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TraceLink Announces Results from FDA DSCSA Pilot Program

Key findings demonstrate value of network solutions to secure and digitalize the pharmaceutical supply chain

The TraceLink pilot focused on two workstreams: digital recalls across a supply network; and, an interoperable blockchain network solution. The pilots included 22 participating companies from pharmaceutical manufacturers, wholesale distributors, third party logistic providers, hospitals and retail pharmacies, including four of Gartner's Healthcare Supply Chain Top 25 and a recognized supply chain leader in the Gartner Magic Quadrant for Third-Party Logistics Providers.

The pilot employed early stage technology solutions to address top pharmaceutical supply chain challenges and establish a deep understanding of how technology can realistically ease those burdens. Both workstreams were designed to create a vision and blueprint for the data, operational processes, business systems, and network connections required to realize DSCSA 2023 compliance and to digitalize pharmaceutical drug recalls.

"The results from our pilot gleaned significant insights that will help solve different, but equally important challenges that the pharmaceutical industry will continue to face until DSCSA 2023, with both workstreams undoubtedly highlighting the value

of a digital network in improving processes and efficiencies within the supply chain," said Shabbir Dahod, president and CEO of TraceLink. "With the only established end-to-end digital supply network for the industry, TraceLink is in a unique position to help the industry begin acting on some of these pilot findings now. This includes improving processes and allowing better visibility, agility, and collaboration among supply chain stakeholders."

Product Recalls Workstream: Digital Recalls Across the Supply Network

Every year, drug related recalls play a significant role in the hundreds of thousands of preventable patient deaths and hospitalizations from 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.

Pilot participants in TraceLink's digital recalls workstream explored ways to solve challenges associated with today's product recall process, plagued by disjointed systems, manual processes, and long delays in communication between supply chain stakeholders including leveraging TraceLink's emerging digital recalls network solution

"Participating in the recalls workstream further demonstrated how inefficient the current industry process is in executing product recalls," said Joe Maki, pilot participant and senior director of pharmacy operations, Novant Health. "The learnings emphasized how a digital recalls platform could vastly improve the execution of recalls by eliminating manual, error-prone processes and would also help to better define accountability among supply chain stakeholders with improved collaboration, ultimately reducing the risk to patients by getting recalled product off the market faster."

The recalls workstream 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, which would require a collaborative effort among industry stakeholders to create an effective blueprint and roadmap for adoption.

For more information on the key findings from the Product Recalls Workstream, view the executive summary.

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

By 2023, DSCSA will require an electronic, interoperable system by 2023 to identify and trace certain prescription drugs. TraceLink's blockchain workstream evaluated existing information, processes, and systems to determine if and how they can meet 2023 DSCSA requirements. Pilot members analyzed the strengths and weaknesses of proposed electronic network models for DSCSA 2023, including the evaluation of TraceLink's interoperable blockchain solution to determine whether blockchain-centric and/or non-blockchain approaches may be effective.

Business processes related to product traceability are extremely complex due to the diversity of the pharmaceutical supply chain. The findings identified blockchain as one piece of a larger technology solution that could support product traceability under the DSCSA 2023 guidelines. However, the pilot strongly indicates that reliance on any single technology or sole platform to meet the DSCSA 2023 guidelines is extremely unlikely.

For more information on the goals and objectives, key findings, and takeaways from the 2023 Traceability Workstream, view the executive summary.

The full TraceLink FDA Pilot Project Program report is available on the company's website. To access the full report, click here.

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