Clinical Supply Distribution Strategy:
Planning for Flexibility in a Changing Trial Landscape

The clinical trial ecosystem is undergoing a structural shift. What was once a relatively linear, site-centric model has evolved into a complex, globally distributed and increasingly patient-driven environment. In this new reality, clinical supply distribution is no longer a downstream operational consideration, it is a strategic enabler of trial success.

Emerging as the defining characteristic of effective supply strategies is flexibility. Often misunderstood as a reactive capability, flexibility should be a deliberately engineered feature of supply chain management, with the most resilient supply chains designed from the outset to accommodate uncertainty, absorb disruption and adapt in real time.

The objective is not simply to have more inventory or more distribution points, it is to create options: options around where inventory is held, how quickly it can be deployed, where it can ultimately be used and how the network can respond when clinical circumstances change.

From Predictability to Variability

Traditional clinical supply models were built on a foundation of assumed predictability. Enrolment curves, site activation timelines and geographic footprints were expected to follow predefined patterns. While deviations occurred, they were typically manageable within fixed distribution frameworks.

Today, variability is the norm. Adaptive trial designs introduce protocol changes mid-study which shift enrolment patterns and associated demand across regions. Decentralised models expand the points of delivery beyond clinical sites to include patients' homes and local care settings. This has fundamentally altered the role of distribution strategy as it must now account not only for what is known, but for what is likely to change.

For supply chain leaders, this means challenging assumptions earlier. Where will demand arise? How quickly could it move? Which inventory should be committed to a particular country and which should remain flexible? Where should stock be positioned to provide the greatest resilience without creating unnecessary inventory or cost?

Flexibility as a Design Principle

Flexibility in clinical supply is built through intentional design, moving away from static planning toward dynamic, scenario-based approaches. At its core, a flexible supply chain strategy integrates three capabilities:

- **Responsiveness:** the ability to adjust supply flows quickly in response to real-time data.
- **Resilience:** the capacity to maintain continuity despite disruptions.
- **Optionality:** the presence of viable alternative pathways for distribution, sourcing and fulfilment.

Consider a multi-regional trial where enrolment accelerates unexpectedly in Asia while slowing in North America. A rigid supply model may struggle to rebalance inventory without delays or waste. A flexible model managed by an experienced supply chain leader, by contrast, anticipates such divergence and enables rapid reallocation



through regional stock pools, adaptable depot configurations and responsive resupply triggers.

Rethinking Network Design

Distribution network design is central to enabling flexibility. Historically, centralised depot models were favoured for their simplicity and cost efficiency. However, as trials become more global and time-sensitive, centralised approaches can introduce latency and risk.

Decentralised or hybrid depot networks offer greater agility, allowing inventory to be positioned closer to demand, reducing lead times and enabling faster response to enrolment shifts. However, increased network complexity requires more sophisticated coordination, visibility and governance.

An optimal distribution model is rarely fixed. It should be adaptable and capable of evolving as the trial progresses or conditions change. This means considering not just where inventory is distributed, but where it is strategically held before the final destination is known. A regional hub can act as a buffer between global manufacturing and individual markets, allowing inventory to be deployed as demand becomes clearer rather than prematurely committing stock to a specific country.

The Role of Data and Visibility

Data are at the heart of a flexible supply chain. Without timely and accurate visibility into inventory levels, site consumption and shipment status, even the most well-designed strategies can falter.

Advanced analytics are increasingly being used to move beyond reactive monitoring toward predictive insight. By identifying patterns in enrolment, dosing and resupply, supply teams can anticipate imbalances before they materialise. For example, predictive models can flag potential stockouts weeks in advance, enabling proactive redistribution or expedited shipments. This shift from hindsight to foresight is critical in an environment where delays can directly impact patient outcomes.

However, visibility needs to extend beyond physical inventory. Supply teams also need visibility of the regulatory, financial and logistical status of that inventory. Understanding whether stock can be rapidly redirected, exported, or released into a particular market can be just as important as knowing how many units are physically available.

