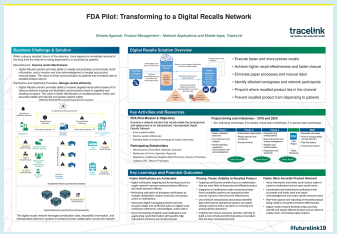
RESOURCES

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



When a drug is recalled, time is of the essence. Removing recalled products from the supply chain immediately can save lives. Read our new poster, which was featured at FutureLink Nashville, to learn how TraceLink is helping life sciences customers manage recalls more quickly and efficiently than ever before.

FDA Pilot: Transforming to a Digital Recalls Network

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

Business Challenge & Solution

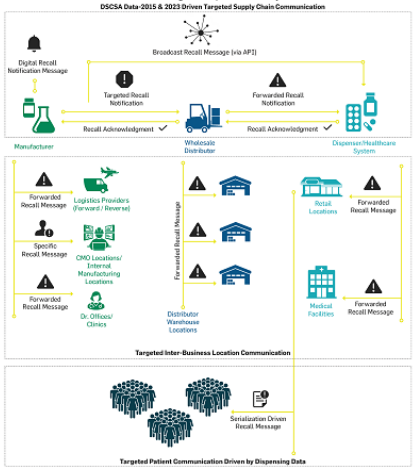
When a drug is recalled, time is of the essence. Lives depend on immediate removal of the drug from the channel or being dispensed to or accessed by patients.

Manufacturers: ***Improve recall effectiveness***

- *Digital Recalls 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*

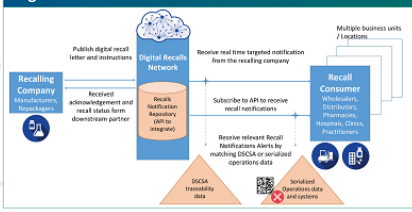
Distributors and Healthcare Providers: ***Manage recalls efficiently***

- *Digital Recalls 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*



The digital recalls network leverages serialization 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 recalls 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
• Goals, evaluation, objectives • As-is discovery and analysis • Recall notification preparation, communication and acknowledgement	• Internal team organization • Recall response and monitoring • Product removal	• Integration and interoperability • Business process and change management • Adoption and implementation • Regulations and standards	FDA Report Public Workshop	• Expanded use cases • Proof of concept design and development • Pilot field testing • Initial solution launch
Mock Recall	Mock Recall	Mock Recall		

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 state of a digital recall notification (delivered, acknowledged, action taken)
- Secure forwarding of digital recall notifications and augmenting recall information with specific mfgr. 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 improves internal search effectiveness
- Use of DSCSA transactional and product identifier data connected to operational systems can speed setting 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 it easier to understand and act upon recall events
- Coordinated and streamlined notifications that accurately and timely track and report acknowledgement and action speeds network action
- Real-time capture and reporting of removed product being visible to all parties enhances effectiveness
- Digital recalls network flexibility helps precisely identify and isolate affected product across a diverse supply chain, minimizing supply impacts

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