U.S. FOOD & DRUG ADMINISTRATION

Drug Supply Chain Security Act Pilot Project Program

Final Program Report

May 2023

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I. EXECUTIVE SUMMARY

The Drug Supply Chain Security Act (DSCSA) directs FDA to establish one or more pilot projects to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.[1] To accomplish this, FDA established the DSCSA Pilot Project Program on February 8, 2019, to help FDA and members of the pharmaceutical distribution supply chain understand the technical capabilities of the supply chain and to assist with identifying system attributes that are necessary to implement the requirements established under the DSCSA to identify and trace certain prescription drugs as they are distributed within the United States. Specific program goals included (1) identifying the system attributes needed to implement the requirements of section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), particularly the requirement to utilize a product identifier for product tracing and verification purposes and (2) assessing the ability of supply chain members to (a) satisfy the requirements of section 582 of the FD&C Act; (b) identify, manage, and prevent the distribution of suspect and illegitimate products as defined in section 581(21) and 581(8) of the FD&C Act, respectively; and (c) exchange product tracing information across the pharmaceutical distribution supply chain in an electronic and interoperable manner. Twenty industry-led pilot projects were selected to participate in the program. Pilot projects started in May 2019 and were completed by June 2020. This is the final program report for the DSCSA Pilot Project Program.

[1] See section 582(j) of the FD&C Act.

II. CONSIDERATIONS FOR THE READER

A. Selection

Selection for the DSCSA Pilot Project Program should not be interpreted as FDA's position on an entity's compliance with regulatory requirements or an endorsement of a particular technology, system, or other approach used in the pilot projects. Under this program, FDA worked with the selected participants to explore and evaluate methods to enhance safety and security of the pharmaceutical supply chain. FDA intends to use this information to inform implementation of the DSCSA.

B. Definitions and Terms

The DSCSA added new statutory definitions[2] which, along with other pertinent terms in the FD&C Act, support the requirements in sections 582, 583, 584, and 585 of the FD&C Act. FDA has also published several guidances[3] to assist industry in understanding terminology and the requirements of the DSCSA. Some program participants have used terms familiar to themselves or commonly used in the industry (referred to as "alternate terms") in place of the terms defined or used in the statute. For portions of this report that were written by FDA, statutory definitions were used as appropriate. Table 1 lists alternate terms used by program participants in their reports provided to FDA that relate to terms used in the statute. A compiled list of acronyms and terms used and provided by program participants is also provided in Appendix A.[4] Inclusion of terms used by program participants in Table 1 and Appendix A in this report are intended to provide clarification but should not be taken as FDA's validation of a trading partner's status or role, nor as FDA's interpretation or endorsement of the use of an alternate term, specific technology, or approach. In addition, FDA has elected not to change the alternate terms used by the program participant(s) in the brief descriptions of each pilot project in Appendix C.

[2] See section 581 of the FD&C Act.

[3] Current DSCSA-related guidances for industry can be found at: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies.

[4] See Appendix A — Acronyms and Terms used in Project Reports for acronyms and terms used and provided by the pilot projects participants in their respective reports.

Table 1. DSCSA Terms and Alternate Terms Used in Pilot Project Reports

DSCSA Term	Alternate Terms in Pilot Project Reports
Entity	
Dispenser	Pharmacy, Hospital, Clinic
Manufacturer	Market Authorization Holder, Virtual Manufacturer
Repackager	(No alternate terms found)
Returns Processor or Reverse Logistics Provider	(No alternate terms found)
Third-Party Logistics Provider	3PL
Trading Partner	TP, Company
The Secretary	The FDA
Wholesale Distributor	Wholesaler, Distributor
Third Party	Solution Provider, Solutions, Systems, VRS Providers
Other	
2-Dimensional Data Matrix Barcode	2D data matrix barcode, 2D DataMatrix, GS1 DataMatrix
National Drug Code or NDC	GS1 GTIN (Global Trade Item Number)[1]
Package or Individual Saleable Unit	Serialized Package, Drug Package, Lowest Saleable Unit, Eaches
Prescription Drug	Drug
Product Identifier	PI[1]
Standardized Numerical Identifier	SNI, Serialized GTIN, SGTIN, sGTIN[2]
Transaction Information	TI
Transaction History	TH
Transaction Statement	TS
Transaction Information, Transaction Statement and Transaction History	T3, TI/TS/TH
Transaction Information and Transaction Statement	TI/TS
Verification or Verify	Product Information Verification, PI Verification

[1]The product identifier is defined under section 581(14) of the FD&C Act as a standardized graphic that includes the product's standardized numerical identifier (composed of the National Drug Code [NDC] and a unique alphanumeric serial number), lot number, and expiration date, in both human- and machine-readable formats. The machine-readable format must be on a data carrier that conforms to the standards developed by a widely recognized international standards development organization. The machine-readable format of the product identifier is required under section 582(a)(9) of the FD&C Act to be in a "2-dimensional data matrix barcode" for packages and in a "linear or 2-dimensional data matrix barcode" for homogenous cases, and verification of the product identifier can occur using "human-readable or machine-readable methods." With respect to product identifier, section 582(a)(9) of the FD&C Act authorizes FDA to allow for the use of other technologies for the data by specifying them in guidance. FDA has not issued such guidance. Therefore, the current requirement is for the product identifier to be in a 2D data matrix barcode for packages and a linear or 2D data matrix barcode for homogenous cases.

Regarding the machine-readable portion of the product identifier, the 2D data matrix barcode, FDA understands that many companies utilize the GS1 Global Trade Item Number (GTIN) to encode the NDC into the 2D data matrix barcode. FDA views this practice as satisfying the requirement for a machine-readable NDC in product identifiers. (See FDA's Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers, Question 5.) As such, many of the pilot projects in this program focused on the use of the 2D data matrix barcode of the product identifier (e.g., processes involving scanning the barcode) and used the term "GTIN" instead of the term "NDC" in their reports. For this program report, we have not changed or modified the use of the term GTIN by pilot project participants; however, we note that a product GTIN and NDC are not the same in total number of characters or format. Specifically, the GTIN in its human-readable format contains additional digits and does not present the NDC in its traditional three-segment format.

[2]The standardized numerical identifier is defined under section 581(20) of the FD&C Act as a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the NDC that corresponds to the specific product combined with the unique alphanumerical serial number of up to 20 characters. The standardized numerical identifier is often abbreviated as SNI. Trading partners may use the GS1 GTIN to encode the NDC into the 2D data matrix barcode. Therefore, some program participants have used the term "GTIN" instead of the term "NDC" in their reports when referring to the NDC portion of the SNI. In addition, some may have used the terms "serialized GTIN," "SGTIN," or "sGTIN" when referring to the SNI. For this program report, we have not changed or modified the use of the terms GTIN, serialized GTIN, SGTIN, or sGTIN by pilot project participants; however, a product GTIN and NDC are not the same in total number of characters or format. Therefore, a serialized GTIN/SGTIN/sGTIN is not the same in the total number of characters and format as the SNI, in part due to the NDC portion of the standardized numerical identifier compared with the GTIN portion of a serialized GTIN.

C. Tables and Figures

Summary tables and figures in this program report were created by FDA. The tables and figures included in individual pilot project final reports that are posted on FDA's DSCSA Pilot Project Program website were created by the pilot project participants and provided to FDA as part of this program. FDA did not change or alter any tables and figures created by pilot project participants.

D. Final Pilot Project Reports by Program Participants

After completion of each pilot project, each program participant created and provided a final pilot project report to FDA as part of this program. FDA has posted the individual final reports on FDA's DSCSA Pilot Project Program webpage to make the reports publicly available to all interested stakeholders. To maintain the integrity and intent of the participant-led projects, FDA did not change or alter the content of any program participant pilot project reports. Some final pilot project reports may contain specific opinions or recommendations that represent the program participant's perspective(s) and do not represent any FDA position or interpretation.

III. PROGRAM DESCRIPTION

FDA established the DSCSA Pilot Project Program on February 8, 2019, to assist members of the pharmaceutical distribution supply chain, including FDA, in developing the electronic, interoperable system that will identify and trace certain prescription drugs as they are distributed within the United States. Specific program goals included (1) identifying the system attributes needed to implement the requirements of section 582 of the FD&C Act, particularly the requirement to utilize a product identifier for product tracing and verification purposes, and (2) assessing the ability of supply chain members to (a) satisfy the requirements of section 582 of the FD&C Act, (b) identify, manage, and prevent the distribution of suspect and illegitimate products as defined in section 581(21) and 581(8) of the FD&C Act, respectively, and (c) exchange product tracing information across the pharmaceutical distribution supply chain in an electronic and interoperable manner.

Development of the program included several steps to obtain stakeholder input to help ensure the program's utility to FDA and the pharmaceutical distribution supply chain. In accordance with section 582(j) of the FD&C Act, FDA announced the Proposed Pilot Project(s) Under the Drug Supply Chain Security Act; Public Workshop; Request for Comments on February 16, 2016. Seeking stakeholder input, FDA held this public workshop on April 5–6, 2016, to provide a forum for stakeholders to discuss proposed design objectives of pilot projects that would explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. The information gathered from the workshop and the public comments submitted to the docket further informed FDA's development of pilot project focus areas and the DSCSA Pilot Project Program.

FDA accepted requests to participate in the program from February 8, 2019, until March 11, 2019. The Federal Register notice from February 8, 2019, explained how FDA would work with stakeholders to establish one or more pilot

projects to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain and what information should be submitted with a request to participate in the program. Participation was open to all pharmaceutical distribution supply chain members; this included manufacturers, repackagers, wholesale distributors, dispensers, third-party logistics providers (3PLs), solution providers, and other stakeholders. Each participant that was selected into the program was responsible for conducting their pilot project, including coordination amongst partnering entities (if applicable) and supplying all funding and resources necessary to conduct each pilot project. Of the 38 proposals and requests to participate, FDA selected 20 projects that represented the diversity of the supply chain including large and small entities from all industry sectors and a variety of focus areas. FDA worked with the program participants as they transitioned from proposals through project planning and execution of their respective pilot projects.

Subsequently, FDA held design strategy meetings on May 8–9, 2019, with each participant (including partnering entities) at FDA's White Oak campus in Silver Spring, Maryland. The purpose of these meetings was to allow the participant to formally present their pilot project including goals, objectives, evaluation methods and finalized details of the project. In addition, it gave FDA the opportunity to ask clarifying questions to better understand the project. A schedule for progress reports based on the nature and duration of the project was also established for each participant.

Pre-launch meetings with each participant were held in May and June of 2019 to refine any outstanding issues from the design strategy meetings and to confirm the progress reports schedule. These meetings also gave program participants and FDA another opportunity to discuss plans before the start of the pilot project.

In addition to the monthly progress reports that were submitted by each program participant, a mid-point call with each program participant was held during November 2019. The mid-point calls were an opportunity for participants to provide an update on the status of their pilot project and discuss any comments or issues with FDA that could affect completion for the participant's project. At the end of each pilot project, the participants provided final reports that FDA reviewed for gross errors in how participants framed statutory requirements. FDA requested clarifications from pilot participants as needed. FDA held participant-only meetings on June 24 and 25, 2020, where each DSCSA Pilot Project Program participant could share a summary of their project, including their goals, results, and lessons learned, with FDA and all other program participants.

On December 8–9, 2020, FDA held a virtual public meeting to provide members of the pharmaceutical distribution supply chain and other stakeholders an opportunity to provide input on strategies and issues related to enhanced drug distribution security and discuss results from FDA's DSCSA Pilot Project Program.[5] Sixteen of the 20 program participants presented summaries of their pilot project on the first day of the public meeting. To allow interested parties additional time to submit comments to the public docket for the topics covered at this public meeting, FDA reopened the comment period for an additional 90 days. FDA will consider public comments in its DSCSA implementation efforts, focusing on the requirements that go into effect in November 2023.

