UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology

Drug Tracking, Tracing, and Verification at the Last Mile of the Pharmaceutical Supply Chain with BRUINchain

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Ronald Reagan UCLA Medical Center

PDG Member & Presenter: Ben Taylor, CEO, LedgerDomain

PDG FDA Pilot Program Round Robin, July 2020

Thanking Biogen serialization team led by Bjoern Rosner, PhD
As well as Imran Shakur
UCLA Health

UCLA Health’s five facilities & >200 clinics serve 600,000 unique patients yearly

UCLA Health Pharmacy’s 300+ staffers support three hospital pharmacies, an infusion pharmacy, two research pharmacies & five retail/specialty pharmacies

UCLA partnered with LedgerDomain to build WORKING APP to apply DSCSA requirements to a large hospital pharmacy: the most complex LAST MILE

Please take a moment to thank UCLA’s COVID responders
Partnering Entities.

LedgerDomain

Built KitChain for Clinical Supply Blockchain Working Group

Member, Hyperledger Project

FDA Naloxone Challenge
fda.gov/NewsEvents/PublicHealthFocus/ucm533711.htm
Last Mile DSCSA Objectives

✨ Assist colleagues to perform robust DSCSA checks & verification
✨ Flag double-counts and surface suspect transactions
✨ Enforce ground truth with exception handling; gradually escalate to 3911
✨ Provide real-time inventory & quarantine at the refrigerator level
✨ Notify colleagues about availability and verification in real-time
Pilot Project Key Outcomes.

BRUINchain Video
https://www.youtube.com/watch?v=mppc2Qvqrdc

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BRUINchain
SUBMITTED TO FDA, JANUARY 2020
Foundations for Interoperability

✧ DATA SCIENCE: GS1-compliant Salable Units (All records divisible to salable units)

✧ IDENTITY: capture Entities, Members & Location

✧ SOURCE: Relational & Blockchain Interoperability

✧ HISTORY: Audit-readiness through immutable time-stamps

✧ LEDGER: Real-time persistent data to query quickly & reliably

When duplicate is scanned, will it be flagged immediately?
Pilot Project Key Outcomes.

Last Mile DSCSA Process Map
Receiving, “Happy Path”, Manufacturer Verification

Manufctr — Verification Request — Rec’vg

P2P blockchain supplemented with department & location info
Privacy & role-based privileges preserved

UCLA Health
Last Mile DSCSA “Sad Paths”

Pilot Project Key Outcomes.

Auditable “Sad Path” Escalates to Generation of 3911

3911 Flow
Framework for Multi-stakeholder Platform

All blockchain nodes agree on single version of truth

Next Steps.

Manufacturer
RDBMS’s

Wholesaler 1
ORG

CA
Node
Blockchain
Wholesaler 1
Private Data

Selvedge
Machine

Orderer
Certificate
Authority

~250 transactions
Per second

Wholesaler 2
ORG

CA
Node
Wholesaler 2
BC
Private Data

Integrated
ORG

CA
Node
Blockchain
Integrated
Private Data

RDBMS Interop

Multi-Dispenser
ORG

CA
Node
Blockchain
Multi-Dispenser
Private Data

RDBMS Interop

Chain Interop

RDBMS Interop
Testing Scalability

**DRUG FEATURES & SCALABILITY**
- >100,000 drugs; >200,000 packages
- Expiration extensions & recalls
- Updated package inserts
- Building block for flagging & 3911s

**TRANSACTION SCALABILITY**
- ~5Bn Rx/year = ~1.5Bn salable units/yr
- 1.5Bn/yr is ~5million per working day
- ~5,200 per minute or **87 per second**
- Fewer hops: RDBMS source & bulk
- 2024 US Target ~250 per second

Next hurdles: user identities (ATP wallets) & fading “human-in-the-loop”
Last Mile Learnings & Perspectives

LAST MILE LEARNINGS
- App barcode scanning 100% on off-the-shelf iPhone
- Expiration, verification & inspection targets all met
- Verifying by interoperating with upstream relational database
- Refrigerator level inventory tracking & soft quarantine required
- Quarantine stickers & trays to achieve physical separation
- Generated 3911 reports automatically (none were needed!)
- >17¢/unit cost borne by dispenser, not including safety stock

DISPENSER PERSPECTIVES
- Barcoding at unit level: barcode size, quality & placement
- Quick verifications have potential to avoid safety stock
- Crisp guidance(s) for white bagging, 3911s, inspection
- “Least cost avoider”... reward compliance with “bottle bill”? 
BRUINchain Key Differentiators

NEAR REAL-TIME GROUND TRUTH on a SCALABLE PLATFORM

➪ Real person scanning real salable unit is initiator
➪ PULL SYSTEM RATHER THAN PUSH

➪ Expiry/verification checks & physical inspections all recorded
➪ Verification by interoperating with upstream databases
➪ "Refrigerator level" inventory tracking (custody vs. inventory)
➪ Soft quarantine built in
➪ Automated 3911 reporting built in
➪ Master Data Management content built in
➪ Recalls and Extended Expiration built in
➪ Updated Package Inserts built in
Acknowledgements

Special thanks to UCLA Health under the leadership of CEO Johnese Spisso, including Marlon Barrios, Veronica Burwick (PharmD), Cheng Cai (PharmD), & Jacquilin Parker; and Victor Dods (PhD), Leo Alekseyev (PhD) & Ben Nichols of LedgerDomain. Grateful for Biogen’s support, from Imran Shakur and Serialization Lead Bjoern Rosner (PhD), including Steve Van Nuffel, Derry Manley, Lindy Blom & Donncha Phelan. Thanks also to Leigh Verbois (PhD), Connie Jung (PhD) & Dan Bellingham, all of FDA; Bob Celeste; and Desmond Hunt (PhD).

Resources

Peer-reviewed study in BHTY...
doi.org/10.30953/bhty.v3.134

Scalability demo...
LedgerPalooza.com/livestream

Scan your own drugs...
LedgerPalooza.com/sad
Appendix 2.

BRUINCHAIN Architecture

OrgAdmin
Channels/Members

SysAdmin
DevOps/Monitor

Governance
Root-of-Trust

App-on-DocuSeal
DocuSeal SDK
Oraculous Interop

SELVEDGE
Fabric DevOps Tools

Selvedge go-SDK
goHFC SDK

OFF-CHAIN
PRIVATE COLLECTIONS
& Syndicated Content

Smart Contracts
Membership
Transactions
Event Services
Consensus
Blockchain
Infrastructure

FABRIC CA ORG
FABRIC CA TOOLKIT
SECURE COMMS (IOSCC)
PEERS & NODES

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Healthcare

DSCSA Pilot Project readiness results

How the industry is preparing for DSCSA Interoperability

Peter Sturtevant, Sr. Director Community Engagement, GS1 US
Scott Mooney, VP Distribution Operations, McKesson Corporation
Antitrust Caution

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We ask and expect everyone to refrain from discussing prices, margins, discounts, suppliers, the timing of price changes, marketing or product plans, or other competitively sensitive topics.

