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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.