Late-Stage Customisation and Inventory Efficiency

One of the most effective levers for flexibility lies in postponement strategies, particularly in packaging and labelling. By deferring country-specific or trial-specific customisations until closer to the point of distribution, organisations can maintain a more flexible inventory pool and reduce the risk of obsolescence resulting from protocol amendments or regulatory changes. It also enables more efficient use of manufactured product, which is particularly important for high-value or rare disease therapies.

For example, rather than producing fully country-specific inventory at the outset a sponsor may maintain a pool of partially kitted inventory then complete the packaging, apply country-specific labelling or add variable text closer to distribution. This can reduce the amount of stock tied to a particular market and provide greater flexibility if enrolment or country participation changes.

However, postponement requires alignment across manufacturing, packaging and regulatory functions, as well as investment in capabilities that support rapid turnaround.

Direct-to-Patient and the Expansion of Distribution Models

The rise of decentralised and hybrid trials has expanded the scope of distribution beyond traditional site delivery. Direct-to-patient (DTP) models are becoming an integral component of modern trial design, offering improved convenience and accessibility for participants.

While DTP introduces clear benefits, it also challenges conventional supply frameworks. Temperature control, chain of custody, patient scheduling and regulatory compliance must all be managed with greater precision.

From a strategic perspective, DTP underscores the need for distribution models that are both flexible and patient-centric. Supply chains must now accommodate individualised delivery pathways while maintaining consistency, quality and compliance.

The growth of DTP also reinforces the importance of strategically located inventory. When supply needs to reach individual patients rather than simply a defined network of clinical sites, the ability to reposition stock quickly can become a significant determinant of service levels.

Managing Global Complexity

Global clinical trials increase regulatory, logistical and financial complexity. Country-specific import requirements, lead times and distribution constraints should be considered from the outset with contingencies built in for regulatory changes and delays.

Integrating a customs strategy with supply chain, regulatory and trade compliance planning can be beneficial with the utilisation of Customs Warehouses and Foreign Trade Zones (FTZs) providing an additional layer of flexibility. Beyond deferring customs costs and supporting working-capital management, they can help sponsors maintain inventory optionality and avoid prematurely committing stock to a specific market.

In the UK and EU, eligible imported goods can be held in a Customs Warehouse under customs control, with applicable duty and import VAT suspended until release into free circulation. In the US, FTZs similarly allow eligible goods to be held under customs control, with duties generally deferred until foreign merchandise enters the domestic market and eligible exports potentially leaving without US duty.

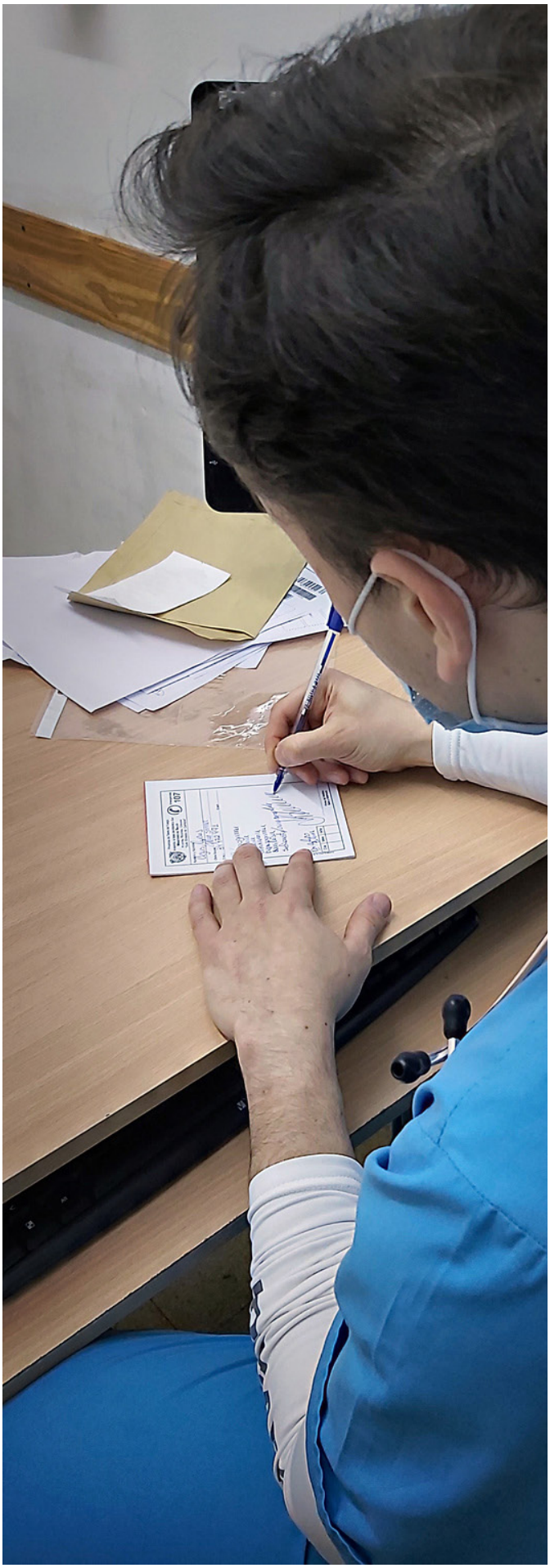
For clinical trials, this is particularly valuable when demand, regulatory approvals or country participation remain uncertain. Instead of committing inventory immediately to individual markets, sponsors can position stock at a strategic regional hub and determine its final destination as the trial evolves.

