

Industry Leadership Insights: Four Essential Steps to Accelerate Clinical-Phase Commercialization Through End-to-End Supply Chain Digitalization

Bringing a new therapy to market is a complex, high-stakes journey—and for clinical-stage pharmaceutical companies, digitalizing the supply chain might not seem like an immediate concern. But laying the right digital foundations early can pay dividends later, enabling end-to-end visibility, instantaneous data access, and stronger partner collaboration. These capabilities help optimize inventory, prevent stockouts, improve forecasting accuracy, and ultimately support faster, more confident decision-making as companies prepare for commercialization.

In a recent episode of the **Orchestrating Outcomes podcast**, Colby Wolfe, former Executive Director and Head of Global Supply Chain at Dyne Therapeutics, a clinical-stage organization, points out that taking steps toward supply chain digitalization can help clinical-stage companies address significant challenges—now and in the future. These challenges include:

- **Disconnected systems, spreadsheets, and email chains** that make it difficult to achieve real-time visibility, intelligent orchestration, and operational excellence.

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- **Fragmented data and non-automated workflows** that hinder efficient production scheduling and increase the risk of delays.
- **Lack of coordination across the supply chain** that slows down the delivery of critical therapies to patients.
- **Future compliance gaps around serialization and traceability** that have the potential to delay product movement and jeopardize on-time, in-full (OTIF) delivery.
- **Product launch delays** that result in lost revenue—potentially thousands or even millions per day.

Wolfe went on to outline four key steps clinical-stage organizations should take to establish a strong foundation for digital transformation before commercialization, setting the stage for long-term success:

1. Establish Visibility Early On

For clinical-stage companies, ensuring visibility by creating integrations with supply chain partners' systems often takes a backseat to R&D and clinical priorities. However, Wolfe emphasizes that delaying investments in digital supply chain digitalizing for too long can lead to significant challenges.

By planning for and beginning supply chain digitalization early, at a foundational level, companies can begin to avoid the pitfalls of fragmented data, overreliance on email chains and spreadsheets, and outdated processes that become increasingly difficult to scale.

> It's far easier to be able to digitalize something from the start, he explained. When you're a behemoth, it's much harder to be able to get everybody on board.

2. Bring CDMOs into Your Digital Strategy

Clinical-stage companies rely heavily on contract development and manufacturing

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organizations (CDMOs) to produce their drug candidates. But aligning on technology-driven processes can be a challenge, especially when CDMOs are managing multiple customers with different workflows and priorities.

The most effective way to gain CDMO buy-in is to show how supply chain transformation directly supports their goals—by streamlining operations, reducing manual work, and improving visibility. For example, by improving the exchange of critical supply and demand information—such as sharing forecasts or providing immediate order status—clinical-stage organizations can help CDMOs stay aligned with production needs, respond more quickly to changes, and reduce the risk of disruptions.

> I think it needs to be a win-win, where you're able to propose something to a CDMO that helps them improve their business, Wolfe said. What you don't want to do is have a win-lose relationship where I'm getting all this information, but you're not getting anything.

3. Build Toward a Scalable ERP Solution

Many clinical-stage companies operate without a formal ERP system in their early phases, relying instead on spreadsheets and emails. However, as they move closer to commercialization, complexity increases due to demand uncertainty, stricter regulatory requirements, expanding supplier networks, and the need for serialization and traceability. This makes manual approaches unsustainable, prompting many organizations to adopt a phased approach, starting with lighter solutions.

> Most of those things in between are what I call 'mom and pop' shops, Wolfe said. It's not a clean, sleek type of solution, but it helps you get there. And that's part of the journey.

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While a strong planning system doesn't automatically enable visibility across external partners, it is a critical first step toward supply chain technology modernization. Clinical organizations that focus on building a solid supply chain and master data foundation can streamline internal operations, reduce reliance on spreadsheets and emails, and prepare for both the integration needed to connect with external stakeholders and compliance requirements.

ERP systems are well-suited for internal enterprise operations and execution, but they are not purpose-built for multienterprise information sharing. For that, digital business networks that seamlessly and cost-effectively integrate the data of internal systems and with those of external supply chain trading partners are required.

> Building towards a sustainable ecosystem means identifying the right and scalable ERP solution and planning tools along with accurate master data setup, said Orchestrating Outcomes host Sarang Deshpande, Senior Solutions Consultant at TraceLink. These are critical must-haves for a successful digital strategy that not only allows clean financial tracking, but also streamlines supply chain processes to manage increasing complexity as the product/company moves towards the commercialization stage.

4. Evolve Your Technology-Enabled Supply Chain as You Grow

A clinical-stage company's digital journey should be an ongoing process. Rather than aiming for an all-in-one solution, Wolfe explained that organizations should take an incremental approach, adding capabilities as supply chain complexity increases and needs evolve. This ensures that investments remain aligned with business needs.

For example, tools like Excel are a popular choice for supply chain planning, but

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relying on it too heavily can lead to a lack of end-to-end supply chain visibility as an organization grows. By leveraging shared planning tools and the real-time exchange of forecasts, for example, clinical organizations can enhance collaboration with CDMOs, improve decision-making, and boost operational efficiency both before and after commercialization.

> You've got to time your transition from Excel to a fit-for-purpose ERP system as your company and product(s) move through various stages of clinical trials, ultimately getting commercialized, Deshpande explained. Digital process optimization can then complement this transition to ensure end-to-end visibility, and more importantly, help the organization respond to volume changes and market changes in a proactive manner.

Laying the Foundation for Long-Term Success

For clinical-phase organizations, taking steps towards supply chain modernization can ensure a smoother path to commercialization and beyond. The visibility and collaboration that digitalization enables help companies improve alignment with CDMOs and avoid supply disruptions, delays, and inefficiencies that can derail critical milestones.

TraceLink Multienterprise Information Network Tower (MINT) empowers life sciences companies and their supply chain partners to modernize supply chain collaboration and enable digital business transaction exchange. With MINT, organizations can:

- **Reduce stockouts and supply disruptions** by gaining continuous visibility into production and inventory.
- **Optimize working capital** by aligning supply with actual demand and reducing excess inventory.
- **Increase operational efficiency** by automating the exchanges of POs, PO acknowledgements, advance ship notices (ASNs), and much more, eliminating

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spreadsheet and email-driven processes.

A strong digital foundation ensures clinical-phase organizations can scale efficiently and avoid costly setbacks. **Contact TraceLink** today to learn more about MINT today.

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