The Hidden Cost of Siloed Clinical Supply Chain Systems

The need for speed in clinical trials is becoming a strategic imperative for sponsors, with looming patent cliffs, rising R&D investment, increasing innovation competition and patient demand forcing a rethink on how quickly trials can be delivered.

While being first to introduce new innovations to market offers a clear advantage, as trial designs evolve and drug compounds advance, crossing the finish line ahead of the competition is becoming more difficult. It is also dependent on a range of factors, a key one being the efficiency and effectiveness of the clinical supply chain tasked with ensuring the right patients receive the right drugs at the right time and in the right condition.

In today's market, sponsors are turning to technology to optimise processes and mitigate risk, and the clinical supply chain is no exception. Supply chain systems underpin modern clinical trials, helping sponsors assure timely supply to sites and patients. Yet when they operate in silos, when data held in one digital supply chain system isn't reflected in another or representative of the physical supply chain, cracks appear that compromise visibility and control. This restricts the ability to make fast and informed decisions to limit waste, keep timelines on track, and patient access open.

Sponsors can no longer afford to operate with fragmented supply chain systems. Prioritising connected, automated and intelligent technology is what will fuel the next chapter of drug development.

The Pitfalls of Siloed Systems

The only consistent thing about operating clinical trials is inconsistency. Maintaining control and protecting patients when unexpected challenges arise demands a proactive approach and that requires complete, accessible and real-time data.

From a study execution standpoint, complexity often emerges without warning. A trial may be progressing smoothly when suddenly, priorities shift and a multi-country expansion is announced. That single decision triggers an array of implications. Is there sufficient supply for these new regions? What are the country-specific labelling requirements? Which regulatory and logistics-based considerations must now be addressed?

Similarly, in manufacturing, scenarios can unfold upstream that delay an API batch needed for future resupplies, leaving sponsor teams needing to quickly determine how to optimise the existing inventory to meet current and projected demand. This requires simultaneously accessing multiple sources of information, actual patient data in the IRT, current and planned manufacturing schedules for primary and secondary packaging and labelling, and distribution requirements across regions. Every piece of data is critical to making informed allocation decisions. The challenge is that the solution to these issues doesn't exist within a single system.

Typically, sponsors rely on several core systems to manage the lifecycle of clinical supplies. Forecasting and simulation tools inform and optimise production campaigns. ERP systems support manufacturing operations and aspects of drug release, shipments and inventory management. IRTs manage patient randomisation and trial supply processes, like drug ordering assignment. Temperature management solutions help identify and avoid excursions. Multiple systems, each with some unique and some shared data and each with an important role to play during multiple stages of the clinical supply lifecycle.

Navigating this fragmented landscape is inherently difficult. When data resides in siloed systems, often managed by separate vendors, it creates blind spots and makes assessing impact and making proactive, informed decisions cumbersome and time-consuming.

The consequences are tangible and immediate, with misaligned data between systems capable of causing excess inventory to accumulate at depots, sitting idle and tying up resources or overloading sites, creating storage and administrative burdens. Even more critically, shortages can occur, jeopardising the ability to randomise patients or, in worst-case scenarios, to continue treating existing patients.

This fragmentation of data directly constrains the ability to act proactively. Decisions that could prevent disruptions or optimise supply are delayed, not because of a lack of expertise or effort, but simply because gathering and consolidating the necessary information takes too long. This is why, in an environment defined by unpredictability and the need for speed, the ability to access integrated, real-time data is what separates reactive crisis management from strategic, proactive clinical supply chain leadership.

The Argument for Integration

From a clinical supply perspective, planning begins with alignment. Teams start by interpreting the clinical protocol, understanding study requirements, patient pathways and dosing schedules, and mapping these against the realities of drug supply, including manufacturing constraints and presentation limitations. This forms the baseline and an initial supply strategy designed to meet the anticipated needs of the study.

However, no study unfolds exactly as planned. As recruitment progresses, the reality begins to diverge from the forecast. Patient enrolment rates shift, country mix evolves and dosing patterns change. Clinical supply teams must continuously reconcile these dynamics against the original plan, assessing

how real-world activity is trending and what that means for supply continuity.

This is where connected data becomes critical. When patient dosing, resupply activity and enrolment trends are integrated directly with forecasting and supply planning, teams gain access to real-time, actionable insights. Forecasts are no longer static; they are continuously informed by what is actually happening. This enables faster, more confident decision-making and creates the conditions for proactive supply management, reducing waste and improving study outcomes.

Connecting systems across the clinical supply lifecycle creates an end-to-end, real-time data environment where all functions operate from the same accurate, up-to-date information, reducing manual effort, improving data integrity and lowering overall risk.

To contextualise this, we can look to a familiar challenge many sponsors face: visibility into actual site-level drug usage, something that, without integration, can undermine forecasting efforts and require manual reconciliation. However, with integrated systems, forecasts can be continuously updated using real-time consumption data. Integration also transforms the ordering and release process. In disconnected environments, manual data entry into IRT systems introduces errors that can delay shipments, disrupt recruitment and result in misallocated or wasted product. By integrating ERP and IRT systems, a closed-loop process is established, from order trigger through to fulfilment, reducing order failures and improving speed. Processes that once took days can be executed in hours, with automation ensuring greater accuracy and a 'right first time' approach.

