The Partnership for DSCSA Governance (PDG) DSCSA Pilot Program Round-Robin Webinar Series

This document provides a high-level recap of PDG's two-part webinar on the Food and Drug Administration's (FDA) Pilot Project Program.[1] The webinar series was held on July 23 and 31 and served as a forum for pilot participants to share their learnings following the conclusion of the Pilot Project program. The focus of the webinar series was to hear from Program participants on the concrete lessons learned from their pilots and how those lessons can shape the industry vision for 2023 interoperability, as required by the Drug Supply Chain Security Act (DSCSA).

Presentation Recaps

LedgerDomain/UCLA Health

LedgerDomain and UCLA Health's pilot, entitled *DSCSA Solution Through Blockchain Technology*, explored how blockchain technology could be used to verify prescription drugs before they are dispensed at "the last mile." The blockchain-based pilot BRUINchain met all the key objectives of the DSCSA for a dispenser using solely commercial off-the-shelf (COTS) technology. Using a "pull" model to interoperate with Biogen's serialization team, the framework proved capable of scanning drug packages for GS1 2D barcodes, flagging expired product, verifying the product with the manufacturer, and quarantining suspect and illegitimate products. In addition, BRUINChain automatically generated reports of suspect product for escalation through to Form FDA 3911. More recently, the framework has been further enhanced with over 240,000 drug packages and with server upgrades now is rated at 3bn transactions per year.

rrfxcel

The rfxcel Verification/Notification Readiness & Extensibility Pilot's objective was to quantify the readiness of the Verification Router Service (VRS) to meet the saleable returns requirement of the DSCSA. In determining the readiness, rfxcel used 16 different test cases to test request response. Ultimately, it was found that all VRS solution providers in the pilot showed an openness to work collaboratively to ensure that the VRS network was fully tested and HDA participation allowed VRS saleable return responses to move faster. Looking ahead, it was noted that there is a need for additional testing with requestors to ensure they can properly interpret all VRS responses.

GSI US

GS1 US, in collaboration with AmerisourceBergen, Cardinal Health and McKesson conducted the Barcode Readability for DSCSA 2023 Interoperability Pilot. The pilot sought to measure year-over-year progress of industry preparedness for DSCSA 2023 interoperability and tracing requirements, in terms of manufacturers packages and homogenous cases. The pilot measured this progress by examining the (1) readability of a barcode either printed or affixed to a product; (2) application of a linear barcode and 2D barcode on a product; and (3) distinguishing between which barcode to read/use. Overall, the results showed progress over the three-year period. The percentage of serialized product with a 2D barcode containing all four DSCSA-required data elements increase from 6.7% and 20.7% in 2017 and 2018, respectively to 74.3% in 2019. The individual results for AmerisourceBergen, Cardinal Health and McKesson are further outlined in the GS1 US presentation.

TraceLink

TraceLink collaborated with 22 members from each segment of the pharmaceutical supply chain to conduct the Digital Recalls Network and DSCSA 2023 Traceability with Blockchain Pilot. The pilot employed two workstreams, the Digital Recalls workstream and the Trace Histories workstream. The objective of the Digital Recalls workstream was to better understand how recalls are currently conducted and how a digital recalls network could be leveraged to improve notifications, execution, tracking, and closure of product

[1] Additional information on the FDA's DSCSA Pilot Project Program is accessible here: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/dscsa-pilot-project-program.

recalls. The objective of the Trace Histories workstream was to analyze current pharma supply chain processes under DSCSA, develop and test approaches for a "gather upon request" model for unit-level traceability, and describe key attributes and requirements for a network solution to meet DSCSA 2023 regs.

The Digital Recalls workstream found a need for an "interoperable, digital network approach" to conduct product recalls effectively. This approach orchestrates real-time information sharing, collaborative team-based workflows, and traceability systems data to improve visibility, speed reaction time, and increase precision throughout the recall event. In support, an industry-wide collaborative effort was recommended to develop an interoperability blueprint for a digital recalls network. The Trace Histories workstream found that DSCSA 2023 will require significant coordination across complex product / data flows, and inter- and intra-company business processes. The team believes that blockchain could be one effective tool in the technology infrastructure. More importantly, interoperability across a diverse, heterogeneous environment for tracing, verification, identity, and credentialing will be critical. The full report can be accessed here.

