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## Clinical supply optimization:

Enhanced service model saves trial sponsor time on supplies

The Vice President of manufacturing for a clinical-stage biopharmaceutical company faced an avalanche of work when a reorganization left him without a clinical supply manager. Planning to start five new clinical trials in six months while managing quality assurance, manufacturing, and supplies for new and ongoing studies, he turned to his Thermo Fisher Scientific account executive with a simple question: “How am I going to do all that?”

Though the manufacturing VP had worked with Thermo Fisher Scientific before, this was the first time our Clinical Supply Optimization service came up as an option. Designed to handle supply forecasting, demand planning, and other high level supply chain management functions, this service appeared to fit the Sponsor’s immediate need and he agreed to proceed.

### New ground rules on working together

The two organizations took an additional step that gave the Clinical Supply Optimization team a larger role in supporting the supply chain. Called the Enhanced Service Model, this step involved a restructuring of the Sponsor-Supplier relationship to set new ground rules on how they would work together. They signed an updated quality agreement that gave the Clinical Supply Optimization team the authority to absorb several tactical activities that had typically been performed by the Sponsor.

These tasks included pre-batch record reviews and the document management supporting the randomization process. With proper controls, operating procedures, and training in place, the Clinical Supply Optimization team adopted the new duties in addition to planning, forecasting and inventory management tasks. Following Good Manufacturing Practices, the Sponsor’s VP retained responsibility for approving label copy, signing off on all packaging runs, and releasing product to clinical sites.

## Manufacturing VP looking to focus on strengths

With these supply tasks off his plate, the VP shifted focus to his strengths of finding new ways to fight disease and developing the best, most cost-effective drug. The team began organizing the supply chains for a series of hepatology studies that used the same oral drug for different indications.

Giving our Clinical Supply Optimization team an enhanced ability to manage supplies provided quantifiable benefits. Including internal handoffs and approvals, the prebatch records and randomization activities took the Sponsor's VP about 10 days to complete. In contrast, our Clinical Supply Optimization team completed them in four days, freeing up valuable time for the Sponsor to focus on other priorities.

## Reduced manufacturing costs

The Sponsor also saved resources when one of the trials began to enroll at a faster rate than expected. In the past when this occurred, the Sponsor would manufacture additional product to make sure newly enrolled patients would have medicine. Our Clinical Supply Optimization team developed a strategy to re-label the same drug from one of the slower enrolling trials. This solution was estimated to be at least five times less expensive – and much faster – than manufacturing new product.

The Enhanced Service Model delivered additional results when several protocol amendments and a geographic expansion threatened to slow progress. Our team helped avoid delays caused by protocol changes by quickly creating and approving an innovative packaging solution that supported the evolving research. For the geographic expansion, we provided supply forecasting and regulatory guidance on label content that was based on past success in the targeted countries.

## More time for strategic manufacturing efforts

Since adopting the Enhanced Service Model the VP has been able to focus more tightly on his core strengths. With extra bandwidth for strategic manufacturing projects, he has increased his contribution to the company's clinical success. Bringing in the Thermo Fisher Scientific supply chain optimization team has helped the company meet vital milestones in the five clinical trials.