If anyone has concerns about the propriety of a discussion, please inform a GS1 US® representative as soon as possible.

Please remember to make your own business decisions and that all GS1 Standards are voluntary and not mandatory.

Please review the complete GS1 US antitrust policy at: www.gs1us.org/gs1-us-antitrust-compliance-policy
DSCSA Pilot Project - Goals/Objectives:

• Measure year over year progress of industry preparedness for DSCSA, in terms of manufacturers’ packages and homogeneous cases.

• Expand the scope of analysis to include the 2023 requirements and quantify impacts of readiness in these areas.

• At a high level, objectives of barcode testing include examination of:
  - 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
Pilot Participants

- **AmerisourceBergen**
  - Wholesale Distributor – Specialty Products – Packages

- **Cardinal Health**
  - Wholesale Distributor – National Logistics Center – Homogeneous Cases

- **McKesson Corporation**
  - Wholesale Distributor - core Rx Products - Packages

- **GS1 US**
  - Recognized International Standards body
Pilot Project Key Outcomes

• Last spring, the Big 3 wholesale distributors and GS1 US scanned over **50k barcodes** in their distribution centers.

• AmerisourceBergen and McKesson, with GS1 US, conducted a third series of barcode assessments of the “packages” to track year over year, progress on serialization of 2D barcodes with 4 Identifiers.

• Cardinal Health and GS1 US conducted the barcode assessment of “homogeneous cases” from pharmaceutical manufacturers with **linear or 2D barcodes** for the 2nd year.

• Scans of packages revealed more than **3-fold improvement** in serialized products, and **homogeneous cases 4 times greater** than the previous year.

Source: 2019 Update: Barcode Readability for DSCSA 2023 Interoperability
Excellent Three-Year Progress

Three-Year Progression of Serialized Products With a GS1 DataMatrix Containing Four Application Identifiers

- 2017: 6.7%
- 2018: 20.7%
- 2019: 74.3%
“It was fantastic to see the percentage increase so high. Now, we just have to fill the gap to get to 100 percent.” Scott Mooney, VP of Distribution Operations, Supply Chain Assurance, McKesson
### Package Results Over Three Years

#### Progress in 2D Barcode Adoption With DSCSA Requirements
AmerisourceBergen and McKesson

<table>
<thead>
<tr>
<th>Year</th>
<th>Packages Scanned</th>
<th>Packages 2017</th>
<th>Packages 2018</th>
<th>Packages 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>16,618</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>21,209</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>17,859</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Source: AmerisourceBergen, Cardinal Health, and McKesson barcode assessments*

- **Packages 2017:** 16,618
  - **6.6%** Readable barcodes with all four DSCSA data elements

- **Packages 2018:** 21,209
  - **20.7%** Readable barcodes with all four DSCSA data elements

- **Packages 2019:** 17,859
  - **72.5%** Readable barcodes with all four DSCSA data elements
Year-over-year significant change with the average expiration date of products being 1.6 years in 2019, compared to 2.3 years in 2018. “This could be a reflection of an industry build of inventory last year with lot-only based products, and in 2019, older inventory was consumed prior to the conversion of serialized packages.” Scott Mooney, VP of Distribution Operations, Supply Chain Assurance, McKesson
Improved Expiration Date

Properly encoding the barcode with the expiration date

• “Out of the 16,300 packages that we scanned, only 183 of these had expiration date issues. This was a huge, positive change and will be especially important when we start exchanging data as trading partners.”

Scott Mooney, VP of Distribution Operations, Supply Chain Assurance, McKesson

Mooney suspects that guidelines like the GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, helped suppliers make this shift.
Better Barcode Quality

• Legibility of barcodes on packages increased.

• In 2017 and 2018, certain barcodes on packages would not scan, since they were applied on shiny surfaces or were printed in inappropriate colors.

“These kinds of problems were nearly absent this year. To the best of my knowledge, we had only two instances where we experienced barcodes in difficult-to-read colors or surfaces. With the quality barcodes, we were able to scan noticeably quicker.”

Scott Mooney, VP of Distribution Operations, Supply Chain Assurance, McKesson
Color: Symbol Bars and Spaces

- **Bars:**
  - Black is best
  - Next best dark blue or green
  - No red, orange, or yellow bars

- **Spaces:**
  - White is best
  - Next best red and orange
  - No blacks, dark blues, or dark greens

### Bars

<table>
<thead>
<tr>
<th>BEST</th>
<th>NEXT BEST</th>
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</thead>
<tbody>
<tr>
<td><img src="image1" alt="Black Bar" /></td>
<td><img src="image2" alt="Dark Blue Bar" /></td>
<td><img src="image3" alt="Green Bar" /></td>
</tr>
<tr>
<td><strong>NO</strong></td>
<td><strong>NO</strong></td>
<td><strong>NO</strong></td>
</tr>
<tr>
<td><img src="image4" alt="Red Bar" /></td>
<td><img src="image5" alt="Orange Bar" /></td>
<td><img src="image6" alt="Yellow Bar" /></td>
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</table>

### Spaces

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<th>NEXT BEST</th>
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</thead>
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<tr>
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<td><img src="image8" alt="Red Space" /></td>
<td><img src="image9" alt="Orange Space" /></td>
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<tr>
<td><strong>NO</strong></td>
<td><strong>NO</strong></td>
<td><strong>NO</strong></td>
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<td><img src="image10" alt="Black Space" /></td>
<td><img src="image11" alt="Dark Blue Space" /></td>
<td><img src="image12" alt="Dark Green Space" /></td>
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<tr>
<td><strong>NO</strong></td>
<td><strong>NO</strong></td>
<td><strong>NO</strong></td>
</tr>
</tbody>
</table>
## Homogeneous Case Results Over Two Years

### Progress in 2D Barcode Adoption With DSCSA Requirements

**Cardinal Health**

<table>
<thead>
<tr>
<th>Year</th>
<th>Homogeneous Cases 2018</th>
<th>Homogeneous Cases 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>6,481</td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>7,996</td>
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</tr>
</tbody>
</table>

- **Readable barcodes with all four DSCSA data elements**
  - **2018**: 15.1% (readable 2D barcodes)
  - **2019**: 78.7% (readable linear barcodes)

- **2018**: 73.3% (readable linear barcodes)

**Source**: AmerisourceBergen, Cardinal Health, and McKesson barcode assessments
“After last year’s assessment, we really dug into the data. We started talking with our suppliers, reaching out to understand any issues. This understanding was crucial for us in order to push for the highest level of compliance. Bad barcodes mean bad problems for the supply chain.”

