CASE STUDY

Optimizing efficiencies and reducing white space across Phase I to Phase III in an oncology clinical trial

A KEY QUESTION

How can a consultative, scientific engagement reduce the white space between phases and provide continuity, saving time and accelerating development?

KEYWORDS Oncology Clinical Trial, Operational Continuity, Site Relationships, Global Feasibility, Process Efficiencies

A drug development sponsor was developing several molecules for the treatment of lymphoma. As the leading molecules entered Phase I First-In-Human (FIH) clinical trials, they enlisted Fortrea as their CRO.

This case study shares how Fortrea supported the progression of one of the molecules from Phase I through Phase III, enabled process efficiencies across multiple studies and delivered results with significant time and cost savings.

Key highlights

Supporting five studies across Phase I to Phase III, Fortrea:

- Supported seamless development and flexibly scaled resources between Phases I-II with a dedicated Compound Management Team
- Applied a consistent operational approach to streamline startup activities across studies
- Established a cross-study data cleaning task force to support data readiness throughout program development
- Supported milestone achievement in a highly complex oncology development landscape
- Enabled efficient, cost-conscious Phase III planning and effective first patient in (FPI) planning
- Optimized operational efficiencies and reduced transition gaps across Phase I to Phase III

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Phase I: Developing a close scientific collaboration with the sponsor

The sponsor was focused on two promising molecules—one that they insourced and one that they asked Fortrea (then operating under the legacy name Covance and later Labcorp) to support nine months after the first study started.

To enhance research efficiency, enable meta-analyses and track progress between the two studies, Fortrea suggested forming a collaboration with the sponsor's medical group and created a Compound Management Team. Operating with a program management mindset across business units and functions, this unique team oversaw the protocol execution, monitored risks and tracked timelines for both Phase I studies through dose escalation.

Phase I FIH–II: Providing continuity to reduce whitespace between phases

Understanding the sponsor's goal of propelling both molecules through their life cycles with minimal disruption or lost time, Fortrea caught up to match the timeline of the insourced Phase I First-In-Human (FIH) study. They then synchronized the two Phase I FIH trials by tracking both molecules simultaneously through their dose escalations and provided strategic insights into the study design for a single Phase II dose comparator expansion study.

To reduce the white space between phases and promote continuity, Fortrea's Compound Management Team retained its key staff, expanded its resources and:

- **Provided flexibility to enable efficiencies:** Fortrea flexibly aligned resources with portfolio demands and rapidly adapted to changing study requirements
- **Leveraged site relationships:** Fortrea leveraged its long-term investigator site relationships to accelerate global site identification and enhanced existing site relationships with the sponsor
- **Created skilled monitoring teams:** Fortrea provided ongoing monitor training to proactively mitigate site-specific issues across the portfolio of studies and trained clinical research associates (CRAs) to identify and manage key side effects, support data cleaning and inform critical safety decisions
- **Shared scientific and operational experience:** Fortrea provided insights from its seasoned scientists, operational specialists and access to key opinion leaders to create a successful strategy

By drawing on its existing knowledge base and applying key strategies, Fortrea achieved significant time and cost savings for the sponsor as they:

Supported efficient development and finalization of the Phase II protocol

Enabled timely first patient in (FPI) planning and study activation

Demonstrated strong enrollment momentum across participating sites

Implemented continuous data review processes to support timely decision-making

Phase III: Recognizing budget efficiencies across an oncology portfolio

Throughout this close collaboration, Fortrea had aligned with the sponsor's culture, built community and demonstrated its commitment to advancing the molecules. The sponsor recognized the value that Fortrea was providing and asked them to support three additional Phase Ib studies of combination therapy regimens.

Using data from the Phase I FIH studies and the comparator Phase II study, the sponsor identified the more promising molecule, started designing the Phase III registrational trial and awarded Fortrea with the pivotal Phase III study. In this study, Fortrea recognized budget efficiencies and accelerated FPI planning.

Two years later, the U.S. FDA granted accelerated approval of the molecule based on the complete response rate, and the molecule ultimately became an approved treatment for lymphoma patients.

Learn how our comprehensive Phase I-III support and scientific engagement around study design can enable informed decision-making and healthcare innovation.

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