This report summarizes FDA's DSCSA Pilot Project Program and participant pilot projects, including the technologies and business or operational processes addressed and the relationship to enhanced drug distribution security requirements.

[5] See FDA's webpage for this public meeting: https://www.fda.gov/drugs/news-events-human-drugs/drug-supply-chain-security-act-pilot-project-program-and-enhanced-drug-distribution-security#event-information.

IV. PROGRAM MILESTONES

FDA's DSCSA Pilot Project Program was established on February 8, 2019, with many of the projects starting in May and June of 2019. Although a few projects finished sooner, all twenty pilot projects were completed by June 2020. The program will be considered complete after FDA's public issuance of this final program report. Table 2 outlines significant milestones achieved throughout the program development and implementation.

Table 2. FDA DSCSA Pilot Project Program Milestones

Date	Milestone
February 16, 2016	Public workshop on proposed pilot projects under DSCSA announced[6]
April 5–6, 2016	Public workshop conducted on proposed pilot projects
April 15, 2016	Request for information related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, and identifying system attributes that are necessary to implement the DSCSA requirements[7]
April 28, 2017	Reopening of comment period until April 30, 2018, for information related to pilot projects utilizing the product identifier for DSCSA requirements[8]
July 20, 2017	Proposed pilot project program announced — 60-day comment period[9]
May 11, 2018	Office of Management and Budget review — 30-day comment period[10]
February 8, 2019	FDA's DSCSA Pilot Project Program announcement[11] and establishment Program enrollment period starts
March 24, 2019	Pilot projects participants selected
May 8–9, 2019	Pilot projects design strategy meetings
May–June, 2019	Pilot projects pre-launch meetings
June 1, 2019	Monthly pilot projects progress reports begin
July 3, 2019	Reopening of comment period until June 28, 2022, for information related to pilot projects utilizing the product identifier for DSCSA requirements[12]
October 29 & November 14, 2019	Pilot projects mid-point calls
May–June, 2020	Pilot projects conclude and final pilot project reports submitted
June 24–25, 2020	Program participant meeting, presentations of project summaries
October 28, 2020	The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting announced[13]
December 8–9, 2020	FDA public meeting conducted on the Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security
March 24, 2021	Reopening of the comment period until June 22, 2021, for the public meeting held on December 8–9, 2020[14]

[6] See 81 FR 7807.
[7] See 81 FR 22279.
[8] See 82 FR 19737.
[9] See 82 FR 33497.
[10] See 83 FR 22085.
[11] See 84 FR 2879.
[12] See 84 FR 31874.
[13] See 85 FR 68342.
[14] See 86 FR 15685.

V. PROGRAM PARTICIPANTS AND PILOT PROJECTS

Table 3 lists selected program participants in alphabetical order by the project leads (i.e., main point of contact) and the pilot project title. Some of the pilot projects have partnering entities that are not listed in Table 3 but are provided in pilot project summaries in Appendix C as the entities were identified and reported by the program participant.

Table 3. Selected Program Participants for FDA's DSCSA Pilot Project Program

Project Lead	Pilot Project Title
AmerisourceBergen/Xavier Health	AmerisourceBergen Xavier Health DSCSA Serialization End-to-End Proof of Concept Pilot
Cardinal Health	Interoperability Data Exchange Errors and Exception Handling
Franciscan Missionaries of Our Lady Health System (FMOLHS)	DSCSA Verification to Improve Product Traceability at FMOL Health System
GS1 US	Barcode Readability for DSCSA 2023 Interoperability
IBM/KPMG/Merck/Walmart	DSCSA Blockchain Interoperability Pilot
ICON INDICES	Web 3.0 Based on Identifier System, An Autonomous System for Electronic Tracing of Product for Pharmaceutical
IDLogiq	IDLogiq 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
Kit Check and Sandoz	Analyzing gaps and addressing key concerns and testing key concepts relating to the 2023 DSCSA requirements by utilizing and adapting existing commercial methods and technologies
LSPediA	Router Service Solution for Verification/Notification and Interoperability 2023
MediLedger	MediLedger DSCSA Pilot
Optel	Improved end-to-end drug supply chain traceability with OPTEL's Intelligent Supply Chain™ technologies
The Optimal Solution	The Optimal Solution DSCSA Pilot Project Industry Blueprint
Partnership for DSCSA Governance (PDG)	PDG Governance Pilot Project
PriMed Pharmaceuticals	Secondary Wholesaler Challenges During Implementation of DSCSA Required Track & Trace Platforms
Providence Health Technologies (PHT)	Small Dispenser Pilot Study
rfxcel	Pilot to Measure VRS Readiness
Rymedi	DSCSA Implementation in Intra and Inter Healthcare System Medicine Transfers
Sanofi	Product Identifier Verifications by a Contract Manufacturer on behalf of a Marketing Authorization Holder
TraceLink	DSCSA 2023 Traceability with Blockchain/Distributed Ledgers and Digital Recalls Network Pilots
UCLA Health	UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology

A. Stakeholder Types

Table 4 lists the general stakeholder types that are included in each respective pilot project as the project lead or partnering entities. Specific partnering entities and quantities are not listed in Table 4, however, a full list of partnering entities is included with each respective pilot project summary in Appendix C — Individual Pilot Project Summaries and may also be found in respective final reports on FDA's DSCSA Pilot Project Program webpage. In some cases, an entity may have acted as multiple stakeholders or some trading partner(s) or respective functions were simulated as part of the pilot project.

Table 4. Stakeholder Type Represented by Each Pilot Project

Project Lead	Stakeholder Type							
	Manufacturer	Repackager	Wholesale Distributor	3PL	Dispenser	Solution Provider	Returns Processor	Standards Organization
Amerisource Bergen/Xavier Health	✓	✓	✓	✓	✓	✓		
Cardinal Health	✓	✓	✓	✓		✓		
Franciscan Missionaries of Our Lady Health System (FMOLHS)			✓		✓	✓		
GS1 US			✓					✓
IBM/KPMG/ Merck/Walmart	✓				✓	✓		
ICON INDICES						✓		
IDLogiq	✓	✓	✓		✓	✓		
Kit Check	✓				✓	✓		
LSPediA	✓		✓		✓	✓		
MediLedger	✓		✓	✓	✓	✓		
Optel	✓		✓		✓	✓		
Optimal Solution						✓		
Partnership for DSC-SA Governance (PDG)	✓		✓		✓	✓		
PriMed Pharmaceuticals			✓					
Providence Health Technologies (PHT)					✓	✓		
rfxcel						✓		
Rymedi					✓	✓		
Sanofi	✓		✓			✓		
TraceLink	✓		✓	✓	✓	✓	✓	
UCLA Health					✓	✓		

Abbreviation: 3PL = third-party logistics provider.

B. Technologies Addressed

Table 5 shows the main technologies addressed across the pilot projects. The level of focus varied among pilot projects and was dependent on respective goals and objectives. A description of the terms used for the technologies listed in Table 5 can be found in Appendix A — Acronyms and Terms Used in Project Reports.

Table 5. Technologies Addressed by Each Pilot Project

Pilot Project	Technology													
	2D Data Matrix Barcode	Barcode Scanners	EDI	GS1 EPCIS Events	Vendor Systems Matching Transactional Information to Scanned Barcodes	Blockchain	RFID or NFC	Internet of Things (Digitally Connected Sensors)	Chemical Temperature Indicator Enhanced 2D Data Matrix Barcode	Industry VRS	zk-SNARKs	APIs and DNS	Artificial Intelligence
Amerisource Bergen/Xavier Health	✓	✓		✓	✓								
Cardinal Health				✓	✓								
Franciscan Missionaries of Our Lady Health System (FMOLHS)	✓	✓	✓										
GS1 US	✓	✓											
IBM/KPMG/ Merck/Walmart				✓		✓							
ICON INDICES	✓				✓								
IDLogiq	✓	✓				✓	✓						
Kit Check							✓						
LSPediA	✓									✓			
MediLedger				✓		✓					✓	✓	
Optel	✓			✓									
Optimal Solution	✓			✓				✓				✓	
PDG	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
PriMed Pharmaceuticals										✓			
Providence Health Technologies	✓	✓	✓										
rfxcel										✓			
Rymedi						✓		✓	✓				✓
Sanofi	✓									✓			
TraceLink				✓		✓							
UCLA Health	✓	✓				✓							

Abbreviations: API = application program interface, DNS = domain name system, EDI = electronic data interchange, EPCIS = electroic product code information services, NFC = near field communication, RFID = radio frequency identification tags, VRS = verification router system, zk-SNARKS = zero-knowledge succinct non-interactive argument of knowledge.

C. Operational Processes Addressed

Table 6 shows the operational processes addressed across the pilot projects.
The level of focus varied among projects and was dependent on the particular goals and objectives of the pilot project.

Table 6. Operational Processes Addressed by Pilot Projects

Pilot Project	Operational Process															
	Quality Assurance	Authorized Trading Partner Determination	Production (product marking)	Packing (Aggrega-tion)	Shipping	Receiving	Unpacking (Disaggregation)	Matching and Reconciliation	Dispensing	Returns	Product Identi-fier Verification	Suspect and Illegitimate Product Procedures	Product Quarantine	Notification	Recall	Manufacturer Mergers and Acquisitions (Transfer of Inventory Ownership)
Amerisource Bergen/Xavier Health			✓	✓	✓	✓	✓	✓								
Cardinal Health						✓		✓		✓						
Franciscan Missionaries of Our Lady Health System (FMOLHS)					✓	✓										
GS1 US	✓															
IBM/KPMG/ Merck/Walmart					✓	✓			✓		✓	✓			✓	
ICON INDICES				✓	✓	✓	✓	✓								
IDLogiq				✓	✓		✓		✓		✓					
Kit Check			✓	✓	✓	✓	✓									
LSPediA										✓		✓		✓		
MediLedger					✓	✓		✓			✓					
Optel			✓	✓	✓	✓										
Optimal Solution					✓	✓					✓					
PDG		✓														
PriMed Pharmaceuticals										✓	✓					
Providence Health Technologies						✓							✓			
rfxcel										✓	✓					
Rymedi	✓					✓										
Sanofi										✓	✓					✓
TraceLink		✓													✓	
UCLA Health						✓	✓				✓			✓		

D. Enhanced Drug Distribution Security Requirements

Section 582(g)(1) of the FD&C Act outlines requirements for enhanced drug distribution security that go into effect on November 27, 2023.[15] These requirements enable the interoperable, electronic tracing of product at the package level[16] and provide foundational concepts to consider for this pilot project program. The program goals of (1) identifying the system attributes needed to implement the requirements of section 582 of the FD&C Act, particularly the requirement to utilize a product identifier for product tracing and verification purposes and (2) assessing the ability of supply chain members to satisfy the requirements of section 582 of the FD&C Act, support DSCSA implementation efforts. Although the enhanced drug distribution security requirements are highlighted below, they should be read in conjunction with other relevant provisions of the law (i.e., sections 581 and 582 of the FD&C Act).

Section 582(g)(1)(A)-(F) of the FD&C Act

(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.

(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

(C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary.

(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required—

[15] See section 582(g)(1) of the FD&C Act.
[16] The phrases "package level" and "unit level" are both used in the DSCSA and should be considered synonymous.

(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or

(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

E. Pilot Project Focus Areas[17]

The DSCSA Pilot Project Program announcement[18] outlined a number of potential issues or focus areas for pilot projects to examine. Table 7 references the primary focus area(s) each pilot project addressed that was identified by the program participants. A focus area was considered addressed by a project if the project included evaluation methods or evaluation metrics for that focus area. Pilot projects that addressed other focus areas that were not listed in the program announcement scenarios are shown in Table 8, some of which may be outside of specific requirements in section 582 of the FD&C Act. The information summarized in Tables 7 and 8 is for analysis and learning purposes and should not be interpreted as an assessment of the participant's compliance with regulatory requirements.