Quentin Dittman, Director of Operations Technology at Cardinal Health

The HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain recommend that manufacturers use two linear barcodes with the NDC represented in the assigned GTIN and serial number in one and the lot number and expiration date in the other, or one 2D barcode encoding all four data elements.
“With full traceability planned for 2023, the ability to track and communicate across the supply chain will be down to the unique lowest saleable unit. This has never been available before and will unlock value and increase accuracy and specificity to new levels.”

Ameer Ali, Senior Manager, Secure Supply Chain & Manufacturer Operations, AmerisourceBergen
TraceLink FDA Pilot Project
DSCSA Trace Histories and Digital Recalls Network

Brian Daleiden, TraceLink Inc.
July 23, 2020
TraceLink’s “2023 Pilot Project Workgroup” was an industry-led project designed to create learnings and explore alternative approaches to prepare for DSCSA’s 2023 requirements and continuing to enhance the efficiency and effectiveness of the pharmaceutical supply chain.

✓ Deeply analyze and describe current pharma supply chain processes for product traceability and recalls
✓ Develop approaches and test requirements for a future digital supply chain infrastructure (systems, processes, data, and network interactions)
✓ Identify the opportunities/benefits and challenges for enabling such a vision
✓ Create a strong body of knowledge to leverage for future exploration and to help inform future discussions across the industry and with the FDA

TraceLink’s pilot project supported two dedicated workstreams to explore key pilot areas:

**Trace Histories**
Interoperable information sharing and “gather upon request” model for DSCSA 2023 compliance leveraging a blockchain-based tool

**Digital Recalls**
Electronic tracing, verification, and notification for patient safety by enabling a digital recalls network
The FDA Pilot Project was an Industry-Led Collaboration
Cross-Industry, Cross-Archetype Discussion was Critical in Understanding Challenges/Opportunities

<table>
<thead>
<tr>
<th>Contract Manufacturers</th>
<th>Pharmaceutical Companies / Repackagers</th>
<th>Wholesale Distributors</th>
<th>Dispensers</th>
<th>3PLs / Return Providers</th>
</tr>
</thead>
</table>
| Patheon, by Thermo Fisher Scientific Sharp | Pfizer  
Bristol Myers Squibb  
EMD Serono / Merck KGaA  
Novartis  
Sandoz  
Johnson & Johnson  
Flexion Therapeutics  
Agios Pharmaceuticals  
Sagent Pharmaceuticals  
Par Pharmaceuticals  
A-S Meds | McKesson Value Drug Company | CVS Health  
Novant Health  
Yale New Haven Health  
Wegmans | PharmaLink  
DHL  
Woodfield Distribution |
Digital Recalls
Workstream
Digital Recalls Workstream

Key Objectives

- Map As-Is Recalls Process
- Identify Current Issues, Risks, and Uncertainties
- Evaluate a Digital Recalls Network Model
- Analyze Evolution and Adoption Path

Key Outcomes

- Execution and closure of product recalls today is slower, less precise, and takes more work for all stakeholders than desired due to:
  - Manual communications and response methods
  - Limited ability to identify and filter stakeholders with affected product
  - Delays in locating and quarantining affected product in inventory and on shelves
  - Complexities in monitoring progress and measuring closure rate

- The pilot team found opportunities to improve coordination, confidence, and performance:
  - Enable more timely and precise recall notifications and stakeholder responses
  - Enhance recalled product identification and quarantine processes in the supply chain
  - Speed the ability to remove recalled product from the supply network
  - Improve the ability to monitor recall progress, leading to a faster and more accurate closure of recall events
Learnings and Takeaways

- Many of the foundational building blocks to enable a digital recalls network are available today: lot-level DSCSA TI information, serialized product identifiers, electronic traceability repositories across the supply chain, collaborative process team environments, and enhanced electronic integration networks and portals driven by DSCSA requirements.

- Incremental opportunities exist to implement elements of an interconnected and interoperable digital recalls network, with each providing a unique set of benefits.
  - Communication – Electronic messaging frameworks for preparation, messaging, and communication of a recall event
  - Response - Supply chain stakeholder initial response and preliminary actions in a bi-directional, more collaborative workflow environment
  - Execute / Close - Inventory / shelf sweeps, reverse logistics coordination, and execution monitoring prior to closure determination executed in coordination with traceability and serialization systems

- Discrete models for each part of the end-to-end recalls process were developed and tested in mock recalls, demonstrating how elements of a digital recalls network could be implemented and deployed in stages, enabling companies to test, to learn, and to optimize.

- Operational process review and change management is critical in building confidence in the approach, coupled by engagement and alignment with FDA expectations and guidance.

- While the primary focus was on improving the recalls process and execution across the supply chain, opportunities were also uncovered and analyzed to potentially improve communication to and engagement with patients in possession of recalled products.
Trace Histories Workstream

Key Objectives
Study business processes and technologies for DSCSA 2023 sTI gathering requirements, and test “gather upon request” approaches using the blockchain-based Trace Histories tool
• Interoperability and Integration
• Data Management and Ownership
• Business Processes and Change Management
• Technical Infrastructure

Key Outcomes
Frameworks for DSCSA 2023 product traceability process and solution value analysis
• Product and data flow use cases highlighting complex, diverse product movement
• Operational environment analyses describing complex process and system interactions
• Network architecture approaches denoting options and considerations for technologies including distributed ledger / blockchain methods
• Interoperability considerations and standards requirements to embrace and manage the heterogeneous nature of the supply chain, its stakeholders, and its systems
Learnings and Takeaways

• We continue to build an understanding and appreciation of the full complexity and diversity of the pharma supply chain – product and data flows, processes, inter-company orchestration.

• The change to this network to enable unit-level traceability and verification (where required) of product across the supply chain will be immense. Russia, EU FMD and DSCSA VRS provide initial indications.

• There won’t be a single “big-bang” technology or system which solves everything.

• Expect the end result to be heterogeneous and highly diverse, making open interoperability and alignment on expectations across stakeholders a critical success factor.

• Many potential technologies or solution approaches, including blockchain-based systems, do demonstrate significant promise but still need more time to be fully understood and tested.

• Equally, if not more important, are the adjustment and maturation of multi-enterprise processes, internal SOPs, etc. to manage serialized product operations and traceability in today’s high volume, increasingly complex product supply chain.

• Future success will also be colored by the ability to build an agile digital supply chain that embraces the full diversity of the end-to-end supply chain, and one that isn’t fragile in managing challenges of data integrity, process exceptions, and unexpected daily issues.
Questions?

For a copy of the final report or to discuss the pilots in more depth:

Brian Daleiden
bdaleiden@tracelink.com
Small Dispenser Pilot Study

Understanding the Impact of the Current and Upcoming Track and Trace Federal Requirements on Small Dispensers

Providence Health Technologies
July 23, 2020
Introduction

Purpose

• What burden if any will small dispensers be taking with the 2013 DQSA Legislations?
• Is the supply chain ready for small dispensers to take on the above-mentioned responsibility?
• What changes/recommendations are required for the above to take place?
## Introduction

**Purpose**

- What burden if any will small dispensers be taking with the 2013 DQSA Legislations?
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- What changes/recommendations are required for the above to take place?

