VIEW POINT

FROM LAB TO PATIENTS: UNDERSTANDING CLINICAL TRIAL SUPPLY CHAIN AND ITS COMPARISON WITH COMMERCIAL SUPPLY CHAIN

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Introduction: The Clinical Supply Chain

Clinical trials, as defined by the World Health Organization (WHO), involve the prospective assignment of human participants to health-related interventions for the evaluation of their effects on health outcomes. The backbone of these trials is the clinical supply chain, responsible for managing, planning, sourcing, manufacturing, packaging, labeling, and distributing investigational products to various clinical sites. This critical component ensures the availability of products in compliance with regulatory standards and Good Clinical Practice (GCP) guidelines.

The clinical supply chain is intricate, involving interconnected processes, stakeholders, and challenges. Effective coordination between pharmaceutical companies, Contract Research Organizations (CROs), Contract Manufacturing Organizations (CMOs), and other stakeholders is essential to optimize efficiency, minimize risks, and support the successful execution of clinical trials. A well-executed clinical supply chain enhances the experience for both patients and investigators, maintaining trial integrity, preventing delays, and ensuring patient safety.

Research indicates that On-time In-full (OTIF) levels in clinical supply chains surpass those in commercial supply chains. This disparity is attributed to the higher stakes involved in clinical trials, where a missed patient dose can disrupt the entire study schedule, lead to ethical violations, and pose potentially life-threatening consequences. Prioritizing high OTIF levels in clinical supply chains is crucial for upholding the ethical and scientific integrity of research trials, simultaneously minimizing costs associated with managing missed doses.