Table 7. Summary of Pilot Projects Focus Areas

Pilot Project	Pilot Program Focus Area							
	Product Identifier	Barcode Quality	Interoperability	Data, Database, and Systems	Aggregation and Disaggregation	Verification and Notification	Exception Handling, Errors, and Inconsistencies	Other Focus Areas
Amerisource Bergen/Xavier Health		✓	✓		✓			
Cardinal Health			✓		✓		✓	
Franciscan Missionaries of Our Lady Health System (FMOLHS)			✓					✓
GS1 US	✓	✓	✓					
IBM/KPMG/ Merck/Walmart	✓		✓	✓		✓		✓
ICON INDICES	✓							
IDLogiq	✓		✓		✓			✓
Kit Check	✓	✓	✓	✓	✓	✓		✓
LSPediA	✓	✓	✓		✓	✓	✓	
MediLedger	✓		✓	✓		✓	✓	
Optel	✓		✓		✓			✓
Optimal Solution			✓					
PDG			✓			✓		✓
PriMed Pharmaceuticals						✓		
Providence Health Technologies	✓	✓	✓					✓
rfxcel	✓			✓		✓	✓	
Rymedi	✓	✓	✓	✓				✓
Sanofi	✓		✓			✓		
TraceLink			✓	✓		✓	✓	✓
UCLA Health	✓	✓	✓	✓		✓		

[17] See Appendix B — Potential Focus Areas and Methods for Pilot Projects published in the DSCSA Pilot Project Program Announcement.
[18] See 84 FR 2879.

Table 8. Other Focus Areas Addressed by the Pilot Projects

Pilot Project	Special Scenario and Other Focus Areas
Franciscan Missionaries of Our Lady Health System (FMOLHS)	Perfect order processing
IBM/KPMG/Merck/Walmart	Recalls at lot level
IDLogiq	Dispensing
Kit Check	Unit dose tracking
Optel	Effect of sampling and product destruction on packing accuracy
PDG	Determination of DSCSA "Authorized" status
Providence Health Technologies (PHT)	DSCSA awareness among small dispensers
Rymedi	Temperature sensitive 2D DataMatrix barcodes to monitor temperature excursions
TraceLink	Recalls
UCLA Health	Tracking within a healthcare system, including dispensing and administration

VI. GENERAL LESSONS LEARNED

The pilot projects of this program represent examples of significant thought, planning, and execution by trading partners and other stakeholders in the pharmaceutical distribution supply chain. These pilot projects explored and evaluated methods to enhance the safety and security of the pharmaceutical distribution supply chain. The goals and objectives of the pilot projects covered several topics or issues focusing on statutory requirements, but also some projects considered value-added processes changes. Many pilot projects covered multiple topics or issues. Topics or issues covered include but are not limited to interoperability, systems and processes for product tracing, verification, serialization and notification, data quality and management, aggregation, exceptions handling, barcode quality, governance, technologies, and implementation. For specific details of each pilot project, including results and lessons learned, refer to the individual pilot project final reports found on FDA's DSCSA Pilot Project Program webpage. General lessons learned from the program are summarized in the following sections.

A. Interoperability Strategies

- Some pilot projects demonstrated interoperability by using a single solution in a centralized manner that trading partners would use to exchange information. Other pilot projects demonstrated interoperability by using a range of solutions for which the interfaces between those solutions enabled exchange of information between trading partners in a decentralized manner. There may be scenarios that involve data exchange in both centralized and decentralized manners.
- Cooperation from trading partners and other stakeholders (e.g., solution providers) will help to achieve interoperability.
- Trading partners and stakeholders should consider how to balance supply chain transparency and security of the data.

B. Standardization

- Although there are many options for the types of approaches or solutions for product tracing and verification, standardization is important to facilitate interoperability.
- Specifically, standardizing the data that is provided, maintained, and received is desired, including how the data is defined and organized. This includes standardizing requests for data and responses to such requests.
- Standardizing certain processes would also be helpful to the supply chain. For example, standardizing how trading partners respond to verification requests from another trading partner may provide efficiencies and understanding between trading partners.
- Certain business practices, including those which may not be specified by the law, could also be standardized to help with supply chain management. For example, standardizing how trading partners handle exceptions (e.g., overages or clerical errors in documentation) may provide efficiencies and clarity between trading partners.

C. Systems

- System modification may result as a trading partner's existing system is upgraded or combined with a new system component.
- Resolving information technology (IT) issues to address operational issues, such as exceptions handling, will be important for successful implementation.

D. Processes

- Although more automation will be integrated into new processes, in some cases, there may be a need for certain manual processes.
- To use the product identifier for product tracing and verification under the enhanced drug distribution security requirements, trading partners should expect changes to some business or operational processes.

E. Data Quality and Management

- The integrity and standardization of the master data for a product is critical.
- Trading partners would benefit from having access to the same master data. This may be a way to support standardization of how the data is used and reduce errors and confusion.

F. Technology

- The number and quality the 2D data matrix barcodes encoded on products in the supply chain with the product identifier required by DSCSA continues to increase.
- Other data carriers and methods to transfer data exist and could be leveraged for supply chain security and other uses (e.g., radio frequency identification [RFID] tags, blockchain).

G. Governance

- A governance body for DSCSA implementation can support trading partners and stakeholder needs, including one that is industry led.
- The structure should ensure communication and discussion of issues across all workgroups.

H. Implementation Issues

- Trading partners should allow for sufficient time needed to onboard suppliers and customers.
- Trading partners should plan for technical issues with establishing direct and indirect (i.e., using a third-party vendor or solution provider) connectivity (involving communications and data transfer) with other trading partners.
- Trading partners should conduct testing, particularly connectivity, with suppliers and customers (prior live operations and in some scenarios, during live operations may be beneficial).
- Challenges will exist when scaling up and operationalizing new systems and processes operations.
- Trading partners should anticipate training of staff to ensure smooth and efficient implementation and workflow integration.
- Small-sized companies may experience additional challenges including potential costs for system changes, upgrades and maintenance.

I. Industry Progress

The pilot projects demonstrated significant industry progress in support of FDA's DSCSA implementation, including the statutory requirements under section 582(j) of the FD&C Act to consider information from pilot projects in the development of guidances for unit-level tracing and standards for the interoperable data exchange under section 582(h)(3) and (4) of the FD&C Act.

VII. PROGRAM SUMMARY AND NEXT STEPS

FDA is using the results and experiences from the pilot projects under this program to inform implementation of DSCSA requirements. However this program report should not be viewed as FDA's endorsement of a particular technology, system, or approach used in the pilot projects. FDA regulations provide FDA's policies and procedures for developing, issuing, and using guidance documents that provide recommendations or interpretations on regulatory issues to stakeholders.[19] These regulations state that FDA will generally provide notice of a draft guidance and opportunity for public comments by stakeholders before preparing and issuing a final guidance document.[20] FDA will continue to utilize guidance documents to provide recommendations or interpretations related to DSCSA requirements.

[19] 21 CFR 10.115.
[20] 21 CFR 10.115(g).

FDA's DSCSA Pilot Project Program met its goals by:

- Including a range of pilot projects that explored the use of the product identifier for product tracing and various other enhanced drug distribution security requirements.
- Representing different sectors of the supply chain and respective challenges and expertise.
- Identifying the system attributes needed to implement the enhanced drug distribution security requirements.
- Assessing the ability of supply chain members to satisfy the enhanced drug distribution security requirements.

This program report includes summaries of participant findings and lessons learned in Appendix C — Individual Pilot Project Summaries. The full reports from pilot project participants are not included in this program report but are available on FDA's website at DSCSA Pilot Project Program.

VIII. APPENDIX A — ACRONYMS AND TERMS USED IN PROJECT REPORTS

Table 9 lists and describes acronyms and terms that the pilot project participants used and how they defined the acronyms and terms within the context of their respective pilot projects. The acronyms and terms may not have the same meaning as DSCSA definitions. This table does not include or represent DSCSA definitions.

Table 9. Acronyms and Terms Used in Project Reports

Acronym/Term	Definition	Pilot Project
ABDC	AmerisourceBergen Drug Comp	AmerisourceBergen/Xavier Health
ABSG	AmerisourceBergen Specialty Group	AmerisourceBergen/Xavier Health
Aggregation	The electronic linkage of "child" serial numbers to a "parent" serial number (e.g. unit serial numbers linked to case serial number, case serial numbers linked to pallet serial number), which is used for efficient assignment of serial numbers.	IBM/KPMG/Merck/Walmart
AI	Application Identifier: a field (typically two digits) at the beginning of a data string that uniquely defines the meaning and the format of the data that follows.	IBM/KPMG/Merck/Walmart
API	Application Program Interface: a set of routines, protocols, and tools for building software applications and integrating disparate software systems.	IBM/KPMG/Merck/Walmart LSPediA MediLedger
ASN	Advance Shipment Notice	Franciscan Missionaries of Our Lady Health System (FMOLHS)
ATP	Authorized Trading Partner	
Authenticate	The practice of checking a Unique Identifier against a set of captured serialized data to determine its authenticity.	LSPediA
CCoC	Confidential Change of Ownership	MediLedger
CMO	Contract Manufacturing Organization, Contract Manufacturer	Sanofi
CPO	Contract Packaging Organization	Cardinal Health
Connection Information	A general term used in this document to refer to the technical information (e.g. end-point URL, security certificates, authentication parameters) needed to establish connection with the responder's repository.	LSPediA
CRM	Customer Relationship Management System	Optimal Solution

Customer Container	The lowest level container that is delivered to the customer or used for an internal transfer order. These may be cardboard boxes, or plastic totes. These may also be aggregated to high level logistic containers such as pallets or air freight containers.	AmerisourceBergen/Xavier Health
Data Matrix	A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. DataMatrix symbols are read by two-dimensional imaging scanners or vision systems.	IBM/KPMG/Merck/Walmart
Data Owner	A trade organization that is an owner of, or has control of, a data pool.	Optimal Solution
Data Pool	A set of data representative of drug supply chain transactions in a data store hosted by a service provider or trade organization.	Optimal Solution
DC	Distribution Center	AmerisourceBergen/Xavier Health
DEA	Drug Enforcement Agency	MediLedger
Dispenser	An entity in the pharmaceutical supply chain, also referred to as a Pharmacy, which is authorized by law to dispense or administer prescription drugs.	IBM/KPMG/Merck/Walmart
DQSA	Drug Quality and Security Act	AmerisourceBergen/Xavier Health IBM/KPMG/Merck/Walmart
DSCSA	Drug Supply Chain Security Act, Title II of the DQSA	Multiple
DNS	Domain Name System	Optimal Solution
EDI	Electronic Data Interchange	Franciscan Missionaries of Our Lady Health System (FMOLHS)
EPC	Electronic Product Code (GS1)	Kit Check
Electronic Product Code Information Services (EPCIS)	EPCIS is a GS1 EPC global standard designed to enable EPC-related data sharing within and across enterprises. This data sharing is aimed at enabling participants in the EPC global network to obtain a common view of the disposition of EPC-bearing objects within a business context. See www.gs1.org/epcglobal.	LSPediA
Electronic Product Code Information Services (EPCIS)	EPCIS is a GS1 data set for sharing event data between trading partners. EPCIS is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain — from business to business and ultimately to consumers.	AmerisourceBergen/Xavier Health IBM/KPMG/Merck/Walmart
Enterprise Resource Planning (ERP)	ERP is the integrated management of main business processes, often in real time and mediated by software and technology. ERP is usually referred to as a category of business management software—typically a suite of integrated applications—that an organization can use to collect, store, manage, and interpret data from many business activities. ERP provides an integrated and continuously updated view of core business processes using common databases maintained by a database management system. ERP systems track business resources—cash, raw materials, production capacity—and the status of business commitments: orders, purchase orders, and payroll.	Optimal Solution and PriMed
Expiry	Date of expiration or the last day the item should be used.	LSPediA
FDA	Food and Drug Administration	Multiple
FDC	Forward Distribution Center: the distribution center that handles the forward distribution to all of customers. FDCs can receive products from the NDC (ABDC) as well as directly from manufacturers.	AmerisourceBergen/Xavier Health
GCP	Global Company Prefix: a unique GS1 identification code for your company obtained through GS1.	LSPediA rfxcel Sanofi
GLN	Global Location Number: part of the GS1 systems of standards. It is a simple tool used to identify a location and can identify locations uniquely where required. The GS1 Identification Key is used to identify physical locations or legal entities.	AmerisourceBergen/Xavier Health IBM/KPMG/Merck/Walmart LSPediA rfxcel Sanofi
GS1	A neutral, not-for-profit, international organization that develops and maintains standards for supply and demand chains across multiple industry sectors.	AmerisourceBergen/Xavier Health IBM/KPMG/Merck/Walmart LSPediA rfxcel