**Partners**

- Providence Health Technologies, Todd Barrett
- Hamacher Resource Group, Dawn Vogelsang
- Advasur, Randy Hoggle
Introduction

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Partners

• Providence Health Technologies, Todd Barrett
• Hamacher Resource Group, Dawn Vogelsang
• Advasur, Randy Hoggle

Participants

• Long Term Care Pharmacies (3)
• Specialty Pharmacies (2)
• Hospital Pharmacies (2)
• Independent Retail Pharmacies (10)
Key Objectives

**Small Dispensers Compliance**

- Assess ability for Small Dispensers to comply with the DSCSA requirements
- Measure awareness of the DSCSA dispenser requirements among four Small Dispenser types
- Assess current state of Small Dispenser readiness for 2020 & 2023 DSCSA requirements
- Calculate associated costs to implement systems
Key Objectives

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Workflow & Best Practice

• Develop best practices model for Small Dispensers compliance
• Simulate full scale workflow in pharmacies and measure impact
Key Objectives

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Workflow & Best Practice

- Develop best practices model for Small Dispensers compliance
- Simulate full scale workflow in pharmacies and measure impact

Product Compliance

- Measure percent of products received at each level of serialization compliance
- Evaluate accuracy of scanned data vs ship notices
Key Outcomes

Small Dispensers Compliance

- Small dispenser pharmacies were willing and able to comply with the DSCSA requirements outlined for dispensers.
- There was no significant difference in prior DSCSA knowledge or awareness between the different dispenser types.
- The study helped dispensers gain confidence that compliance could be achieved.
- It is anticipated that our dispensers could spend over $15,000 per annum to properly scan, identify, and verify each serialized product. Extrapolating industry wide for over 67,000 dispensers, the average cost of this endeavor would be over $1 billion annually.
Key Outcomes

Small Dispensers Compliance

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Workflow & Best Practice

• In developing the processes for implementation and execution of data collection for the study, we determined that it was best to standardize “Best Practices” for drug product procurement and inventory maintenance.
• Dispensers agreed to make changes that improved workflow and improved scanning efficiency. However, most pharmacies found that the scanning, and more significantly the prompts to take pictures of non-compliant drugs, created significant barriers within their workflow.
Key Outcomes

Product Compliance

• The non-compliance rate for barcodes when we began the study was reasonably high and, as predicted, improved as the study progressed. As non-serialized inventory within the supply chain was consumed, it was replaced with DSCSA compliant labeling.

• Data received via the electronic advance ship notices (ASNs) were of poor quality with many of the required data elements missing. In some instances products were missing National Drug Code (NDC) records. Additionally, there were challenges in discerning whether a ship date should be present and added to the shipment notice upon transmission.

• While most manufacturers and labelers incorporated the assigned legacy NDC numbers into the Global Trade Item Number (GTIN) format, there was no assurance that this was universal, nor reliable.
Conclusion & Recommendations

Continued Education

- Make available more continuing education programs for pharmacists
- Provide detailed training and resource programs on FDA Guidance and upcoming regulations required for both dispensers and wholesale distributors
- Work with Pharmacy Associations and Trade Groups to provide educational programs describing how FDA Guidance impacts decisions for pharmacy dispensers
Conclusion & Recommendations

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**Data Input & Mapping**

- Development of a GTIN to NDC crosswalk data index is imperative
- Alternatives to scanning the incoming prescription product shipments should be evaluated to meet product lot level validation
## Conclusion & Recommendations

### Continued Education

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### Data Input & Mapping

- Development of a GTIN to NDC crosswalk data index is imperative
- Alternatives to scanning the incoming prescription product shipments should be evaluated to meet product lot level validation

### Product Compliance

- Encourage suppliers to provide data in an electronic format to dispenser customers
- Work with suppliers and manufacturers to standardize data elements within ASNs (EDI 856 formatted data)
Cryptographic Identity Authentication (CIA)

IDLogiq Inc.
FDA DSCSA Pilot
Introduction – Workflows of Entities Participated in the Pilot

- MFG
- Wholesaler
- Repackager
- Pharmacy or hospital
- IDLogiq
- Consumer
- Distributed Directory Service
- DSCSA WebService
- Consumer WebService
- IDLogiq
- EPCIS
- Ledger

Products

- Alexso
- Simulator
- Distributor
- Dispensers

- EPCIS
- Ledger
Examples / Demo
Example Screenshots of Errors, Exception Condition

- **Repackaging:** Invalid ownership of product
- **Aggregation:** Items has already been aggregated
- **Dis-aggregation:** Item has already been disaggregated
- **Repackaging:** Item has already been repackaged
- **Counterfeit detected viaCryptographic ID Authentication**
Video Track and Trace of a Product Life Cycle
### Shipping Information

<table>
<thead>
<tr>
<th>Shipped Date</th>
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<tbody>
<tr>
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<td>SA3, LLC</td>
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<tr>
<td>Shipped To</td>
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#### (TI) Item Shipped

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</table>
Pilot Project Key Outcomes

• Interoperability
  – ASN EDI 856 legacy or vendor-specific proprietary XML still widely used
  – Issues with getting cooperation from a different technology provider. We think this will continue to be a major hurdle for the industry because it is more political than technological problems.

• Serialization
  – Common trend: use GTIN

• Barcode
  – Successful on both curved and flat surface
  – Also, NFC was successfully used together with barcode

• Aggregation/Disaggregation
  – Without good process automation software, production could be heavily impacted

• Verification/Notification
  – Human errors due to mismanagement should be seriously considered
  – Without robust automation software, this would be a very challenging task
Key Conclusions and Recommendations

• Interop will require cooperation from ALL parties.
  – Not so much a technology issue, but a complex topic politically
  – Recommendation: FDA to promote corporation between all technology developers and trading partners.
  – Interop test lab, test suites

• Automation software is necessary for package level tracing at all phases of production and DSCSA events to mitigate errors / exception condition due to technical and human errors.
  – Aggregation, Disaggregation, Repackaging, Shipping, Receiving, simple ownership transfer

• Would be helpful if FDA defines a standard and examples for the details of the report and terminology inside TI and TH.
  – Potential interop issues
THE END

Contacts:
Email: info@dlogiq.com,
Product Identifier Verifications by a CMO on behalf of MAH

Pilot Results, July 23rd 2020
Agenda

- Objective and Introduction
- Pilot Project Participants
- Pilot Project Outcomes
- Pilot Project Conclusions
- Pilot Project Recommendations
Objective and Introduction

