



ANCILLARE

WHITEPAPER

Clinical and Ancillary Supply Chain Management:

THE EVOLUTION FROM COMMODITY PROCUREMENT
TO A SYSTEMIC SUPPLY CHAIN MODEL

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Clinical Supply Chain, Simplified™

ABSTRACT

According to the U.S. National Institutes of Health, nearly 240,000 clinical trials were registered as of February 2017, comprising all 50 U.S. states and 195 countries. More strikingly, over half of these studies included global (i.e., non-U.S.) sites. Global clinical trial sites tend to be more than geographically disparate: sites are also culturally distinct, differently regulated and at the mercy of unique transportation networks and infrastructures. While the benefits of worldwide studies have been appreciated for decades, the implications are still not fully understood among many study sponsors. Typically, within sponsor organizations, the best perceived solution to globalization has been to scale commodity sourcing and procurement processes. However, the commodity procurement approach fails to accommodate the full scope of management challenges presented by multi-site, multi-country protocol designs. These challenges pertain not only to procurement, but also to efficiency, compliance, distribution, privacy, ethics, and budget. The value and benefits of a systemic alternative, called *Clinical and Ancillary Supply Chain Management*, is explored herein.

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INTRODUCTION

Laboratory, scientific and clinical research consumable supplies and durable equipment, more widely known within the clinical trial community as ancillary supplies, comprises a multibillion dollar segment of the larger clinical research industry. Manufacturers and distributors of ancillary supplies are often publicly traded, employ tens of thousands of associates, and report annual sales in the billions of dollars. Indeed, demand for ancillary supplies is higher today than ever in history. As well it should be: the importance of reliable, state-of-the-art equipment and supplies cannot be overstated in the process of enabling ongoing research of innovative, life-saving therapies.

However, demand is only the tip of the iceberg with respect to the commodity supply equation. As demand for ancillary supplies has increased, so too has oversight and competition. Today, fulfillment of sponsors' commodity equipment and supply needs presents an unprecedented set of unique challenges. The set of variables that must be contended with just to meet minimum thresholds, adhere to study protocol, and achieve key performance indicator goals is necessarily broad and cross-functional.

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From logistics and procurement to budget and timeline to compliance and documentation, privacy and ethics, the factors that must be contended with to successfully match sponsor requirements are sufficiently demanding and variable. Because of this, a dedicated Clinical and Ancillary Supply Chain Management function is not a luxury, but in fact, a necessity.

The Management Philosophy of Supply Chain Planning

The classical approach to supply management in clinical trials is unusually similar to how a consumer might approach the retail shopping process: as a need that can be fulfilled via off-the-shelf products. Indeed, most clinical and ancillary supplies and study equipment are commodities, not unlike a week's worth of food: supplies that must be identified, acquired, safely stored and handled, and consumed before expiration to prevent waste. Furthermore, the ubiquity of catalog-style commodity suppliers has buttressed the notion that off-the-shelf procurement is the best, and perhaps even the only, viable approach to clinical and ancillary supply procurement. However, procurement decisions surrounding clinical and ancillary supply long outlive the point of purchase. The smallest nuance, if overlooked, can lead to millions worth of product and financial waste, expose the trial sponsor to regulatory penalties, and most vitally, pose real human health risks.

During the last decade, certain trial sponsors have recognized that identifying, procuring, distributing and fulfilling said commodities is a delicate and complex decision tree which demands expertise, attention and, perhaps most importantly, a singular focus. For that reason, numerous sponsor organizations, including large pharmaceutical companies, now have a delineated supply chain function.

Within top sponsor organizations, the effects of systemic change to clinical and ancillary supply chain management have been noteworthy. When a study's supply plan is examined, designed, implemented and optimized throughout the trial in parallel form to the study's protocol, extraordinary efficiency can be realized. One such sponsor—a top five global pharmaceutical company—achieved a 30% cost reduction compared to its traditional *a la carte* and off-the-shelf approach to commodity products, simply by outsourcing the responsibility to a dedicated Clinical and Ancillary Supply Chain Management organization. The success of the program can be credited almost entirely to the sponsor's initial recognition that systemic change was, in the first place, necessary.

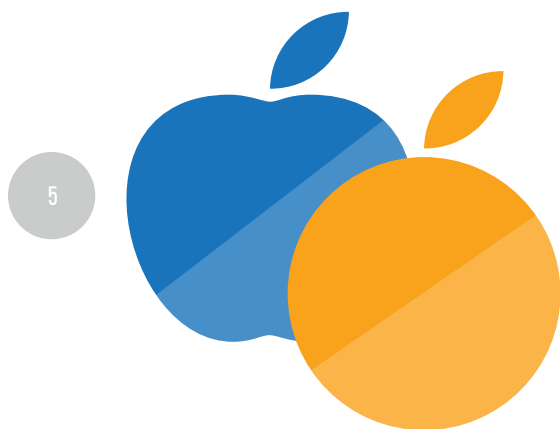
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Clinical and Ancillary Supply Chain Management team tracked over 30% fewer shipments to sites, reducing the burden of incoming receipts on site-level management teams.

