



## RESOURCES

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# What is the TraceLink Cloud Community?



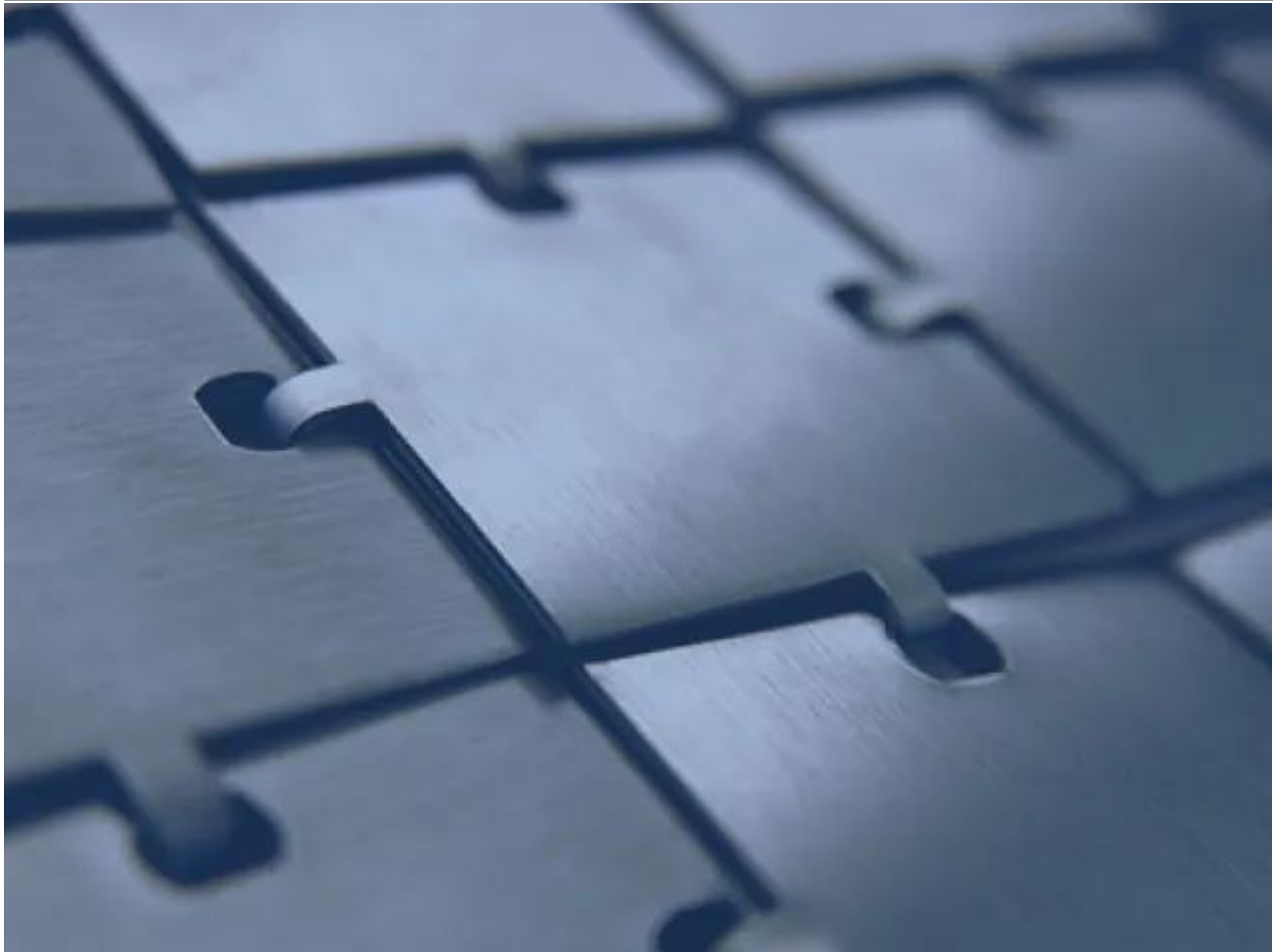
In today's rapidly evolving compliance landscape, how can you get a 360-degree view into what's going on in the Life Sciences industry? Hear Brian Daleiden, VP of Industry Marketing, talk about opportunities to network and share information with companies from across the entire supply chain.

### **United States**

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Subscribe to stay informed with the latest patient-centric agile supply chain thought leadership content.

### **More Serialization and Compliance Resources**



### **TraceLink: The World's Largest Integrated Digital Supply Network**

TraceLink's network digitally connects the end-to-end pharmaceutical supply chain. See the infographic.