Risk as a Constant, Not an Exception

Risk is often treated as an external factor to be mitigated but in reality it is an inherent aspect of clinical supply. Transportation disruptions, geopolitical events, tariffs, regulatory changes and environmental factors are not anomalies, they are ongoing variables that must be managed continuously.

A flexible distribution strategy embeds risk management into its design. This includes:

- Diversified transportation routes and carriers.
- Strategic safety stock aligned with risk profiles.
- Predefined contingency plans that can be activated without delay.
- Alternative depot and distribution pathways.



- Appropriate customs and trade strategies that preserve inventory optionality.

Critically, these plans must be operationalised, not just documented. Simulation exercises and scenario testing can help ensure that teams are prepared to respond effectively under pressure.

Cross-Functional Integration

Early cross-functional engagement is essential for a successful supply strategy. Decisions made during protocol development such as visit schedules, dosing regimens and site locations have direct implications for distribution. Integrating supply expertise at this stage can prevent downstream challenges and enable more efficient trial execution.

The same principle applies to customs and trade strategy. Decisions about manufacturing location, packaging configuration, inventory ownership and regional distribution can have significant implications for duties, taxes, import requirements and the ability to redirect inventory.

Bringing these disciplines together early allows sponsors to design the supply chain around the clinical programme rather than attempting to retrofit flexibility after the network has already been established. Equally important is ongoing alignment. As trials evolve, continuous communication across functions ensures that supply strategies remain synchronised with operational realities.

Looking Forward: Designing for the Unknown

Clinical research is becoming more complex, personalised and decentralised, placing greater demands on clinical supply chains. In this environment, flexibility is no longer an advantage, it is a strategic requirement.

The most resilient supply strategies are built around options, not fixed pathways. Data-driven forecasting, regional inventory networks, postponement and strategic use of Customs Warehouses and Foreign Trade Zones can help sponsors anticipate change, protect inventory and respond quickly as trial requirements evolve.

The supply chains best positioned for the future will combine strategic foresight, real-time visibility and operational agility creating the flexibility to move, hold, redirect and deploy inventory as clinical programmes evolve.

Ultimately, clinical supply distribution is about more than moving product. It is about ensuring the right investigational therapy reaches the right patient, at the right time, wherever they are.

Edward Groleau



Ed Groleau has over 30 years of experience in pharmaceutical drug development on both the pharma and vendor sides. The first half of his career was spent in various laboratories from analytical method development to solid state characterisation and polymorph screening, to stress degradation and chemical characterisation. He left the labs and moved into clinical supplies in 2003 providing all aspects of CSM support to maintain clinical programmes. He joined PCI in 2018 and became Sr. Director of PCI's Supply Management And Readiness Team (SMART).