With integration, sponsors also spend less time resolving discrepancies and more time acting on insights, accelerating material release and reducing operational friction. Connected systems strengthen compliance and patient safety too. For example, linking temperature monitoring directly to supply systems ensures that any material affected by excursions is automatically quarantined, preventing patient assignment and simplifying audit readiness. In an environment where delays and disruptions are inevitable, system integration is what enables clinical supply teams to move from reactive management to proactive control.

Implementing Change

Beyond operational efficiency, the shift toward integrated clinical supply chains is being driven by broader strategic imperatives, most notably speed to market and the rise of advanced analytics and AI across drug development. For sponsors, accelerating timelines has direct financial and patient impact. Industry analyses consistently show that even modest reductions in development timelines can translate into significant revenue gains and earlier patient access to therapies.[1] In this context, the ability to make fast, informed decisions, enabled by accessible, connected data, becomes a critical differentiator.

At the same time, the industry is rapidly embracing AI and advanced analytics to optimise clinical trial design, execution and supply planning. These technologies promise faster insights, improved forecasting accuracy and greater automation across the supply chain. However, their effectiveness is dependent on data quality and completeness. AI models are only as powerful as the data they can access. Fragmented systems limit visibility, constrain analysis and ultimately diminish the value these technologies can deliver. As such, integration is quickly becoming a foundational requirement for sponsors seeking to capitalise on AI and data-driven decision-making.

Despite this, many sponsors face practical barriers to integration. Clinical trials are inherently complex, often involving multiple vendors, each operating their own systems and data structures. Integration can introduce additional cost (financial and in terms of time to set up) and is sometimes perceived as too late to implement once a study is underway. Vendor dependencies, particularly in areas such as IRT, can further complicate efforts, with integration requiring negotiation, alignment and investment across multiple stakeholder groups. Resultingly, integration is often deprioritised in favour of meeting immediate study milestones, reinforcing the very fragmentation that limits long-term efficiency, agility and speed.

Overcoming these barriers requires a more intentional and strategic approach. First, data integrity must be treated as a foundational pillar. Establishing a single source of truth, or as close to one as possible, reduces the risk of discrepancies across systems and ensures that all stakeholders are working from consistent, reliable data. Without this, even minor misalignments can have significant downstream impacts, from failed randomisations to incorrect supply allocation.

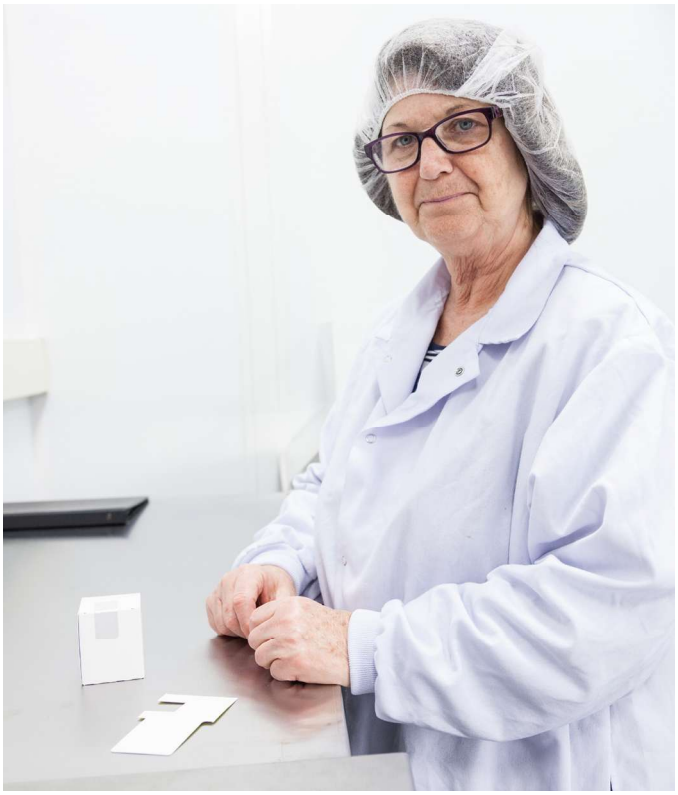
Second, interoperability must be designed into the ecosystem. Rather than relying on manual data transfers or isolated platforms, systems should be able to communicate seamlessly, enabling near real-time synchronisation of critical data points. This connectivity is what enables the closed-loop, insight-driven supply chain required for proactive decision-making.

Finally, change management can't be ignored. Integration isn't just a technical exercise; it requires cross-functional alignment, early planning and prioritisation at the organisational level. Sponsors that consider integration early in study design are better positioned to avoid costly retrofitting and can ensure clinical supply is embedded as a core component of the broader data strategy. Without this alignment, even well-designed systems can fail to deliver their full value.

Getting Drugs to Market: Changing Patients' Lives

Clinical trial success increasingly depends on speed, but expediting trial timelines is made harder by growing complexity and fragmented clinical supply chain systems. When critical data is spread across disconnected platforms, visibility is compromised, decision making is delayed and risk increases.

Getting drugs to market faster, so patients have access to breakthrough therapies, is made easier by integrating supply chain systems. With a unified, real-time view of data, sponsors



can embrace proactive planning, faster and more accurate decision-making, and improved operational efficiency.

As pressure to accelerate drug development intensifies and as AI and advanced analytics become more central, connected systems are no longer optional. They're essential for maintaining competitiveness and ensuring reliable patient access.

REFERENCES

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