**Traditional**

All SNs in MAH VRS Repository

**Verification Delegation:**

All SNs in CMO VRS Repository
# Pilot Project Participants

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<thead>
<tr>
<th>Company</th>
<th>Type</th>
<th>Contact</th>
<th>Size: Number of employees</th>
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<td>Sanofi</td>
<td>Manufacturer</td>
<td>Arthi Nagaraj <a href="mailto:Arthi.Nagaraj@sanofi.com">Arthi.Nagaraj@sanofi.com</a></td>
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<td>McKesson</td>
<td>Wholesale Distributor</td>
<td>Scott Mooney <a href="mailto:Scott.Mooney@McKesson.com">Scott.Mooney@McKesson.com</a></td>
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<td>Advanz Pharma</td>
<td>Virtual Manufacturer</td>
<td>Chris Humphrey <a href="mailto:Chris.Humphrey@advanzpharma.com">Chris.Humphrey@advanzpharma.com</a></td>
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<td>Saad Achouri <a href="mailto:sachouri@adents.com">sachouri@adents.com</a></td>
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</table>
Pilot Project Outcomes

- CMO and MAH DSCSA responsibility only known to the 2 parties
- Dependence on solution providers during investigations
  - Challenges on different terminologies and interfaces used by solution providers
  - Significant time needed to investigate even in a small pilot with 3 solution providers, 1 wholesale distributor & 2 manufacturers
- This process in effect tested the Mergers and Acquisitions logic.
Pilot Project Conclusions

- Interoperability and delegation of verification is possible between the Contract Manufacturer (CMO) and the Marketing Authorization Holder (MAH) using the VRS network.

- Demonstrated that delegation is effective

- Parties involved in delegation need a clear understanding of who is responsible for what
Pilot Project Recommendations

• **Set up an agreement on who is responsible to load the LD**
  • If GTIN is initially pointing one entity (MAH) and is then delegated to the CMO, updating the Look up directory with the GTIN pointing to the CMO did not automatically update the network

• **Understand the HDA Specifications**
  • The start and end date fields in the LD entry by the CMO overlapped with the dates in the LD entry by the MAH. Due to this, the LD update by the CMO was rejected

• **Standardize key functionalities**
  • Different terminologies and system functionalities used to achieve the same action between service providers cause confusion when debugging an issue

• **Understand how the ERP or serialization system master data ties to the VRS master data**
  • Production as a CMO for a MAH may mean having the GLN of the MAH in internal serialization systems. Depending on system connectivity and data flows, you may end up with a response to the VRS request with the CMO GLN instead of the MAH
Pilot Project Recommendations

• Capture error messages by intermediate systems
  • In a test performed, the manufacturer report showed that the verification was false (as expected) but the distributor received an error

• Alignment on who triggers a communication when there is a false verification or an error

• Perform a complete network test prior to “go-live”
  • Perform a full test in the production environment with provisions/discretions on triggering a suspect product. A full test can help bring other issues to the surface, including which party raises the error
THANK YOU
PDG Governance Pilot Report
FDA DSCSA PILOT PROJECT PROGRAM

June 24, 2020
Partnership for DSCSA Governance (PDG)

A collaborative forum dedicated to developing, advancing, and sustaining an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S.

www.dscsagovernance.com

@DSCSAGovernance

Alissa McCaffrey, Leavitt Partners
Staff Lead, PDG Pilot Work Group

Brian Lee, affiliated with Bristol-Myers Squibb
PDG Board Member
Chair, PDG Interoperability Committee

Matthew Price, affiliated with Medline Industries
PDG Board Member
Co-Chair, PDG Pilot Work Group
PDG Guiding Principles

1. All supply chain sectors should work collaboratively to establish efficient, viable, and effective systems and processes to protect patients through compliance with the DSCSA 2023 requirements.

2. 2023 system architectures should be governed by trading partners through a balanced, independent, sector-neutral legal entity.

3. The governance body’s activities should support interoperable exchange, interoperable verification, and interoperable tracing, as required by the DSCSA.

4. Rules for membership and use will incent participation.
PDG Structure

General Membership
(Trading Partner Members and Association Members)

Staff

Officers

Board

Appoints

Appoints

Appoints

Appoints

Dialogue

Recommendations

Dialogue

Recommendations

Committee Chair

Committee Chair

Committee/Subcommittees

Interoperability Committee Chair

Interoperability Committee/Subcommittees

Technical Work Group

Membership Committee Chair

Membership Committee/Subcommittees

Finance Committee Chair

Finance Committee/Subcommittees

Appoints

Elections

Employees/Contracted

Elections

Volunteers

Interested Stakeholder Groups
Pilot Objectives & Outcome

Objectives

1. Ensure that the structural and organizational aspects of the governance body allow the organization to meet the goals of governance.
2. Improve governance systems and processes at the outset of governance body formation.
3. Identify challenges with the operation of the governance body’s initial systems and processes for governance.

Outcome

Success; Industry can collectively and collaboratively govern the DSCSA interoperability environment as needed to support successful implementation.
Pilot Work Group Participants

Manufacturers/Repackagers
- Bristol Myers Squibb
- Endo Pharmaceuticals
- Genentech
- Johnson & Johnson
- Pfizer
- Sanofi

Wholesale Distributors/3PLs
- Hercules Pharmaceuticals
- The International Warehouse Logistics Association (IWLA)
- Inmar Intelligence
- McKesson
- Medline Industries

Dispensers
- CVS Health
- Uptown Pharmacy
- Walgreens

Technical Experts
- Chronicled
- TraceLink
- rfxcel
- Providence Health Technologies
- Second Generation/.med
Pilot Scope

Governance structures and processes were tested in the context of a governance use case: Developing proposed systems and processes for confirming the “authorized” (as defined in the DSCSA) status of trading partners.

- **Business Requirements**: Common, agreed upon business requirements for compliance with DSCSA. 
  
  *E.g., source against which ATP status must be confirmed, frequency with which it must be confirmed*

- **Interoperable Electronic Systems**: Identification of methods, standards, and technologies needed for interoperable electronic systems that satisfy the business requirements.

  *E.g., standards for electronic credentials conveying ATP status*

- **Ensuring Adherence to Requirements and Technology**: Methods and mechanisms that provide assurance to other TPs that business and technology requirements are being met.

