

Clinical trials

Accelerating clinical supply timelines for an emerging biotech sponsor

How in-house packaging, labeling, and translation management helped meet an aggressive First Patient In deadline.

Emerging biotech companies face intense pressure to advance early-stage clinical trials while navigating complex supply chain logistics. Many operate with limited funding tied to key clinical milestones, making any delay a critical risk. Investors and stakeholders expect steady progress, so any disruption—whether in regulatory approvals, supply chain management, or site readiness—can impact both trial success and financial stability. Unlike larger pharmaceutical companies with in-house infrastructure, emerging biotechs rely on external partners to manage these complexities.

One innovative biotech company faced this reality when preparing for a global Phase II trial. They needed to achieve First Patient In (FPI) within just 14 weeks of signing their quote—a demanding timeline under any circumstances, made even more difficult by a holiday shutdown period. As a new customer transitioning from another vendor, they needed confidence that their clinical supply needs, including packaging, labeling, and regulatory translations, would be handled efficiently and without delay. Any misstep could impact site readiness, patient enrollment, and overall trial progress.



Comprehensive clinical supply support on a tight timeline

The original vendor lacked the infrastructure to meet the required turnaround for clinical label proofing and approvals, creating a critical roadblock as FPI approached. Without a solution in place, delays in label approvals could have disrupted trial timelines. The sponsor needed a partner who could execute with both speed and precision, ensuring that all active label protocols were designed, proofed, and approved within the condensed timeline.

With limited time to ramp up, the sponsor required a seamless onboarding process and a highly coordinated approach to packaging, labeling, and supply management. Comparator drug and ancillary material availability had to be secured early to prevent disruptions, while regulatory translations and labeling needed to be completed without unnecessary delays. Every step had to align precisely because any inefficiency or misstep could push the study off schedule and jeopardize the trial's success.

To keep the project on track, Thermo Fisher Scientific's clinical trials team took an integrated approach, providing seamless coordination across all supply chain components. A dedicated project management team oversaw each stage, streamlining packaging and labeling within the same facility to improve efficiency. To support trial requirements, the customer chose single-panel wraparound (WAO) labels, ensuring clear and compliant product identification while optimizing the packaging process.

In-house label manufacturing prevented supply shortages, while the ATLASSM translation management platform accelerated regulatory approvals by using a compliance-driven phrase library. By stepping in to manage the label proofing process, Thermo Fisher ensured approvals stayed on schedule, keeping the trial on track. Consistent cross-team collaboration minimized communication gaps, maintaining steady progress toward FPI.

Delivering on accelerated timelines

Despite the compressed timeline and holiday disruptions, the sponsor successfully met their FPI deadline just 14 weeks after signing their quote. Key milestones included:

- Completing full Master Service Agreement (MSA) and Quality Technical Agreement (QTA) within three weeks
- Finalizing packaging and labeling on schedule, with in-house label manufacturing ensuring material availability
- Maintaining efficient cross-team collaboration to reduce administrative delays
- Using the ATLAS platform to expedite translation and regulatory approval processes
- Moving from award to execution in three months

By integrating critical supply chain activities and maintaining close collaboration, Thermo Fisher helped the sponsor meet an ambitious deadline without sacrificing quality or compliance. By keeping the trial on schedule, this engagement reinforced the value of a fully integrated clinical supply strategy and laid the foundation for continued collaboration.



Contact Thermo Fisher Scientific to learn more about our clinical trial packaging and labeling services.

Contact us

Learn more at **thermofisher.com/patheon**
 or email us at **pharmaservices@thermofisher.com**
 or call **+1 919 226 3200**