CASE STUDY

Flexible FSP resourcing meets evolving needs for an oncology biotech

A KEY QUESTION

How can a flexible, trust-driven FSP relationship evolve alongside a growing oncology biotech to optimize clinical operations and deliver measurable results?

KEYWORDS Fortrea FSP, Oncology Studies, Biotech, Hybrid Approach, Risk Mitigation, Clinical Development, Process Innovation

Fortrea Functional Service Provider (FSP) was selected by a mid-sized biotech to initially support its Clinical Data Management, Electronic Data Capture (EDC) Programming and Clinical Reports Programming. As their oncology program matured, the biotech continued to redefine its priorities and expanded its FSP needs to include Clinical Operations and Trial Master File (TMF) Management.

Learn how Fortrea FSP has addressed challenges, driven process innovation and supported strategic operations to enhance efficiency and reinforce its long-term commitment to the biotech sponsor's success.

Building trust and transparency

Fortrea FSP initially entered the relationship with high expectations from the biotech's senior director, who had previously worked with Fortrea through another client. While Fortrea FSP had demonstrated reliability with the former client, the team still needed to build trust with the biotech sponsor and develop a deep understanding of their oncology portfolio.

After hiring the right-fit team members with oncology experience, Fortrea FSP supported the collaboration by:

Developing and reinforcing cross-functional collaboration across clinical development teams: With centralized documentation and regular review of metrics, Fortrea FSP has helped guide decision-making and develop strong collaborations across the biotech.

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Offering a hybrid SOP approach: The biotech sponsor requested a hybrid approach for standard operating procedures (SOPs). Fortrea FSP used a blend of the sponsor's process and its own, for example, with clinical programming templates, until the sponsor established their own processes.

Leading key process innovations: To support the sponsor, Fortrea FSP has led study startup efforts, implemented external data workflows for laboratory vendor sample management, created vendor-specific data transfer plans (DTPs) and provided medical coding oversight as needed.

Anticipating needs and risks: Throughout the relationship, the Fortrea FSP team has proactively identified and communicated potential risks, offered mitigation strategies and provided recommendations for enhancing processes and tools to ensure alignment and minimize project risk.

Flexibly adjusting resources: Fortrea FSP has implemented a contingency plan that enables rapid scaling of resources during periods of high-volume work to meet critical data management deliverables and assume additional responsibilities while scaling back to preserve the sponsor's budget during less intense periods.

Managing complexity with collaboration

After the biotech experienced significant changes, they relied on Fortrea FSP to help them close 50% of their sites. To support this immense effort, the Fortrea FSP team first designed a tracker to consolidate all site closure approvals in one centralized location, which improved visibility and efficiency for the sponsor's clinical trial managers (CTMs). The FSP team also took the lead on the site closure process, coordinating closely with the third-party CRO through consistent communication.

Through persistent follow-up and strong collaboration with the CRO, Fortrea FSP made substantial progress toward the site closure goal, highlighting the critical importance of teamwork, cross-functional collaboration, proactive tracking and regular review of study metrics to guide decision-making.

Establishing a flexible FSP relationship

Since 2018, Fortrea FSP has helped a biotech advance its oncology portfolio through a full-time employee (FTE)-based contract and has served as an extension of its team by providing:

- Clinical data management
- Clinical programming
- Spotfire programming
- Tableau programming support
- Electronic data capture (EDC) programming (InForm and Rave) and user access
- External data review
- Medical coding
- Clinical operations
- Trial master file (TMF) management

To meet the biotech's shifting priorities and organizational changes, Fortrea FSP continues to quickly scale its resources and deliver flexible support across key studies.

Measuring the results of strong support

After several years of collaboration between Fortrea FSP and the biotech sponsor, the FSP team fully understands their processes, anticipates their needs and requirements and mitigates potential risks to keep studies on track.

Last year, the team was pleased to achieve several key metrics as they supported 15 oncology studies. These metrics included:

- Maintaining the time to fill (TTF) in less than 30 days to meet urgent business needs
- Achieving over 90% employee retention by strategically placing right-fit candidates in key roles
- Delivering quality validation at 95-100%
- Configuring 100% (41) reports on time
- Reaching nearly 90% success in functional delivery, which is a strong indicator of team alignment and execution

The Fortrea FSP team will continue to adjust its services and scope of work to meet evolving requirements as it invests in the relationship and helps the sponsor make a difference for people living with cancer.

In a recent Voice of the Customer survey, Fortrea FSP was recognized for several strengths:

> "Fortrea FSP comes up with new ideas to improve the data review plan listings, programming and comment tracking. They don't just follow a linear process—they think outside the box and suggest better ways to work."

> "Fortrea FSP provides flexible resourcing, great support in budget management and serviceable staff."

Learn how Fortrea FSP can flexibly serve as an extension of your team:

fortrea.com/clinical-solutions

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