CASE STUDY

Strategically guiding a biotech molecule through its product development lifecycle

A KEY QUESTION

How did Fortrea help a biotech company reduce development gaps (white space) and assist in advancement of a therapy from early phase to late-stage?

KEYWORDS White Space Reduction, Regulatory Strategy, Cardiometabolic Therapy, Patient-Centric Solutions, Biotech

A biotech focused on cardiometabolic diseases needed a CRO who could do more than execute trials. They needed strategic guidance to navigate their novel molecule from post-discovery through late-stage development. By collaborating with Fortrea across every phase, which commenced with regulatory consultancy, the sponsor successfully advanced their asset through complex regulatory pathways, recruited patients across global sites and reached a significant milestone, being the initiation of the key Phase III outcomes trial.

Enabling seamless transition between phases to reduce white space, Fortrea provided comprehensive support to connect strategy and execution from one stage to the next, spanning:

- Consulting
- Phase I PK/PD
- Phase IIa/IIb
- Phase III Full-Service Clinical Trial

Without the need for piecemeal transactional outsourcing, each phase with Fortrea represented an opportunity for the sponsors to make data-driven decisions for a more reliable delivery and strategically position them for success.

Demonstrating a program-level commitment with a product development mindset

From the earliest stages, Fortrea's Product Development Team took a program-level approach, demonstrating the flexibility and scientific depth of a right-sized CRO. The sponsor engaged Fortrea Consulting to review existing data across chemistry, manufacturing and controls (CMC), nonclinical and clinical domains, identify potential regulatory gaps and develop a comprehensive roadmap that integrated regulatory, clinical, medical, market access and commercial strategies.

This early involvement proved critical. Fortrea helped the sponsor mitigate potential clinical hold issues, interpret and incorporate regulatory advice in real time and build a strategic plan that could withstand investor and board scrutiny.

Fortrea

> “Our goal in the early phase was to mitigate any potential clinical hold issues for this biotech sponsor and assist them with developing a strategic plan for development. We determined how to address safety signals, interpreted and incorporated regulatory advice in real time and advised the sponsor on how to proceed.”
>
> **Global Regulatory Consultant**

Advancing through Phase II with seamless execution

The sponsor quickly advanced into Phase II, awarding Fortrea three additional Phase II studies along with complementary support for regulatory consulting and investigational new drug (IND) maintenance. As part of this, alternative administration options were explored which broadened the success-to-market opportunities.

To eliminate white space between development phases and maintain momentum, Fortrea grounded the relationship with three integrated tenants:

- **Working in parallel to provide adaptability.** To support the biotech sponsor, Fortrea created a cohesive team that united regulatory specialists, vendors, key opinion leaders (KOLs), clinical pharmacology, clinical operations, physicians, market access and other collaborators. By establishing trust across all stakeholders, Fortrea minimized handoff delays and kept the sponsor’s objectives at the center of every decision. This was supported by a robust governance model and oversight from leadership in both organizations to eliminate roadblocks and follow progress
- **Leveraging institutional knowledge and scientific leadership for continuity.** Following a one-team approach, Fortrea coordinated cross-functional efforts to leverage the full capabilities of the organization. This high-touch approach involved scientific, strategic and operational delivery specialists from the cardiovascular therapeutic area, product development and regulatory consulting to promote innovation and collaboration
- **Synchronizing teams for smoother phase handoffs.** By incorporating lessons learned from the regulatory, clinical and operational teams in each study, Fortrea improved communication between functions, transferred knowledge and mitigated risk in the subsequent studies. Within two and a half years, the sponsor advanced into Phase III

Navigating Phase III challenges with a collaborative approach

When the sponsor reached Phase III, they asked Fortrea to provide full-service clinical trial services. This phase brought new challenges that required creative and proactive problem-solving and calculated risk-taking:

- **Addressing regulatory concerns:** Unlike the Phase II study, which used an active comparator, the Phase III study compared the investigational product to a placebo. This caused regulatory delays with some regulatory agencies. Fortrea needed to formulate compelling scientific justifications to convince global regulatory agencies that the benefits for clinical trial participants outweighed the risks
- **Tailored recruitment strategy:** Fortrea’s experience shows that sites typically enroll most patients within the first six months of activation, followed by a gradual decline. To sustain recruitment, Fortrea implemented a recruitment strategy of continuously identifying and activating new high-quality sites and countries, leveraging its broad network and experience. When recruitment targets required expansion, Fortrea proposed adding a new country. Despite initial concerns about data quality, Fortrea conducted due diligence and offered a risk-sharing financial agreement. The sponsor was impressed by the sites’ performance and continued adding more sites in that country
- **Increasing patient retention with patient-centric solutions:** The patient profile included many elderly, medically fragile patients. Fortrea worked with sites to offer mobile clinical services and premium patient transportation services, which helped increase retention. In countries where transportation services are accessible, 15% of patients utilized these services. In this study where patient retention could have been a limiting factor, offering support tailored to individual needs can provide significant advantages

> “We were highly involved with sites to support patient-centric practices. We helped sites offer several options: home visits performed by site staff, Fortrea mobile clinical services or use our vendor’s transportation services to reach a site. This boosted retention and helped make visits easier for patients who might have challenges getting to an on-site visit.”
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> **Senior Project Manager**

The outcome: Achieving strategic milestones through a molecule development mindset

Fortrea's adaptive collaboration with the sponsor enabled them to overcome complex challenges at every development stage, from post-discovery to late-stage trials. With Fortrea handling the process across the development lifecycle, the sponsor could reduce white space, by removing traditional, transactional outsourcing and creating a seamless transition from one stage of development to the next.

By proactively addressing regulatory hurdles, innovating patient recruitment and retention strategies and aligning with commercial objectives, Fortrea not only helped the sponsor advance their novel cardiometabolic therapy but also paved the way for strategic milestones such as FDA Fast Track designation and a fast path to marketing.

This collaboration underscores Fortrea's commitment to accelerating drug development and delivering solutions that have the potential to transform patient care globally through a molecule development mindset.

Learn more on how Fortrea helps design, conduct and manage cardiovascular drug and device trials to enhance operational efficiency.

fortrea.com/therapeutics/cardiovascular

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