ThermoFisher SCIENTIFIC

CASE STUDY

Managing Clinical Ancillary Supplies at a Global Scale

CLINICAL ANCILLARY MANAGEMENT EXPERTISE HELPS BIOPHARMA COMPANY OVERSEE A LARGE, GLOBAL TRIAL FROM START THROUGH FINISH

Introduction

Managing clinical ancillaries for a multi-national trials involves more than just procurement. It requires critical knowledge of strategic logistics, regulations, inventory, expiration timelines and project requirements. The goal is to oversee a myriad of details for trial Sponsors so they can remain focused on drug development.

The challenge

A biopharmaceutical company was entering a Phase III trial that included 45 countries and an enrollment target of 4,000 patients in a randomized, double-blind, placebo-controlled study. Initially, the company hoped to oversee a portion of the ancillary supply management activities themselves. Ultimately they realized

they didn't have the bandwidth, especially in some of the international markets.

Many challenges may arise when managing ancillary inventory that could negatively impact trial results. Without engaging an expert who is aware of these challenges and can offer creative alternatives, the company might face increased costs and/or study delays that keep patients from receiving critical treatments.

The solution

The Sponsor engaged their Clinical Ancillary Management (CAM) team to help manage the process. The final scope of this study involved 32 countries and approximately 250 SKUs, with the Thermo Fisher Scientific team managing the entire project.

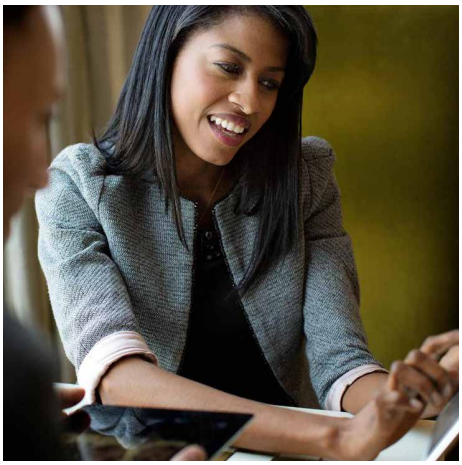
Early planning required conversations with both the Sponsor and Clinical Research Organization (CRO) to understand not only what products support the protocol, but also which brands/styles can be used at various sites across multiple countries. Once the list of supplies was finalized, the Thermo Fisher Scientific Supply Chain Manager identified available options, including cost-effective alternatives to the Sponsor's in-house products. The Supply Chain Manager worked diligently with the Sponsor to identify which countries could be supported by their own product and which countries required another brand.

A key organizational element for any trial is maintaining a study tracker by country for all clinical ancillary products. This makes it easier to track procurement, site initiation visits, inventory and expiry dating, and site shipment status so time, budget and resources are not wasted. Most importantly, paying keen attention to site initiation visit (SIV) dates ensure shipments arrive and are checked well before patients begin the study. The Supply Chain Manager maintains constant communication with the trial Sponsor and their designated CRO's. Through weekly meetings they review status by country, reporting on how many patients have received product.

Thermo Fisher Scientific manages site shipment requests through various options: manual shipment request forms, web order entry via their web portal or through an Interactive Voice Response System (IVRS). The Sponsor chose to use manual shipment request forms but, during the study startup phase, recognized this approach required more resources. Although the Thermo Fisher Scientific Supply Chain Manager offered alternate solutions, these options did not fit within the budget. The Sponsor proposed collaborating with their IT department to modify an internal IVR platform. Despite excellent teamwork, the Sponsor's IT resources were reassigned on another priority and the team conceded to using the manual shipment request form.

Continuous oversight

Throughout a study, the Thermo Fisher Scientific Ancillary Supply Chain Manager maintains constant oversight to ensure ancillaries arrive on time, in full and without damage in advance of the Sponsor's need. Over the course of a study issues arise. Changes in package type or style of supply can impact patients that have



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existing materials.

Suppliers might drop support for a given product. Each time an issue presents itself, the Supply Chain Manager proactively identifies options and communicates with the Sponsor to remedy.

At one point in the study the Supply Chain Manager observed an influx of damage in resupply inventory delivered to a Latin America Thermo Fisher Scientific facility. facility. Working with the facility's inbound team to examine photos of both the outside and inside of the package, they determined there was insufficient packing material to cushion the inventory. The Thermo Fisher Scientific Ancillary team worked directly with the Sponsor's supplier to implement new procedures. As a result, the Sponsor realized considerable financial and time savings by minimizing product loss, storage costs associated with damaged goods, trial delays and destruction fees.

As this study begins to enter the closeout phase, the Thermo Fisher Scientific Ancillary team will play a key role in determining what happens to remaining inventory. The first step is preparing a disposition report with information from the investigator sites and distribution facilities housing inventory. The Supply Chain Manager evaluates the cost-benefit of returning site supplies, storing for use at a later date or disposing of them properly (including destruction certificates where required). Typically, Sponsors are unaware of all the fees associated with returning inventory to a GMP environment, including shipping boxes, labels, freight and customs. Knowing these costs can add up quickly, the Thermo Fisher Scientific Ancillary team advises the Sponsor so the best possible solution can be implemented while remaining within budget, and compliant with country regulations.

Having issues resolved quickly and efficiently resulted in a time and resource savings for the Sponsor, and a stronger overall relationship with options for further collaborations.

Conclusion

Through regular communications with the Sponsor and its CROs, the Thermo Fisher Scientific team is able to understand the project scope and assign the appropriate project resources. Using their expertise to create a detailed project plan, they manage the forecast and supply process, anticipate issues before they become problems and proactively present solutions.

The Sponsor reaped tremendous value based on Thermo Fisher Scientific's ability to:

- Source ancillaries across multiple geographic markets
- Manage logistics across a global footprint
- Comply with country-specific regulations
- Resolve issues in a timely manner
- Propose cost-effective solutions throughout the process

The Sponsor acknowledged the Thermo Fisher Scientific Ancillary team for making everything during this phase of the trial run so smoothly - even between scheduled meetings. Having issues resolved quickly and efficiently resulted in a time and resource savings for the Sponsor, and a stronger overall relationship with options for further collaborations.

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