Case Study

Building Supply Chains & Systems for High-Touch Operating Models

Service Areas: Commercial Systems, Enterprise IT Solutions, Supply Chain, Commercial Supply Chain Launch Readiness
Lifecycle Stage: Commercial

Converge develops commercial supply chain business processes, commercial systems architecture, and last mile strategies.

Our client was an emerging pharmaceutical company focused on rare diseases, in clinical trials with an ultra-orphan drug. There were two competitive therapies also in development, so they began preparations for commercial launch on a compressed timeline to ensure they were first to market.

The treatment was essentially defining a new disease state and required a complex operating model involving physician and patient education, patient baseline testing, self-administration, cold-chain logistics, and treatment monitoring. The model also required bundling the treatment with additional services, data, and education to ensure the benefits and improve patient outcomes.

In addition, this was our client's first product launch. They wanted to demonstrate an ability to execute as a commercial company and earn a reputation as a good partner with patients, physicians, and payers.

Converge conducted a launch readiness assessment to provide visibility to what preparations were still needed. It revealed areas that required further process definition. The company also identified internal knowledge/experience gaps, in areas including commercial launch management, patient services development, and systems implementation. Senior leadership engaged Converge to develop commercial scale business processes, commercial systems architecture, and the "last mile strategies" for moving the drug product to the administration site.

Patient-Focused Business Process Design

Converge began by establishing a centralized commercial launch team. This group identified departmental ownership for key tasks and developed the integrated project plan for launch

preparation. Together, we defined and mapped each customer-facing business process along with the product and information flows from warehouse to patient.

For example, there was a small risk that patients could undergo numerous treatment rounds successfully and then potentially experience a sudden life-threatening adverse event. As a result, we designed the business processes to alert decision-makers of unusual results. The process required baseline testing prior to the initial treatment and then regular patient monitoring throughout the treatment experience. It was vital to provide high levels of information visibility. So, while data was collected at the individual patient level, it was then integrated upstream into several relevant information systems, where the results were linked with patient records available to both the physician and our client's Patient Services team, so decisions could be made whether to continue or pause treatment and to schedule delivery of the next round of the drug.

Developing & Implementing Commercial Systems Architecture

Process design collaboration transitioned into establishing a common understanding of the commercial systems required to execute the patient model. After launch, these systems would support the physician and patient communities, along with the supply chain, manufacturing, and distribution networks.

When development shifted to implementation, the Converge team stood up each system, including:

- A Customer Relationship Management (CRM) platform to support physician interaction. It provided criteria for disease recognition, information about available therapies, and how to qualify patients for treatment.
- The Patient Services platform for patient onboarding and ongoing monitoring of patient conditions. It housed records of patient and physician intent, test completion, education and training completion, and proof of funding source/reimbursement.
- A Risk Evaluation & Mitigation Strategies (REMS) program with three distinct audiences that was managed by one external vendor. REMS are typically only needed for physicians. However, the level of risk involved in this treatment warranted training and certifying the patients and pharmacies as well.
- Distribution and logistics systems that communicated with each other as needed to handle supply chain management and execution. These systems registered orders from the hospital, relayed information to the 3PL, and coordinated delivery to patients.

Defining Last Mile Strategies

"Last mile strategies" are the critical processes and solutions that move products from their final distribution point to the site of administration. Typically, the administration site is a pharmacy or hospital. However, for our client's treatment, the last mile involved direct-to-patient home delivery.

This high-touch patient and physician services model raised many questions that typical supply chain launch planning does not confront.

We worked with the company to ensure that their processes and systems addressed:

- Designing the packaging for easy and safe use by the patient independently,
- Delivering the drug as a single unit, and
- Maintaining the right temperature during shipping and delivery.

Status Today

With the commercial systems, supply chain, and last mile strategies in place, Converge led a cross-functional mock launch. Each part of our client's organization tested the processes, systems, and handoffs between the internal and external partner ecosystem.

We "experienced" the process of onboarding a patient and walking through the entire course of treatment with no issues. Then we introduced issues and prepared contingency scenarios. For example, the team worked out how patients and physicians would be notified if lab numbers were outside acceptable limits.

The exercise was completed with enough time to remediate issues before they ever affected real patients.

This client's treatment has since launched in Europe, and they are fully prepared for U.S. launch. Upon reexamination almost a year later, over 95% of the processes we developed were still utilized and even further enhanced.

In addition, the company replicated this approach for their second product. They were ready well in advance of receiving approval and have since launched successfully in Europe and the U.S.

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