CASE STUDY

How Fortrea brought an agile partnership approach to delivering a new oncology model.

A leading pharmaceutical company was developing several molecules for the treatment of a hematologic malignancy. With the goal of supporting their two lead compounds in Phase I first-in-human trials—with no disruption or lost time—the client selected Fortrea as their partner.

This case study shares how the Fortrea Compound Management Team delivered scientific expertise and flexibly responded to challenges as they managed the two trials in parallel, which quickly grew into a suite of studies spanning early clinical development to late-stage development.

Providing a dedicated team

Fortrea assigned their Compound Management Team to provide a tailored approach. With this consistent team, they enabled a seamless process and continuous collaboration as the molecules advanced from early clinical development to late-stage development.

The team also adapted dynamic study requirements and accommodated amendments, addressing regulatory agency input on dosage and the need for additional dosing safety cohorts to explore the combination of two novel investigational compounds.

Supporting a complex program

The client had already started their Phase I trial for the first molecule, nine months before they had hired Fortrea to support the second molecule. The Fortrea team synchronized the timelines for the outsourced trial to match the client managed trial by implementing a single Compound Management Team, managing risks and opportunities across both trials.

These trials later rolled into a subsequent Phase II noncomparative study followed by two studies to test the safety and efficacy of triplet-combination regimens. This work ultimately led to a Phase III study registration.

KEY TAKEAWAYS

- Synchronized two early-phase molecules to allow for parallel trials followed by a late-phase triplet-combination trial
- Formed a collaborative relationship across medical monitors and project management teams to accurately recognize and report adverse effects
- Supported the client with one unified Fortrea Compound Management Team to eliminate white space between phases
- Delivered subject matter expertise and optimized operational strategies to ensure successful development, meet enrollment goals and reach key milestones on time
- Demonstrated leadership by closely listening to the client and aligning with their culture and core values

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Developing a collaborative partnership across development phases

Beyond creating efficiencies across the trials to enable seamless drug development, the Fortrea team also leveraged their long-term investments in site relationships to proactively mitigate risk and meet enrollment deadlines.

On the monitoring side, Fortrea started by forming a collaborative relationship among the client's medical monitor, the Fortrea medical monitor, project management teams and the monitoring team. The Fortrea medical monitor then coached study teams and site monitors to effectively identify and manage key side effects—peripheral sensory neuropathy and neutropenia—as well as identify and report expected or unanticipated toxicities directly to the client from the field. This alliance helped ensure that the study team and the monitors were well trained on the therapeutic landscape and response criteria.

Meeting milestones and expanding the scope of work

As the studies progressed and proficiencies were gained, data cleaning was achieved in near real time, ensuring that all milestones and safety decisions were met on or ahead of schedule. The Fortrea informatics team used data modeling tools to track both molecules through the Phase I trials and the combined Phase II trial.

Based on positive interim data cuts to the Phase II study and three Phase Ib studies, the client decided to launch two Phase II triplet-combination studies. With Fortrea's key team members already working on the Phase II development plan for nearly nine months, the client found that moving into Phase II was a seamless transition.

Delivering for the client

Working as a single compound management team to support this complex program, Fortrea simultaneously propelled both molecules from early-phase to late-phase, without disruption or lost time. As the compounds moved between the client's internal development organizations, the same Fortrea team delivered a seamless knowledge base and a streamlined operational process, which helped avoid expensive delays, reduced learning curves and enabled strategic decision making for the client.

This in-depth collaboration allowed the team to:

1. Complete the final Phase II protocol **within eight weeks** of the recommended Phase II dose
2. Achieve IRB approval of the Phase II protocol four weeks later with the first patient dosed within another four weeks **(~16 weeks after the recommended Phase II dose)**
3. Reach their enrollment goals for Phase II **(~35% ahead of schedule)**
4. Deliver the pivotal Phase III study registration **on time**

How collaboration changed the trajectory of the Sponsor's drug

This complex program revealed the true value of an in-depth collaboration that involved proven people, streamlined processes, long-term site relationships and ongoing training. As a result, data metrics were delivered in near real time throughout the process, allowing the client to make informed decisions about their molecules and life cycle investments. Running study phases concurrently advanced the process, saving time and money in this highly competitive therapeutic area.

CLIENT TESTIMONIAL:

"I have been in this industry for 17 years and have worked with many, many CROs, but I have enjoyed working with this Fortrea team above any others!"

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