A Unique Team Assembly

Optimally, a clearly delineated Clinical and Ancillary Supply Chain Management function will constitute a unique team assembly. Expertise in logistics, warehousing, reclamation, sourcing and procurement, distribution, kitting, labeling, technical support, material returns and disposition, product type and category and Sunshine Act compliance, as well as skillsets such as contract negotiation and relationship management, are necessary to achieve maximum cost reduction and study efficiency. For most sponsors, achieving that sort of team profile is a tall order. However, the benefits are obvious. In one study, a Clinical and Ancillary Supply Chain Management team tracked over 30% fewer shipments to sites, reducing the burden of incoming receipts on site-level management teams.



Apples & Oranges:

Different Commodities, Different Requirements

Each study's protocol is different, and therefore demands unique levels of attention and consideration. To illustrate, imagine a Phase I clinical trial with three study sites. Site A, in Argentina, has just recently been contracted, and requires new refrigeration equipment. Site B, in Brazil, has also only recently been contracted, but has a centrifuge shortage. Meanwhile, a mature study site, Site C, in China, has exceeded its recruitment goals, but now must contend with depreciating large appliance equipment and rapidly depleting medical product inventory.

It's easy to see how different sites in different geographies at different stages in a development program can present a whole host of management challenges, well beyond what a simple click-and-order approach could possibly accommodate. The greater the complexity of the study protocol, the greater the importance of a dedicated function to address said complexities. The ideal candidate to fill such a function should have a network of vetted suppliers, sufficient expertise to assure the quality of equipment against the trial's minimum

requirements, and understand the regulatory environment, all while remaining abreast of current trends with respect to every aspect of the Clinical and Ancillary Supply Chain process, in order to make sound recommendations and find creative solutions to unique problems.

In one such case, a top three global pharmaceutical sponsor was launching an oncology study that required blinded administration of an infusion drug. A dedicated Clinical and Ancillary Supply Chain Management team was charged with identifying an infusion bag cover with a half-dozen specifications. After an exhaustive vetting process, the team determined an off-the-shelf solution did not exist which met every specification. As a solution, the team's product engineers designed, prototyped and delivered a new infusion bag to match the study's protocol requirements. The bags were produced in increments of 100,000 and shipped to depots and to clinical sites throughout the world to accommodate the ongoing needs of the clinical development program.

Current Industry Standard Model is Limited to Execution Stage

PLANNING	EXECUTION	CLOSE-OUT
	Packing	
	Distribution	
	Procurement	

VS.

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Ancillare Process Allows for Global Turn-Key Operations

PLANNING	EXECUTION	CLOSE-OUT
Protocol Analysis <ul style="list-style-type: none"> • Specifications • Therapeutic Area • Countries 	Procurement <ul style="list-style-type: none"> • Expiry Management • Lease vs. Buy • Cost Planning • Supplier 	Reclamation <ul style="list-style-type: none"> • On Site • In Country • Return for Reuse • Auction/Donate
Supply Plan <ul style="list-style-type: none"> • Procurement • Distribution • Resupply • Reclamation & Disposition 	Kitting <ul style="list-style-type: none"> • Initial Site Shipment • Resupply • Expiry 	Disposition <ul style="list-style-type: none"> • On Site • In Country • Sunshine Act compliance
	Distribution <ul style="list-style-type: none"> • Centralized • Regional • Hybrid/Local • Resupply 	Review & Submissions

