Case Study

Improving Clinical Supply Chain Management by Establishing End-to-End Visibility

Service Areas: Clinical Operations, Demand & Operations Planning, Manufacturing, Supply Chain
Lifecycle Stage: Clinical

Emerging pharmaceutical companies frequently place responsibility for clinical supply chain management on their clinical operations team and CROs. This approach can work initially for small, resource-constrained organizations. However, it does not help companies build the internal capabilities, knowledge, and resources to successfully run their clinical supply chain over time as they grow.

One client developing enzyme-based therapies was conducting a randomized and blinded pivotal Phase III clinical trial. Along the way, testing parameters changed as they prepared to expand the trial footprint. The changes could increase the supply requirements. Since an additional manufacturing run would be a multimillion-dollar investment, the company wanted confirmation that another run was truly necessary.

The internal resource charged with supply planning was part of the Clinical Operations team. Due to the individual's clinical operations responsibilities, they were blinded to maintain the integrity of the study. However, to truly examine the demand/supply dynamics and assess manufacturing requirements, access to unblinded data was necessary. Management engaged Converge to analyze the demand/supply situation, prioritize supply issues and resolutions, and proactively manage clinical supply chain activity.

3 Clinical Supply Chain Management Tools: Supply Plan, Demand Plan & Manufacturing Plan

To verify whether they needed another manufacturing run, Converge conducted a supply availability assessment. Results showed the amount of supply required for the company's active trials as well as the planned expansion. The assessment also confirmed that they needed another manufacturing run to ensure adequate supply.

After resolving the critical investment questions, we collaborated with this client to develop a set of spreadsheet-based supply planning tools. The first of these was the Supply Plan, which provided data to improve their overall supply position.

Focus then shifted to demand planning. A Demand Plan establishes the drug amount needed for a study based on how the company expects patients to enroll. It identifies critical study-specific variables such as total number of patients/countries involved and active enrollment rates. Then, it captures those values at a given moment in time. This company's Demand Plan would be updated with real-time enrollment data and factor in anticipated future enrollment.

Demand Plan information flowed back into the Supply Plan and forward into what would become a documented Manufacturing Plan.

Working with the company's CMC leaders, we built a shared understanding of key factors such as batch sizes, limitations, drug expiry/shelf life, and typical losses. This information yielded a Manufacturing Plan enabling optimization of several shelf-life extension activities with the packaging and labeling vendor.

With a Supply Plan, Demand Plan, and Manufacturing Plan in place, the client now had a clear picture of their clinical supply chain and tools to manage it going forward.

Status Today

Our initial supply assessment confirmed the need for a manufacturing run that ensured no interruption to the clinical trials. Our further work enabled the company to consider accelerating the expansion to new geographies with confidence in supply continuity.

Today, our role is maintaining and actively managing the clinical demand and supply planning process. Converge also supports Clinical Operations with proactive planning, along with investigating and mitigating site-related, inventory-related, and IRT-related supply chain issues.

Their Senior Director of Clinical Operations has comprehensive, end-to-end visibility into the clinical supply chain, and a trusted partner managing the plans on their behalf, from strategy to execution. With additional clinical studies anticipated over the course of the next year, we are preparing for the next evolution of their planning tools to provide more robust planning and analysis as clinical supply chain complexity grows.

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