Improving Supply Chains

Keeping Up With Industry Trends: The Importance of a Dependable Clinical Supply Chain

Making sure trial sites, clinicians, and patients get the product they need at the right time is integral to the success of a clinical trial. How can clinical trial supply chains adapt to increasingly complex therapies and cold-chain requirements?

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A commonly heard saying for anyone who has worked in a drug development organisation is: 'It costs a million dollars a day in lost revenue if a competitor gets to market first.'

While the exact revenue number can be argued, what cannot be is the ever-increasing pressure placed on pharmaceutical and biotech companies to accelerate drug launches. Further complicating the situation is a growing demand for clinical studies and the increased complexity of their designs, as well as a transition to more temperature-sensitive biologic products. These challenges, along with the persistent need to be cost-efficient, are driving a new view in the way of clinical supply management. In the end, the success of a trial will depend on both the development of more innovative drugs, as well as a well-organised, effective, and compliant clinical supply chain.

From Small Molecule to Biologics

While most treatments on the market currently consist of small molecule drugs, a clear shift towards biologics has been observed in pharmaceutical research and development strategies.

According to *Biopharma Trend*, in the period covering 2011 to 2017, biologic sales revenue grew by 70%, reaching $232 billion. The share of the total pharmaceutical market that biologics held in that period increased from 16% in 2006 to 25% in 2016. In addition, for the top 20 product sales in 2020, biologics accounted for 12 products (60%) compared to 8 products for small molecules (40%) (1).

With the transition away from small molecule towards biologics comes greater challenges from a clinical supplies management perspective. The Global Clinical Trial Supplies Market Report 2022-2030 states that the rise in the global biologics pipeline and temperature-sensitive drugs are expected to increase the complexities related to logistics of clinical trial supplies (2).

Most notably, biologics are more sensitive than small molecule drugs, and often require the product to be stored at cold or ultra-frozen temperatures during the various

handling stages of a trial: packaging, labelling, and distribution.

This requirement creates complexities that can only be overcome with efficient, well-designed, and carefully implemented strategies developed by experienced clinical supply professionals who are well-versed in cold-chain supplies management. By utilising the expertise of experienced professionals in the clinical supplies space, drug discovery organisations can maintain their focus on what they do best – developing drug therapies that save and improve the lives of people in need around the world.

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Enabling Progress Through Dependable Clinical Supply Chains

It may be easy for one to assume that packaging, labelling, and distribution activities are straightforward processes. Often, a trial investigator or patient receives a simple-looking vial, bottle, or kit box, covered with a label.

This may not appear complicated at first glance; however, in reality, these results can be extremely complex due to a variety of factors, such as ever-changing supply quantities, the addition of new countries or cohorts, frozen conditions, and equipment requirements. If not managed efficiently and proactively, these challenges can jeopardise a clinical trial's product availability, and even worse, its integrity.

The best way to mitigate these risks is by partnering with a team of clinical supply professionals with the knowledge, expertise, SOPs, and systems in place to prepare and strategise for every eventuality, from before the trial starts through to its finish. Some crucial factors to consider when selecting a clinical supplies management partner include:

Global Reach

Sponsors should prioritise partners who have their own facilities for clinical trials in key geographic areas on every continent. Geographic coverage drives cost efficiency, facilitates efficient supply planning, and increases flexibility. The increased freedom for market developments and innovation in clinical research in emerging markets (for example China, Brazil, Russia, India, and South Africa) makes relying on global capabilities even more crucial. Having a choice of supply routes will enable clients to cover study demand (3).

Adapting to the Local Market

While 'Think Global, Act Local' may be an overused phrase, it couldn't be more relevant to the current clinical trial landscape. A clinical supplies provider with a track record of experience in the region can save sponsors time and money. For example, working with a global supplier that has local entities where comparator products can be purchased, received, and held locally in their own depots, results in better pricing. What's more, market knowledge ensures that packaging and labelling services are compliant with local regulations.

Clinical Trial Supplies Domain Expertise

Clinical Trial Supplies are a specialty industry with unique and exacting requirements, where a deep domain

expertise in both clinical packaging and labelling, as well as comparator sourcing, is needed. It is difficult for companies that are not fully dedicated to clinical trial supplies to build the infrastructure and processes needed to excel in this area. For comparator sourcing in particular, a complete understanding is needed on how the generic market and tenders operate, to ensure continuity of supply and avoid a change in product submission halfway through a trial.

Adapting Clinical Supplies Management Solutions to the Clinical Trial

A reliable clinical supplies provider will act as a strategic partner and invest the time needed to devise a customised strategy that meets the exact needs of the project at hand. This can include introducing new methods of managing clinical trial supplies, with built-in flexibility, for the entire length of a study (for instance, through the use of specific technology).

Clinical trials are always subject to change – especially given recent global crises and external world factors impacting supply chains – and the ability to adapt quickly can keep the study on track. Many large companies can be tied to their established procedures. A client-focused clinical supplies partner with vast knowledge of how to address the ever-changing needs of clinical trials should react quickly to requests, and be nimble enough to provide quick turnarounds.

The Advantages of a Direct-to-Patient Model in a Clinical Supply Chain

The Direct-to-Patient model (DtP) is now common practice in the clinical trial sector, or rather, most professionals within the industry are familiar with the general concept behind this approach to clinical supplies. According to Global Data, a record number of around 1,300 trials with a decentralised and/or virtual component are expected to initiate in 2022, representing a 28% increase from 2021 (4). But what does implementing the model really entail and how can it help sponsors gain a competitive advantage?

DtPs are services that are part of the greater concept known as decentralised clinical trials. In a nutshell, supplies are prepared, packaged, labelled, and then shipped directly to the home of the patient or caregiver. Patients no longer have to visit the clinical site for diagnosis, labs, and data collection, which is a challenge for many. This method also enables sponsors to avoid shipping to, and storing supplies at, clinical sites. Several types of DtP may be implemented, including site-to-patient, depot-to-patient, pharmacy-to-patient, and plan-to-patient. They all have one thing in common, however: a well-established logistics process to compliantly deliver medicine without breaching patient confidentiality.

Patient centricity and making clinical trials more accessible to wider patient populations is the overarching aim of decentralised trials. Serving this purpose can only result in a more competitive advantage for sponsors – consistent and diverse recruitment, speed to market, and naïve indication recruiting, to name but a few benefits.

In addition, DtP goes hand-in-hand with personalised medicine, and forms of clinically administered dispensing. As an example, injection dosing in an assisted living facility would benefit from this patient-centric model. Personalised medicine is undeniably the future of clinical development, and it will benefit any sponsor or service provider to put in place or develop a DtP solution to be at the forefront of this shift in clinical trial roll-out.

In summary, Clinical Supplies Management is a complex process with many moving parts, and current industry trends – such as the shift to biologics – make the accurate management of a supply chain a key factor to the success of a clinical trial. The criteria outlined above will help to secure a solid clinical supply programme from the onset and mitigate risk throughout the duration of a study. While nothing can completely eliminate the possibility of delays and disruptions, the careful selection of project partners can reduce their impact on a trial and help sponsors stay on time and on budget, moving an Investigational Medicinal Product through the clinical testing process as smoothly as possible.

References

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Rocco holds a Bachelor's in Chemistry and a Master's in Business from Moravian University, US, and has more than 17 years' experience in supply chain and GMP related processes. After obtaining his undergraduate degree, Rocco joined Merck & Co., Inc. as a Production Scheduler and subsequently held roles of increasing responsibility.

His last position, before joining Clinigen in 2022, was Director and Site Head of US Clinical Supply Operations.