

Executive Summary; 2023 Traceability Workstream, TraceLink's Interoperable Blockchain Network Solution with Trace Histories

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 analyze how the industry will be impacted by the upcoming DSCSA 2023 regulations. This included researching 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.

Goals and Objectives:

This workstream set out to look at the systems, processes, information, and stakeholders in use in today's pharmaceutical supply chain to evaluate how they can be leveraged to meet 2023 DSCSA requirements, while also analyzing the strengths and weaknesses of any proposed electronic network model for DSCSA 2023. This included evaluating TraceLink's blockchain solution to analyze whether blockchain-centric and/or non-blockchain approaches may be most relevant in a given business or operational situation.

Summary of Findings:

Trace Histories, TraceLink's interoperable blockchain network solution, was specifically designed to aid the end-to-end supply chain in satisfying the 2023 requirements surrounding product traceability for DSCSA. The findings confirmed that the business processes related to product traceability are extremely complex, and identified blockchain as one of many possible technology components that could support product traceability under the DSCSA 2023 guidelines. Due to the diversity of systems, processes and stakeholders that make up the supply chain, relying on any single technology or sole platform to meet these guidelines, however, is extremely unlikely.

Key Takeaways:

The findings for product traceability indicate that standards, processes, and systems for identity management and credentialing are essential to product traceability and digital, interoperable systems more generally but no single technology or sole platform is the answer. TraceLink recommends that industry players embark on additional work on identity management and credentialing, as well as an expanded focus on data integrity and workflows involving data mismatches, in order to find the most optimal path forward for meeting 2023 traceability requirements of the DSCSA and beyond.

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