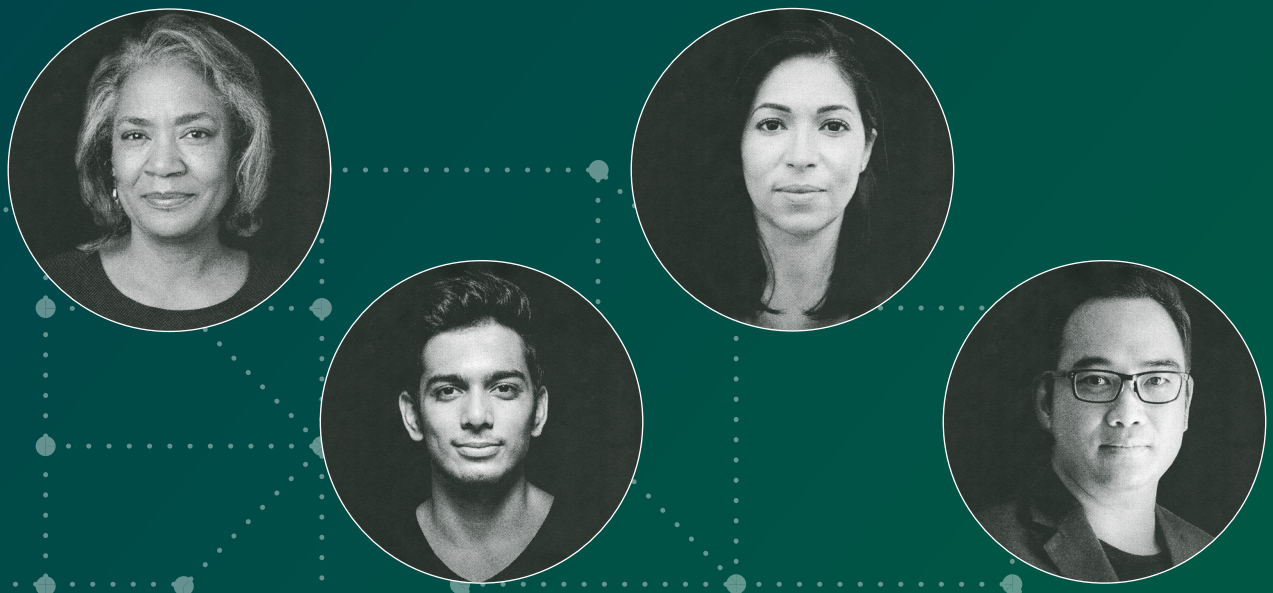
DIGITAL TRANSFORMATION OF THE SUPPLY CHAIN

How Data-Driven, End-to-End Orchestration Will Enable Faster Recalls, Fewer Drug Shortages, and Better Patient Outcomes



INDUSTRY SNAPSHOT | FUTURELINK NASHVILLE

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NETWORK FOR GREATER GOOD

Introduction

> "The pharmaceutical industry is the most important industry. This is our higher calling, and we all need to break down the barriers in order for us to really work for the greater good."
>
> **– Shabbir Dahod**, President and CEO, TraceLink

The global pharmaceutical supply chain is undergoing a dramatic transformation that will lead to significant improvements in operational efficiency and patient care, according to industry insights and polling data collected from **more than 240 attendees** at FutureLink Nashville.

The proliferation of product serialization and track and trace regulations around the globe is converging with the rise of increasingly specialized medicines, evolving distribution models, and the growing need for precise, patient-centric supply chain orchestration. Combine those factors with the ever-present need to control costs, eliminate waste, and meet demand, and it's clear this is a challenging time for the pharmaceutical industry—but it is also ripe with opportunity.

While serialization at a global scale introduces new complexities, it is also the catalyst for an industry-wide digital transformation that will help companies solve legacy problems and reimagine the future of the supply chain.

Most companies today lack real-time visibility and control over what happens to products after they leave the organization's four walls or the purview of direct trade partners. But serialization can create a new, data-driven digital capability for the pharmaceutical industry—a way to track serialized inventory with unprecedented speed, scale, and accuracy to solve legacy challenges in a fraction of the time it takes today. Managed properly, this will result in improved drug safety, faster and more efficient recalls, fewer drug shortages, and most importantly, better patient care and access to critical medicines.

To realize the business benefits of digital transformation, organizations require an enabling technology—a powerful digital network platform—that eliminates barriers to integration with trading partners, provides the foundation for end-to-end supply chain visibility, and empowers companies to improve care by orchestrating the supply chain around the needs of patients.

