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

Under the FDA Pilot Project Program, TraceLink led a cross-industry, cross-functional team of industry leaders from each segment of the United States pharmaceutical supply chain to study, analyze, and prepare recommendations on two key challenges facing all stakeholders.

Pilot members included:

- **Contract Manufacturers:** Thermo Fisher/Patheon; Sharp Packaging
- **Pharmaceutical Manufacturers:** Agios; A-S Medication Solutions; Bristol-Myers Squibb; Flexion; Johnson & Johnson; Merck; Par Pharmaceuticals; Sagent; Sandoz; Novartis
- **Wholesale Distributors:** McKesson; Value Drug Company
- **Retail Pharmacies/Healthcare:** CVS Health; Novant Health; Wegmens; Yale New Haven
- **Logistics Providers:** DHL; PharmaLink; Woodfield Distribution

The Digital Recalls workstream analyzed how pharmaceutical recalls are executed today and examined how a digital recalls network could be realized to improve the rapid and precise communication, management, execution, and closure of product recalls across the supply chain.

The Traceability workstream analyzed how the industry will be impacted by the upcoming DSCSA 2023 regulations, to research the critical capabilities and requirements for a network solution to meet these requirements, and to study the potential role of blockchain/distributed ledger technology combined with serialization, traceability, and other existing technology solutions.

The team's findings for both workstreams were submitted to the FDA. To receive the full 50 page report via email, enter your information in the form. Executive summaries for each workstream can be viewed below.

Digital Recalls Executive Summary
2023 Traceability Executive Summary

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