

## Case Study

# Scaling for Clinical while Preparing for Commercial *Introducing Demand & Supply Planning*

**Service Areas:** Supply Chain, CMC, Clinical Operations, Commercial Launch, Finance

**Lifecycle Stage:** Clinical

Assumptions and decisions built into clinical trial design have a major impact on emerging companies' capacity planning and supply strategy. Protocol changes affect enrollment rates, production volumes, regulatory activities, logistics and managing data. It makes planning particularly challenging for both clinical and commercial production.

Our client was an emerging biologics company initiating a global Phase III clinical trial of their orphan drug. The intentionally lean CMC team was working hard to adjust the formulation and plan production considering dynamic clinical trial enrollment numbers. They were also supporting numerous other programs in the portfolio at varying stages of development.

The trial design called for significantly higher volumes of the product and would require a 500% increase in manufacturing capacity.

The company's planning process was typical of many emerging biotech firms - unstructured and lacking cross-functional coordination.

### Understanding the Business Dynamics

The company engaged Converge to improve clinical supply management for the Phase III trial while laying the foundation for future commercial supply planning.

The goal was to help the Tech Ops team develop inventory and planning strategies, identify necessary changes, and implement a new scalable planning process.

Converge's team of experienced industry veterans designed a stage-appropriate planning process. Our approach involved developing targets for inventory and safety stocks, providing supply and demand modeling and analytics, aligning the organization around roles and responsibilities, and providing support for day-to-day supply management and planning.

The first step was to understand the client's virtual supply network. We built alignment on critical supply and demand assumptions and visually mapped what was currently in place. This brought transparency to cross-functional roles and day-to-day planning activities across Clinical Operations, Clinical Supply, Quality and CMC.

The work not only provided visibility and enhanced understanding of the former planning process, but also helped identify important areas of business uncertainty. This was critical for developing a planning model unique to the dynamics of this client's business.



## Fit-for-Purpose Planning Makes A Difference

Many clinical stage companies struggle to see the relevance of structured planning. Well-established processes like Sales & Operational Planning (S&OP) seem cumbersome and inappropriate because there is no sales activity yet. Roles can be difficult to map in small lean organizations.

Converge has adapted the core concepts of S&OP's demand and supply balancing to address this issue and make planning appropriate and scalable at various stages of growth.

For this client, we established Demand & Operational Planning, a "lite" version of S&OP, designed to address questions like:

- When do we need to begin API production?
- How much material do we need to allocate for clinical demand vs. other activities?
- Can we wait until topline data is available before making significant investments in the next production run?
- How can we support the sequence of countries expected to enroll patients?
- Where should we position supply?
- If enrollment accelerates/slows, what will the impact be on supply, inventory & production requirements?

D&OP was a paradigm shift for this client and made a substantial improvement in their ability to plan and react to the inevitable demand and supply changes.

The discipline of the process equipped their team to discuss risks and opportunities, as well as make decisions with important clinical, manufacturing, and financial implications.

The value of avoiding stockouts to the clinic and/or costly expiry issues easily rises to millions of dollars, so the ROI on this easy and inexpensive effort is very positive.

## Status Today

Our client is progressing in the clinical and technical development of their lead product candidate and is maturing in an understanding of planning and its importance.

D&OP outputs and analytics keep the organization aligned on the plan and ensure cross-functional coordination as they prepare for growth and commercialization.

Converge continues to partner with this company to support clinical and commercial supply planning, extending the capabilities and bandwidth of their in-house team. We lead the execution of day-to-day planning activities and enhance the D&OP process as it evolves into a key business forum for operational and financial decisions.

The client intends to build their commercial supply organization as their clinical programs progress toward approval and launch. Converge will help with this transition, transferring knowledge and training these new internal resources.

*Converge Consulting serves the Life Sciences industry with strategy, operations and execution expertise. We collaborate with biotech, pharmaceutical and cell/gene therapy companies to achieve important business objectives. The Converge approach focuses on bridging the gap between sound strategy and reliable execution. [www.convergeconsulting.com](http://www.convergeconsulting.com)*