INFECTIOUS DISEASE CASE STUDY

Implementing agile solutions to successfully deliver a vaccine clinical trial in China

Executing a fast-paced clinical trial in hospital emergency departments (ED) is not an easy job. It requires rigorous planning, enhanced site support, flexible resourcing, and close oversight to produce high quality data and protect the safety of clinical trial participants.

A Chinese biotech sponsor was planning to launch a Phase III clinical trial to investigate a vaccine against a preventable disease in healthy adults presenting at the ED. The sponsor was seeking full service support of a contract research organization (CRO) partner and requested bids from large global CROs and smaller local Chinese CROs.

Their primary concerns in considering global CROs revolved around cost implications and the ability to meet their aggressive timelines without compromising quality.

This case study shares how Fortrea employed approaches to successfully deliver a Phase III industry-sponsored clinical trial, manage the inherent complexity of a vaccine trial and run a successful study.

KEY TAKEAWAYS

Working as one cohesive team, the sponsor and Fortrea were able to successfully deliver this vaccine study by:

- Responding to urgent requests to accelerate start-up and effectively meet the sponsor's corporate milestones
- Implementing tactics at sites that ensured proper vaccine handling, dosing, and cold chain management to protect the safety of trial participants
- Delivering enhanced support to sites to boost enrollment, protect the primary endpoint and promote data quality
- Completing enrollment 1.5 months ahead of schedule and reducing the overall study timeline and costs incurred by the sponsor

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Recognizing challenges and responding with urgency

	Study challenge	Fortrea solution
Facilitating rapid site activation	The sponsor wanted to begin the study immediately and had already selected a lead investigator site to fast-track for activation. However, the sponsor and study team soon discovered that the site's processes were too complex to support early start-up, placing the study at risk of meeting the critical first participant in (FPI) milestone.	Recognizing the need to pivot the site start-up strategy or risk missing the sponsor's corporate milestone, Fortrea quickly identified alternative sites and helped the sponsor select another lead investigator site. The study team was able to fast-track activation at the new lead site enabling the site to recruit the first participant and meet the sponsor's target FPI milestone.
Ensuring proper vaccine management	Among the greater challenges to fast-enrolling vaccine clinical trials is ensuring proper vaccine handling and cold chain management to prevent the loss of investigational vaccine potency, minimize wastage and avoid dosing errors.	Early on, Fortrea confirmed sites had reliable vaccine storage, temperature monitoring equipment and standard operating procedures (SOPs) to expedite site selection and start-up. During monitoring visits CRAs ensured sites were thoroughly trained on vaccine dosage and administration by a qualified person to minimize the risk of dosing errors. They also worked closely with the sponsor to oversee cold chain reporting at the sites and implemented procedures for reporting deviations and holding the investigational product until use, including detailed instructions in the pharmacy and lab manuals.
Meeting recruitment targets	The sponsor assumed responsibility for having study-specific recruitment materials developed including posters for the hospital waiting room. Unfortunately, the materials were not available until mid-way through the recruitment period, which had a greater impact on recruitment than the sponsor anticipated.	To jumpstart recruitment the Fortrea clinical team worked with each site to generate study awareness within the hospital, develop a recruitment roadmap and implement tactics for identifying, educating, and obtaining informed consent from potential study participants. The team also shared best practices of enrolling sites with sites that were struggling. When the recruitment materials were finally available, the investigators used approved wording to post the study on WeChat, the most popular social media platform in China with more than 810 million users.

Delivering enhanced support to sites

During study planning, implementation and overall execution, Fortrea provided enhanced support to site staff. The increased level of support included:

Implementing a flexible staffing plan: To meet the sponsor's aggressive timelines, Fortrea ramped up site identification, CRA and start-up resources to rapidly identify and activate sites and ensure all study systems were set up and ready to "go live" in advance of FPI. We also developed a scalable resourcing plan that enabled us to quickly add and flex resources depending on sites' enrollment volume, quality and training needs.

Protecting the primary endpoint: As the primary endpoint for this study was immunogenicity, the CRAs assured all required procedures were being adhered to at sites during each monitoring visit. This included ensuring sufficient volume was obtained during blood draws and that syringes were not used. This reduced the risk of hemolysis in the serum preparation. They also confirmed the correct blood vial was used for volume draw (i.e., serum separator tubes vs. silicon coated tubes) as using the wrong tubes could interfere with immunogenicity testing.

Proactively promoting data quality: To effectively manage the large volumes of data coming in at a rapid speed, Fortrea CRAs worked diligently to flag systemic and repeated protocol deviations at sites. This helped reduce, and in some cases eliminate, source data verification (SDV) backlog at sites. Additionally, CRAs continually encouraged site staff to perform timely EDC data entry and query resolution, especially at higher enrolling sites, to ensure data completeness and accuracy.

Reflecting on the efforts of a successful collaboration

As a result of the agile, site-centric solutions Fortrea delivered for the sponsor, the study enrolled 675 participants at 28 sites 1.5 months ahead of contract, reducing the overall study timeline, achieving study endpoints and ultimately generating cost savings for the sponsor.

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