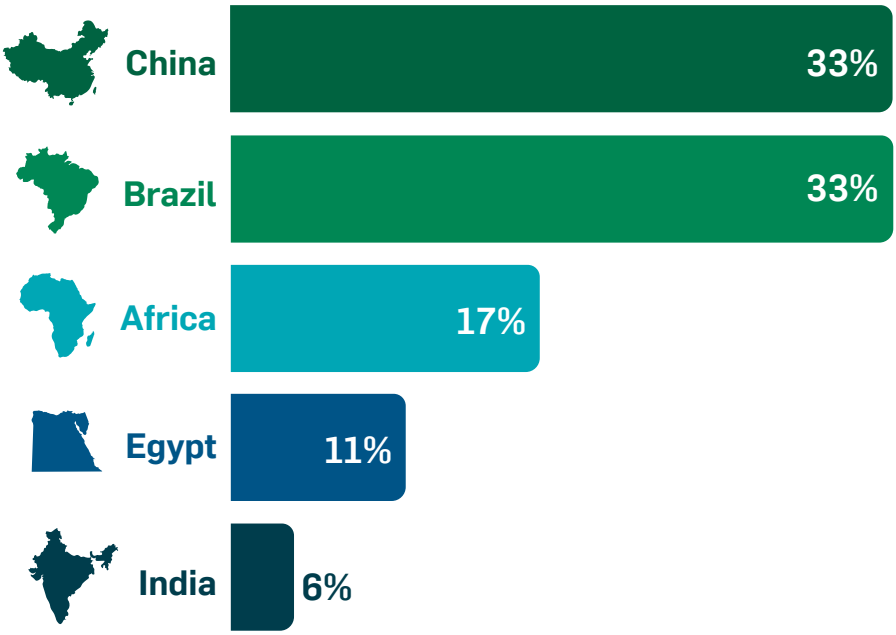
At FutureLink Nashville, business leaders from across the pharma supply chain came together to discuss industry trends and challenges and explore how serialized inventory on a digital network platform can create the foundation for game-changing innovation.

Emerging Regulations Require a Global Compliance Platform

> "Increasingly, countries across the globe are looking to protect patients or improve access to medicines or to facilitate the ease of movement of medicines across the supply chain."
>
> **– Brian Daleiden**, Vice President of Industry Marketing and Community, TraceLink

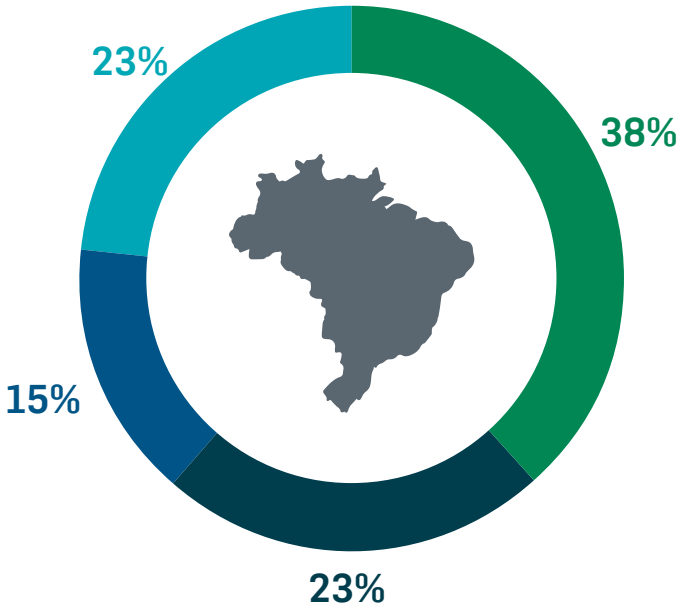
The adoption of serialization and traceability regulations is accelerating in countries around the world. While coding, serialization, and data exchange standards exist, global regulations are not converging on a single approach. This diverse regulatory environment is challenging global pharmaceutical companies in their efforts to improve operational efficiency while achieving compliance. It also underscores the need for a single, global compliance platform that can help companies manage and adapt to emerging regulatory requirements in places like Brazil and Egypt in addition to larger, more established markets like the US, European Union, Russia, and China.

What are the emerging country/region regulations that concern you the most?



FutureLink polling data shows that emerging regulations in China and Brazil are most concerning to pharma supply chain companies, while a strong majority—more than 60%—indicated that Brazil either is or will be a strategically important market.

Do you consider Brazil to be a strategically important market for your company?



