Clinical Ancillary Supplies

Category Insights

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Introduction

Clinical Ancillary Supplies cover a large portion of the product portfolio required for conducting clinical trials. These are non-drug supplies and range from documents, consumables, disposables, clinical supplies, laboratory equipment, diagnostic devices, e-diaries, etc. among others. Due to the diverse nature of product types, costs, and volumes included in the category it gets difficult for sponsors many times to craft a one-stop strategy for the management of Clinical Ancillary Supplies. Initially, this was just a procurement-based category that evolved to sourcing, project management, strategic sourcing with different strategies for a different class of products.

Today, the supply chain management of these products/materials has become very challenging due to the increased complexity of clinical trials, diversification of service providers/suppliers, the requirement for maintenance, repair, and recalibration of devices, etc. Other factors such as Storage, Packaging and Labelling, Regulatory Documentation, etc. also need equal attention. Timely and Correct shipments on trial sites are important not just for conducting clinical trials successfully but also for the Clinical Site Activation process. The rise in complexity of the management of clinical supplies has also given a push to strategic sourcing of clinical ancillary supplies.

Growth Factors

- Virtual Clinical Trials: The need for virtual clinical trials in increasing especially in developed markets. This is happening due to various reasons such as the Covid-19 pandemic, the inclusion of more females, patient retention among the working class of people especially parents, etc. This opens an entirely new paradigm that includes both challenges and opportunities for supply planning and management for trial materials.
- Biopharmaceutical Clinical Trials: Clinical trials involving Biologics is one of the prominent growth factors for this market. In such trials, the sponsor needs specific injectable devices as per IMPs, more monitoring devices, laboratory equipment such as freezers, incubators, etc.
- Emerging Markets: Sponsors are constantly increasing their clinical trials in emerging markets due to various benefits such as cost-effectiveness, availability of naïve-treatment population, diverse population, more disease penetration, etc. All emerging regions such as LATAM, Africa, ME, and APAC have their challenges and benefits for the supply chain.
- POCDs: Sponsors and Investigators need to quickly understand various parameters about patients they are looking to enroll. This includes quick diagnostics of health issues such as Serological Analysis, Cardiac Situation, Blood Pressure, Cholesterol, Urinalysis, etc. This is giving rise to the use of more Point of Care Diagnostics (POCDs) before & during a clinical trial.
- Regulations: In developed markets, the respective regulatory bodies are keeping close checks to avoid bribes & perks in the form of giving medical devices and equipment to investigators and hospitals by sponsors. Similar such regulatory reforms are in place now in many emerging markets. This gives rise to proper supply management of medical devices and equipment. Although this creates a problem of reverse logistics which leads to the high overall cost, but the supply chain is now evolving to consider this factor.

Other growth factors include an increase in Chronic Diseases, Linguistic considerations in different countries, etc.

Type of Service Providers

As mentioned earlier, the increase in complexity in conducting clinical trials is also giving rise to diverse players in the market. Below are some of the key players and they have significance based on geography to be covered, product types, supply requirements, etc.

- Clinical Trial Supply Companies: These are service providers who offer complete supply chain solutions for clinical trial supplies which also include IMPs supplies and Comparators Sourcing along with storage and shipments. Many of such companies also offer Clinical Ancillary Supplies as a bundled service.
- Specialists: These are the players who offer dedicated clinical ancillary supply service offerings. The service providers include Ancillare, Quipment, ImperialsCTS, etc. Rental Equipment supplies is one of their biggest service offerings.
- CROs: Some CROs such as Parexel, PRAHs, Covance, etc. also offer management of Clinical Ancillary Supplies at various stages such as central planning and management as well as at regional/local level of procurement.
- 3PLs: Companies like Marken and World Courier offer various options for Clinical Ancillary Supplies management, but their major role remains in two areas such as management of shipments as well as more forward integration in LATAM and Africa regions.
- Medical Device Manufacturers: Increased use of Biologics in clinical trials also increase the use of standardized/specific injectable. This gives rise to more inclusion of manufacturers in supply chain planning and management based on the scale of requirement. This is also valid in case of any specific high-cost equipment/device which is standardized across a greater number of countries for use in clinical trials. Also, they can be useful in recalibration and repair services through their own local offices in different countries or through a network of registered distributors.

