7 Improvements in Clinical Supply Chain Management Your CFO Will Love

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"The right dose of the right medicine delivered to the right patient at the right time...and at the right cost".

This is the ultimate objective that every drug supply chain strives to achieve, be it commercial or clinical. New drug development is a time-consuming and expensive process. In many cases, supply chain excellence represents even greater strategic significance for R&D organizations, as it enables successful planning and execution of complex clinical trials and ensures on-time milestone achievements. This, in turn, accelerates speed to approvals for novel and breakthrough medicines and enhances the quality of patient life – especially in those therapeutic areas where treatment is currently unavailable. A well-run supply chain also reduces cash burn throughout the costly clinical development cycle and helps free up cash to fund additional promising pipelines.

Compared to their commercial counterparts more advanced in the maturity curve, clinical supply chains (https://clarkstonconsulting.com/insights/sop-clinical-supply-chain/) face greater challenges from both demand and supply perspectives. On the one hand, unpredictable patient enrollment leads to fluctuating demand signals, frequently causing supply disruptions. On the other, due to the exploratory nature of clinical trials, actual study results in the early phases may require changes to formulation to achieve the most desirable way for the investigational drug to be administered to patients with the longest possible shelf life.

Inevitably, the lack of an established manufacturing process and execution experience leads to unreliable drug supply, which may put patients and milestones at risk. This is especially true for biologics programs, which commonly require more complex manufacturing methods and high-variance yields. In addition, the industry has seen increasing adoption of adaptive design methods, which boosts clinical research by cutting time and cost. This calls for greater supply chain visibility and agility. Clinical supply chains must now be able to quickly respond to demand and supply changes as a study progresses. Many traditional clinical supply chain management philosophies can no longer support the planning and execution of innovative clinical designs.

However, similar challenges faced by clinical supply chains are not unfamiliar to the commercial practitioners. In today's volatile and complex global environment, building a reliable, responsive and resilient supply chain has increasingly become a top priority for many pharmaceutical companies. In doing, supply chain leaders seek to not only synchronize ever-

changing demand and supply at optimal costs, but also enable visibility and agility throughout the entire commercial drug value chain. Great strides have been made to achieve supply chain excellence in terms of process, technology, and organizational structure.

Many supply chain best practices were tailored to the life sciences industry and have been continuously improved over the past decades. Now, there is a great opportunity for clinical supply chain practitioners to learn from their commercial peers. By adapting and adopting the right commercial best practices, clinical supply chains become more effective, cost-efficient, and agile in delivering the right treatments to the right patients. Not only that, the evolution of clinical supply chain management in your business can also serve as a strategic differentiator to sustain lengthy and cash-intensive new drug development cycles, transition across patent cliffs, and more rapidly bring more breakthrough medicines to the global market.

There are many proven supply chain practices commonly used in the commercial side—which are the most relevant to clinical?

Transforming clinical supply chains by leveraging commercial best practices generally starts with an in-depth analysis of commonalities and nuances between the two types of supply chains from demand, supply, and regulatory perspectives. With that understanding, you can begin developing a roadmap of actionable steps and considerations. No two clinical supply chains are identical and adoption path might differ based on the size of the R&D organization and maturity level. However, the following seven best commercial practices are recommended for quick adoption to bring about positive changes to master supply planning process across drug substance/API, drug product, and finished goods product stages.

Centralized Planning

Establish a centralized planning organization established to act as a liaison to integrate clinical operations (ClinOps), the chemistry, manufacturing, and controls (CMC) team, and clinical supply managers to synchronize demand and supply for all product stages. Through this liaison, the CMC team can better focus on drug development and manufacturing, leveraging up-to-date demand information consolidated across all studies to drive feasible supply plans.

Meanwhile, ClinOps will have visibility into projected supply available, leading to increased transparency and better decision making to maximize patient and study outcomes.

Planning Bill of Materials

Adopt the traditional planning bill of materials (BOM) to list the structure of all materials in scope of the master planning at the program level, including placebos and comparators for blinded studies. Dependent demand (e.g., drug substance and API) is derived from the independent demand (labeled and packed finished goods); common material demand is consolidated at the appropriate level based on the BOM structure to allow for centralized visibility and manufacturing and/or sourcing decisions. Planning BOM ensures all critical materials are properly accounted for and enables the adoption of time-phased materials requirement planning (MRP) logic.

