Executive Summary; Product Recalls Workstream: Digital Recalls Across the Supply Network

A cross-industry, cross-functional team of industry leaders from each segment of the United States pharmaceutical supply chain collaborated for six months in 2019 under the FDA Pilot Project Program to study, analyze, and prepare recommendations on how to improve the current drug recalls process for all stakeholders.

Goals and objectives:
Every year, drug related recalls result in hundreds of thousands of preventable patient deaths, hospitalizations, and adverse event experiences. In addition, a report published by [McKinsey](#) points to these recalls costing the pharmaceutical industry more than $4B+ in direct labor and recall management expenses; and tens of billions of dollars in potential product liability lawsuits, lost drug sales, and brand erosion.

In an effort to reduce the impact recalls have on the industry, TraceLink's digital recalls workstream was designed to evaluate and enhance current product recall management and notification processes within the pharmaceutical supply chain by leveraging serialization data, traceability information, and interoperable electronic systems. The goal was to determine the business and patient safety benefits achievable through the establishment of a digital recalls network including the improvement of rapid and precise communications, management, execution, and closure of product recalls across the supply chain.

Summary of Findings:
This pilot workstream explored ways to solve the challenges associated with product recall processes, which are frequently plagued with disjointed systems, manual processes, and long delays in communication between supply chain stakeholders. By leveraging serialization and traceability tools, as well as TraceLink's emerging digital recalls network solution, pilot participants were able to examine real world applications of the digital recalls lifecycle across each stage of the process and among various stakeholders.

Findings from the pilot demonstrated the critical need for an interoperable, digital network approach to orchestrate product recalls effectively, through real-time information sharing, and coordinated processes among stakeholders across the entire end-to-end supply chain. Pilot participants determined that this approach will not only improve patient safety, but support and improve the recalls process for the entire diverse supply chain.

Key Takeaways:
In conclusion, this pilot identified a strong opportunity to improve the drug recalls process with the integration of bi-directional communications and digital recall notifications to bolster response times across the execution phase. It is TraceLink's recommendation that to achieve the vision of a digital recalls network and transform the process, there be a collaborative effort among industry stakeholders to create an effective blueprint and roadmap to adoption that takes into consideration the entirety of the supply chain.

For an in-depth review of the pilot findings, [download](#) TraceLink's full FDA Pilot Project Program report.