Key Focus Areas

Some of the key focus areas for sourcing of clinical ancillary supplies include the following:

- Standardized Equipment for trial sites: Sponsors and Trial Planners need to first isolate the equipment which are standardized across most of the clinical trial sites. This gets useful in sourcing under a centralized system with more supply planning and execution involved in it.
- Right Supplies at Right Site at Right Time: Many times, the items reach the wrong address especially among trial sites in emerging markets. This affects trials in various factors such as additional shipment costs, potential delay in patient treatment, potential delay in trial start-up, increase packaging, labelling, and paperwork, etc.
- Reduction of Wastes/Unused items: Proper planning and management are important from two aspects i.e.
  - Reduce overall wastes/unused items by predictive analysis of trials,
  - by proper management of un-used equipment.
- Procurement Vs. Rentals: Sourcing of equipment such as Centrifuges, ECG Machines, Freezers, Incubators, Refrigerators, Ovens, Fluid Warming Systems, Scales, etc. can be planned as per the number of units required, shipment distances, cost, and timelines, frequency of requirements, availability of local options, etc. Equipment can be sourced on a rental basis based on the overall cost factors involved in it.
- Reverse Logistics: Due to regulatory requirements as well as the cost involved in many types of equipment and devices such as Centrifuges, Freezers, etc. there is always a need for pick-up and shipment of those equipment back to central/regional warehouse. This again involves huge shipment costs, but the supply chain scenario is evolving now.

- Regulatory: There are many aspects that need careful study and consideration such as custom clearance requirements, documents requirements, engagement with trial sites and investigators, proper destruction and reverse logistics of various materials, perks, gifts, and payments involving clinical material supplies, etc.
- Maintenance, Recalibration, and Repair Services (MRR): Many times, this gets less attention during the planning phase. However, if planned properly, there is a potential cost saving of 2-5% of overall category spend through using proper channels and agreements for MRR services. For this, a sponsor/service provider may need to engage with the manufacturer or authorized device distributors on local/regional levels.
- Right Sourcing Strategy with Right Mix of Service Providers: This depends on product requirement, geographic proximity to central warehouse or labs, supply chain infrastructure, local availability of products, etc. The sponsor can include various types of service providers after careful consideration and with the local team's inputs.

Other focus areas also include Storage, Packaging and Labelling Requirements, Pooling of Study Kits, Central Vs. Regional Depots, etc.

Engagement Strategy

This includes some of the engagement models between sponsors and service providers. The use of each of the engagement models is based on trial supplies requirements and company policies.

- Regional Engagement: Regional engagements can be very useful in emerging markets where the supply planners can rope-in CROs. The clinical trial monitoring can be bundled up with supply requirements at the local level.
- Centralized Vs. Decentralized: Supply planners need to demarcate supplies among centralized sourcing vs. decentralized sourcing. For an instance, IV Bags/Fluids may not be available frequently in many parts therefore it needs proper sourcing planning.
- Management Outsourcing: Sponsors sometimes outsource supply management to a service provider such as a CRO where they need to collaborate with sourcing and supply chain agency such as Specialist or CTS company.
- Hybrid Model: This includes various strategies at the same time.
- FTEs Based working Model: This includes a mix of supply planners from sponsor, CTS company, and CRO. The CRO or CTS company often provides a team of experts to sponsor during the complete execution of the clinical trial.

Holistically, the Clinical Ancillary Supplies is a very dynamic and challenging part of overall clinical trial management. It always required a high level of consideration while planning and execution processes. This may lead to savings in the overall supply budget to the tune of 2-10% based on many factors.

Category Intelligence

We have prepared a very useful and strategic intelligence on the overall Category. This includes various reports and database.

For more inputs, please reach out to us at bd@essentialmarketinsights.com

Appendix:

1. Primary Interactions with Investigators in various regions
2. Primary Interactions with Clinical Trial Supply companies in various regions
3. Primary Interactions with Clinical Depots in various regions