The Drivers of Success in Ancillary Supply Chain Management

With an emerging clinical trial ancillary supply chain, and little research into effective management models, it has never been more urgent for management systems to step up to an increasingly complex trial landscape

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Today's pharmaceutical landscape relies increasingly on outsourcing efforts. Meanwhile, global rules, laws, and regulations continue to evolve at a rapid pace, and pressure to expedite market approvals for new drugs mounts. Due to the intertwined factors, a new, extremely complex global 'ancillary' supply chain has emerged. In this era of change, how does the ancillary supply chain respond to the needs of a rapidly changing industry and create better outcomes for drug discovery organisations and their patients?

The clinical trial ancillary supply chain (CTASC) – a global, extremely complex, highly variable, unregulated, and decentralised system – manages the flow of non-drug materials to sites for clinical investigator and patient use. Pharma organisations have elected to outsource requirements for ancillary supplies distribution (medical devices, laboratory equipment, patient supplies, etc.) to preferred partners that manage the chain via an integrated, end-to-end process. These preferred partners are staffed with medical professionals, as well as quality, regulatory, and supply chain experts, who conduct protocol and patient dosing schedule analyses, determine product selection based on trial specifications and country of use, review in-country regulatory and equipment licensure requirements, and source and procure supplies to arrive on site prior to first patient first visit (FPFV). A detailed supply plan is presented to the sponsor organisation prior to study kick-off, providing the roadmap by which the CTASC organisation will manage the flow of goods throughout the trial. In addition to the information noted above, the supply plan depicts the processes by which the CTASC will provide support for ongoing import and export regulatory analyses and control, inventory and depot management, estimated timelines for shipments on demand or in advance of patient arrivals, and reclamation and disposition processes for all supplies remaining at each site as the clinical trial closes. To achieve these goals in this highly complex market, CTASC organisations must utilise innovative technology, predictive analytics, and data mining to forecast demands, improve internal and external operations and deliverables, and drive value across the chain and throughout the course of the clinical trial.

Achieving successful outcomes for these highly complex global trials is heavily dependent on the clinical trial drug and ancillary supply chains, and a significant portion of this increased spend (approximately 40% of the total) is a direct result of costs associated with the clinical trial supply chain (1-3). It is important to note that effective and efficient supply chain management are key elements that yield overall successful clinical trial results and outcomes.

Many factors come into play that influence the ancillary supply chain at the 'pre' (trial kick-off and initial supply), 'in' (resupply), and 'post' (material reclamation and disposition activities and reporting) phases. A few of these factors are as follows:

1. CTASC ships medical devices and lab equipment to global clinical trials. Trial clinicians gather, record, and submit patient data to authorities (trial monitors and regulatory agencies). It is necessary

to provide standardised medical devices and lab equipment across all global sites to ensure consistency and reliability of the retrieved data.

2. Medical devices and lab equipment requiring factory calibration and up-to-date certificates are maintained at sites and presented to authorities as proof of compliance. The CTASC manages and is accountable for this process across the globe. Out-of-date or improperly calibrated devices will result in rejection of data by authorities while there exists the potential to pose extreme risks. These include cost escalations and trial delays to pharma organisations, as well as concerns for patient safety during treatments.
3. In-country import regulations for medical supplies change in many countries frequently and without notice. If shipments are in transit during a change in regulations, the products will be returned to the CTASC organisation and sites will go without the required supplies to conduct the trial.

It becomes apparent that standardised products, quality assurance and regulatory compliance, product expiry/calibration requirements, and on-hand evidentiary documentation issues have the potential to challenge the provider and, in worst-case scenarios, cause trial derailment with huge financial ramifications to the drug discovery organisation. As a result, it becomes imperative that all clinical trial materials and evidence of their handling are properly prepared with strict adherence to regulatory requirements prior to distribution (4). The clinical trial supply chain entails much specificity compared to the standard supply chain as disruptions and stoppages may arise when viable solutions fail to provide the needed specificity. Aspects of expiration dating, bulk product availability, and specific country labelling requirements are elements for careful analysis when developing and initiating the clinical trial supply chain (3-4). The internationalisation of business, diversity, and complexity of new drugs and the diminishing protection provided by patents are some of the factors driving change (5). It is important to provide an overview of characteristics of planning processes utilised by pharma organisations for drug supply and CTASC organisations to best facilitate the reader's understanding. **Table 1 (page 58)** depicts some of the similarities and differences between a drug supply chain and the CTASC.