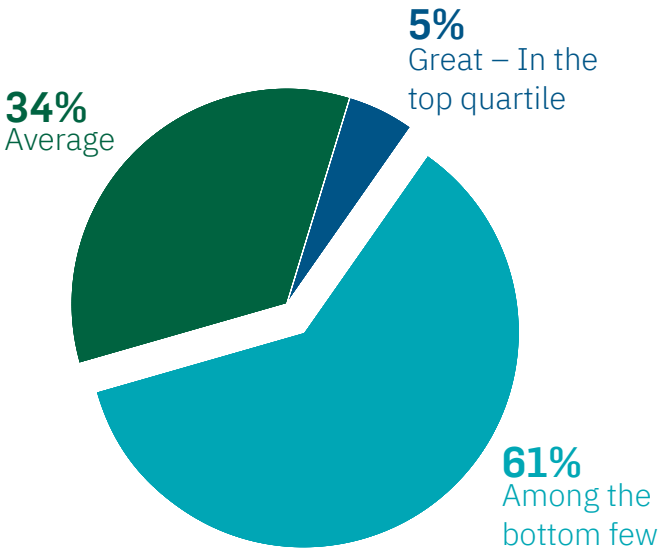
- Yes. We have a significant product portfolio or distribution services for the Brazil market.
- Yes. It is a strong future growth market for us, although today, we have few or no products there.
- Not really. We have some products there but the volumes aren't high or we are expecting to leverage partners.
- Unsure. We are still trying to understand the local market and how these regulations may impact our market plans.

Reduction of Drug Shortages Tops List of Supply Chain Digitalization Benefits

> “In the future, technology is not going to be our constraint, it’s going to be our talent and our ability to innovate.”
>
> **– Joe Dudas**, Vice Chair, Mayo Clinic

The majority of FutureLink attendees recognize that the industry has much work ahead to achieve digital maturity. But they also recognize the benefits that supply chain integration on a digital network platform will deliver. The combination of serialization, digitalization, and seamless integration with trade partners means supply chain players will have greater visibility into product availability and movement. The result will be fewer drug shortages, better patient access to medicines, and greater control over environmentally-sensitive pharmaceuticals as they travel from manufacturer to patient.

How do you think the pharma industry compares to other industries in digital maturity across strategy, culture, organization, and capabilities?



Drug shortages are one of the biggest challenges facing the pharmaceutical industry and patients who depend on it. Shortages can cause delays in treatment or force doctors to choose less-effective therapies when drugs of choice are unavailable.

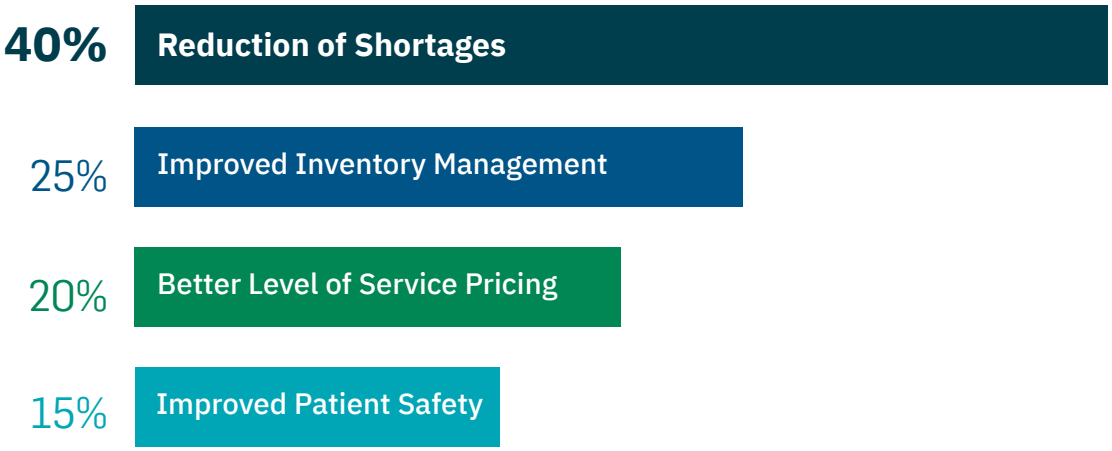
56%

of hospitals have changed patient care or delayed therapy due to drug shortages.

– US Food and Drug Administration

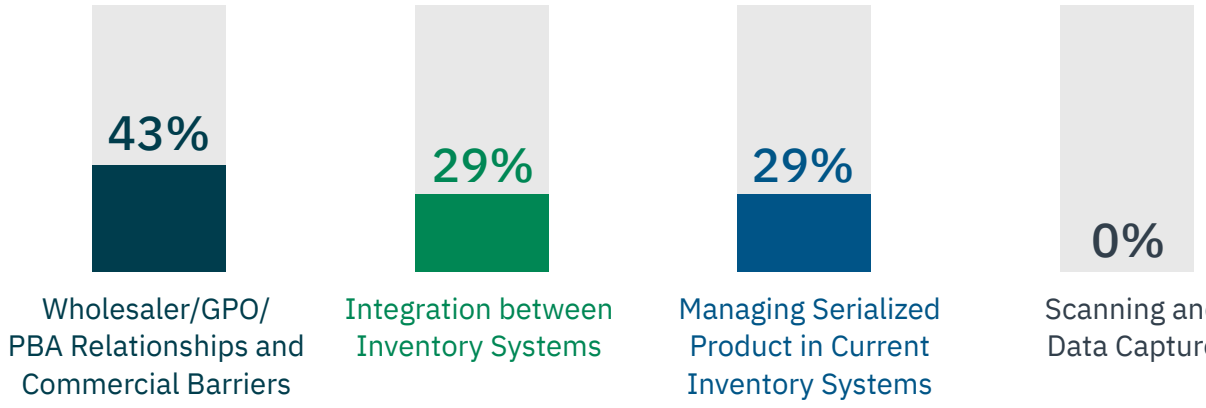
Business leaders at FutureLink see a reduction in drug shortages as the biggest benefit of increased visibility between manufacturers and dispensers, followed by better inventory management, and improved service levels.