Multi-echelon MRP Tool

A time-phased, multi-echelon MRP tool should be adopted to translate study enrollment and dosing regimen projections, at the highest level, into actionable FG demand forecast for each clinical trial. Based on the common MRP logic, the FG demand will automatically drive the multi-echelon supply and inventory planning process based on pre-defined planning parameters. Master supply planning is an iterative process throughout the program lifecycle and supply plans are continuously updated based on the most recent information while taking into consideration firm and frozen windows to stabilize supply plans and minimize last-minute changes. The days of “buy big and buy early” are gone – expensive expiry and write-offs are over. Clinical supply chains should move to the time-phased MRP approach to build a more demand-driven and leaner supply chain aiming for the right products at the right time in the right quantity with the minimal waste.

Simulation Capabilities

Scenario planning is widely used in the commercial supply chains to evaluate demand and supply risks and develop mitigation plans. Similar capabilities should be incorporated in the clinical MRP tool to enable what-if analysis, promote cross-functional problem-solving, and bring data-driven decision-making to life. From a technical standpoint, the initial MRP tool can be Excel-based for easy adoption and quick benefit realization. However, due to the limitations of spreadsheets, supply chain planning software should be carefully evaluated, selected, and implemented to best meet the business needs as maturity grows.

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Pilot Monthly "S&OP" Process

Sponsored by the senior executives, an S&OP-like process tailored to clinical supply chains should be designed and piloted at the program level. The monthly S&OP platform brings ClinOps, CMC, logistics, regulatory and finance functions together, align goals and priorities, and proactively address escalated issues and risks. The output of the process is a single set of numbers signed off by key stakeholders that drives cross-departmental actions toward a common goal. Misalignment and surprises are no longer typical or acceptable. More advanced clinical supply chains further incorporate financials into the S&OP process (units and dollars), providing clear visibility into financial implications and funding requirement, and enabling data-driven investment decision-making.

Weekly Control Tower Process

The Control Tower process is a fairly new concept but it has gained great popularity among many commercial practitioners in recent years. This weekly process increases the visibility and agility that allow R&D organizations (https://clarkstonconsulting.com/insights/rd-processes-systems-innovation/) to quickly respond to short-term exceptions. Unexpected changes in demand and supply will always be a reality. Yet the Control Tower process facilitates a recovery plan to minimize the negative impact on patients, milestones, and cash burn.

Key Performance Indicators (KPIs)

Using metrics to assess and measure supply chain and operational robustness is an excellent way to glean insights into inefficiencies and highlight areas for continuous improvement, both internally to the R&D organization and externally to supply chain partners, such as contract manufacturing organizations (CMO), contract packaging organizations (CPO), and contract research organizations (CRO). However, implementing too many KPIs at once can be overwhelming due to the large amounts of manual data gathering, analysis, and reporting requirements, especially when resources are scarce. Clinical practitioners should start building a metrics-driven supply chain organization by implementing a basic balanced scorecard focusing on core supply chain capabilities. Some recommended KPIs are forecast accuracy, production adherence, and patient on time in full (OTIF).

Conclusion

Clinical supply chains, while unique and differentiated from commercial supply chains, can benefit largely from adopting commercial best practices. R&D organizations that can identify inefficiencies within their supply chain and new product development life cycles will be able to adapt and evolve to be more agile, more transparent and much leaner. And while R&D budgets are often strapped, investing in supply chain excellence has the potential to yield massive return on investment.

Looking ahead, trends like precision medicine (https://clarkstonconsulting.com/insights/personalized-medicine-2019/), Car-T, and gene therapy are becoming more prominent, and rare diseases remain of critical emphasis for pharmaceutical and biotech companies. In this shifting landscape, if operated successfully, clinical supply chains can serve as a strategic differentiator to ensure organizations are optimizing the development outcomes and truly delivering the best quality and value as possible to the patients, to the company, and to the shareholders.

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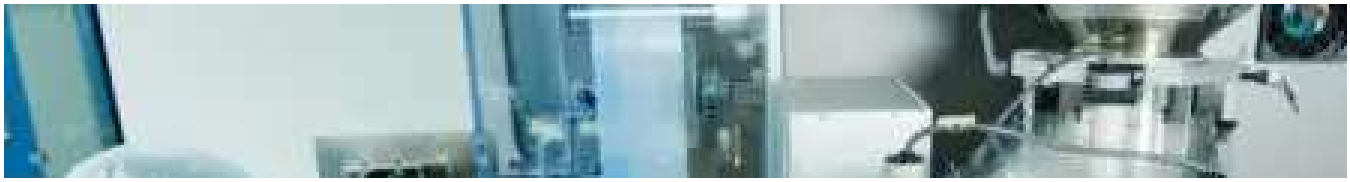

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