate risk
- **Demonstrating continuous improvement:** As the sponsor's oncology portfolio has expanded and new changes are introduced, Fortrea FSP continues to implement process improvements and deliver additional value for the sponsor

While nurturing a productive partnership and evolving to meet unique requirements, the Fortrea FSP team has been pleased to earn an exceptionally high Net Promoter Score® (NPS), which measures customer satisfaction and the likelihood to recommend Fortrea's FSP services to others. As part of the NPS survey, the sponsor provided several comments to justify their high score of Fortrea:




"We have a long working relationship with Fortrea. Love your commitment to continuous process improvement."

"Fortrea FSP provides responsiveness, quality, flexibility."

"Fortrea FSP provided several database builds. Several successful data deliveries."

"Fortrea FSP is maintaining timelines for database locks and migrations."

Building on this long-standing collaboration, Fortrea looks forward to driving continued value for the sponsor, delivering quality results and advancing the sponsor's oncology portfolio to ultimately make a difference for people living with cancer.



Learn more about how Fortrea FSP delivers flexible CRO services at a global scale:

<https://www.fortrea.com/clinical-solutions/delivery-models>

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