  *E.g., FDA regulation incorporating requirements, a PDG badging program, standardized contract language*
1. Methods/mechanisms for engagement with technical experts
2. Methods/mechanisms for engagement with non-members
3. Methods/mechanisms for engagement with FDA and regulators
4. Incorporation of, and ability to leverage, existing/prior non-PDG efforts
5. Allocation of responsibilities between the Board, Interoperability Committee, and Work Groups
6. Handoffs and relationship between Board, Committees, and Work Groups
7. Board participation
8. Work Group structure and participation
9. Meeting (Board and Committee) cadence and organization
10. Execution of project plan
11. Outputs/documentation

Metrics to Evaluate Governance Structures & Processes
# Key Findings

<table>
<thead>
<tr>
<th>PDG Formation</th>
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<tbody>
<tr>
<td>Sufficient Membership</td>
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<td>Successful Formation</td>
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<td>Sufficient Financial Commitments</td>
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<th>Notable Pilot Successes</th>
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<tr>
<td>Meaningful technical participation</td>
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<tr>
<td>Valuable FDA presence</td>
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<tr>
<td>Effective use of prior work</td>
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<td>Prior work not seen as binding</td>
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<td>Fair and equal participation</td>
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<td>Fair and balanced decision making</td>
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<td>No major process issues</td>
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Conclusions & Recommendations

Lesson 1: Ensuring Respect for Output

Recommendation: Define consensus and determine appropriate input
Conclusions & Recommendations

Lesson 2: Speed vs. Substance

Recommendations:
- Allow for discussions of appropriate depth and detail
- Leverage voting mechanisms, but avoid premature voting
- Manage meeting length and frequency
Lesson 3: Difficulty of Isolating One Use Case

Recommendations:
- Acknowledge the broader context
- Emphasize cross-work group communication
- Agree on key principles and assumptions for 2023
### PDG Formation Activities

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<td>September 30, 2019</td>
<td>Non-binding Membership Commitments Due*</td>
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<tr>
<td>October 4, 2019</td>
<td>Entity Officially Incorporated</td>
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<td>October 11, 2019</td>
<td>Expression of Intent to Run for Board Seats Due</td>
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<td>October 14, 2019</td>
<td>Governance Body Kick-Off Meeting</td>
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<td>October 15 – October 30, 2019</td>
<td>Board Elections</td>
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<td>November 13, 2019</td>
<td>Board Officially Seated; Entity Officially Named the Partnership for DSCSA Governance (PDG)</td>
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<td>November 21, 2019</td>
<td>Board Meeting; Committee Chairs Appointed</td>
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<td>December 12, 2019</td>
<td>Board Meeting</td>
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<td>December 13, 2019</td>
<td>PDG Membership &amp; Prospects Meeting</td>
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<td>December 16, 2019</td>
<td>Public Rollout of PDG</td>
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<td>January 2020</td>
<td>Committee Activity Begins</td>
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*Non-binding membership commitments were solicited to determine whether there was sufficient interest to move forward with formation of a governance body. The commitments received by September 30, 2019 indicated that there was sufficient cross-sector industry interest in establishing a governance body to move forward with formal incorporation of the entity.
Governance Use Case: Business Requirements

Reliable demonstration/documentation of authorized status
  ▪ E.g., What is the source documentation of authorized status?

Responsibility for confirmation of authorized status
  ▪ E.g., Who is responsible for confirmation, and how can that be delegated?

Identification of the correct trading partner
  ▪ E.g., Who is the trading partner in a co-licensed partner scenario?

Frequency of confirmation of authorized status
  ▪ E.g., How frequently must authorized status be confirmed/updated?

Resolution of exceptions and non-confirmation authorized status
  ▪ E.g., How are other “network” participants notified if there is a failure of authorized status?

Relationship with user authentication
  ▪ E.g., How can authorized status be incorporated into systems and processes for user authentication?
Methods

DSCSA FDA Governance Pilot

- Accepted: April 2019
- Industry Workshop: May 2019
- Continued Conversation
- PDG Formation: Nov. 2019
- Pilot WG Formed: Dec. 2019
- Pilot Use Case Discussion: Jan. 2020 – April 2020
- Mid-Pilot Survey
- End-of-Pilot Survey
- Final Report: April 2020
Key Findings

Learnings: Mid-Pilot Survey

- To better evaluate the incorporation and use of prior work, the Pilot Work Group should discuss/leverage prior work in additional ways.
- Roles and responsibilities of the Work Group, Committee, and Board should be made more explicit and are not yet well-understood by Work Group members.
- PDG should provide additional clarity to Work Group members around which portions of substantive work product should be elevated to the Board.
- To better evaluate Work Group/Committee operations, the Work Group should find additional opportunities to leverage and assess the voting process.
- Materials and recaps should be distributed sooner.
- The majority of work plan items have not been completed on time. PDG should seek to balance speed/efficiency of output and depth of discussion over time.
- Pilot Work Group output should be disseminated with additional context for those not involved in the conversations.
Key Findings

Learnings: End of Pilot Survey

- Participants have varying levels of technical expertise. PDG should be intentional about recognizing this diversity and using it to its advantage.
- Conversations to-date have not required deep technical expertise. PDG should explore and find the best ways to “deep-dive” into technical solutions.
- PDG members need more clarity on the roles and responsibilities of each part of the organization. PDG should consider creating an explanatory document on governance roles and responsibilities.
- For efficiency and participation purposes, PDG should consider utilizing tools for real-time feedback/voting rather than taking offline polls.
- PDG should continue to work on ensuring continuity of conversations and explore tools in addition to meeting recaps to assist those who miss a call.
- PDG should continue to explore the appropriate role of the Board in substantive conversations.
- Active participation across all sectors and organizations continues to be a concern. PDG should consider the use of tools such as real-time polling or cold calling to improve participation.
- PDG should continue to promote membership and participation in the dispenser sector.
Appendix
<table>
<thead>
<tr>
<th>Terms</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAH</td>
<td>Marketing Authorization Holder</td>
</tr>
<tr>
<td>CMO</td>
<td>Contract Manufacturer</td>
</tr>
<tr>
<td>PI</td>
<td>Product Identifier. This consists of the GTIN, Serial number, Lot and Expiry</td>
</tr>
<tr>
<td>GTIN</td>
<td>Global Trade Identification Number. This is part of the GS1 standards that can be used by companies to identify their Trade items</td>
</tr>
<tr>
<td>DSCSA</td>
<td>Drug Supply Chain Security Act</td>
</tr>
<tr>
<td>VRS</td>
<td>Verification Router Service. This is an interoperable solution used to primarily address DSCSA verification requirements for the Saleable returns’ regulation</td>
</tr>
<tr>
<td>HDA</td>
<td>Healthcare Distribution Alliance. HDA is a national organization representing primary pharmaceutical distributors</td>
</tr>
<tr>
<td>LD</td>
<td>Lookup Directory. This is akin to a phonebook where manufacturers store their products’ GTINs so that the VRS knows to route the verification request to the correct manufacturer’s repository of product identifiers</td>
</tr>
<tr>
<td>GLN</td>
<td>Global Location Number. This is part of the GS1 standards that can be used by companies to identify their locations</td>
</tr>
<tr>
<td>Pilot</td>
<td>A small-scale study to evaluate feasibility of a concept</td>
</tr>
</tbody>
</table>
Interoperability Data Exchange Errors & Exception Handling DSCSA Pilot Project

Darlene Bond

6/25/2020
Agenda

• Introductions
• Key Objectives
• Key Outcomes
• Conclusions and Recommendations
• Next Steps
Introductions

• John “Quentin” Dittman - Director, Deployment Leader
  5100 Rings Road, Dublin, Ohio 43017
  Phone #: 614-757-3376
  E-mail: john.dittman@cardinalhealth.com