If dispensers and manufacturers were to have improved visibility into both supplier inventory availability and dispenser inventory levels and consumption rates, what might be the biggest benefit?



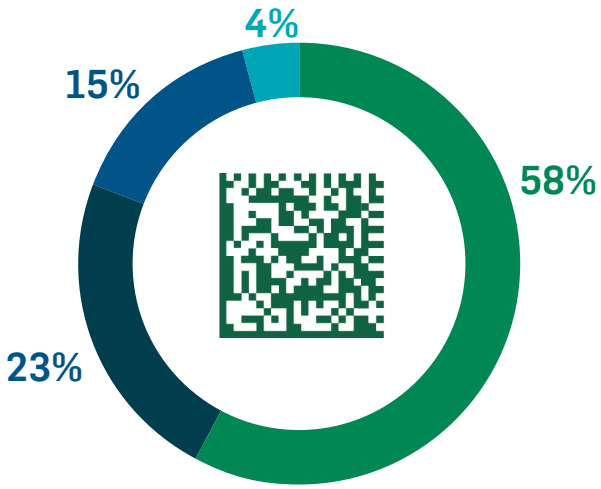
While the benefits of improved supply chain visibility are clear, business challenges continue to stand in the way. Coordinating with trade partners is the top challenge, followed by integrating inventory management systems, and difficulties associated with managing serialized product in current inventory systems.

What might be the largest challenge to improved inventory visibility and collaboration between dispensers and manufacturers?



Serialization and regulatory compliance initiatives present their own visibility problems. The vast majority of FutureLink attendees lack full visibility into the lifetime of serial numbers from provisioning to decommissioning.

What are the challenges you face in monitoring serialization compliance?



- I do not have end-to end visibility across all systems, from provisioning a serial to last seen operation on that serial.
- It is very difficult to understand what is the latest operational and compliance status of serials in a commissioned lot or a delivery.
- I do not know how to ensure/track if all required serials are included for a specific compliance report.
- I do not track compliance on a regular basis after a compliance report goes to production, so this does not apply to me.

Excursion Tracking Challenges Point to Need for Supply Chain Orchestration

> "When you think about trade partners along the supply route, they don't have any centralized place to put real-time tracking data. This is a problem that is screaming for a network solution."
>
> **– Larry Hall**, Smart Supply & Logistics, TraceLink

The pharmaceutical industry loses billions each year as a result of environmental excursions during product shipping that aren't caught in time. Typical processes for monitoring environmental excursions today involve proprietary devices and sensors, siloed and disparate data sets, and error-prone manual processes. The result is a lack of end-to-end visibility and environmental failures. Solving this problem requires a network solution that provides universal device adapters, simple onboarding of trading partners, and massive scale to manage high volumes of data in real time.

$15 billion

in annual losses across the global pharmaceutical supply chain due to temperature variations during transit.

– FedEx Healthcare Solutions

FutureLink polling data shows that most companies currently do not learn about environmental excursions until it's too late to save the product—if they find out at all.

When my company's products have had environmental excursions in the past, usually...

52%
We find out after it is too late to save the product.

