CASE STUDY

Fortrea

Delivering global confidence for a China-based sponsor's first clinical trial conducted in both the U.S. and China



A KEY QUESTION

How can a highly collaborative approach help accelerate cross-border study activation and enrollment for a China-based sponsor's first study conducted in both the U.S. and China?

KEYWORDS Dyslipidemia Clinical Trial, Site Networks, Investigator Engagement, China-U.S. Trial Delivery, Regulatory Strategy, Project Management, Cardiovascular Product Development, Cross-Border Delivery

A China-based sponsor planned a Phase II study for its compound, including its first-ever clinical study conducted in the United States. Seeking a clinical research organization (CRO) with experience supporting studies within Asia Pacific (APAC) and across global regions, they selected Fortrea to lead the study and advance their broader cardiovascular product development pipeline. This engagement reflected the sponsor's need for a cardiovascular CRO experienced in executing complex, multi-region clinical trials with consistency and speed.

This case study shares how Fortrea approached a demanding cross-border study and delivered an on-time Phase II across two continents, while maintaining strong budget control.



Recognizing cross-border clinical trial challenges

Fortrea identified several operational and cross-border clinical trial challenges:

Challenge	Background
Low recognition of the China-based sponsor in the U.S.	Investigator engagement and market credibility were low, reflecting a broader challenge China-based clinical trial sponsors may face in gaining investigator confidence and driving enrollment in the U.S.
Multiple protocol amendments	Following the U.S. Food and Drug Administration (FDA) review of the initial submission, two protocol amendments were required
Parallel regulatory pathways	China sites submitted their regulatory filing using the initial protocol version agreed with the China Center for Drug Evaluation (CDE), while FDA-driven amendments were still being finalized and approved for the U.S.
An aggressive timeline for first patient in (FPI)	Fortrea had only ~20 weeks from the award date to reach FPI
A higher-than-expected screen failure rate	Fortrea observed a high screen failure rate of 76%, which was slightly higher than the pre-award estimate



Executing a coordinated cross-border strategy

Knowing the study needed to move quickly to address the challenges and meet the sponsor's goals, Fortrea enabled a proactive trial management approach. This involved:

Establishing a unified cross-regional governance model	An experienced China-based Project Manager worked closely with experienced U.S. and China Clinical Team Leads and created a coordinated study headquarters that provided consistent direction and facilitated knowledge sharing across regions
Strengthening U.S. investigator engagement	To bridge the gap between the China-based sponsor and U.S. investigator community, Fortrea's Cardiovascular/Metabolic Therapeutic Area Leader played an active role in engaging U.S. key opinion leaders and participating in virtual investigator meetings
Applying screening insights to optimize pre-screening procedures	In response to the higher-than-expected screen failure rates, Fortrea conducted a detailed analysis across both regions, identified trends and shared insights with sites to strengthen patient education and enhance pre-screening procedures
Providing continuity to drive more efficient execution	From pre-award through study execution and the final database lock, Fortrea maintained a single, dedicated Project Manager across the full study lifecycle, which helped preserve study knowledge, enabled seamless coordination across regulatory and operational activities and supported proactive risk identification and management
Flexibly allocating resources at a key juncture	Fortrea proactively front-loaded resources across project management, study start-up and site identification during the critical early stages of the study. This flexible resourcing approach enabled multiple start-up activities to progress in parallel, supported rapid site identification and activation and helped maintain momentum toward key study milestones
Leveraging existing relationships to accelerate start-up	In the U.S., Fortrea relied on its established site networks to identify 50+ sites with access to the target population within one month. Established site relationships and central IRB pathways were then leveraged to facilitate clinical trial agreement negotiations, reduce start-up complexity and support faster site activation

Reviewing the results of a collaborative approach

With these coordinated actions, Fortrea rapidly initiated the lead China site within three months after Good Clinical Practice (GCP) submission, and all U.S. sites were activated within two months of the latest protocol availability. Despite delays associated with FDA comments and protocol amendments, U.S. enrollment was completed on time.

Overall, Fortrea achieved several significant milestones:

Exceeded the enrollment target
Enrolled 143 patients vs. 132 planned

Beat the enrollment timeline
Completed enrollment in China three months ahead of plan; U.S. enrollment completed on time despite FDA delays

Completed the overall study one day ahead of the planned schedule

Beyond meeting the study's initial goals, the sponsor recognized the value of generating U.S. patient diversity data to inform future global development. The sponsor developed a close collaboration with Fortrea's medical leadership team, creating opportunities for broader scientific discussions supporting the sponsor's cardiovascular development pipeline beyond the individual study.

This successful U.S. delivery also reinforced the sponsor's confidence in working with a global CRO for cross-border work.

Reflecting on lessons learned from a multi-region clinical trial

Fortrea credited success in the study to several factors:

- **Continuity** proved a key differentiator, as a single Project Manager engaged from pre-award through database lock, paired with a dual-region Clinical Team Lead structure, helped deliver the study across the U.S. and China
- **Early involvement from medical and therapeutic area specialists** helped improve protocol feasibility and helped develop investigator relationships as the sponsor entered a new market
- **Fortrea's existing site relationships** with strong, established sites were critical as the sponsor entered a new region
- **Proactive regulatory management and continuous communication** enabled activities in China and the U.S. to progress in parallel—without allowing FDA-driven amendments to cascade into broader study delays

Together, Fortrea's collaborative practices provided the structure, flexibility and speed required to successfully execute the sponsor's complex Phase II study and expand their global development opportunities.

Want to learn more?

Get more information about Fortrea's global clinical development experience and how it can help sponsors expand into new markets fortrea.com

©2026 Fortrea Inc. All Rights Reserved.
CS_0142_CV in U.S. and China_1026