

Agility and flexibility are key in delivering tandem mega oncology trials in a highly complex clinical trial landscape

A KEY QUESTION



How can an innovative delivery model create a robust global infrastructure for two simultaneous Phase III oncology mega-studies?

KEYWORDS

Breast Cancer, Global Clinical Trials, Study Startup, Site Selection, Data Management, Regulatory Submission, Hybrid Delivery Model, Vendor Management, Global Feasibility, Patient Enrollment Strategy



A large global pharmaceutical sponsor had been developing a breast cancer therapy, competing alongside four similar studies to enroll study participants. They chose Fortrea to support two Phase III trials in parallel, spanning 45+ countries, 1400+ sites, 10,000+ study participants and a planned duration of 15 years.

The program's structure is unique as the entire study is outsourced to Fortrea. However, clinical start-up and operations in certain countries are managed by Academic Research Organizations (AROs) and sponsor affiliates. In this model, Fortrea retains operational leadership for both studies, with all parties utilizing Fortrea's tools, systems and processes.

This case study highlights a few notable areas in the program and Fortrea's role in:

1

Implementing a unique hybrid delivery model with the sponsor and AROs to drive efficient operations

2

Leading feasibility and site selection across 45+ countries

3

Managing global, regional and local vendors in a highly complex environment

1 Implementing a unique hybrid delivery model to align global stakeholders and accelerate governance

To kick off the sponsor's program, Fortrea compiled a comprehensive list of study-level stakeholders, including representatives from over 40 vendors, line managers, department heads, therapeutic area leads and oversight managers, spanning Fortrea, the sponsor, affiliates and participating AROs. With this list, Fortrea:

- **Established a multi-level governance structure:** Fortrea identified, aligned and documented stakeholder expectations and requirements
- **Developed a purpose-built communications framework:** Fortrea assigned dedicated points of contact and efficient communication channels between the sponsor and AROs supported by standardized work instructions, process guides and unified tracking tools to bring consistency and control to site selection activities
- **Created external user profiles for internal systems:** Fortrea streamlined system access so that all parties—the sponsor, affiliates and AROs—could securely access essential platforms and systems, such as Fortrea's TMF, CTMS and EDC, and access targeted training

2 Leading feasibility and site selection

Working within this hybrid framework, Fortrea was tasked with leading the feasibility and site selection efforts to maximize engagement and expertise across all key target regions worldwide

Beyond aligning each group to the global site selection timelines and following their own process for site selection, Fortrea needed to:

- Avoid competition with ongoing studies
- Implement consistent, diverse patient enrollment
- Model site activation data across all parties
- Generate financial and operational efficiencies

Recognizing the value of a well-balanced global footprint, the teams collaborated to strategically select sites, approaching 2,000+ sites across 60+ countries to identify 1,400+ that were both interested and viable—including fast-growing markets in the Middle East and Africa. They evaluated each location's infrastructure, patient population, diversity and cost profile and:

- **Developed a patient modeling approach:** The teams used historical and feasibility recruitment rates to estimate patient contributions per entity. Outreach efforts spanned all tier 1 and tier 2 countries, engaging 45+ countries and aligning efforts across entities
- **Performed ongoing checks on competing studies:** The teams monitored competing studies and rapidly added sites when other studies concluded enrollment or were canceled
- **Created flexible costing models:** Site selection in this complex, multi-stakeholder environment required adaptable costing models. Financial considerations were integrated into site and country selection, providing an optimal spread and value for the study

By expanding beyond traditional geographies, Fortrea could address the program's scale and complexity, offer robust enrollment and fewer competing trials and support sustainable study delivery and future research opportunities, building the strongest possible site mix for the sponsor.

Managing 80+ global, regional and local vendors through an integrated oversight model

With 54 vendors in the first study and 81 in the second study, Fortrea faced a complex vendor ecosystem that risked resource fragmentation, process inconsistencies and operational bottlenecks. To keep both studies moving ahead in parallel, Fortrea:

- **Created a task-ownership matrix:** The team streamlined responsibilities, minimized fragmentation and duplication, keeping the right experts focused on high-impact activities

- **Developed clear work instructions**, including process maps and unified KPI tracking, to align all stakeholders and maintain consistent execution
- **Adapted with agility** to address fluctuating resources, shifting workloads and site-level constraints, including study prioritization when a site could support only one of two studies

Throughout delivery, Fortrea continuously reassessed its processes, finding new efficiencies, testing creative ways of working and identifying opportunities for sites and vendors to support both studies simultaneously.

Reviewing the impact of the strategic implementation

Through the hybrid delivery model, Fortrea:

- **Provided a data backed list of high potential sites** and incorporated insights from all stakeholders, giving the sponsor a clear path to smarter, faster decision making
- **Strengthened the selection strategy with proprietary site performance metrics** to help the sponsor to reprioritize some of its originally mandated sites
- **Achieved cost-efficient solutions** with strong vendor relationships and overlapping sites
- **Enrolled significantly ahead of schedule**, with the first study achieving its last subject in six months ahead of schedule and the second study expected to achieve last subject in nine months ahead of schedule
- **Earned a Net Promoter Score (NPS) of 9**, demonstrating strong sponsor satisfaction

Looking ahead

Fortrea will actively respond to continuous advancements in breast cancer treatment and help the sponsor's studies adapt to changes in the standard of care to remain attractive to patients and sites. Cost management will remain a priority, with ongoing efforts to identify efficiencies through AI, process optimization and potential design changes. The team will also review and evaluate all vendor contracts associated with the program to provide optimal value for the study.

Fortrea will continue to drive progress with agile, solutions-focused support, aligning stakeholders and accelerating the path to bring this innovative treatment to patients sooner.

Incorporating lessons learned

- **Align with the sponsor's operations:** Fortrea navigated complexities, avoided bottlenecks and streamlined collaborative efforts
- **Proactively anticipate high resource demands:** Fortrea managed internal stakeholder expectations and proactively prepared for high resource demands
- **Coordinate activities to gain efficiencies:** Fortrea achieved efficiencies by determining which third-party services would overlap and coordinating vendor activities in parallel studies



The story behind the trial

Scan the **QR code** to hear first hand from those involved in the project about how this global Phase II oncology program was delivered.

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