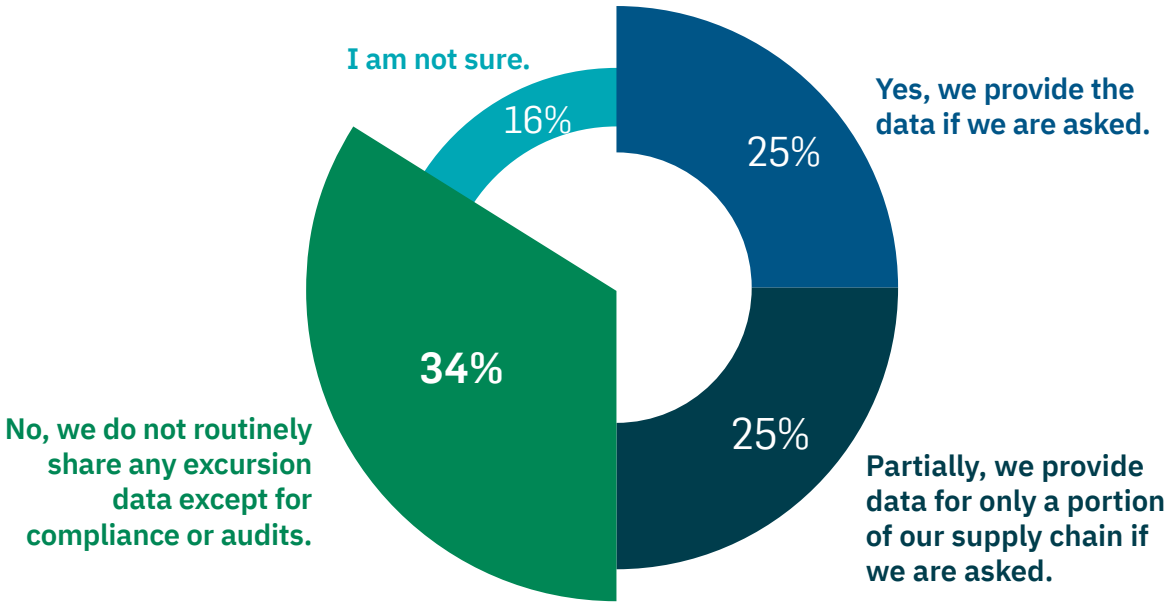
35%
We do not know after it leaves our ownership and control.

13%
I am not sure.

0%
We know right away and stop it before product is damaged.

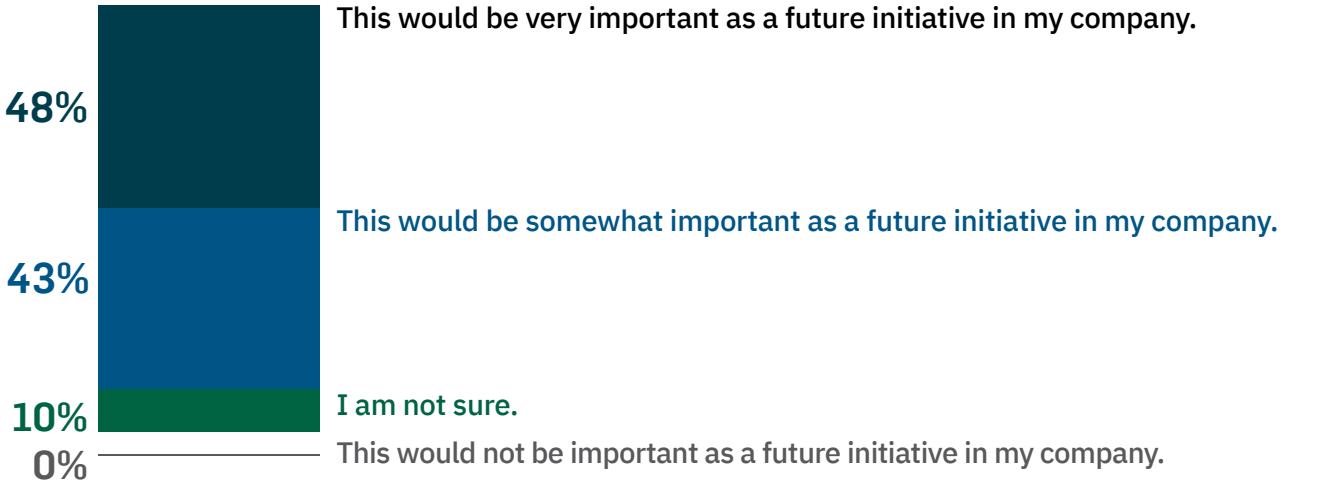
While most business leaders at FutureLink make a practice of sharing at least some excursion tracking data when asked for it, more than a third do not routinely share excursion data at all. By collaborating more freely with supply chain partners on a network platform, companies can reduce the chances of financial losses due to temperature excursions. More importantly, increased collaboration and temperature monitoring will help ensure that patients receive needed medicines in time and under the correct environmental conditions.

Does your company currently provide any potential excursion event data for cold chain product to your patients or dispensing locations?



The ability to associate real-time excursion monitoring events to unique product serial numbers or sets of serial numbers will ensure more precise supply chain orchestration and enable rapid decision making at all levels of granularity.