GS1 DataMatrix	A two-dimensional (2D) barcode that holds large amounts of data in a relatively small space.	AmerisourceBergen/Xavier Health LSPediA
GS1-128	An application standard of the GS1 implementation using the Code 128 barcode specification. The former correct name was UCC/EAN-128.	AmerisourceBergen/Xavier Health
GTIN	Global Trade Item Number: an identifier for trade items developed by GS1. For the purposes of serialization the industry will be using a 14 digit GTIN which contains the encoded 10-digit NDC.	AmerisourceBergen/Xavier Health IBM/KPMG/Merck/Walmart LSPediA MediLedger rfxcel Sanofi
GxP	Good (x) Practices: guidelines established in the United States by FDA.	IBM/KPMG/Merck/Walmart
HDA	Healthcare Distribution Alliance; the national association representing primary, full-service healthcare distributors. HDA member companies deliver more than nine million prescription medicines and healthcare products to more than 165,000 settings including chain and community pharmacies, hospitals, nursing homes, physician offices and clinics in every state and territory.	LSPediA MediLedger rfxcel Sanofi
HIN	Health Industry Number: administered by the Health Industry Business Communications Council.	MediLedger
HIPAA	Health Insurance Portability and Accountability Act	IBM/KPMG/Merck/Walmart
Homogeneous Case	A packaging container, often called a case or shipper, that contains all of the same NDC or product.	AmerisourceBergen/Xavier Health
IFT	IBM Food Trust™: built on blockchain, IFT is a software-as-a-service (SaaS) solution that enables product traceability across the supply chain ecosystem.	IBM/KPMG/Merck/Walmart
Intercompany Shipments	Shipments that move between AmerisourceBergen facilities, specifically from the national distribution center to forward distribution centers, as well as sales between ABDC and ABSG.	AmerisourceBergen/Xavier Health
Interoperable Electronic System	Having transactions from one or more systems understood by another.	AmerisourceBergen/Xavier Health
IoT	Internet of Things: a system of interrelated computing devices, machines and objects that are provided with unique identifiers, and are enabled to transfer data over a network.	IBM/KPMG/Merck/Walmart
Item	The product's secondary package; typically, a carton (also referred to as "smallest saleable unit").	LSPediA
LD	Look-up Directory: directory that contains the connectivity information of the responder's repository fulfilling the verification request. This is akin to a phonebook where manufacturers store their products' GTINs so that the verification router service knows to route the verification request to the correct manufacturer's repository of product identifiers.	LSPediA rfxcel Sanofi
MAH	Marketing Authorization Holder	Sanofi
Manufacturer	Entity or organization responsible for packaging the product.	LSPediA
Master Data	Core data that are essential to operations in a specific business or business unit.	LSPediA
NDC	National Distribution Center: model in which manufacturer sends product to a central point for a majority of drug company purchases and they then are routed to the forward distribution centers for distribution to the dispensing customers.	AmerisourceBergen/Xavier Health
NDC	National Drug Code: number used to identify drug products.	IBM/KPMG/Merck/Walmart
Network Operator	A service or solution provider that is operating a distributed networking or ledger technology such as a blockchain.	Optimal Solution
NFC	Near Field Communication	IDLogiq
Node	A resource on the network that participates in the exchange of data or contributes compute and network resources to facilitate the exchange of data between other network resources.	Optimal Solution
Node Operator	A trade organization or service provider participating in a distributed network or ledger technology that is operating a node.	Optimal Solution

Non-Homogeneous Case	A packaging container that contains mixed products or sometimes used in the event of a partial case of homogeneous products.	AmerisourceBergen/Xavier Health
PDSA	Pharmaceutical Distribution Security Alliance	rfxcel
Pharmaceutical Manufacturer	An entity in the pharmaceutical supply chain, also referred to as the Market Authorization Holder (MAH), that is authorized to manufacture a prescription product.	IBM/KPMG/Merck/Walmart
Pharmaceutical Supply Chain	Various entities that operate in the pharmaceutical ecosystem, ranging from manufacturers and distributors to third-party logistics providers and dispensers (pharmacies).	IBM/KPMG/Merck/Walmart
PI	Product Identifier: defined by DSCSA as a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier, that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.	LSPediA rfxcel Sanofi
Pilot	A small-scale study to evaluate feasibility of a concept.	Sanofi
PIQ	Product Identifier Query	Sanofi
PIV	Product Identifier Verification	Sanofi
Product Case Label	The label that is applied to homogeneouscases. This typically contains the GTIN, quantity, lot, expire, and quantity encoded in both linear and 2D DataMatrix barcodes.	AmerisourceBergen/Xavier Health
Product Identifier	A standardized graphic that includes, in both human-readable form and on a machine-readable data carrier, that contains the standardized numerical identifier, lot number, and expiration date of the product.	AmerisourceBergen/Xavier Health
Product Verification (DSCSA Term)	The terms "verification" and "verify" refer to determining whether the product identifier affixed to, or imprinted on, a package or homogeneous case corresponds to the standardized numerical identifier and lot number and expiration date assigned to the product by the manufacturer or the repackager.	AmerisourceBergen/Xavier Health
Provider	The entity providing access to the verification router service network through their own verification router service.	LSPediA
Repository	The Responder's systems that will minimally store the 4 PI data elements and provide the response to the verification request.	LSPediA
Requestor	Party that submits a verification request; for example, in the context of "dscsaSaleableReturn," a pharmaceutical wholesaler or distributor.	LSPediA
Requestor ID	A unique identifier assigned to Requestor entities that are registered and authorized to use the verification router service.	LSPediA
Responder	Party that responds to a verification request; for example, in the context of "dscsaSaleableReturn," a pharmaceutical manufacturer or repackager.	LSPediA
Responder ID	A unique identifier assigned to Responder entities that are registered and authorized to use the verification router service.	LSPediA
RFID	Radiofrequency Identification	Kit Check
S/N, SN	Serial Number	LSPediA
Saleable Returns	Returned products intended for further distribution. Typically includes pharmaceutical product ordered in error or that is no longer needed by a pharmacy due to changes by the patient; saleable returned product must include certification that the product has been stored under manufacturer's requirements.	AmerisourceBergen/Xavier Health
SDxS	Serialized Distributed Extensibility Services: an open-source project that facilitates data exchange over the internet via a secure distributed decentralized broadcast or direct connection.	Optimal Solution
Serial Number (S/N, SN)	Character string that is given to a product in addition to a product number in order to differentiate the individual piece from all the other pieces.	LSPediA
Serial Number Match	A serial number match indicates that the serial number record is in the internal enterprise system and it is okay to take an action against it. Matching occurs using the GTIN, Serial (sGTIN) during receipt and pick/pack/ship. At Returns, the match includes sGTIN, lot, and expiration date.	AmerisourceBergen/Xavier Health
Serialization Data	The group of data associated with the group of serialized items.	LSPediA

SGLN	Serialized Global Location Number: global location number after a URI codification format.	LSPediA
SGTIN	Serialized Global Trade Item Number: for the U.S. market, sGTIN is a serialized GTIN and refers to the GTIN + SN combination. A serial number by itself is not unique until combined with a GTIN. For example, (01)00304562199999(21)1003451 is a valid serial number, whereas (21)1003451 is not because it is not with an associated GTIN.	AmerisourceBergen/Xavier Health, LSPediA, MediLedger
Shipper Label	A label that is applied to non-homogeneous cases, or customer containers, and pallets. This label often contains logistics information and the SSCC(18).	AmerisourceBergen/Xavier Health
SKU	Stock Keeping Unit: finished pack unit of dispense, the lowest level commercial pack.	LSPediA
Smart Contracts	An application on a blockchain. Defines the relationship between two or more parties and can enable automation of business processes among network members which can eliminate operational inefficiencies by automation and provide greater accuracy.	IBM/KPMG/Merck/Walmart
SNI	Standardized Numerical Identifier: defined by section 581(20) of the DSCSA as "a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters."	LSPediA
Solution Provider	A commercial entity that actively supports trade organizations within the drug supply chain ecosystem.	Optimal Solution
SSCC(18)	Serial Shipping Container Code: an 18-digit number used to identify logistics units. To automate the reading process, the SSCC is often encoded in a barcode, generally GS1-128.	AmerisourceBergen/Xavier Health
SNI	Standard Serialized Numerical Identifier: a set of numbers or characters used to uniquely identify each package or homogenous case. The SNI is composed of the National Drug Code (in GTIN format) that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.	AmerisourceBergen/Xavier Health
Supply Chain Partner	Customer, supplier, or partner that participates in the manufacturing, distribution and sale of products.	LSPediA
Tag Identification (TID)	A unique and immutable number encoded in all standard UHF Class 1 Gen 2 RFID tags.	Kit Check
TI	Transaction Information	IBM/KPMG/Merck/Walmart MediLedger
Tote	Container that is used to store drug product during the picking processes.	AmerisourceBergen/Xavier Health
Trade Organization	A commercial entity that actively ships or receives drug product within the drug supply chain ecosystem.	Optimal Solution
TP	Trading Partner	Multiple pilot projects
Transaction ID	A unique identifier assigned to requests that are initiated within the verification router service.	LSPediA
UI	User Interface	IBM/KPMG/Merck/Walmart
Validation	Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.	LSPediA
VR	Verification Request	rfxcel
VRS	Verification Router Service: an interoperable solution used to primarily address DSCSA verification requirements for the saleable returns' regulation.	LSPediA rfxcel Sanofi
Wholesale Distributor	An entity in the pharmaceutical supply chain that purchases product from the manufacturer and distributes the product to dispensers.	IBM/KPMG/Merck/Walmart
XML	Extensible Markup Language	rfxcel
XML handler	Java component that writes an outbound integration message into a file in XML format that conforms to GS1 standards.	IBM/KPMG/Merck/Walmart
zk-SNARKs	Zero-Knowledge Succinct Non-Interactive Argument of Knowledge: a mathematical proof concept where possession of information can be proven without revealing that information.	MediLedger

IX. APPENDIX B — POTENTIAL FOCUS AREAS AND METHODS FOR PILOT PROJECTS

The DSCSA Pilot Project Program Announcement[21] outlined potential issues or focus areas for pilot projects to examine and evaluation methods to use *(Figure 1)*.