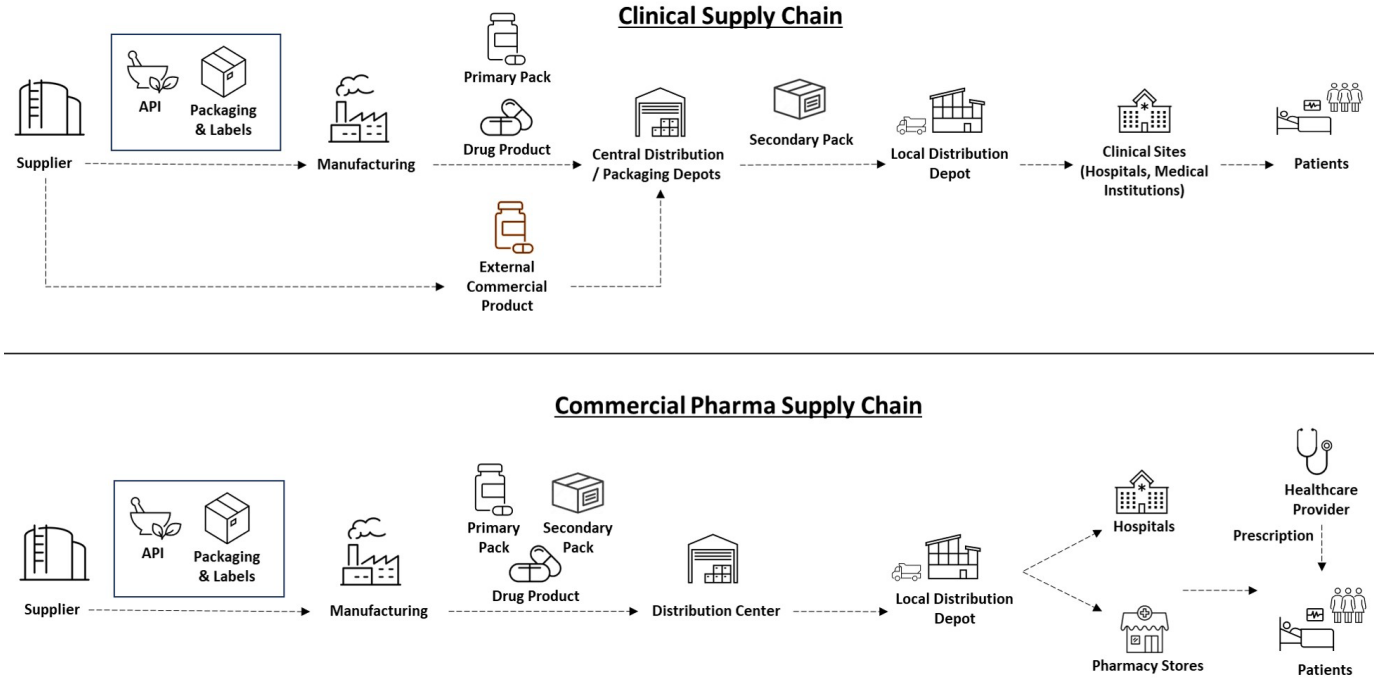

Fig1: Commercial Supply Chain vs Clinical Supply Chain

The below table summarizes some of the key differences between commercial and clinical supply chains:

Focus Area	Commercial Supply Chain	Clinical Supply Chain
Objective	It focuses on ensuring efficient, cost-effective, and timely distribution of market-authorized pharmaceutical products to meet market demand while maintaining product quality and compliance.	It facilitates timely and accurate delivery of investigational drugs and supplies to clinical sites, ensuring integrity of the trial and maintaining patient safety.
Forecasting & Planning	1. Historical sales, market research, competition analysis and disease prevalence rates are the major inputs in forecasting engine 2. Time-series based, and AI/ML-based algorithms can be utilized for processing of inputs to generate demand forecast 3. Constrained demand forecast is then generated by taking into consideration of marketing, sales, and finance 4. Accuracy is high as compared to clinical trials 5. Output from F&P is used for setting sales targets and manufacturing planning	1. Demand originates from Clinical Study Protocol which mandates a particular patient recruitment for each phase which acts as the base for forecasting 2. Time-series based, and AI/ML-based algorithms cannot be utilized but methods like Monte-Carlo simulations have been used to incorporate different independent variables 3. Accuracy is less owing to high variability associated with patient enrollment and changes in study protocol 4. Output from F&P is used for determining trial feasibility, budgeting, resource allocation, and patient recruitment strategies
Sourcing	It majorly focuses on securing cost-effective and reliable suppliers for mass production and distribution of pharmaceutical products.	It involves close collaboration with specialized suppliers that can provide small batches of materials for R&D, adhering to regulatory requirements. Along with sourcing of IMP, the sourcing of External Commercial Product is needed to support blinding.
Manufacturing	It is typically large scale aimed at producing pharmaceuticals in large volumes to meet market demand and generate economics of scale.	Assembly of kits is in small and non-uniform batch sizes for multiple sites across geographies.
Inventory Management	It is forecast-driven, and its major focus is on cost optimization aimed towards minimizing the cost of ordering and cost of holding inventory.	It focuses on 100% service to clinical trials participants and cost is the least concern. An adequate amount of inventory is kept offsetting losses from overages and avoiding any missed dosage to patient as per the schedule.
Packaging Components	Often contain individual units (tablets, vials) in single packages.	Kits with multiple components, including the IMP, comparator drugs, placebos, syringes, needles, labels, and study

		instructions in multiple languages. These kits are designed for specific patient groups and study protocols.
Labelling	Commercial labeling serves multipurpose for Logo (brand appeal) as well as has detailed information about dosage, shelf life, side effects, and storage instructions for consumers.	Labeling identifies unique batch numbers, study participant IDs, and blinding information. Blinding requirements - single, double, triple - necessitates specific label formatting and packaging to maintain trial integrity.
Distribution	High volumes of products are shipped to meet the demands of the wider consumer market from manufacturers to DCs, hospitals, and pharmacies with the focus on efficiency and availability.	Distribution is highly customized considering involvement of multiple smaller batches and kits. A fleet of vehicles with temperature-specific requirements are provided to support the distribution at point of trials and sites.

