ThermoFisher SCIENTIFIC

CASE STUDY

UNITED WITH INNOVATION & INSIGHTS

Supplier collaboration delivers innovative solution for trial sponsor

Sponsor taps its suppliers for innovation, value

In clinical trials using interactive response technology (IRT) drug dispensation is normally triggered after site activation or patient screening. Both triggers require an element of site seeding, especially when dealing with a trial that has four treatment arms, as was the case in this study.

In this trial, however, the study Sponsor did not have enough bulk drug to support the traditional site seeding strategy. The investigational product was a rare and expensive biologic being tested for an indication that is usually treated with small molecule medicines. Sending a forecasted amount of the vials to the sites prior to the day of randomization threatened the study's viability due to limited availability of the bulk drug.

Leveraging long-term relationships

The sponsor selected Thermo Fisher Scientific to manage its clinical supply chain, and also chose a leading IRT provider for the trial. This technology decision was based in part on the strong relationship between two organizations, as well as a top contract research organization (CRO) the Sponsor had been working with since early in development.

The subject matter experts from the three companies collaborated to address the issue of limited bulk availability. With a long history of engagements, the service providers orchestrate the delicate balance between supply chain, clinical operations, and technology requirements. The stakes were high in this trial, a 500-patient study with 300 clinical sites in 12 countries with four sub depots. There was a likelihood of no enrollment at some sites and associated waste given the unpredictability.

After analyzing lab test requirements in the draft protocol, the Thermo Fisher Scientific Supply Chain Manager determined there was a potential timeframe between randomization and drug dispensation. If this time gap could be established as a minimum of five days, the IRT could pinpoint the correct treatment arm, and define the number of vials needed for each patient using a weight-based calculation.

Early engagement was the key to success

The recommendation to stipulate a five day waiting period between randomization and dispensation was an insightful protocol interpretation made possible by this early involvement. When the laboratory stated it needed only three days to produce lab results, the collaboration team was able to probe into this estimate. What they learned was that a three day turnaround for lab results was possible but not probable. That made it easier to come to agreement on the five day waiting period, which was formalized in the protocol with no impact on study timelines.

The strong relationship between the collaborating suppliers continued to play out in the IRT development

The Thermo Fisher Scientific Supply Chain Manager advised the IRT programmers on how to customize the system to handle delayed dispensation. A member of the Clinical Supply Optimization team, this manager knew the system's capabilities because he had been intimately involved in developing technology standards during earlier projects.

The IRT engineers customized their system to meet the study goals while minimizing waste. Once launched, the system had the intelligence to set weight-based dosing after randomization then trigger dispensation. This enabled the team to send the exact quantity and kit type for each patient with minimal overage, totally eliminating the need for wasteful site seeding.

The trial launched with this innovative technology and brought high value by reducing waste

As noted, if traditional site seeding had been followed this trial might not have moved forward due to limited supply. Meeting the study initiation goal was a huge milestone made possible by a collaboration that brought innovation to the clinical supply chain.

+1 919 226 3200 • thermofisher.com/patheon • pharmaservices@thermofisher.com

COL34224 0921

ThermoFisher SCIENTIFIC