Figure 1 — Focus Areas and Methods

Pilot project focus area	Potential issues to examine	Potential evaluation methods
Product Identifier	• Processes related to the requirement for manufacturers to affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce. • Methods used to issue and manage serial numbers (*e.g.,* including a contract manufacturer's role if applicable or how a repackager associates its product identifier with the product identifier assigned by the original manufacturer). • Different representations for the product identifier (*e.g.,* different formats of the National Drug Code or serial number).	• Impacts of different representations of the product identifier on systems or processes: —Number of errors. —Time to process. —Time to reconcile differences.
Barcodes	• Readability of a barcode either printed or affixed to product, including impact of environmental and human factors. • Application of linear barcode and 2D barcode on product. • Distinguishing which barcode to read/use	• Barcode read error rates: —Number of items unnecessarily quarantined or held up. —Time and resource impacts.
Interoperability	• Process and technical challenges due to a variety of potential solutions (*e.g.,* type of database used and system architecture for exchanging information among trading partners). • Maintaining the integrity of information contained in the barcode of serialized product throughout the distribution supply chain (*e.g.,* a trading partner goes out of business or one acquires another business). • Different methods for exchanging information (*e.g.,* the use of Electronic Data Interchange, Electronic Product Code Information Services, and other solutions separately).	• For both decentralized and centralized models, time implications: —To investigate suspect and illegitimate products. —For notifications required within the statutory timelines. —Related to scaling up from pilot to full production. • Product tracing information (across multiple partners): —Capability to retrieve the information. —Accuracy of the information (within and between systems). • Security and access: —Evaluate and document access levels for trading partners.
Data/Database/System Issues.	• Data quality from beginning to end of the product lifecycle and vice versa. • System performance when full or partially loaded with data. • Data format or processes for data transfer: —Use of technical standards for defining data attributes to enable interoperable transfers. —Methods to handle the "master data" (product-specific data) and transaction data separately to minimize "master data" redundancy. • Integration into individual/company data systems • Control and access to data by trading partners, FDA, or other federal or state officials (data governance). • Ability of the system to record product status (*e.g.,* to indicate expired, illegitimate, in error, quarantined) at all packaging levels.	• System Performance and Effectiveness: —Time to access and use product tracing information once that data is received into a system. —Quality of product tracing information. —Number of breaches to system. —Number of attempts to breach the system that were prevented or minimized. • Data and product flow. —Number of unsuccessful attempts to access data and operational impacts. —Number of system interactions within one, and amongst multiple, trading partners. —Time and resource changes on operations when data and product not moving at same time (*e.g.,* product arrives before data arrives). —Time for location/ownership/status changes to be reflected in the system. —Time of product flow delays and associated costs due to system or data problems.
Aggregation/Disaggregation	• Multiple levels of adoption of inference, by different trading partners. Impact of inference gaps, changes or errors in data, particularly downstream when searching or examining the data; how can errors be corrected.	• Number of system and product interactions within one, and amongst multiple, trading partners. • Time required to conduct aggregate/disaggregate operations and transactions. • Accuracy of aggregation data (measure error counts). • Time to gather aggregation/disaggregation data for investigations and notifications. • Time to resolve errors in data.

[21] See 84 FR 2879.

Verification/Notification	• Process for investigation of suspect or illegitimate product, including any communication or coordination:. —Making and responding to verification requests .. —Making, responding to, and termination of notifications. —Responding to requests for information ..... —Testing boundaries of the system	• Response times: Current vs. future process. • Time needed to obtain product tracing information to respond to a request for verification. • Time needed to make, respond to, or terminate a notification. • Time to gather product tracing information to support an investigation for a suspect or illegitimate product, or a recall. • Percentage of items that are successfully verified vs. those that were targeted for verification. • Number of connections/queries needed to gather product tracing information in response to a verification or notification request.
Exception Handling/Errors/ Inconsistencies.	• Identify 'honest errors' (*e.g.*, over/under shipments, clerical errors, or aggregation errors). • Correcting 'honest errors'	• Percent of errors detected: Compare exceptions introduced vs. exceptions detected: —Identify the first step in the process where an error is detected. • Number of new or changed processes needed to accomplish DSCSA goals: —Time and resource impacts. • 'Honest Errors': —Number of items unnecessarily quarantined and held up. —Time required to detect and correct errors. —Impact on trading partners to correct errors. • Barcode read error rates: —Number of items unnecessarily quarantined or held up. —Time and resource impacts.
Special Scenarios	• Situations when data and product do not move together. • Situations when serialized product are sold and distributed along with non-serialized product.	• Error rates for special processes: —Number of items unnecessarily quarantined or held up. —Time and resource impacts. • Accuracy of linkage between original manufacturer product identifier and repackager-issued product identifier.

X. APPENDIX C — INDIVIDUAL PILOT PROJECT SUMMARIES

The following section includes summaries of the twenty pilot projects included in the DSCSA Pilot Project Program. Each summary includes the program participant, the pilot project title, the duration of the pilot project, and a brief description or executive summary written by the program participant. For individual pilot project final reports, also completed by pilot project participants, see links to project reports at FDA's DSCSA Pilot Project Program webpage. The participant summaries as well as the final participant project reports represent each program participant's perspective(s) and do not represent any FDA position or interpretation of law, assessment of compliance with any statutory or regulatory requirement(s), or preference or endorsement of any technology or approach.

1) AmerisourceBergen & Xavier Health

Pilot Project Title: AmerisourceBergen Xavier Health End-to-End 2023 Proof of Concept Pilot

Duration of Pilot Activities: 6 months

Description

This end-to-end Proof of Concept (POC) pilot examined interoperable exchange of Transactional Information (TI), and Transactional Statement (TS) and evaluating the significant operational impact in a 2023 environment. The POC pilot provided insight into where the industry is today and the challenges for successful 2023 implementation. The project involved the major trading partner types of manufacturer, wholesale distributor and dispenser and utilization of the 2-dimensional data matrix barcode of the product identifier, aggregation of product into cases, shipping and receiving product and exchanging TI and TS data for serialized packages throughout the trading partner's systems.

The pilot project also sought to identify exceptions, operating costs and potential disruptions with implementing 2023 requirements.

The pilot project sought to examine exchange of product and package-level serialized data in the form of TI and TS from nine (9) manufacturers, one (1) wholesaler and two (2) dispensers (a retail pharmacy chain and a hospital system). Technical interoperability was demonstrated through the exchange of TI/TS data using three (3) different solutions.

The pilot project utilized GS1 EPCIS (version 1.2) event messages to exchange TI and TS information and aggregation data (packaging hierarchy) and compare against the physical exchange of product scanned at each exchange end point.

A large volume of transactional data (in real time) was used in the pilot which helped identify some issues and test out actual conditions at the trading partner sites.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
AMAG/ICS	Manufacturer	51–200
AmerisourceBergen	Wholesale Distributor, Manufacturer (Private Label); Repackager; 3PL; Specialty Pharmacy	10,001 +
Amgen	Manufacturer	10,001 +
Apotex	Manufacturer	10,001 +
Eli Lilly	Manufacturer	10,001 +
EMD Serono	Manufacturer	501–1000
Genentech	Manufacturer	10,001 +
J&J	Manufacturer	10,001 +
Mylan	Manufacturer	10,001 +
Pfizer	Manufacturer	10,001 +
rfxcel	Solution Provider	Not provided
SAP	Solution Provider	10,001 +
The Christ Hospital	Dispenser	5001–10000
TraceLink	Solution Provider	n/a
Walgreens	Dispenser	10,001 +

2) Cardinal Health

Pilot Project Title: Interoperability Data Exchange Errors and Exception Handling

Duration of Pilot Activities: 7 months

Description

Systems that claim to be compliant generally are not meeting standards and guidelines based on initial industry data exchange. This creates variations and deviations making it difficult to receive data in an interoperable manner for 2023.

All of which causes errors in being able to consume data as a downstream trading partner and to efficiently resolve data integrity errors. The participants notice these errors in a variety of ways that the project defines in their final report as "transmission errors." These range from the simple to the complex formatting issues, time sequencing errors, incorrect syntax, and missing data fields. These types of errors cause entire files to fail and stops operational processes. As the participants encounter errors today, most trading partners are not capable of correcting these errors once product and data have been produced and sent.

There is also general industry acknowledgement that during regular transactions between authorized trading partners there were instances in which product received and data received do not match, particularly in transactions in which individual units have been aggregated to a larger container and do not match the aggregated serialized data the seller sent to the buyer. This means a downstream trading partner has product but no record of receiving that product's transaction data, including its product identifier. These mismatches are inevitable given the relative immaturity of processes and the volume of product that rapidly moves between authorized trading partners. It is expected that over time, as systems mature, the rate of mismatches will decline significantly. For the purposes of this pilot these were defined broadly as "aggregation errors."

Given the volume of products involved and in order to avoid interruptions in patient care, it is important that there be ways to distinguish these commercially routine exceptions (transmission and aggregation errors) between established trading partners from true suspect or illegitimate product situations.

Trading partners need to have business processes for data reconciliation in place to resolve such issues. These processes may allow for a trading partner to resolve a data reconciliation concern internally. Other data reconciliation situations were not amenable to an internal resolution and required that the entity seek the assistance of its trading partner, likely the manufacturer.

Participant/Partnering Entities

Company	Stakeholder Type
Cardinal Health	Wholesale Distributor
Cardinal Health Specialty Solutions (CHSS)	3PL
Major Pharmaceuticals (Cardinal Health business unit)	Repackager
Cardinal Health Packaging Solutions (CHPS)	Contract Packager Organization (CPO)/Repackager
Cardinal Health Pharmaceutical Distribution	Wholesale Distributor
150 unnamed companies	Manufacturers, Contract Manufacturer Organization (CMOs), and Wholesale Distributors

3) Franciscan Missionaries of Our Lady Health System (FMOLHS)

Pilot Project Title: DSCSA Verification to Improve Product Traceability at FMOL Health System

Duration of Pilot Activities: 6 months

Description

This pilot explored the current (2019–2020) Lot Level Transaction Information, Transaction Statement, and Transaction History (T3) data provided via EDI Advance Shipment Notice and a dispenser's ability to reconcile DSCSA information with order information. Prior to this pilot, the dispenser was retrieving T3 information from the wholesaler's portal. This represented the first attempt at automating T3 exchange via EDI 856 messages.

TI, TH, TS information provided by the wholesaler via EDI 856 messages were matched against the product received by the dispenser. Received product was barcode scanned in order to make the match with wholesaler TI data.

Inaccurate DSCSA Transaction Information could cause disruptions in the receiving, matching (ordered product, shipment information and product received) and inventory position of a dispenser. Mitigation requires manual effort to track down errors and correct for them.

The pilot included transactions between a wholesale distributor and a dispenser (hospital). Processes that were in scope were shipping (documented via EDI 856, Advance Shipment Notice) and receiving. EDI 856 data was compared with product received via barcode scanning. This pilot used the current lot level TI, not serialized product TI that is required in 2023.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
Franciscan Missionaries of Our Lady Health System (FMOLHS)	Dispenser	14,0000 +
McKesson	Wholesale Distributor	80,000
ConsortiEX	Solutions Provider	Under 500

4) GS1 US

Pilot Project Title: Barcode Readability for DSCSA 2023 Interoperability

Duration of Pilot Activities: 4.5 months

Description

Previous barcode assessment studies were conducted by AmerisourceBergen and McKesson in 2017, and again in 2018 with the addition of Cardinal Health, each year facilitated by GS1 Healthcare US. This pilot project continues the barcode assessment analysis on pharmaceutical products distributed from wholesaler distribution centers (customer facing). It would measure year over year progress in the measurement of the industry preparedness for DSCSA in terms of manufacturers' packages and homogeneous cases. The pilot would expand the scope of analysis to include the 2023 requirements and quantify impacts of readiness in these areas.