• Darlene Bond - Consultant, Business Analysis – Pharmaceutical Distribution IT
  5100 Rings Road, Dublin, Ohio 43017
  Phone #: 614-553-3031
  E-mail: darlene.bond@cardinalhealth.com
Key Objectives

Focus on two types of exceptions that occur within point-to-point serialized data transmission via EPCIS

Transmission Exceptions

• Identify data transmissions exceptions
  o file structure format
  o data element format
  o event sequencing
  o EPC event chronology
  o late transmissions
  o missing data elements

• Quantify the percentage of transmission errors received within our samples

Aggregation Exceptions

• Identify how aggregation exceptions are discovered by downstream trading partners and the resulting impact

• Measure the accuracy of aggregation data within our samples
## Key Outcomes

### Transmission Exceptions

<table>
<thead>
<tr>
<th>Exception Type</th>
<th>Data Samples Collected</th>
<th>Exception Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late Data Arrival</td>
<td>114</td>
<td>31%</td>
</tr>
<tr>
<td>EPC Event Chronology</td>
<td>44</td>
<td>12%</td>
</tr>
<tr>
<td>Master Data Missing</td>
<td>40</td>
<td>11%</td>
</tr>
<tr>
<td>EPCIS Structure Issues</td>
<td>40</td>
<td>11%</td>
</tr>
<tr>
<td>XML Structure Issues</td>
<td>40</td>
<td>11%</td>
</tr>
<tr>
<td>AS2 Setup/Transmission</td>
<td>26</td>
<td>7%</td>
</tr>
<tr>
<td>Incorrect Data Format</td>
<td>26</td>
<td>7%</td>
</tr>
<tr>
<td>Missing Required Data Element</td>
<td>18</td>
<td>5%</td>
</tr>
<tr>
<td>Master Data Setup</td>
<td>6</td>
<td>2%</td>
</tr>
<tr>
<td>Serial Number Configuration</td>
<td>4</td>
<td>1%</td>
</tr>
<tr>
<td>No Error</td>
<td>3</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>MQ Issue</td>
<td>1</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>System Processing Exception</td>
<td>1</td>
<td>&lt;1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>363</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
Key Outcomes

Transmission Exceptions

Resolution - For exception resolution we focused on the impact to warehouse operations

• Resolution for Late Data Arrival exceptions received the highest priority:
  o Master Data Setup and Master Data Missing exceptions
    – IT resolves by manually entering the missing master data into the event management system and reprocessing the EPCIS file
    – Industry Master Data sharing solutions like Global Data Synchronization Network and HDA Origins exists and could be used to integrate into our solutions, however these solutions are not widely embraced by industry
    – Most errors originated from our 3PL business wherein Master Data is exchanged/managed in an ERP outside EPCIS, and EPCIS is used primarily for chain of custody purposes
Key Outcomes

Transmission Exceptions

System Processing Exceptions

- Customized pre-processing logic was created out of necessity to cope with inefficiently assembled and/or large EPCIS files
- Configuration fine-tuning with our event management system was employed to address unusually large EPCIS messages
- Custom tools were created to provide warehouse personnel improved visibility into the event management system before receiving serialized products
## Key Outcomes

### Aggregation Exceptions Among Receiving Exceptions

<table>
<thead>
<tr>
<th>Exception Type</th>
<th>Data Samples</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item to case aggregation mismatch</td>
<td>170</td>
<td>35%</td>
</tr>
<tr>
<td>EPCIS SNI data not found</td>
<td>147</td>
<td>30%</td>
</tr>
<tr>
<td>SNI not found and no other SNIs belonging to this lot with valid disposition exist</td>
<td>82</td>
<td>17%</td>
</tr>
<tr>
<td>SNI disposition is invalid. No other SNIs belonging to this lot with valid disposition exist</td>
<td>20</td>
<td>4%</td>
</tr>
<tr>
<td>SNI disposition is invalid. But other SNIs belonging to this lot with valid disposition exist</td>
<td>18</td>
<td>4%</td>
</tr>
<tr>
<td>Case to pallet aggregation mismatch</td>
<td>12</td>
<td>2%</td>
</tr>
<tr>
<td>Scanned serial number Lot and exp date does not match with SNI Data returned</td>
<td>11</td>
<td>2%</td>
</tr>
<tr>
<td>SNI not found but other SNIs belonging to this lot with valid disposition exist</td>
<td>8</td>
<td>2%</td>
</tr>
<tr>
<td>Scanned lot does not match lot in EPCIS data</td>
<td>6</td>
<td>1%</td>
</tr>
<tr>
<td>Scanned expiration date does not match Expiration Date in EPCIS data</td>
<td>3</td>
<td>1%</td>
</tr>
<tr>
<td>Scanned barcode is not an item</td>
<td>2</td>
<td>0%</td>
</tr>
<tr>
<td>SNI found, but no item to case aggregation found</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Scanned serial number, lot and expiration date does not match with SNI data returned</td>
<td>11</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>491</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
Key Outcomes

Aggregation Exceptions

Resolution - For exception resolution we focused on the impact to warehouse operations

• Resolutions for the **Item to case aggregation mismatch, EPCIS SNI Data Not Found** and **Case to pallet aggregation mismatch** exceptions received the highest priority:
  - **Item to case aggregation mismatch** or **Case to pallet aggregation mismatch**
    - Item to case disaggregation events are processed and case EPC is decommissioned
    - Case to pallet disaggregation events are processed and pallet EPC is decommissioned
    - In either situation, a custom **EPCIS Reliability Report** provides necessary exception information used to regroup with our CMOs
  - **EPCIS SNI Data Not Found** exception during the receiving process
    - Custom tools were created to provide warehouse personnel improved visibility into the event management system before receiving serialized products
Conclusions and Recommendations

Transmission Exceptions

• Data Exchange Sampling
  o 150 manufacturers, repackers, CMOs, wholesale distributors and Cardinal Health business units.
  o 11 EPCIS providers

• Documentation
  o Cardinal Health published guidelines for exchanging serialization data with trading partners
    — Extensive work with trading partners on product/location master data and EPCIS format/structure issues.
  o Systematic exchange master data between Cardinal ERPs and the event management systems.
  o Trading partners to include the product and location master data within the EPCIS documents

• Success Criteria
  o Third party engagement to onboard trading partners
    — Generating appropriate EPCIS documents before vendor onboarding activities.
  o To successfully exchange serial number data in the pharmaceutical supply chain, trading partners must adhere to published GS1 standards and HDA industry guidance with no custom modifications.
Conclusions and Recommendations

Aggregation Exceptions

• Aggregation data sampling
  o Barcodes from randomly selected pallets, cases and items of serialized products
    – Scanned during receiving
    – Compared to the serialized EPCIS data

• Documentation
  o Reporting: EPCIS Reliability Report to track aggregation issues by repackager or by NDC.
  o Monitoring serial numbers allocated to repackagers of the Cardinal Health owned products.