When thinking about environmental excursion tracking data tied back to serialized product data…



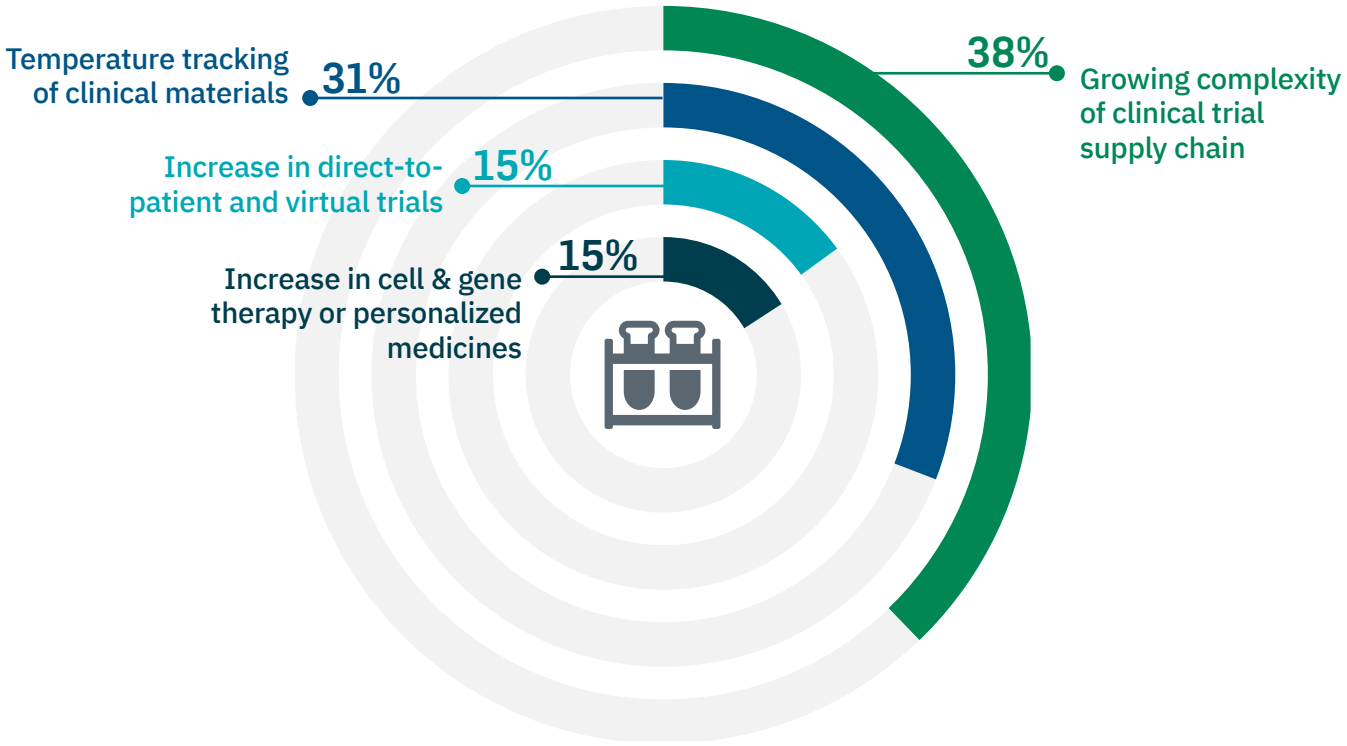
Excursion event tracking is a prime example of a supply chain process that requires high levels of collaboration and integration between trading partners. By monitoring excursion events in real-time over a fully-integrated, digital supply network of trading partners and smart sensors, pharma supply chain companies will create the foundation to protect their brands and improve patient outcomes.

Increased Complexity of Clinical Trials Calls for a Digital Network Solution

> "The importance of knowing the right clinical product is with the right patient and is in the right condition has never been greater."
>
> – **Dan Walles**, General Manager, Track & Trace, Compliance, TraceLink

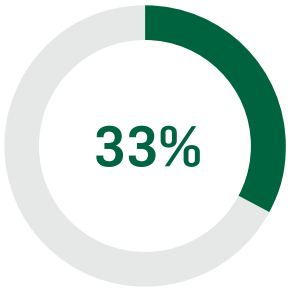
Clinical supply networks are becoming increasingly complex due largely to the rise of virtual trials, direct-to-patient medicines, personalized medicines, and cell and gene therapies. At the same time, the number of players involved in clinical trials is increasing, and pharma companies want to find ways to shrink clinical trial timeframes. These factors are pushing the limits of how clinical supply chains are set up today.

What is the top emerging trend impacting your clinical trial strategy?

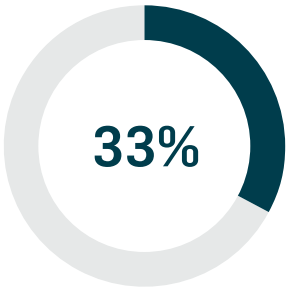


A digital supply network will be key to helping pharma companies adapt to the rapidly changing world of clinical trials. In addition to enabling real-time integration and data exchange with trade partners and ensuring proper temperature controls, a digital network platform provides an opportunity to develop new mobile technologies to support virtual trials.