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**illes**

*Solutions and Partnerships*



**What is a "Proven" Serialization Solution?**

With deadlines looming, hear how to determine if a serialization system has truly been tested, and what the consequences of an unproven solution might be.

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## FDA Pilot: Transforming to a Digital Recalls Network

Shweta Agarwal, Product Management – Network Applications and Mobile Apps, TraceLink

### Business Challenge & Solution

When a drug is recalled, time is of the essence. Lives depend on immediate removal of drug from the channel or being dispensed to or accessed by patients.

**Manufacturers: Improve recall effectiveness**  
Digital Recall solution provides ability to rapidly and precisely communicate recall information, and to receive real-time acknowledgment of receipt and product removal status. The value is timely communication to patients and increased rate of recalled product returns.

**Holders and Healthcare Providers: Manage recalls efficiently**  
Digital Recall solution provides ability to receive targeted recall alerts based off of inbound delivery tracking and facilitates communication back to suppliers and recalling company. The value is faster identification of recalled product, timely and accurate credits and refunds and greater patient safety.

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The digital recalls network leverages penetration data, traceability information, and interoperable electronic systems to enhance timely collaboration across the network.

### Digital Recalls Solution Overview

- Execute faster and more precise recalls
- Achieve higher recall effectiveness and faster closure
- Eliminate paper processes and manual labor
- Identify affected consignees and network participants
- Pinpoint where recalled product lies in the channel
- Prevent recalled product from dispensing to patients

### Key Activities and Resources

#### FDA Pilot Mission & Objectives

Examine a network solution that would enable the development and deployment of an standardized, interoperable Digital Recalls Network

- Ensure patient safety
- Improve system efficiencies
- Facilitate faster and secure exchange of recall information

#### Participating Stakeholders

- Manufacturers (Diversified, Specialty, Contract)
- Distributors (Full-line, Specialty, Regional)
- Dispensers (Healthcare/Hospital, Retail Pharmacy, Grocery Pharmacy)
- Logistics (3PL, Returns Processor)

#### Project timing and milestones – 2019 and 2020

- 20+ individual workshops, 9 bi-weekly virtual team workshops, 3 in-person team workshops

Phase 1	Phase 2	Phase 3	2020
<ul style="list-style-type: none"> <li>Goals, evaluation, objective</li> <li>As-is discovery and analysis</li> <li>Recall activation preparation, communication and acknowledgment</li> </ul>	<ul style="list-style-type: none"> <li>Internal team organization</li> <li>Recall response and planning</li> <li>Product removal</li> </ul>	<ul style="list-style-type: none"> <li>Integration and interoperability</li> <li>Business process and change management</li> <li>Adoption and implementation</li> <li>Regulatory and standards</li> </ul>	<ul style="list-style-type: none"> <li>Expanded use cases and development</li> <li>FDA Report</li> <li>Pilot team testing</li> <li>Initial solution launch</li> </ul>

### Key Learnings and Potential Outcomes

#### Faster Notifications are Achievable

- Digital notification targeting and forwarding across the supply network improves communications efficiency and recall execution efficacy
- Minimizing replication of divergent notifications by multiple stakeholders reduces confusion and speeds action on notifications
- Interactive digital messaging provides real-time accurate insight into confirmed status of a digital recall notification (delivered, acknowledged, action taken)
- Secure forwarding of digital recall notifications and augmenting recall information with specific reg. instructions enhances sub-recall processes

#### Precise, Timely Visibility to Recalled Product

- Targeting notifications enables focus on stakeholders that are most likely to have potential affected product
- Integration of notifications with transactional data from traceability systems and operational data ensures improved internal search effectiveness
- Use of DSCSA transactional and product identifier data connected to operational systems can speed selling inventory status and alerts in receiving and pick/pack/ship operations
- Visibility into returns processor activities will help to build a more timely and informed picture of product that has been removed/returned

#### Faster, More Accurate Product Removal

- More informative and timely recall notices makes easier to understand and act upon recall events
- Coordinated and streamlined notifications that accurately and timely track and report acknowledgment and action speeds network action
- Real-time capture and reporting of removed prod being visible to all parties enhances effectiveness
- Digital recalls network flexibility helps proactively identify and isolate affected product across a slim supply chain, minimizing supply impacts

#futurelink

### Case Study: TraceLink | FDA Pilot - Transforming to a Digital Recalls Network

Find out how TraceLink helps pharmaceutical manufacturers and dispensers manage recalls more quickly and efficiently than ever.

