

# From China to the world: Advancing a biotech's oncology therapy to achieve FDA accelerated approval

## A KEY QUESTION



How can biotech-focused experience help drug development sponsors in China anticipate clinical trial challenges, minimize risk and navigate today's global regulatory landscape?

## KEYWORDS

Lung Cancer, Global Product Development, Biotech, APAC, Study Execution, Regulatory Submission, Precision Medicine



## Introduction

A Chinese biotech was developing a novel lung cancer treatment and needed an experienced CRO to run its multinational Phase I/II clinical trial. They were familiar with Fortrea's long-standing, local presence in China and asked the team to provide full-service support and leverage its global footprint.

This case study shares how Fortrea developed a strong working relationship to address challenges, agilely respond to the sponsor's requests and prepare high-quality data to receive accelerated approval by the U.S. Food and Drug Administration (FDA).

## Key elements of success

The study involved 200+ patients from 90+ investigational sites across 13 countries, including China, to reach both Asian and non-Asian patient populations. The sponsor relied on Fortrea to provide global trial management and delivery while scaling solutions with ever-evolving requirements. To deliver reliable results, Fortrea needed to:

<b>Establish trust</b>	Fortrea's team in China had already established a connection with the sponsor's senior leadership team through networking. This connection helped build trust and establish collaborative practices as Fortrea began to understand the sponsor's priorities, develop a strong working relationship and serve as an extension of the sponsor's team.
<b>Anticipate and address risk</b>	Fortrea recognized that the global, year-end holiday season, followed by the Lunar New Year holiday, could impact the study's tight schedule. To minimize risk to the timeline and keep the study moving ahead, they coordinated internal resources and developed a comprehensive backup plan.
<b>Rapidly respond to changes</b>	Understanding that biotech product development can move quickly, Fortrea needed to respond to the sponsor's urgent requests and take prompt action. Fortrea found that cross-functional collaboration helped prioritize tasks and share realistic milestones—for both the sponsor and the internal study team—while also promoting consistency and enabling more predictable delivery.
<b>Promote transparent communications</b>	With regularly scheduled meetings, Fortrea's project team and senior leaders promoted transparent communication with the sponsor. They also provided ad hoc availability to the sponsor through a direct messaging application, which provided convenience and helped enable quicker response times.
<b>Provide biotech-minded operations</b>	To enable swift decision-making and help the sponsor meet critical trial milestones, Fortrea empowered key leaders and project managers with clearly defined roles. They mapped escalation paths, tracked critical tasks and quickly escalated any issues to Fortrea's China-based delivery director, who could directly connect with the country leads and operational teams. With this high level of oversight and responsiveness, Fortrea increased internal visibility, proactively addressed risk and helped keep the timelines on track.

## Navigating complexity to receive FDA accelerated approval

Throughout the study, Fortrea demonstrated agility and adaptability, aligning with the sponsor's evolving requirements and meeting tight delivery timelines. With its strong operational team, cross-functional roles and transparent communication, Fortrea also confirmed its commitment to help the sponsor reach patients faster and achieve accelerated approval from the FDA.

Fortrea continues to support the trial as the sponsor fulfills its global vision to address unmet medical needs and benefit patients worldwide.

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