Package-level scanning involved prescription drugs and specialty products. Case level scanning involved faster and slower moving ambient products and cold chain products. The assessments were to determine industry's progress in implementing serialization requirements of DSCSA for encoding the product identifier (i.e., barcode) on packages and homogenous cases and adherence with GS1 Standards. With results from these assessments, AmerisourceBergen, Cardinal Health, and McKesson are able to follow up and share results with their individual supplier manufacturers and repackagers so that they can continue to make any course corrections, as needed.

- In the study, participants scanned individual unit "packages."
- Intent was to scan entire sets of inventories in these locations at the forward pick locations in the distribution centers, representing ~90% of Rx, DSCSA drugs in the US supply chain (Ambient and Cold Chain products).
- The testing encompassed the entire landscape of pharmaceutical manufacturer products including Large, Medium, and Small Branded, Generic, and Specialty.
- Specific manufacturer names and details are not shared in the project report.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
AmerisourceBergen	Wholesale Distributor	20,000
Cardinal Health	Wholesale Distributor	40,400
McKesson	Wholesale Distributor	78,000
GS1 US	Standards Organization	164

5) IBM/KPMG/Merck/Walmart

Pilot Project Title: DSCSA Blockchain Interoperability Pilot

Duration of Pilot Activities: 6 months

Description

This pilot project proposed a blockchain solution to examine the use of this technology in verifying and tracking pharmaceutical products in preparation for future DSCSA requirements. The four organizations of this project believe that blockchain technology with its shareable ledger, immutable data, and inherent ability to track drug provenance, is uniquely qualified to address the various challenges of the pharmaceutical supply chain. The business community understands that digital transformation of this nature requires experimentation and continuous iteration as the technologies mature and evolve.

The pilot project was designed to allow for rapid alerts between supply chain partners if a medication recall were to occur, with granular identification of the impacted lot. Today, this notification process is highly manual and fragmented using various disparate systems, and thereby increasing the response time and number of patients impacted by the recall. The specificity enabled by marking serialized product in addition to using blockchain technology to quickly identify location of recalled lots and notify relevant supply chain partners eliminates unnecessary communication and prevents valid product from being quarantined resulting in less pharmaceutical waste.

To assess if blockchain would be a suitable technology to address the needs of the pharmaceutical supply chain, the pilot team proposed two objectives:

1. Demonstrate that blockchain can provide a common record of product movement by connecting disparate systems and organizations to meet DSCSA 2023 interoperability requirements in a secure way
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

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
IBM	Solution Provider	Not provided
KPMG	Solution Provider	Not provided
Merck	Manufacturer	Not provided
Walmart	Dispenser	Not provided

6) ICON INDICES

Pilot Project Title: Web 3.0 Based on Identifier System, An Autonomous System for Electronic Tracing of Product for Pharmaceutical

Duration of Pilot Activities: 6 months

Description

The program team sought to pilot a shared data platform (named "Web 3.0 System") using technology created by ICON INDICES to assign a Digital-Address ID and use it as the drug package's serial number. As stakeholders in the supply chain create traceability events, these events are given a Navigation ID, or encrypted digital address of the event within the Web 3.0 System and is linked to the package serial number's Digital-Address ID within the Web 3.0 System. These addresses are referred to as cell locations within the system and are used to index information about the drug products and traceability events within a distributed events repository system. The system allows trading partners to trace the events affecting movement of a product.

The program used simulation to depict stakeholders (Manufacturer, 3PL, Wholesale Distributor and Dispenser), drug products, and traceability events.

Participant

Company	Stakeholder Type	Size (# Employees)
ICON INDICES	Solution Provider	Not provided

7) IDLogiq

Pilot Project Title: IDLogiq Next Generation Advanced REAL FIPS-Compliant[22] Cryptographic ID Authentication with Transaction Ledger Powered by Blockchain/Distributed Ledger Technology for Decentralized Heterogeneous Global Network Computing Environment

Duration of Pilot Activities: 4.5 months

Description

This pilot project aims at helping the FDA and all the stakeholders to understand the process and evaluate the pilot project, once completed, with the collective hope of optimizing safety and security of the pharmaceutical supply chain ecosystem.

The system used for this pilot project involves multiple processes, from the manufacturing entity to the dispenser (pharmacy). The system will precisely record all events (aggregation, repackaging, disaggregation, shipping) in the standard EPCIS format using our digital ledger, which includes the "who, what, where, when, how" information of all events related the transfer of goods in the supply chain.

The project included the following activities for end-to-end testing of:

- 200 products through entire product life cycle, beginning from manufacturer issuance, repackaging by repackager and shipping out to pharmacy.
- 200 products from manufacturer issuance, repackaging by repackager and shipping out to pharmacy.
- 1000 products from manufacturer issuance, aggregation of products into containers by manufacturer, disaggregation of products at the repackager, repackaging by repackaging, aggregation of products at the repackager, and shipping out to pharmacies.
- 1100 products through entire product life cycle, from manufacturer issuance, to aggregation of products into containers by manufacturer, to disaggregation of products at the repackager, repackaging by repackager, aggregation of products at the repackager, and shipping out to pharmacies using Near-field communication labels to track 100 products throughout its lifecycle.
- 2100 products through entire product life cycle, from manufacturer issuance, to aggregation of products into containers by manufacturer, to disaggregation of products at the repackager, repackaging by repackager, aggregation of products at the repackager, and shipping out to pharmacies. Of those total 2100, we performed 1000 pilot test of data matrix labels with IDLogiq cryptographic authentication and usage of Near-field communication labels to track 100 products throughout its lifecycle.

[22] The Federal Information Processing Standard (FIPS) Publication 140-2 is a U.S. government computer security standard used to approve cryptographic modules.

Participant

Company	Stakeholder Type	Size (# Employees)
Alvogen	Manufacturer	Not provided
Alexso/SA3	Repackager/Wholesale Distributor	75
Digital Business Solutions, Inc.	Dispenser	25
Alpha Medical Pharmacy, Inc.	Dispenser	14
Good Life Pharmacy, Inc.	Dispenser	12
Prescription Services, Inc.	Dispenser	12
IDLogiq	Solution Provider	Not provided

8) Kit Check and Sandoz

Pilot Project Title: Analyzing gaps and addressing key concerns and testing key concepts relating to the 2023 DSCSA requirements by utilizing and adapting existing commercial methods and technologies

Duration of Pilot Activities: 6 months

Description

This pilot focuses on the enhanced requirements for package-level tracing and verification that go into effect in 2023 and explores the use of radio frequency identification (RFID) as an alternative data carrier to the 2D (data matrix) barcode. The overall goals of this pilot are to show how an RFID data carrier and a centralized model for electronic data exchange can reduce costs of DSCSA compliance, improve accuracy of tracking items throughout the supply chain, and ensure interoperability between supply chain stakeholders.

The technology chosen for this pilot project involves serialization coupled with a cloud-based master data repository (MDR) that has broader applications and can easily be used to track drug products at other levels of aggregation such as the carton, case, and pallet. Since DSCSA has a focus on saleable units, most of this report will focus on use of the technology at that level or discuss cases where it can be equivalently used at either the unit-dose or saleable unit level without much difference.

Although DSCSA compliance will not be achieved by RFID alone, this pilot project explores the combination of barcodes at the saleable unit coupled with RFID at the unit-dose in many circumstances (1) presents a tremendous value proposition for numerous supply chain participants and customers and (2) allows us to better solve many of the supply chain problems that may have inspired DSCSA in the first place.

Participant

Company	Stakeholder Type	Size (# Employees)
Kit Check, Inc.	Solution Provider	>50
Novartis/Sandoz	Manufacturer	>1,000
Nephron Pharmaceuticals	Manufacturer - Contract	100–500
Coral Gables Hospital	Dispenser	>500
Hackensack University Medical Center	Dispenser	>500

9) LSPediA

Pilot Project Title: Router Service Solution for Verification/Notification and Interoperability 2023

Duration of Pilot Activities: 4.5 months

Description

LSPediA has developed a way to use product identifiers for verification that deters counterfeits through its Verification Router Service (VRS) solution. This pilot used LSPediA's VRS solution called, OneScan, to perform barcode scan, data collection, and business transactions. After pilot participants scanned the barcode on packages and homogenous cases, the data elements were parsed from barcode and the solution performs transactions including product verification, product investigation, and product status change, and interoperability. This pilot simulated verification of returned packages by having requestors scan on-hand live inventory in their distribution centers. The pilot also simulated negative verification mock drug packages (i.e., seed bottles made by LSPediA). The results of this testing will demonstrate that VRS solutions are a viable path to DSCSA compliance and can be put in place by trading partners in accordance with the 2023 deadline.

This project tested the following capabilities using 9 products with different packaging levels (i.e., item, bundle, case):

- TI/TS exchange
- Packing/Aggregation (used a non-production workaround)
- PI verification
- Suspect product handling
- Illegitimate product handling
- Form FDA 3911 reporting
- Interoperability
- Exception handling
- Transmission errors

Participant/Partnering Entities

Company	Stakeholder Type
LSPediA Inc.	Solution Provider
Kowa Pharmaceuticals America, Inc	Manufacturer
Ingenus Pharmaceuticals, LLC	Manufacturer
Auburn Pharmaceutical Co	Manufacturer
AmerisourceBergen Corp	Wholesale Distributor
Smith Drug Company	Wholesale Distributor
SpartanNash Company	Dispenser

10) MediLedger

Pilot Project Title: MediLedger DSCSA Pilot

Duration of Pilot Activities: 6 months

Description

The overall vision of this project was to create a system that could confidentially track the change of ownership of prescription medicines without requiring trading partners to reveal data to each other or require a centralized system to hold the information. The team believes that a neutral industry platform, which does not exist today, would enable the facilitation of information exchange and proactive validation of rules that would highlight immediately if there were reasons to believe the product was suspect. This platform could bring the critical benefits that other countries are experiencing with government or consortium run systems without the drawbacks of such approaches.

The technical approach examined standards that already exist and potential gaps in standards and discussion of the concerns around the realities of how the supply chain would operate that could add complexity to such a rigorous rule enforcement system. The industry as a whole can drive the design of the solution so that any misalignment can be identified quickly and solved in a collaborative way that is focused on drug safety.

The following High-Level System Requirements were used to guide this pilot project:

- Enable every authorized organization in the Pharma industry to plug into the system
- Ensure 100% privacy of data committed to blockchain ledger with zero leakage of business intelligence
- Process 2000+ transactions/second (as determined by industry peak shipment windows)
- Complete verification requests in less than 1 second
- Create specifications to solve aggregation/de-aggregation, saleable returns, and exception handling
- Create a level playing field to eliminate potential for vendor lock-in

The project established guiding principles and a governance structure to manage consensus, issues and opportunities that arose as part of the effort.

The solution developed under this pilot project used three core technologies:

1. Private messaging between clients to exchange confidential messages between trading partners by leveraging EPCIS standards.
2. Blockchain as a shared, immutable ledger to register the proof of the authenticity of transactions and execute smart contracts. The blockchain will enforce business rules, such as only one company can have legal ownership of a serialized unit at a given time (no double transfer).
3. zk-SNARKs to further enhance privacy by ensuring no business data is revealed.

The key design pattern of the solution focuses on the handling of a serialized unit. Each unit is managed as a non-fungible token with the custody assigned to a trading partner. Custody of a serialized unit can be transferred, and the transfer function is governed by the smart contract deployed on the blockchain. Smart contracts can be designed to enforce business rules which are agreed upon across the industry or across trading partners. The current custodian initiates the transfer and the recipient of the transfer needs to accept it in order to complete the transaction.