When delivered in conjunction with the study protocol,

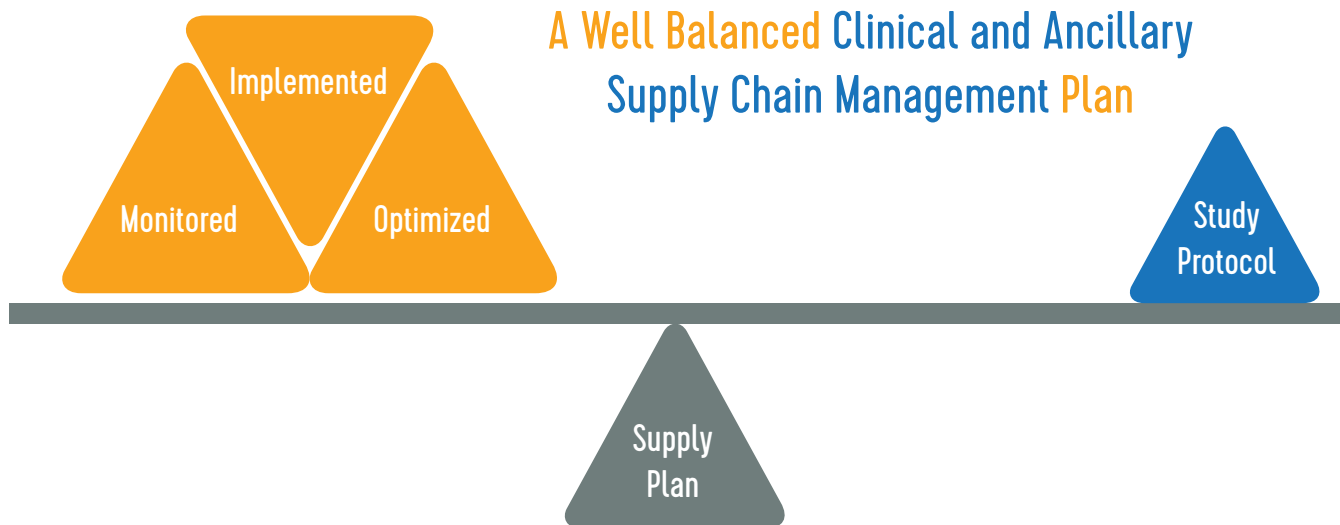
A Supply Plan can be monitored, implemented and optimized throughout the duration of the clinical trial.

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Leveraging Supply Planning to Achieve Study KPIs

History has shown success with respect to any measure of key performance correlates with a well-balanced Clinical and Ancillary Supply Chain Management program. Enrollment as one such example. A Supply Plan should be created in tandem with the protocol design process, and include full and thorough consideration of myriad factors, such as demand analysis and forecasts, logistics plans, usage plans, and final returns and disposition programs.

When delivered in conjunction with the study protocol, a Supply Plan can be monitored, implemented, and optimized throughout the duration of the clinical trial. An end-to-end Supply Plan is flexible, measurable and illuminating. Insights yielded by the Supply Plan often allow sponsors to engage specific countries much earlier than anticipated, ensuring the sponsor can maintain enrollment scheduling.



A Well Balanced Clinical and Ancillary Supply Chain Management Plan

The Supply Plan also serves to manage investigator, participant, and supplier expectations. Many global clinical development programs tend to fall behind due to unpredictable or frequently adjusted milestone dates. A well-forecasted clinical trial is significantly less likely to fall behind. The resulting advantages include higher site staff morale and productivity, higher data integrity, reduced budget waste, and more predictable medical and patient health outcomes.

Global Regulatory Compliance and Reporting Considerations

In the eyes of any regulatory authority, ignorance of the law is not an excuse for lack of compliance. The pattern of deployment of new regulations by the FDA and EMA, state-based and local regulatory bodies, and other international authorities, suggests the rapid-fire pace of new regulations will continue, and should therefore be expected by sponsors.

A fully stocked Clinical and Ancillary Supply Chain Management team will possess the competency to handle documentation for any of the countless regulatory nuances which are indicated by a global clinical trial. The team will possess the knowledge and bandwidth to address and account for import taxes and fee reporting for international shipments, as well as meeting any number of related Sunshine Act requirements.

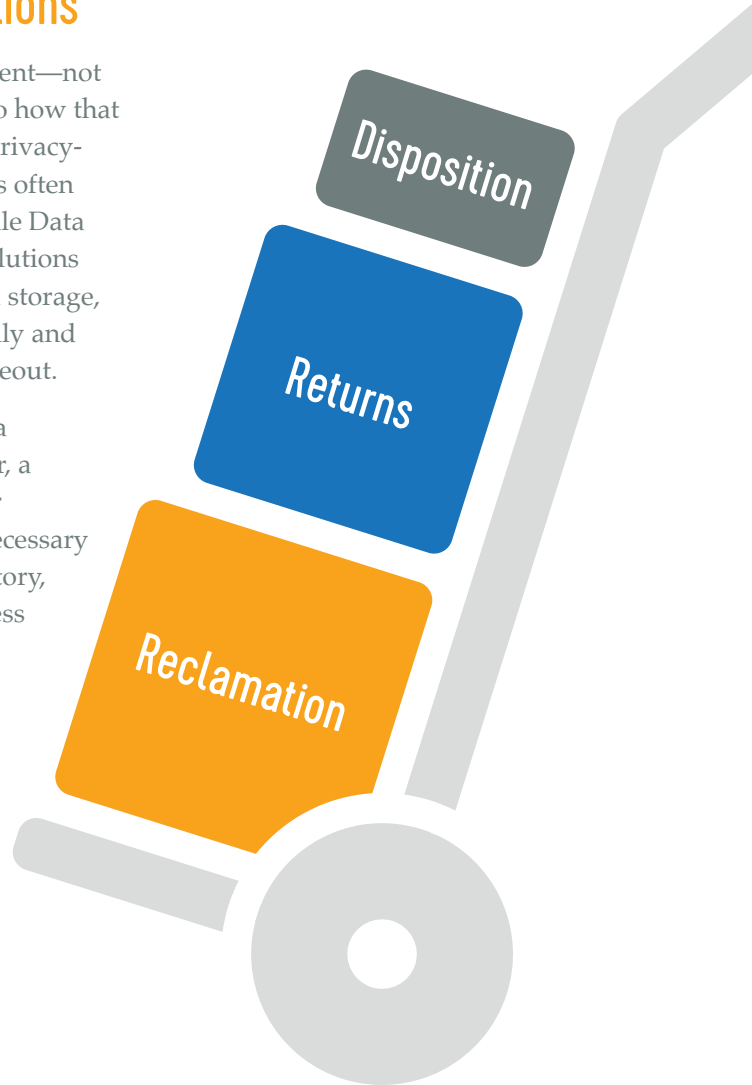
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Patient Privacy and Ethical Considerations