Providence Health Technologies (PHT)

The PHT's FDA Small Dispenser Pilot Study sought to determine the readiness of small dispensers operating in the retail, hospital, long-term care, and specialty markets to comply with 2023 DSCSA barcode and labeling requirements. The pilot study found: (1) additional education is needed and there should be detailed training and resources (e.g., FDA guidance); (2) scanning of received drug orders should be mainstream for dispensing pharmacies; and (3) FDA should instruct wholesalers to standardize data formats, including serialization and adherence to quality data submission.

IDLogiq

IDLogig's pilot program entitled, *Next Generation Advanced REAL FIPS-Compliant Cryptographic ID Authentication with Transaction Ledger Powered by Blockchain/Distributed Ledger Technology for Decentralized Heterogeneous Global Network Computing Environment* was focused on developing a solution to meet the verification, product tracing, and interoperability requirements of the DSCSA. Following completion of the pilot, it was determined that automation software is necessary for package level tracing at all phases of production. It was also recommended that the FDA define a standard and provide examples for the details that are to be included in the tracing/verification report and the terminology inside the TI and TH.

Sanofi

Sanofi's pilot program entitled, Product Identifier Verifications by a Contract Manufacturing Organization on behalf of a Manufacturer Authorization Holder was done in collaboration with McKesson, Advanz Pharma, and Adents. The pilot was focused on interoperability and the delegation of verification between 2 parties. The pilot found that interoperability between the Contract Manufacturer (CMO) and the Marketing Authorization Holder (MAH) using the VRS network is possible and that the delegation is effective, however, the parties involved in delegation need a clear understanding of what are each one's responsibilities. Some of the recommendations following the conclusion of the pilot include the need to (1) set up an agreement on who is responsible to load the Lookup Directory; (2) standardize key functionalities; (3) understand how the ERP or serialization system master data ties to the VRS master data; (4) capture error messages by intermediate systems; and (5) align, as an industry, on who triggers a communication when there is a false verification of an error.

Partnership for DSCSA Governance (PDG)

PDG's FDA Pilot Program was initially proposed by the Pharmaceutical Distribution Security Alliance (PDSA) and later transferred to PDG upon its formation. PDG's pilot program focused on testing the ensuring that the structural and organizational aspects of the governance body allowed the organization to meet the goals of governance, improving governance systems and processes at the outset of governance body formation, and identifying challenges with the operation of the governance body's initial systems and processes for governance. Upon completion of the pilot, it was found that industry can collectively and collaboratively govern the DSCSA interoperability environment as needed to support successful implementation. The full pilot report can be accessed here.

Cardinal Health

Cardinal Health's FDA pilot entitled, *Interoperability Data Exchange Errors and Exception Handling* was developed to determine how well participants adhered to transmission and aggregation exceptions that occur within point-to-point serialized data transmission via ECPIS. Overall, the pilot found that most transmission and aggregation exceptions had the ability to be resolved, including events that were out of sequence, contained inappropriate Global Location Numbers and missing data elements.

MediLedger

MediLedger's DSCSA Pilot project was done in collaboration with 26 organizations across the pharmaceutical supply chain and evaluated the effectiveness of a blockchain technology solution to satisfy the interoperable and electronic tracing (at the package level) requirements of the DSCSA. Overall, the pilot program showed that a blockchain solution allows for the chain of custody and provenance to be assured and the authenticity of the drug transaction to be confirmed with each transaction. The pilot project highlighted the need for strong participation and adoption across industry and that should a blockchain technology solution be used to for DSCSA interoperability, it should have an "open system architecture" with appropriate governance to oversee the "function of the system and ensure compliance with industry agreed business rules and standards." It was also highlighted that there is a need for standards to make multiple systems interoperable so that disparate systems can be made interoperable. The full pilot report can be accessed here.

Kit Check

Kit Check partnered with Sandoz (a Novartis division), Hackensack University Medical Center, and Coral Gables Hospital. Their pilot focused on the combination of item serialization (using RFID data carriers) and a Centralized Item Registry ("CIR") with open APIs for software integration with supply chain partners and hospital customers. Their findings included:

- Manufacturer aggregation using RFID was faster, more accurate, and cost-neutral relative to barcode-based methods and led to better data and improved DSCSA compliance.
- Serialization, combined with the CIR, enabled better approaches to handling recalled items. It allowed for automatic detection, streamlined customer notifications, and the blocking items from use in automated workflows. It also helped manufacturers process, track, and report on their handling of recalls.
- Benefits for detecting and managing suspect and illegitimate products were similar to those for recalls, plus Kit Check added the ability to automatically detect counterfeit labels and unusual item movement throughout the supply chain.