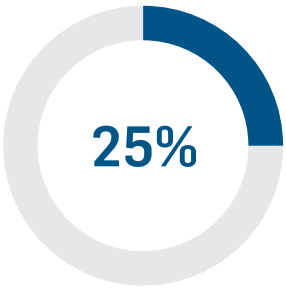
What is the top emerging trend impacting your clinical trial strategy?



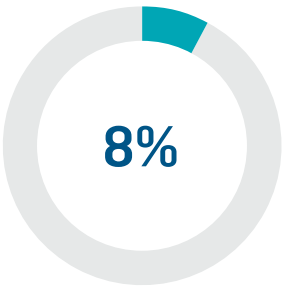
My systems are unable to rapidly integrate to external systems for real-time data exchange.



Monitoring end-to-end temperature exposure is labor intensive and error prone.



My systems cannot support mobile app development to support virtual and direct-to-patient trials.



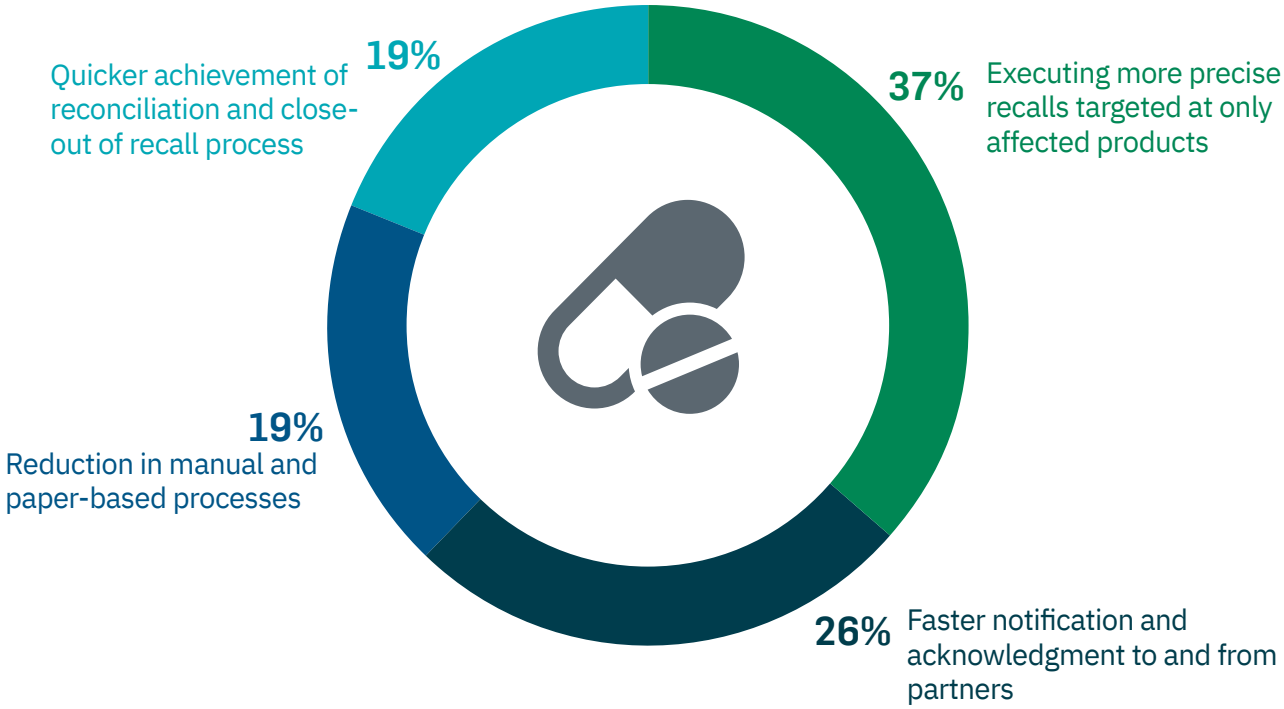
My systems and processes cannot meet the condensed timelines required for cell and gene therapy trials.

Supply Chain Transformation Will Lead to Great Things—Like Digital Recalls

> "It's a huge complicated mess whenever a recall happens—even though it is relatively routine, and we do get them every day."
>
> **– Joe Maki**, Senior Director, Pharmacy Business Operations, Novant Health

Traditional methods of managing product recalls in the pharmaceutical industry are fragmented, decentralized and characterized by time-consuming and error-prone manual processes. In the worst cases, inefficient recall processes can put patient lives in danger. They can also result in serious product liability risks for pharmaceutical manufacturers. The recalls management process is a key example of how the end-to-end pharmaceutical supply chain will see vast improvements as a result of collaboration on an integrated supply network.

