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CASE STUDY

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Clinical supply optimization:

Clarifying the relative risk of change

The clinical team at a top ten pharmaceutical company struggled with the delicate balancing act between controlling the costs of a major oncology trial and making strategic investments that would pay off in the long term.

Working with a high value asset in an environment of cost containment, they were highly sensitive to any decision that might waste their investigational medical product across hundreds of sites in 20 countries. But they also recognized the importance of ensuring no cancer patient of theirs would be lost at this late stage due to a drug shortage or stock out. Key members of this cohesive group had invested many years of their lives into the program, cheering as the asset advanced through the pipeline, giving hope to their patient population.

To get more perspective on all sides of the issue, the team reached out to a range of internal and external stakeholders, including their vendor for Interactive Response Technology (IRT). The sponsor's clinical group considered the merits of everyone's input and then decided on a path they felt would most effectively balance the needs of the patient with their financial constraints. From the IRT vendor's perspective, what emerged most clearly out of these discussions was that business needs were important but that the patient always came first.

Clinical sites begin to experience issues

The trial launched and for the first few months recruitment went well. But then the sites began experiencing issues and frustrations. From the sponsor's perspective, all systems seemed to be perfectly coordinated.

Personnel at the sites were able to follow all three protocols with relative ease, and the quality of the initial data checked out. Still, something wasn't quite right at the sites. And whatever it was did not become apparent despite detailed analysis of all potential problem areas.

At this point, with frustration and fear of failure rising, the sponsor called on a resource that had delivered in the past – Thermo Fisher Scientific. Coming into a tense situation, our Clinical Supply Optimization team met personally with the clinical leaders and all key stakeholders in order to complete due diligence as quickly as possible. They combed through every detail of the study with the eye of a quality auditor, interviewing site directors to get insights available only to an unblinded collaborator. This work flowed quickly and our team soon discovered what appeared to be the root cause.

The IRT vendor – acting on the clinical team's emphatic direction to put the patient first – implemented a resupply algorithm that ensured the sites never ran out of study drug. In theory, it was the right thing to do. In practice, it was a mess.

Why were the sites complaining? Because they were getting up to four shipments of the study drug every month! Opening boxes and packing slips, logging into the IRT and pharmacy systems, getting the drug into storage, making sure every bit of paperwork was in order. "They were doing all of those tasks four times a month for the same study," says the Clinical Supply Optimization team leader. "It was a massive burden."

Making things easier for sites and patients

By over supplying the sites to make sure patients didn't go without drug, the IRT system actually made life difficult for the site personnel. One goal of Clinical Supply Optimization is to make things easier for sites and for patients. Clearly, there needed to be a change made to the IRT in this situation. But change is hard, and when the clinical team heard this recommendation the original fear of failure cropped up again. It's working well enough, they stated. There were no supply outages. Dosing was on schedule. The attitude that prevailed was all too common: "Why fix it if it isn't broken?"

The answer to that, of course, depends on your perspective. Thermo Fisher Scientific was charged with bringing a new vision to the table, giving the sponsor another way of looking at the question.

Thinking strategically about the issue, our team proposed that the IRT vendor make a revision to the resupply parameters. If no change was made, the supply budget was going to have to increase by at least 30% over the next accounting period due to the excessive volume of shipments. This fact alone reframed the debate for the clinical team.

In many cases, this one included, Clinical Trial Optimization is about weighing the relative risk of the status quo against moving to an unknown but predictable future. Our experienced team stresses that it makes sense to proactively adjust the supply plan during the conduct of a trial. It should never be a "once and done" objective.

Initially, the sponsor clinical team was in reactive, locked down, mode which was understandable – there was a lot on the line. The 30% increase in the supply budget opened their eyes to the need for an adjustment. To add extra reassurance about making the change midstream, our team proposed making the change on a trial basis so it could revert back to its old configuration if any issues were encountered. The Clinical Supply Optimization lead stated "We were pretty confident that this was the right direction, but wanted to offer a solution that gave them the security to say 'We can go back to the way it was before." There was always a way out, and it made the new direction more palatable. The proposed change plan included robust monitoring to identify any issues before they could throw a new obstacle in the process.

The Thermo Fisher Scientific team's intuition proved to be true. The change resulted in a 25% reduction in shipment volumes over a three month monitored period with no increase in stock outs at the site or depot level. Thermo Fisher Scientific helped to deliver a successful program while saving the sponsor several million dollars in clinical trial supply costs.

The sites now receive just one shipment per month on average, down from up to four per month. By showing respect for the needs of the sites, the new algorithm makes it more likely that personnel will handle the drug appropriately. Most importantly, patient and site satisfaction was vastly improved.

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