CASE STUDY

Enabling success in global clinical trials: Fortrea's strategic solutions for biotech

A KEY QUESTION

How does Fortrea deliver proactive and impactful solutions to help biotech sponsors overcome complex clinical trial challenges and accelerate program milestones?

KEYWORDS

Biotech, Strategic Solutions, Clinical Trial Acceleration, Risk Management, Global Recruitment, Dermatology, Site Engagement, Operational Excellence

Background

A sponsor initiated a pivotal global Phase III clinical initiative evaluating an oral, next-generation drug, for moderate-to-severe plaque psoriasis. The program comprised two main randomized, double-blind, placebo and active comparator controlled trials and a subsequent long-term extension study. This ambitious program aimed to enroll over 1,700 patients globally, with strict timelines and regional recruitment targets.

Key challenges faced

The sponsor faced several key challenges during the program. It aimed to achieve the Last Patient In (LPI) milestones for both studies within tight timelines. Managing recruitment across diverse geographic regions, particularly in Japan, introduced complexity due to local regulatory requirements and site management needs. Maintaining high-quality standards was essential given the scale and global scope of the trial. Budget efficiency had to be balanced with the allocation of sufficient dedicated resources to deliver success. Additionally, proactive risk management was critical, especially in addressing challenges related to accelerated drug supply due to rapid recruitment and site-related issues, which required robust and timely mitigation strategies.

Fortrea

Fortrea's strategic solutions

- **Proactive collaboration:** Established an Acceleration Team comprising leadership from the sponsor and Fortrea to continuously monitor progress, proactively assess risks and closely align key milestones
- **Relationship building:** Fortrea and the sponsor maintained a strong focus on building site relationships in the Dermatology space. This strategic collaboration significantly enhanced relationships and site engagement
- **Robust start-up and recruitment strategies:** Assigned dedicated global Project Managers and Clinical Trial Leads for personalized oversight
- **Enhanced quality management:** Early engagement of dedicated Quality Leads (QL) and systematic Quality Assurance (QA) plans, regular QA meetings and proactive "coffee connects" facilitated early identification and timely resolution of Quality Events (QEs)
- **Risk identification and prevention:** Implemented strategies to identify and address risks related to accelerated timelines, drug supply and site management expectations. Fortrea together with the sponsor, emphasized early issue detection, timely action on constraints and constructive risk elevation to facilitate seamless trial operations, including Japanese site contributions under compressed timelines
- **Budget and scope control excellence:** Adopted transparent scope management, clear budgeting practices and a structured bonus-penalty system, motivating team performance and ensuring efficient resource allocation. Achieved multiple performance bonuses without incurring any penalties, demonstrating superior budget control and effective resource management
- **Culture of collaboration and recognition:** Fostered a "one team" mindset through regular governance and operational meetings, maintaining alignment between the sponsor and Fortrea teams
- **Site collaboration:** Fortrea's dedicated site collaborator approach drove consistent engagement, swift feedback incorporation and improved site performance

Outcomes and impact

Fortrea addressed the sponsor's complex clinical trial needs by achieving recruitment milestones ahead of projected timelines. The original patient recruitment target in Japan through effective risk management and proactive planning was achieved. Targeted strategies were implemented that led to the completion of recruitment **six months earlier** than initially expected. Additionally, Fortrea secured effective quality and risk management throughout the trial, maintaining high standards and uninterrupted progress.

Client testimonial

"The team has done incredible work and elevated itself beyond my wildest hopes. It's wonderful to see how much the team enjoys working together."

Senior Vice President, Development Operations

Fortrea's strategic collaboration, comprehensive approach and dedication to quality positioned this Phase III program for exceptional success.

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