Accelerator™ Drug Development

Collaborative timeline management drives speed and simplicity in global vaccine trial

Proactive alignment across clinical trial services enabled faster execution and on-time delivery

Coordinating packaging, labeling, distribution, site activation, and patient recruitment for a global Phase III vaccine study is a complex endeavor. Add to that the demands of cold-chain logistics, challenging regional clinical site activations, and varying quality agreement requirements, and the risk of delay compounds quickly.

That was the case for one global biopharma customer conducting a high-stakes Phase III vaccine trial that began in 2023. The study spanned over 6,000 subjects, 170+ sites, and more than 20 countries, with early site activations planned in Central America and Central Asia. The customer had already locked in aggressive first patient in (FPI) milestones, but maintaining supply chain readiness across such a diverse geography while ensuring compliance with investigational medicinal product (IMP) requirements was a critical challenge.

At a glance

- Global Phase III vaccine trial: >6,000 subjects, 170+ sites, 20+ countries
- Complex supply requirements: ultracold IMP distribution, regional labeling, and tight FPI timelines
- Thermo Fisher Scientific helped enable early ID testing by aligning quality agreement parameters
- **Results:** 5-weeks time savings on IMP release, on-time delivery to support FPI, and a scalable model for future trials

Supply chain and regulatory complexity impact FPI

The customer's primary challenge was getting IMP to clinical sites to meet FPI milestones while navigating complex global ultracold supply chain and regulatory requirements. While the clinical supply strategy required speed, expertise, and precision coordination, ambiguity across regions and multiple quality agreements with differing requirements threatened to slow the process and delay site readiness.

With multiple partners and stakeholders involved, the risk was not only a delay in shipping, but a cascade effect impacting the broader FPI enrollment timeline. The customer needed a partner that could navigate regulatory nuances, streamline logistics, and reduce ambiguity across processes—while maintaining compliance.

Coordinated oversight and early issue resolution

Thermo Fisher Scientific's clinical trial operations and clinical supply teams worked side by side with the customer and internal stakeholders to establish a coordinated timeline and mitigate the risk of delays. During a review of quality agreement stipulations, a Thermo Fisher team member identified a discrepancy between actual operational capabilities and limitations around ID testing.

The team worked proactively to clarify and quickly align the quality agreements so that ID testing could begin earlier than initially planned. This earlier start unlocked five weeks of time savings for IMP release and enabled on-time shipments to support critical FPI milestones across all initial regions.

The collaboration went beyond troubleshooting—it created shared accountability, simplified timelines, and reduced handoffs across clinical packaging, labeling, distribution, site activation, and patient recruitment activities.

Enabling repeatable success

By identifying and resolving potential bottlenecks before they affected the timeline, the team ensured a successful startup while establishing a repeatable framework for future trials. The customer is now applying the same integrated oversight model to other studies in its pipeline, using aligned expectations and proactive communication as a foundation for smoother, faster execution.

Thermo Fisher's ability to deliver clear governance and operational continuity while working flexibly within customer requirements enabled not only immediate trial success but also long-term value.

Learn how **Accelerator™ Drug Development** streamlines clinical execution at scale.