For sponsors, the conclusion of the study is a pivotal moment—not merely due to the implications of final data, but also due to how that data has been collected and stored on a site-by-site level. Privacy-sensitive data and records, such as patient health history, is often stored latently by commodity equipment as it is used. While Data Management teams and cloud-based data management solutions have reduced the prevalence of data redundancy and local storage, it should not be assumed that all equipment is automatically and necessarily compliant during database lock and study closeout.

Commodity returns, disposition and reclamation is, then, a necessary step in service to the patient, and for the sponsor, a requirement to advance to the next phase of its business or research objectives. This process of “reverse logistics” is necessary to coach each clinical site through determining final inventory, and facilitating compliant removal of all remaining or excess clinical and/or ancillary supply. A Clinical and Ancillary Supply Chain Management team will also possess relationships with strategic partners with expertise in “white-glove” removal that will not disrupt site operations.



MARKET CONDITIONS, COMPETITION DEMAND CONTINUED ADAPTION AND INNOVATION

In the realm of new therapy development and outsourced clinical research, there's no shortage of competition.

Technology has in many ways simplified and streamlined clinical research processes. However, it has also lowered barriers to entry. It's easier today than ever for promising compounds and innovative therapies to enter the R&D pipelines of competitors. Increased competition has driven down prices—and, in many cases, profit margins. As a result, R&D leadership has faced increasing pressure to reduce development costs.

A clearly delineated Clinical and Ancillary Supply Chain Management function, when fully deployed across the development program, can address profitability and margin challenges in three key ways. First, it creates efficiency. The function serves to illuminate the latent, or hidden, costs that go unseen via a traditional commodity procurement approach, and leverages bulk-buying power that would not otherwise be achievable. Second, Clinical and Ancillary Supply Chain Management digitizes various logistical data points, creating opportunities to accurately and predictively resupply global sites.

To adequately stock sites to improve time to market without overstocking them and creating waste is no small feat. But a function that's singularly dedicated to the task has been shown to not only meet such requirements, but find replicable methods of doing so. Third, Clinical and Ancillary Supply Chain Management offers flexibility. On-the-fly decisions can be made, and implemented, to ramp up or limit commodity and supply expenditures as rapidly as necessitated by enrollment conditions. A dedicated team is one that is turn-key, and allows medical, scientific, data management, regulatory, and other essential functions to maintain focus on seeking and enabling clinical breakthroughs without the distractions of the supply process.

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CONCLUSION

The complexities of global clinical trials demand a custom approach to—and, therefore, a singular focus on—commodity products. The clinical trial of the future will treat Supply Chain Management as a self-contained function, not unlike the way Clinical Operations, Data Management, Biostatistics, and Pharmacovigilance are universally accepted as separate functional areas today. For sponsors whose global clinical trial teams are accustomed to the more classical commodity sourcing and procurement approach, a systemic evolution will require close examination of the study's Clinical and Ancillary Supply Chain at the earliest possible moment in its next clinical development program. To be thoroughly vetted for its value as a separate functional area, with the potential to realize savings of up to 35% of total study costs, a Supply Plan should be developed, and a dedicated team retained, to manage the process of Clinical and Ancillary Supply Chain throughout the development program's entire lifecycle.

ABOUT ANCILLARE, LP

Ancillare, LP is the first and only organization dedicated exclusively to end-to-end Clinical and Ancillary Supply Chain Management. Headquartered in Horsham, PA, with four master depots and 19 strategic depots positioned globally, Ancillare is the preeminent provider of supply chain management services for leading pharmaceutical and biotechnology companies, as well as medical research and contract research organizations. For more information about Ancillare, visit Ancillare.com.

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