The system will ensure that only the authorized manufacturers of a particular product can provision their own serialized units on the blockchain. The project created a test user interface and system performance was evaluated.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
AmerisourceBergen	Wholesale Distributor, 3PL	21,000
Amgen	Manufacturer	21,000
Cardinal Health	Wholesale Distributor, 3PL	21,000
Center for Supply Chain Studies	Consultant	5
Chronicled	Solution Provider	50
Dermira	Manufacturer	100
FedEx	3PL	425,000
FFF Enterprises	Wholesale Distributor	425
Genentech	Manufacturer	14,000
Gilead	Manufacturer	11,000
GS1 US	Standards Organization	160
GSK	Manufacturer	100,000
Inmar	3PL	2,200
Lilly	Manufacturer	34,000
Maxor	Dispenser	1,000
McKesson	Wholesale Distributor, 3PL	80,000
Novartis (Sandoz)	Manufacturer	125,000
Novo Nordisk	Manufacturer	43,000
Pfizer	Manufacturer	117,000
Sanofi	Manufacturer	110,000
Vaxserve	Wholesale Distributor	150
Walgreens	Dispenser	350,000
Walmart	Dispenser	2,100,000

11) Optel

Pilot Project Title: Improved End-to-End Drug Supply Chain Traceability with OPTEL's Intelligent Supply ChainTM Technologies

Duration: 13 months

Description

The pilot project used simulated products to examine the transfer of serialization data to and from all the different parties of the pharmaceutical products distribution chain during the processing of the physical serialized products, without any corruption or blocking issue, from the manufacturer to the dispenser.

The test strategy that was to demonstrate this interoperability consists mainly in modifying physical electronic product code (EPC) dispositions on simulated physical products at each stage of the distribution chain, and to reconciliate the simulated physical products dispositions with the EPCIS serialization data after each modification of an aggregation. The intention behind this strategy is to simulate a distribution scenario compliant with the Drug Supply Chain Security Act (DSCSA) requirements which is as close as possible to a real-life compliant pharmaceutical products distribution use case.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
AmerisourceBergen	Wholesale Distributor, 3PL	21,000
Amgen	Manufacturer	21,000
Cardinal Health	Wholesale Distributor, 3PL	21,000
Center for Supply Chain Studies	Consultant	5

12) The Optimal Solution

Pilot Project Title: The Optimal Solution a Federated Approach to Designing the Interoperable DSCSA

Duration of Pilot Activities: 4.5 months

Description

Optimal Solution Pilot team was initially working to determine how to apply blockchain technologies to solve the challenges at hand. The team put a lot of focus on data privacy and security, as well as consensus compute performance, storage, and scaling around a blockchain-based solution. After many iterations going back and forth on which consensus algorithms to use and what to store on-chain, the team came to the realization that the expansion of transaction volumes (when the FDA requirement moves to including product identifiers in transaction information) would eventually not be as cheap as expected for node operators, and the overall cost of an interoperable drug supply chain. It was at this time that the team took a step back to reflect on the initial approach taken and decided to re-frame the solution with existing technologies while maintaining the key benefits of a blockchain-based solution.

The pilot project brought together a number of solution providers, each with their own expertise and technology and sought to demonstrate that technology within the blueprint and pilot project execution. The technology that was to be explored included:

- Trusted Labels — e-Fingerprinting (using the 2D DataMatrix for anti-counterfeit measures),
- Internet of Things (IoT) — Supply Chain Visibility in Transit (connected sensors to access product condition in transit),
- Blockchain — Distributed Ledger Technology
- Analytics and Machine Learning — Anomaly detection and value beyond compliance (to sense exception and nefarious patterns of behavior within the overall system and to report to the proper entity)
- Mobile Apps — Geo fencing and Access (using Geofencing[23] to determine where a product was and its pattern of movement)

Even though the pilot project made the change mid-course, it had gathered a volume of information on supply chain processes (internal and external to the trading partners) and also the technology that was to be highlighted. That volume of information makes up the bulk of the three documents[24] submitted at the conclusion of the pilot.

This summary report will focus on the lessons learned pre-scope-change and then the new scope (mostly documented in the "Optimal Solution Final Conclusions Addendum.")

[23] Although "geo fencing or geofencing" was not defined in this pilot project by the participants, for the purposes of this report, we considered the concept of "geofencing" to be the use of the Global Positioning System (GPS) satellite network and/or local radio-frequency identifiers (such as Wi-Fi nodes or Bluetooth beacons) to create virtual boundaries around a location. The geofence is then paired with a hardware/software application that responds to the boundary in some fashion as dictated by the parameters of the program., Fitzpatrick, Jason. "What is Geofencing?" How-To Geek, 21 Sept. 2016, www.howtogeek.com/221077/htg-explains-what-geofencing-is-and-why-you-should-be-using-it.

[24] "Optimal Solution Pilot Blueprint," "Optimal Solution Final Conclusions," and "Optimal Solution Final Conclusions Addendum."

The Optimal Solution proposed to "provide the FDA with a plan for meeting and exceeding the concept of DSCSA leveraging the latest technologies" by blueprinting and piloting a proposed interoperable system that can identify and trace prescription drugs throughout the supply chain. The pilot initially identified blockchain as the technology upon which the platform would be blueprinted and piloted. During the blueprinting phase, the team concluded that blockchain may not be the best solution and decided to "re-frame" their solution with existing technologies while maintaining the key benefits of a blockchain-based solution. The team then created a proposed framework for a secure interoperable system by which trading partners and organizations can exchange data, named Serialized Distributed Extensibility Services (SDxS) involving a key focus on data privacy and security.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
CalQLogic	Solution Provider	Not provided
FarmaTrust	Solution Provider	Not provided
RxTransparent	Solution Provider	Not provided
Systech	Solution Provider	Not provided
T-Systems	Solution Provider	Not provided
Dyadis	Solutions Provider	Not provided

13) Partnership for DSCSA Governance (PDG)

Pilot Project Title: DSCSA Governance Processes

Duration of Pilot Activities: 5 months

Description

The Pharmaceutical Distribution Security Alliance (PDSA) worked for over a year to develop a proposed structure for such a governance body. In March 2019, PDSA published that proposed structure and began to engage trading partners beyond PDSA in discussion of the proposed structure. Although the pilot proposal was submitted to FDA by PDSA, responsibility for the pilot transitioned to the Partnership for DSCSA Governance (PDG) upon successful formation in November 2019.

Once a critical mass of supply chain entities agreed to a governance body structure, the governance body was established. The process of developing broad stakeholder support for a governance structure (including a funding model) and legal formation of the governance body took approximately 8 months. It is these agreed upon organizational structures that were piloted by PDG.

The goal of this pilot project (PDG Pilot) was to test, learn from, and refine the organizational structure and processes of a DSCSA interoperability governance body (now formally PDG). A variety of governance metrics were established at the outset of the pilot for formal evaluation of 11 governance processes and PDG structural elements. Testing these structural elements and processes to evaluate the ability of PDG to successfully govern the DSCSA interoperability environment required PDG to formally exercise each process within the context of a substantive use case. Therefore, the pilot workgroup was tasked with the development of proposed systems and processes (e.g., business requirements) for confirming the "authorized" (as defined in the DSCSA) status of trading partners.

The substantive use case was purposefully limited in scope to support experiential learning related to governance processes for collaboration between the governance body and FDA, collaboration between the governance body and technology providers, the role of committees within the governance body, documenting and publishing use case outputs, and other processes. Through the testing of governance, however, the pilot also examined and solved for the best ways to determine if an entity is an authorized trading partner (i.e., manufacturer, repackager, wholesaler, third party logistics provider, dispenser). Details of the deliberations and conclusions related to this use case will become an input to the PDG Interoperability Committee as it develops a blueprint for interoperability in 2023.

Participant/Partnering Entities

The PDG Pilot Work Group was comprised of representatives from PDG and the members which represented the following stakeholder companies:

Company	Stakeholder Type	Size (# Employees)
PDG	Governance Body	Not provided
Bristol Myers Squibb	Manufacturer	Not provided
Endo Pharmaceuticals	Manufacturer	Not provided
Genentech	Manufacturer	Not provided
Johnson & Johnson	Manufacturer	Not provided
Pfizer	Manufacturer	Not provided
Sanofi	Manufacturer	Not provided
Hercules Pharmaceuticals	Wholesale Distributor	Not provided
The International Warehouse Logistics Association (IWLA)	3PL	Not provided
Inmar Intelligence	3PL	Not provided
McKesson	Wholesale Distributor	Not provided
Medline Industries	Wholesale Distributor	Not provided
CVS Health	Dispenser	Not provided
Uptown Pharmacy	Dispenser	Not provided
Walgreens	Dispenser	Not provided
Chronicled	Solution Provider	Not provided
TraceLink	Solution Provider	Not provided
rfxcel	Solution Provider	Not provided
Providence Health Technologies	Solution Provider	Not provided
Second Generation/.med	Solution Provider	Not provided

14) PriMed Pharmaceuticals

Pilot Project Title: Secondary Wholesaler Challenges During Implementation of DSCSA Required Track & Trace Platforms

Duration of Pilot Activities: 5.5 months

Description

This pilot project illustrated the challenges a small secondary wholesale distributor will encounter while implementing the November 27, 2019, DSCSA requirement for Verification Routing Services (VRS) for Saleable Returns. This project also considered the upcoming product identifier (serialization) requirements under DSCSA for wholesale distributors. The project will identify factors that have delayed implementation, caused strain on operational and financial assets, and ultimately made compliance a difficult task to accomplish with limited resources in a niche sector of the drug supply chain. These challenges should be taken into consideration when assessing the time and resources required for all trading partners to achieve the necessary level of compliance.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
PriMed Pharmaceuticals	Wholesaler	~20

15) Providence Health Technologies (PHT)

Pilot Project Title: FDA Small Dispenser Pilot Study

Duration of Pilot Activities: 8 months

Description

The primary focus of the pilot study was to identify and measure the ability of small dispensers to comply with the requirements of the new FDA DSCSA federal requirements. Secondly, PHT sought to identify awareness of the DSCSA requirements among dispensers, identify burdens in workflow changes needed to accommodate compliance, measure costs that might be incurred with compliance, determine adequacy and type of data received from suppliers, and measure trending of data quality and data present on product shipped that might indicate when compliance benchmarks might be achieved.

Participants in the study were chosen from four categories of dispensers including retail pharmacy, hospital pharmacy, specialty pharmacy, and long-term care pharmacy. These subgroups of the dispensing pharmacy environment represent the majority of small dispensers in the market and all four of these pharmacy sectors are well represented by small dispensers.

The pilot project sought to obtain the data present in the transaction information submitted to the pharmacy from the supplier and compare those data with the information present within the 2D barcode on each package. The findings included: discrepancies in barcodes and EDI data, records of missing or unreadable barcodes as well as barcodes with missing data.

Participant/Partnering Entities

Company/State(s)	Stakeholder Type	Size (# Employees)
Providence Health Technologies, LLC	Solution Provider	Not provided
Hamacher Resource Group, Inc.	Solution Provider	Not provided
Advasur, LLC	Solution Provider	Not provided
3 Long Term Care Pharmacies	Dispenser	< 25
2 Hospital Pharmacies	Dispenser	< 25
2 Specialty Pharmacies	Dispenser	< 25
10 Retail Pharmacies	Dispenser	< 25

16) rfxcel

Pilot Project Title: rfxcel Verification/Notification Readiness & Extensibility Pilot

Duration of Pilot Activities: 5.5 months

Description

This pilot project tested the readiness of the Verification Router Service (VRS) network by executing a series of tests based on the original test cases provided by the Healthcare Distribution Alliance (HDA) and augmented by the relevant VRS specifications. This FDA pilot will produce an aggregated result that will help to quantify the overall readiness of the VRS network.