Table 1: Commercial Supply Chain vs Clinical Supply Chain

Challenges in the Clinical Supply Chain

The number of registered clinical trials has increased significantly in recent years. As of January 17, 2024, there were nearly 479,000 clinical studies registered globally which is a significant jump from 2,119 registered trials in 2000. In addition to the surge in numbers, which is a consequence of advancements in medical research, the trials have also gotten more complex along with the demand for shorter and smaller trials. Furthermore, the global pandemic, COVID-19 pushed the clinical trials to be more decentralized while also emphasizing participants to be better informed about the trial protocols and associated risks.

Below are some of the key challenges associated with the clinical supply chain:

- **Forecasting Accuracy:** Variability in demand leads to higher safety stocks, causing increased wastages and disposal costs. Inaccuracies in planning contribute to inventory accumulation, amplifying errors upstream.
- **Inventory Management:** Precision in managing inventory is crucial to prevent patient loss due to stockouts and mitigate expenses associated with overstocking. Optimizing supply levels is vital for uninterrupted patient dosing and trial success, minimizing financial impacts.
- **Distribution Complexity:** Shipping in temperature-controlled settings across diverse locations introduces logistical complexities in the supply chain. Suboptimal systems from packaging and dispensing sites, coupled with the critical need for specific transport temperatures, contribute to challenges in ensuring product integrity and effectiveness.
- **Complex Operations:** Regional variations in regulations, import/export rules, and expiry date requirements create a challenging operational landscape. Flexibility and adaptation are essential for effective management.
- **Traceability:** End-to-end traceability is critical for inventory optimization and reducing wastages. The lack of real-time monitoring infrastructure poses challenges in drug tracing and inventory optimization.
- **Cost of Comparator:** Escalating costs challenge budget constraints, necessitating strategic approaches to secure cost-effective sources for essential reference treatments.

Trends Affecting Clinical Supply Chain

The clinical trial supply chain is being revolutionized by technological advancements, shifting industry dynamics, and evolving patient needs, with far-reaching implications for the development of new drugs and therapies. Below are some of the key factors responsible for this significant transformation in clinical supply chain:

- **Adaptive Trials:** Modifications are often made in ongoing clinical trials to make it more flexible by adjusting doses and incorporating new information, and to improve effectiveness by dropping ineffective treatment arms. These frequent changes in study designs and inventory needs can cause stress on the supply chain in terms of responsiveness. Supply chain agility with real-time monitoring and strong collaboration between stakeholders will help in executing these trials. Also, modular packaging and adaptable packaging solutions to accommodate changes in treatment regimens can also help in supporting the adaptive trials.
- **Decentralized Trials:** Shift in some or all clinical trial activities from traditional clinical sites to local healthcare provider or a patient's homes by using Digital Health Technologies (DHTs), has been aimed at enhancing patient experience and reducing attrition due to travel challenges for patients. These, however, adds to increased distribution complexity with multiple delivery sites. Supply chain emphasis will be on accommodating Direct to Patient (D2P) shipping and remote fulfillment.
- **Virtual trials:** These are conducted entirely remotely with minimal and no in-person contact between participants and researchers. The goal is to maximize flexibility and convenience for participants, reduce cost, and improve global reach. Heavy reliance is on digital platforms for patient engagement and data collection. It needs centralized logistics for drug storage and distribution since physical trial sites are not present. Also, IoT and real-time monitoring of drug shipments are required for integration into supply chain infrastructure.
- **Digitalization and Data Integration:** The increasing use of digital technologies for real-time data tracking, inventory management, and supply chain visibility, is enhancing overall efficiency and transparency. Increased focus on integration of technology, including wearables, and 5G connectivity, enhances real-time tracking and monitoring of the supply chain. Digital transformation encompassing cloud computing, cyber security, blockchain, and AI/ML becomes imperative for ensuring data security, transparency, and operational efficiency.
- **Sustainability in Clinical Trial Supply Chain:** Clinical trials now use reusable packaging, temperature-controlled containers, and environmentally friendly packaging materials to reduce waste and carbon emissions.
- **E-labels:** Replacing traditional paper-based drug labels with electronic labels (e-labels) and using Electronic Data Capture (EDC) to collect, store, and manage research data electronically to reduce the need for paper-based documentation, could help in reducing the wastage.

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