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The CTASC organisation faces a multitude of challenges that influence performance outcomes such as shortened lead times, little or no visibility of the project during the pre-planning/pre-protocol launch phase, uncertainty in product licensure, and in-country regulatory changes, etc. Simply stated, the 'perfect storm' brews as the threat of the CTASC abilities to meet demands of the clinical trial grows with each passing day. So, the question remains: how may CTASC experts mitigate risks and overcome the threat of field service disruptions and failures?

Many researchers suggest that supply chain preparedness and success are achieved by developing strategic operational and inventory models. One common strategy is the utilisation of process simulations that include regulatory and import/export preparedness, current and historical field data analysis, and looking ahead to anticipate adverse events. The ability of supply chain experts to develop adaptive designs and appropriate processes and procedures may fundamentally contribute to the success of clinical supply chain execution (4, 6-7).

Modern business visionary Peter Drucker coined the phrase, "innovate or die" (8). While there have been countless examples of paradigm shifts in the market across all industries that demonstrate Drucker's philosophy (e.g., Woolworths, Polaroid, Alta Vista, Kodak, Blockbuster, Borders), if we heed Drucker's edict, and as a participant in this emerging and ever-evolving ancillary supply chain, our next question becomes: how do we innovate? How do we achieve this considering that supply-based clinical chains operate in an enviroment of

constant flux? The answers to these questions are far from simple. While a vast quantity of research on clinical trial drug supply exists in scholarly and practitioner literature focusing on a plethora of topics, including supply chain optimisation, continuous improvement, best practices, transactional cost analysis, capacity planning, risk mitigation, etc. (9-14), limited research exists on the topic of the CTASC management. In fact, many pharma organisations believe that a just-in-time, 'one size fits all' supply chain model would best serve the market. With this emergent supply chain projected to grow year over year, this simplified model would not only pose risk to the clinical trial itself, but also to the patients it serves. An increase in scholarly and practitioner research efforts are essential to ensure an understanding of the supply chain, build theory,

Characteristics of the supply chain	Drug supply chain	CTASC
Products are critical to the end point of the trial. Observations and data collected originating from these products are reported to authorities throughout the course of the trial and the during drug approval stage	Yes	Yes/no Data collected from some equipment (centrifuges) and supplies (pregnancy test) are critical to end-point results and are reported to authorities
Proactive, organised approaches exist to determine demand, supply chain optimisation, production planning, capacity, utilisation plans, infrastructure support, and investment in order to mitigate risk	Yes 12-24 months prior to trial launch	No 1-6 weeks prior to site initiation visit and FPFV
Pharma leadership teams are intimately involved in the planning and process stages	Yes Led by medical and clinical operations teams	No Led by operational teams such as global trial management (GTM)
In-country approvals are conducted by the Ministries of Health (MOH) for clinical products. This includes in-country drug registrations, gathering of certificates/documents and import clearances well in advance of shipment release	Yes MOH approves comparator and study drugs. These drugs appear on all import documents	No Ancillary supplies are not included on MOH approvals. Import of record documents are prepared by the CTASC at time of request. There is the imminent risk of delays and refusals during shipment
Supply chain lead times are clearly delineated to GTM, CRA, and global clinical sites so that receipt and inspection at clinical sites is brisk	Yes Sites receive advance delivery schedules and are prepared to receive and inspect all deliveries	No GTM requests supplies at site 2-8 days prior to when supplies are required. CTASC coordinates and manages all aspects of the delivery
Product manufacturers are identified and negotiated procurements contracts are signed	Yes	No Late-stage factory negotiations and procurement initiatives take place
Supply forecasts and shipping schedules are shared with factories and supply chain	Yes	No High risk of product shortages
All supplies are approved for use in all countries where clinical trial occurs	Yes Products are listed on MOH approval documents in all countries	No Many products are not pre-approved for use in all countries. There is a high risk of procurement and shipping delays
In-country regulations remain consistent throughout the course of the trial	Yes Once MOH approval is granted, shipments flow without interruptions	No Product regulations change without notice, posing risk to supply chain and delivery timelines

Table 1: Similarities and differences between a drug supply chain and CTASC

and identify new topics of study. As new research is released, practitioners in CTASC organisations can build more efficient models, better serve their pharma customers, grow their businesses, increase competitive advantage, and deliver value to the pharma organisations and, most importantly, to the patients they serve.

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Dr Joanne Santomauro, CEO and Founder of **Ancillare,** LP, created the clinical and ancillary supply chain management industry in 2006. Prior to the company's launch, pharma, biotechnology, contract, and medical research organisations had little transparency to the overall supply chain and had a limited grasp of the associated costs, processes, and regulatory and compliance requirements of this diverse global supply chain. Joanne's 35 years of supply chain expertise led the company to launch its market-leading model.

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