During the testing timeframe many VRS test targets could not be tested due to incomplete connection issues. These issues were further hampered as many VRS Providers moved to new Quality Assurance environments in preparation for the November 2019 deadline — a move that broke working connections.

Restoring connections was difficult. Many of the new connection issues occurred in mid to late Q4 as VRS Providers were focused initially on meeting the November 2019 deadline and then assessing strategy based on the FDA's announced enforcement delay. As a result, this pilot was extended into Q1 2020 when resources were more available and focused to restore VRS connections. This shift also allowed this pilot to leverage the efforts of the HDA to restart the testing effort using the HDA test plans created by the HDA working group.

The revised testing approach focused on 16 different Request/Response scenarios across a total of 11 different VRS Responders using 8 different Lookup Directory (LD) Routers. VRS network and illustration of the following VRS architecture types:

- **Vertical VRS Providers** offer both the VRS Response and LD Routing functionality via a common provider. Most often this solution is provided by a vendor that also offers serialization and compliance solutions, but this can also be offered by a single manufacturer if desired.
- **Federated VRS Providers** deliver VRS Response and LD Routing via different solution providers and/or companies, and the LD Router solution is managed by one provider whereas VRS Responder functionality is provided by multiple vendors or manufacturers.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
rfxcel	Solution Provider	Not provided
Vantage Solutions	Solution Provider	Not provided

17) Rymedi

Pilot Project Title: DSCSA Implementation in Intra and Inter Healthcare System Medicine Transfers

Duration of Pilot Activities: 6 months

Description

This pilot examined the implementation of interoperable DSCSA compliance technology, providing immutable genealogy and multi-partner data access, alongside the standard operating procedures within hospital and clinic networks after they take custody of medicines from wholesale distributors and third-party logistics providers (3PLs). Focusing on specialty medicines, the pilot tested DSCSA-required data capture, tracking and sharing of medicine transfers across different geographic sites within and between healthcare provider systems, while avoiding the need to move large amounts of data across the supply chain.

The solution approach integrates the blockchain-enabled tracking and data management technology of Rymedi with the temperature-monitoring barcoded intelligent label from Zebra Technologies, along with their labeling and data capture solutions. Technology integration was part of the pilot, demonstrating interoperability between systems. However, the greater focus was on workflow integration and business value identification in order to zero in on challenges for at-scale market adoption of heightened visibility in the quality tracking of medicines beyond the status quo in large healthcare systems.

One way of framing the pilot approach is the integration of Quality Management System (QMS) Automation with Digital Real-World Evidence (RWE) capture. The ideal scope would be to mirror the degree of supply quality monitoring visibility one gets with a structured phase 4 clinical trial. If appropriately integrated into clinical workflows and pharmacy operations supporting clinical care, the same QMS platform would provide RWE of value to many different organizations for different purposes, from clinical operations improvements to clinical research approval streamlining. The quality monitoring features would be part of an integrated platform delivering other kinds of value in order to justify added costs and change management efforts to achieve workflow adoption. Such an integrated e-health architecture instantiates the "Learning Health Systems" model healthcare system and regulator innovators have been envisioning since the late 2000s.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
Rymedi	Solution Provider	Not provided
Temptime Corporation (now Zebra Technologies)	Solution Provider	Not provided
Indiana University Health	Dispenser	Not provided
WakeMed Hospitals & Health	Dispenser	Not provided
Center for Supply Chain Studies	Consultant	Not provided
University of San Diego, School of Medicine, Global Health Policy Institute	Consultant	
Good Shepherd Pharmacy & Remedichain	Consultant	Not provided

18) Sanofi

Pilot Project Title: Product Identifier Verifications by a Contract Manufacturing Organization (CMO) on behalf of a Manufacturer Authorization Holder (MAH)

Duration of Pilot Activities: 10 months

Description

The pilot project tested the ability of a Contract Manufacturer (CMO) to provide Product Identifier (PI) verifications on behalf of a Market Authorization Holder (MAH). CMO's encode GTIN, Serial Number, Lot #, and Expiry on the Unit-of-Sale and Case/Shippers in accordance with the DSCSA requirements. The serialized batches are shipped to the MAH, but that does not mean the PI data was sent to the MAH. Because some of the serialization activity may have been completed prior to the implementation of automated data exchange platforms, the PI information for electronic verifications is stored within the CMO's level 4 serialization solution provider. In other words, the original PI data is stored in the CMO's system, not in the MAH's system. This Pilot project was structured to examine whether a MAH can delegate an electronic verification request to the system that has the original PI data for the verification response. This project leveraged the Verification Router Service (VRS) network currently being built for verifications of saleable returns.

The pilot included a CMO, MAH, wholesale distributor, and service provider, focusing on the PI Verification process for saleable returns. Specifically, the pilot focused on the ability for a CMO to be delegated the responsibility to provide PI Verification responses to the wholesaler that the MAH had sold the product. The pilot also relied on the industry developed Verification Routing Service (VRS) based on Healthcare Distribution Alliance (HDA) specifications.

The MAH in the pilot was a virtual manufacturer (holds the Marketing Authorization but does not operate manufacturing facilities of their own). In the pilot, the CMO manufactured, packaged, and shipped the product to the MAH and also provided DSCSA electronic services including PI Verifications to requesting trading partners of the MAH.

The pilot relied on the VRS for routing of PI Verification requests. The VRS includes synchronized Lookup Directories[25] to control where the PI Verification request is routed. The delegation was accomplished in two phases, in the first phase, the verifications were done by the MAH (Lookup Directory pointed to the MAH). In the second phase, the verifications were delegated to the CMO (Lookup Directory pointing to the CMO) to respond.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
Sanofi	Manufacturer	110,000
McKesson	Wholesale Distributor	80,000
Advanz Pharma	Manufacturer	400
Adents	Service Provider	100

[25] A Lookup Directory includes a table of manufacturer product IDs (GS1 GTINs with embedded NDCs) along with the address of where the manufacturer's PI Verification interface is located. The VRS system looks up the GTIN in the request and routes the request to the PI Verification interface listed. The series of local Lookup Directories are updated frequently in order that they all hold the same information.

19) Tracelink

Pilot Project Title: DSCSA Traceability with Distributed Ledgers and Digital Recalls Project

Duration of Pilot Activities: 6 months

Description

This pilot project brought together a diverse set of participants from across the pharmaceutical supply chain to examine ways to enhance patient safety, improve pharmaceutical security, increase operational efficiency, and decrease business risk related to the end-to-end supply chain processes involved in pharmaceutical traceability under DSCSA and pharmaceutical product recalls.

One workstream studied the opportunities to provide increased public health and business benefits by enhancing the process for initiation, communication and reconciliation of pharmaceutical recalls in the supply chain through a digital recalls network.

The other workstream studied the underlying requirements of supply chain members to meet DSCSA 2023 regulations which include, but are not limited to, systems and processes for stakeholders to build upon request a unit-level trace history of all serialized transaction information going back to the manufacturer. This included analyzing how companies comply with DSCSA today and the future system attributes and process changes that may be necessary for the diverse members of the supply chain for 2023.

Both workstreams established a deep foundational knowledge of the information and processes involved, using early-stage technology solutions to support investigation and analysis of potential industry solutions to these challenging problems. Both pilot projects were also deeply informed by previous FDA and industry activities, including FDA public meetings and guidance documents. The intent for both pilot projects was not to build a case for a specific technology or solution. Instead, our focus was to develop a holistic view of how pharmaceutical traceability and product recalls occur today, and 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 recalls. This report is a comprehensive subset of the significant ideas and insights developed during the pilot.

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
TraceLink	Solution Provider	Not provided
Thermo Fisher/Patheon	Manufacturer	Not provided
Sharp Packaging	Manufacture	Not provided
Agios	Manufacturer	Not provided
A-S Medication Solutions	Manufacturer	Not provided
Bristol-Myers Squibb	Manufacturer	Not provided
Flexion	Manufacturer	Not provided
Johnson & Johnson	Manufacturer	Not provided
Merck	Manufacturer	Not provided
Par Pharmaceuticals	Manufacturer	Not provided
Pfizer	Manufacturer	Not provided
Sagent	Manufacturer	Not provided
Sandoz	Manufacturer	Not provided
Novartis	Manufacturer	Not provided
McKesson	Wholesale Distributor	Not provided
Value Drug Company	Wholesale Distributor	Not provided
CVS Health	Dispenser	Not provided
Novant Health	Dispenser	Not provided
Wegmans	Dispenser	Not provided
Yale New Haven	Dispenser	Not provided
DHL	3PL	Not provided
PharmaLink	Returns Processor	Not provided
Woodfield Distribution	3PL	Not provided

20) UCLA Health

Pilot Project Title: UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology

Duration of Pilot Activities: 6 months

Description

As part of the FDA's DSCSA Pilot Project Program, UCLA and its solution partner, LedgerDomain, focused on building a complete, working block-chain-based system, BRUINchain, which would meet all the key objectives of the Drug Supply Chain Security Act (DSCSA) for a dispenser operating solely on commercial off-the-shelf technology. The BRUINchain system requirements include scanning the drug package for a correctly formatted 2D barcode, flagging expired product, verifying the product with the manufacturer, and quarantining suspect and illegitimate products at the last mile: pharmacist to patient, the most complex area of the drug supply chain.

The project demonstrates a successful implementation where product-tracing notifications are sent automatically to key stakeholders, resulting in enhanced timeliness and reduction in paperwork burden. At the core of this effort was a blockchain-based solution to track and trace changes in custody of drug. As an immutable, time-stamped, near-real-time (50-millisecond latency), auditable record of transactions, BRUINchain makes it possible for supply chain communities to arrive at a single version of the truth. BRUINchain was tested with real data in a real-world setting at one of the busiest pharmacies in the United States.

In addition to communicating with the manufacturer directly for verification, BRUINchain also initiated "sad path" reporting, which culminates in the origination of a Form 3911 to FDA. During the study, a 100% success rate was observed across scanning, expiration detection, counterfeit detection and paperwork reduction from approximately 1 hour to less than a minute. Based on this performance, DSCSA compliance for the 4.2 billion prescriptions dispensed each year is estimated to cost dispensers at least 17 cents per prescription, and potentially much more depending on regulatory interpretation and speed of verification. The study concludes by touching upon policy considerations aimed at addressing these challenges while enhancing the detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

This pilot project focuses within the hospital (pharmacist to patient), exercising product barcode scanning, alerting to expired product, verifying product with the manufacturer (Product Information Verification), quarantining suspect and illegitimate product and generating FDA form 3911s for illegitimate products.

The pilot project chose to use one product (SPINRAZA® to fully test the system's track and trace capability. The traceability started with the dispenser's receiving point and continued through the pharmacy and clinics. The following checks were tested in the system:

- Verify that the barcode data matches the human readable on the package label
- Verify that the product is fit for distribution (measured by the Expiration Date)
- Obtain Product Information verification from the manufacturer
- Visual inspection of the package

Blockchain technology (BRUINchain) was used for its immutable,[26] time-stamped, near-real-time, auditable record of transactions capability.

From a DSCSA perspective, the pilot project tested:

- Manufacturer printed 2D DataMatrix (barcodes)
- Product Information Verification (with manufacturer interacting via email)
- FDA form 3911 generation
- Trading Partner (manufacturer) alerts to suspect and illegitimate drugs

Participant/Partnering Entities

Company	Stakeholder Type	Size (# Employees)
UCLA	Dispenser	~ 300 (Pharmacy only)
LedgerDomain	Solution Provider	Not provided
Drug Manufacturer	Manufacturer	Not provided

[26] Information written to a blockchain cannot be changed or deleted. Much like accounting systems, changes must be made by offsetting transactions, retaining its audit capability.