Following the conclusion of the pilot, Kit Check recommended that the FDA allow for the use of RFID as a data carrier for the DSCSA serial number (can be coupled with barcodes for fallback functionality) because of the numerous points of value it enables throughout the supply chain.

IBM/KPMG/Merck/Walmart

IMB, KPMG, Merck, Walmart's DSCSA Blockchain interoperability Pilot focused on studying blockchain's effectiveness for tracing prescription drugs and vaccines. The pilot was designed to allow for rapid alerts between trading partners if a medication recall were to occur. In assessing the suitability for a blockchain technology solution to meet the 2023 DSCSA interoperability requirements, the pilot was designed to test whether a blockchain solution could: (1) provide a common record of product movement by connecting disparate systems and organizations in a secure way; and (2) improve patient safety by triggering product alerts and increasing visibility to relevant supply chain partners in the event of a product investigation or recall. Following the conclusion of the pilot, it was determined that blockchain was successful in meeting the goals of the pilot. The participants also state that to foster industry adoption, an egalitarian, inclusive, open-sourced commercial solution should be considered to help launch a blockchain network intended for information exchange of the pharmaceutical product transactions in the United States. The full pilot report can be accessed here.

Rymedi

Rymedi's pilot project entitled, *DSCSA Implementation in Intra and Inter Healthcare System Medicine Transfers* focused on determining the feasibility of blockchain and IoT technology to monitor specialty medication transfers by integrating quality management systems and real-world evidence. The pilot project found that there is promise of QMS-RWE integration for learning health systems, challenges remain in adoption of quality tracking to patient use, value remains in stepwise change management for manufacturers and trading partners, and there is ease with permissions management and data rights standards.

Franciscan Missionaries of Our Lady Health System (FMOLHS)

FMOLHS' pilot program entitled, *DSCSA Verification to Improve Product Traceability at FMOL Health System* was done in collaboration with McKesson and ConsortiEx. The pilot was focused on automating delivery and confirmation that dispensers have valid T3 for each product received from trading partners and capturing and achieving perfect order via electronic data interchange (EDI) and automatic identification and data capture (AIDC) for a touch-less process from trading partners through pharmacy receiving areas. It was found that the EDI process flow is complex, and EDI is not the same and could not be repurposed. Following the pilot, ConsortiEx found that additional work is needed to get to an ideal state and there is a need for better communication across supply chain partners. McKesson found that there are challenges with pulling data on the same product from different systems, which highlighted the immature state of harmonization and the need for indexes to be aligned. FMOLHS continues to look for partners to work on the completion of: (1) perfect order touchless 3-way match with bar code scanning at receipt (Advance Ship Notice EDI 856 plus PO Ack EDI 855 drop shipments match pharmacy barcode scans creating Order Receipt EDI 861); and (2) push scan of DSCSA Product Identifier, Lot Number, Expiration Date and Serial Number to inventory system and point-of-care cabinets.

LSPediA

LSPediA's pilot project entitled, *Router Service Solution for Verification/Notification and Interoperability 2023* focused on utilizing LSPediA's OneScan solution for verification, notification, and interoperability and was done in collaboration with over 11 organizations across the pharmaceutical supply chain. The pilot was successful in (1) verifying over 20,000 packages; (2) garnering broad participation across the supply chain; (3) completing 10 verification scenarios covering returns, positive, negative, recall, suspect, counterfeit, illegitimate, theft, fraud, and phishing; and (4) piloting interoperability via Router Service instead of traditional EPCIS data exchange via AS2 connections. It was determined that existing technology (Router Service Network, OneScan solution) can be used for verification and 2023 interoperability. However, despite the success of the pilot, it was noted that supply chain improvement is needed. The full pilot report can be accessed here.

The Optimal Solution

The Optimal Solution pilot was developed in partnership with Systech, RxTransparent, FarmaTrust, T-Systems, Cryptowerk, and CalQLogic. The pilot was designed to test a solution to meet DSCSA 2023 requirements by (1) utilizing a digital e-Fingerprint layer of security to create an immutable track and trace ledger that improves visibility and enhances counterfeiting detection at the product level; (2) capturing the Internet of Things (IOT) and Cold Chain information to leverage data for additional consumer insight and analytics; and (3) deploying blockchain as the infrastructure to enable interoperability. The pilot was successful in demonstrating the ability of the blockchain technology to meet DSCSA 2023 requirements.