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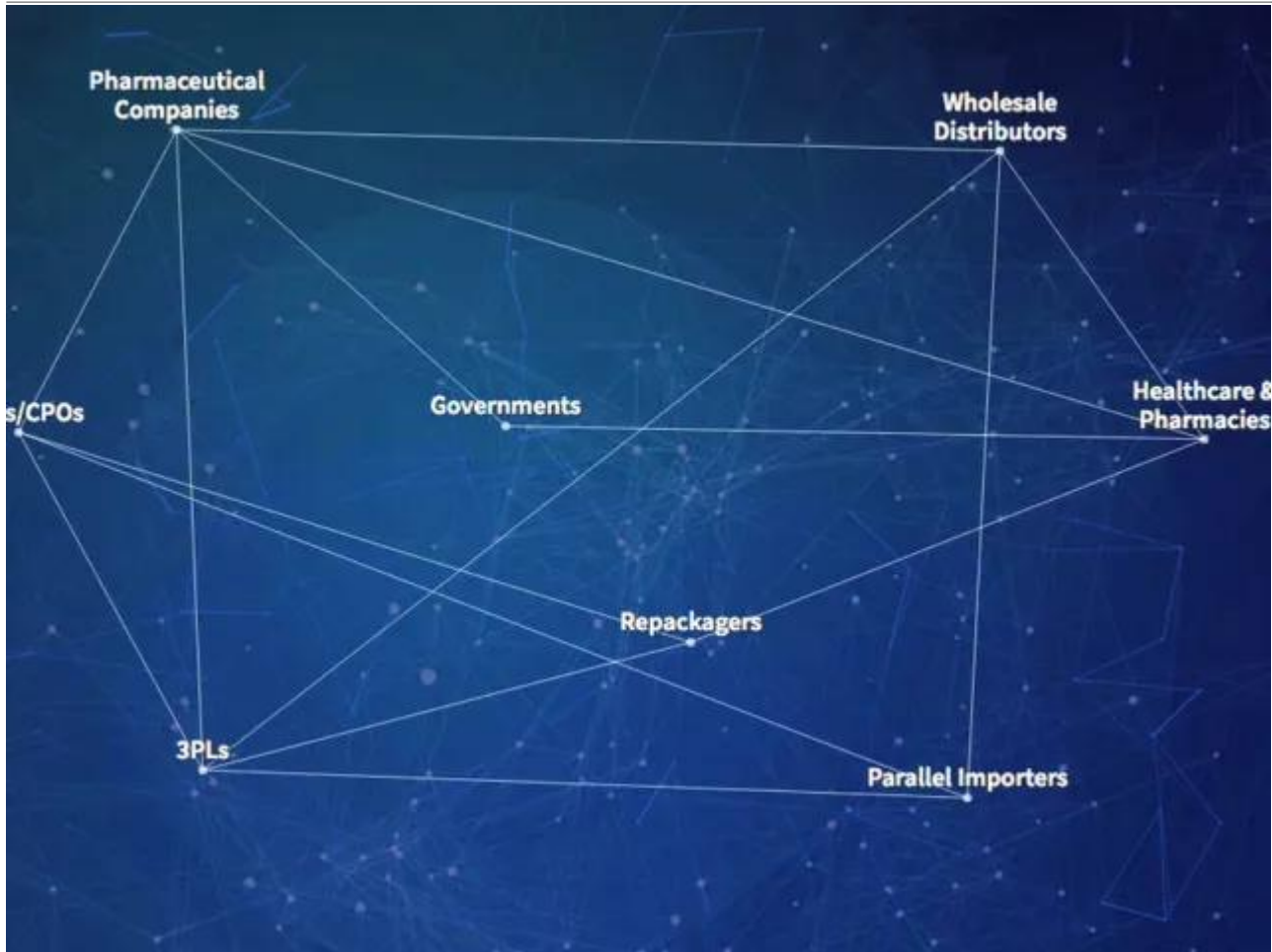


**Caitlin C**  
*Manager, Implementation Project M.*

**Minimizing Time and Risk with an End-to-End Network**

Watch this video to see why traditional point-to-point architecture is not a good fit for new track and trace serialization regulations.

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### **Smarter CMO Onboarding: Speed Up Serialization with Network Efficiency**

Learn how a network approach is the best way to boost the efficiencies of CMO onboarding with brand owner customers.

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**The TraceLink Life Sciences Cloud: Talking to Companies in Their Own Format**

The TraceLink network plays translator for more than 235,000 companies, seamlessly exchanging compliance data with customers, suppliers and trade partners.

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