ThermoFisher SCIENTIFIC

CASE STUDY

UNITED WITH COMMITMENT & COMPASSION

Clinical supply optimization:

Mid-size pharma rejects bulk, avoids shortage

Investigator supported studies streamlined

The key to a successful program of investigator supported studies is maintaining productive relationships with the physicians at the clinical sites. These relationships were a concern for a top ten pharmaceutical company when Thermo Fisher Scientific became involved with the program.

With unique protocol requirements and widely different levels of clinical trial experience, the investigator supported sites placed huge demands on the pharmaceutical company's clinical supplies team. Instead of focusing on their multiple Phase III studies, their clinical supplies team found themselves distracted by the demands of numerous clinical trial units testing multiple compounds.

This complexity of supply needs threatened to interfere with the higher level priorities of the investigators and the company.

- The physicians at the sites were focused on leadership in oncology treatment and securing funds for research, not the intricacies of setting up a supply forecast
- The clinical team wanted to concentrate on finding new indications and new populations that would give them a head start on the next round of clinical trials, not on the overwhelming diversity of needs at the investigator sites

Both had a vested interest in the success of the investigator studies, but were struggling to make the relationship work.

Adding continuity to the drug supply process

At first, the Supply Optimization team provided standardized ways to coordinate studies among all the lead clinical trial units. We worked with these lead sites to roll out a series of working tools that improved information flow about expiry dates, supply level forecasting, distribution challenges, and other details. Our team became the central point of contact between the pharmaceutical company and the lead sites, taking the pressure off the company's clinical supplies team and adding continuity to the process, which had been impacted by fluctuations in staffing levels.

Building the gap between the two parties, Thermo Fisher Scientific was able to streamline the relationships. We acted as an arbitrator to enforce certain supply standards without creating hard feelings among investigators. For example, when one of the lead clinical trial units decided they wanted to add an additional country, our team advised them of the timelines and requirements involved. With this insight, the investigator site decided against the expansion and stayed within the established timeline.

Investigator supported studies increase from 14 to 45

Providing the clinical trial units with a better understanding of processes, requirements, and timelines became our primary mission in this relationship. Over time the number of investigator supported studies increased as the pharmaceutical company expressed delight in the new way the trial supplies were being managed. From 14 investigator supported studies a few years ago, the program has grown to encompass 45 studies with more scheduled to come aboard in the near future.

Today, prior to study starts, the Thermo Fisher Scientific team offers input to the lead clinical trial units regarding the protocol design, forecasting, and other parts of drug supply and distribution strategy. There is a premium on minimizing waste because some compounds are in short supply or have short expiry dates. Engaging us early in the study design and using the new structure for supply management has paid off for the clinical sites and the pharmaceutical company. Not only have relationships been maintained and research advanced, but supplies are beating established metrics. On time shipments have exceeded 90%, with the delays limited exclusively to holiday periods. And in no instance has a patient failed to get drug due to a supply shortage.

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