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CASE STUDY

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Clinical supply optimization:

Process improvement reduces study startup phase by 40% and drives improved supply chain execution

Today, biopharmaceutical sponsors are under intense pressure to reduce the time required for drug development. As a result, these sponsors are continually searching for new approaches to reduce lead-time and costs without affecting the quality of the clinical trial deliverables and execution.

The Challenge

As one example, a global top 10 biopharmaceutical sponsor reached out to Thermo Fisher with a clear requirement: Reduce the study startup phase to 91 days. In other words, comparator sourcing and blinding, kitting, packaging, labelling and distribution to the sites had to be executed within this short window.

Typically for this type and size of trial, the study start-up phase from took about five months (from the time the sponsor requested the drug to the release of the medication at the depot). The Thermo Fisher Scientific operations team embraced the ambitious goal of reducing timelines by 40% to achieve an optimized supply chain of just three months.

In order to achieve this challenging lead time reduction the Clinical Supply Optimization team at Thermo Fisher was deployed. The lead Clinical Supply Chain Manager deployed the Enhanced Service Model for supporting the client, applied lean management principals, and analyzed the complete clinical supply chain for the existing study start-up phase and all subsequent interactions between the stakeholders. They identified potential opportunities to streamline and eliminate “waste” in the process in order to reduce handoffs and time. This included eliminating costly bottlenecks as well as steps that often required rework.

The Solution

The Clinical Supply Optimization Enhanced Service model was deployed with the client as a part of the solution. The Clinical Supply Chain Manager took responsibility for the following activities:

- Pre Batch Record Change Order Review and Approval
- Master English Label Design
- Randomized (kit /med ID list) request and approval
- Approval of variable label text
- Handling of Packaging Requests

The Clinical Supply Manager was not only creating most of these items, but also approved them on behalf of his customers. This simplified process saved an average 30% of the sponsor's time.

Another key element of the solution was a clear and transparent RACI (Responsible, Accountable, Consulted and Informed persons) document, which prevent misunderstandings by detailing roles and responsibilities for every step in the clinical supply chain. Furthermore, to eliminate bottlenecks, rework and unnecessary waiting time in the study start-up phase, the Clinical Supply Manager introduced systematic checklists for each contracted service to guarantee that the right information is available at the right time in a coordinated way. For example Thermo Fisher compiled a checklist for packaging. Our Clinical Supply Chain Manager facilitated a supply-kick-off meeting where the involved parties vetted all specifications simultaneously. "In order to cut the lead time it was crucial to have the Sponsor, CRO and the IRT provider all in one meeting at the same time". Each checklist was then approved and signed by the Clinical Trial Lead, Clinical Trial Supply (CTS) team and the CRO in order to guarantee an efficient production process.

ATLAS℠ Label Translation Service deployed one of the primary operational bottlenecks delaying the overall supply chain, was label text translation. According to the sponsor, "We lost too much time with translating the label text and waiting for approval. And there was basically no time for rework". Therefore the Sponsor, CRO and Thermo Fisher decided to standardize the label texts as much as possible and build a label text library. The sponsor's standardized label text was translated upfront into 56 country versions and stored for the sponsor's use. This enabled proactive, early approval of the label text, including the current regulatory requirements from the CRO.

Conclusion

The Supply Chain Manager for this study indicated, "One crucial element of the collaboration between the sponsor and the Clinical Supply Chain Manager was that the sponsor truly partnered with Thermo Fisher. We are a part of their team and as such have deeper insights into their requirements and constraints." When the Clinical Supply Optimization team is engaged the Clinical Supply Chain Manager is at the center of all clinical supply communications, acting as the main point of contact for any request whether that is comparator sourcing, forecasting, packaging, labeling, ancillary management or distribution. As a consequence Thermo Fisher was able to drive efficiencies across the entire supply chain more effectively.

After one year of trial oversight and execution, Thermo Fisher has been able to achieve 12 months of timelines under the 90 day goal, with timelines as low as 60 days routinely seen.

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