In what area do you believe your organization might gain the most value from digitalizing recall communication and execution?



For pharmaceutical companies, the challenges of managing recalls today run the gamut from limited visibility into recall effectiveness to problems associated with managing multiple, overlapping recall notifications.

For pharma companies, what are the most challenging aspects of today's manual recall processes?

29% Limited visibility into recall effectiveness and yields

21% Managing multiple, overlapping communications for same recall event

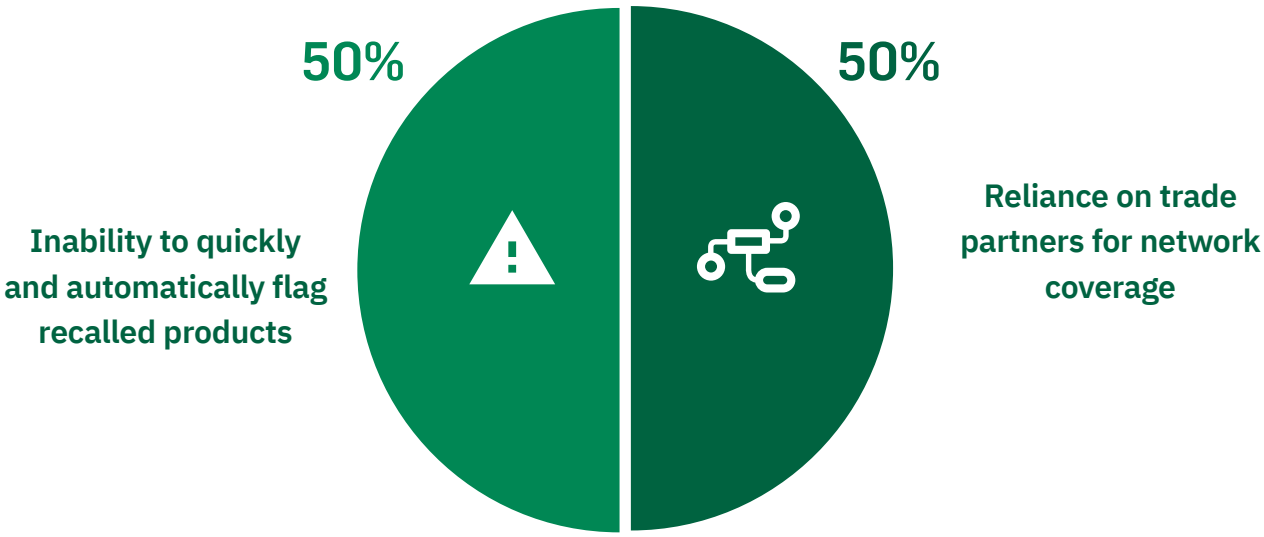
21% Complex response logistics to identify and manage recalled product

14% Wide scope of outreach to diverse points of product inventory

14% Manual paper notifications and response

Hospital and retail pharmacy employees spend a great deal of time responding to recall notifications and searching for product that may have never been received or is no longer in inventory. Their biggest challenge is the inability to quickly identify and remove recalled products and notify affected patients. Many dispensers also report that they are far too dependent on supply chain partners, such as pharma companies and wholesalers, for the identification and removal of recalled products from the supply chain.

For dispensers, what are the most challenging aspects of today's manual recall processes?



0%
Managing multiple simultaneous recalls events

0%
Manual paper notifications

0%
Understanding the actions to take for a recall event

Fast-Track Your Digital Transformation with TraceLink

The pharmaceutical supply chain is going through a period of monumental change driven by an increasingly complex global regulatory environment; growing pressure to boost operational efficiency and streamline costs by modernizing traditionally cumbersome and error-prone processes; and the rise of personalized medicines, which require close-knit supply chain collaboration and precise patient-centric orchestration.

To remain competitive, pharma supply chain companies need to integrate systems and capitalize on product serialization to ensure end-to-end inventory visibility. But the time, complexity, and effort associated with creating point-to-point integrations with trading partners is cost prohibitive. Ensuring success in this environment requires an enabling technology—a vast digital network of trading partners in the cloud—that eliminates obstacles to integration and allows companies to choreograph the supply chain around the specific needs of the patient.

TraceLink is the world's largest integrated supply network, enabling digitalization and patient-centric orchestration across the life sciences supply chain, from manufacturers to distributors to hospitals and pharmacies. TraceLink is partnering with life sciences companies to solve legacy challenges and improve all aspects of supply chain operations, including:

- Fewer drug shortages and better patient access to medicines
- Improved environmental excursion monitoring
- Increasing revenue through better inventory management
- Regulatory compliance on a global scale

TraceLink gives pharma supply chain companies the power to see more, share more, and do more together. **Contact TraceLink today to learn more**.