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# FDA Approves TraceLink DSCSA Pilot Submission for Network Solutions; Delivering 2023 Traceability By Leveraging Blockchain and Digital Recalls Across a Supply Network

TraceLink Inc., the world's largest integrated digital supply network providing real-time information sharing for better patient outcomes, today announced the acceptance of its participation in the Food and Drug Administration (FDA) Pilot Project Program under the Drug Supply Chain Security Act (DSCSA). TraceLink's pilot project focuses on two workstreams; an interoperable blockchain network solution and digital recalls across a supply network, both intended to bring together participants of all sizes from across the pharmaceutical supply chain to enhance patient safety and address challenging business processes through network connectivity and innovative software solutions.

"We are excited to move forward on the FDA pilot project with our customers, representing companies of different sizes, complexities, and operational use cases from all segments of the supply chain. Combining insights from these leading companies with TraceLink's digital supply network will garner compelling

information that will contribute to the innovation, security, and interoperability of the U.S. supply chain,” said Shabbir Dahod, President and CEO, TraceLink. “The objectives of the FDA pilot program align closely with TraceLink’s mission of developing new solutions that will drive visibility and collaboration, resulting in not only increased security and safety, but ultimately, the improvement of human life.”

Unique to TraceLink’s pilot project is the inclusion of a very diverse set of industry stakeholders including large pharmaceutical manufacturers, biopharmaceutical companies, contract manufacturers, repackagers, wholesale distributors, major retail pharmacy chains, diversified healthcare systems, third-party logistics providers and returns processors. The two workstreams will explore new approaches for interoperable information sharing and the use of verification and notification for enhancing patient safety, while maintaining data privacy and ownership.

### **2023 Traceability Workstream: TraceLink’s Interoperable Blockchain Network Solution with Trace Histories**

The blockchain workstream will bring together end to end stakeholders from the supply chain to evaluate how blockchain can be used to help companies meet 2023 DSCSA transaction information gathering requirements.

This workstream will leverage TraceLink’s blockchain solution, Trace Histories as one of the tools to develop a blueprint for the industry for an open, interoperable network to fulfill the requirements for full unit level traceability across the supply chain. Trace Histories is a distributed ledger network that enables safe and secure information exchange between authorized partners with a unique “gather upon request” model. Unlike other industry initiatives that require use of a single blockchain system throughout the industry, Trace Histories was purpose-built for standardization to support interoperability across blockchain and non-blockchain networks.

The objective of this workstream is to provide key learnings for each stakeholder to prepare for and meet the 2023 deadline as an industry.

**Product Recalls Workstream: Digital Recalls Across the Supply Network**

TraceLink’s digital recalls worksteam is intended to evaluate and enhance current recall verification and notification processes within the pharmaceutical supply chain by leveraging both lot level and serialization data on a digital supply chain network. Current recall processes within the industry are largely manual and time-consuming, creating inefficiencies and putting patient safety at risk. While individual companies have standing recalls processes in place, the existing recalls process is costly and ineffective when viewed across the supply network. In working toward the objectives of this workstream, pilot participants will evaluate different methods of effectively exchanging information on a network and coordinating with supply chain partners to prevent recalled product from reaching patients.

Both workstreams will gather ongoing participant feedback and are expected to be complete in the fall of 2019.

**Related Content**



**Fixing Recalls: FDA Pilot Tackles a Legacy Challenge—7 Broken Practices and 5 Guiding Principles for Change**

Seven broken product recall practices across the end-to-end pharma supply chain—and five guiding principles for change.

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**FDA Pilot Report: Digital Recalls Network and DSCSA 2023 Traceability with Blockchain**

See the results of TraceLink's FDA pilot project that focused on two workstreams; digital recalls and blockchain with participants from 22 companies across the supply chain

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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 diagram illustrates the digital recall process flow. It starts with a 'Digital Recall Information Provider' (Manufacturer) sending a 'Recall Acknowledgment' to a 'Recall Administrator' (Dispenser). The dispenser then sends a 'Recall Acknowledgment' to a 'Recall Administrator' (Manufacturer). The process involves 'Recall Information Provider' (Manufacturer), 'Recall Administrator' (Dispenser), and 'Recall Administrator' (Manufacturer). The flow is supported by 'Recall Information Provider' (Manufacturer), 'Recall Administrator' (Dispenser), and 'Recall Administrator' (Manufacturer). The flow is supported by 'Recall Information Provider' (Manufacturer), 'Recall Administrator' (Dispenser), and 'Recall Administrator' (Manufacturer).

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

**Digital Recalls Solution Overview**

The flowchart shows the interaction between the 'Recalling Company' (Manufacturer), the 'Digital Recall Network', and the 'Recalled Consumer' (Dispenser). The Recalling Company sends 'Recall Acknowledgment and real-time return confirmation' to the Digital Recall Network. The Digital Recall Network sends 'Recall Acknowledgment and real-time return confirmation' to the Recalled Consumer. The Recalled Consumer sends 'Recall Acknowledgment and real-time return confirmation' to the Digital Recall Network. The Digital Recall Network sends 'Recall Acknowledgment and real-time return confirmation' to the Recalling Company.

- 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, objectives</li> <li>As-it-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 training</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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