• Success Criteria
  o As manufacturer, CMO and repackager packaging line processes mature, we expect to see fewer aggregation errors.
  o Expect any aggregation errors encountered to be handled in an “as needed” manner.
Next Steps

Transmission Exceptions

• Transmission of EPCIS data to downstream trading partners
  o Analyzing the need for document or process changes to support them.

• Investigating the use of a web-based portal
  o Allows dispensers to access serialization data
  o Avoids sending of EPCIS documents.

Aggregation Exceptions

• Exploring an internal “trusted” vendor process
  o Make receiving serialized products more efficient

• Creating tools to allow product flow
  o Align disposition of serial numbers with product movement.
Questions?
Agenda

- Introductions
- FDA Pilot Objectives and Overview
- Pilot Conclusions
- Next Steps
MediLedger Pilot Leads

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Eric Garvin  
Head of Pharma Solutions, Chronicled  
121 Minna Street  
San Francisco, CA 94105  
eric@chronicled.com  
773-858-4998
MediLedger Basics
MediLedger Basics

- Trusted, real-time industry-wide network to automate the way trading partners do business together

Questions:
- Are these raw materials from the correct supplier?
- Is this product authentic?
- Was my supplier’s rebate correct?
The MediLedger Network

A secure, decentralized, peer-to-peer messaging network and blockchain network become the backbone for solutions between trading partners.

- Maintain total control over your private data
- Proof for every update published to blockchain

The MediLedger Node
- Peer-to-Peer Interface
- Blockchain Interface

Internal ERP System

Blockchain Network

Peer-to-Peer Network
MediLedger FDA Pilot Report - Published February 2020

Cross-industry effort to evaluate blockchain as a solution to DSCSA 2023 track and trace requirements

Manufacturers
- Pfizer
- AMGEN
- Genentech
- Novartis
- Gilead
- Hikma
- Dermira
- Lilly
- GSK
- Sanofi

Wholesalers
- McKesson
- AmerisourceBergen
- Cardinal Health

Dispensers
- Maxor
- Walmart
- Walgreens

Others
- Chronicled
- GS1 US
- FedEx
- INMAR Intelligence
- Center Supply Chain Studies
Pilot Objectives

Model supply chain events

- Attempt to model serialized data exchanges for prescription drugs using a blockchain/ledger-based system.

Define what’s possible

- Explore questions about the technology’s viability:
  - system performance
  - IT architecture
  - adoption challenges

Determine how errors can be managed

- Important to solutions to meet DSCSA 2023 will be the ability to manage error conditions that will proliferate when transactions are at the serial number level.

Pilot as an academic exercise

- The MediLedger pilot was not a commercial endeavor. The objective was to show what the industry thought about blockchain solutions for complying with DSCSA in 2023.
FDA Pilot Report
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FDA Pilot Request: Drug Supply Chain Security Act, 2023
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Working Group Approach
Guiding Principles
High Level System Requirements
Technology Solution
Solution Overview
Test User Interface
System Performance
Standards
Exception Handling
Suspect or Stolen Product Scenarios
System Adoption
Authorized Trading Partners
Vision for Use of Blockchain
Solution Overview
Guidelines for Governance
Blockchain Interoperability
Summary/Next Steps

https://www.mediledger.com/fda-pilot-project
MediLedger FDA Pilot Report - Highlights

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Guidelines for Governance
Blockchain Interoperability
Summary/Next Steps

- Used MediLedger prototype
- Collected information via testing of this prototype and simulation of business processes
- Used staged data for testing and simulated transactions
- Explored weaknesses in the supply chain and the simulation of “bad actors”

https://www.mediledger.com/fda-pilot-project
MediLedger FDA Pilot Report - Highlights

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Summary/Next Steps

● Industry First
● Increase Safety
● Inclusive / Fair
● Company Controlled Data

https://www.mediledger.com/fda-pilot-project
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System Adoption
Authorized Trading Partners
Vision for Use of Blockchain
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Guidelines for Governance
Blockchain Interoperability
Summary/Next Steps

- Enable participation by all authorized trading partners
- Ensure 100% privacy of data
- Process 2000+ transactions/second
- Manage aggregation/deaggregation and exception handling scenarios
- Eliminate potential for vendor lock-in

https://www.mediledger.com/fda-pilot-project
The overall vision of our work 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.
MediLedger FDA Pilot Report - Highlights

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Blockchain Interoperability
Summary/Next Steps

- **Private messaging** between Clients to exchange confidential messages between Trading Partners by leveraging EPCIS technology and standards.
- **Blockchain** as a shared, immutable ledger to register the proof of the authenticity of transactions and execute smart contracts.
- **zk-SNARKs** to further enhance privacy
Chain of custody and provenance can be assured

Business rules for each transaction can be enforced by blockchain smart contracts in real time, while keeping each company’s data 100% private.

Additional supply chain benefits for participants

Trust established by a blockchain network can be leveraged to flag suspicious product and automate exception handling.

Strong adoption required

Long-term success will require strong participation and adoption from all segments of the supply chain. (manufacturers, wholesalers, dispensers, service providers, etc.)

Interoperability standards are required

Without appropriate standards, it is unlikely that disparate track and trace systems can be interoperable.
MediLedger
How it could work
The MediLedger Network

A secure, decentralized, peer-to-peer messaging network and blockchain network become the backbone for solutions between trading partners.
DSCSA 2023: How it could work

1. GTINs managed on current systems
   - Complete control over private data behind internal firewall

2. Commissioned sGTIN records published on blockchain
   - Posts record of input transaction on blockchain

3. Ship product and send electronic record of transaction
   - Distributor

4. Blockchain Network
   - Authenticates registered trading partners as the product origin
   - Validates unique product identifiers
   - Allows for payment automation and rapid dispute resolution

The MediLedger Node
- Peer-to-Peer Interface
- Blockchain Interface
FDA Pilot Next Steps

PDG: Looking to industry direction on business requirements and expectations for interoperability

MediLedger Supply Chain Working Group: Topics will be discussed as they come up on Supply Chain Working Group

Industry dictates timing: Solution timing will depend on industry timing
Thank you!
For more info: eric@chronicled.com
Key Objectives

- Improve accuracy of tracking items throughout the supply chain
- Improve DSCSA compliance
  - Increase data accuracy (reduce rework due to errors)
  - Reduce cost
- Ensure interoperability between supply chain stakeholders
Key Outcomes

RFID Benefits
- Scan many at once
- Scan without line of sight
- TID anti-counterfeit mechanism
Key Outcomes

Centralized Master Data Repository
- Unlimited item attributes
- Not constrained by barcodes
- Dynamic attributes change over the item’s life

Compliments other tech
- Ex: blockchain

Maintains related data
- Ex: serial number in ASN/EDI
- Ex: GTIN
Key Outcomes

Serialized item lookups

Expiration & “Beyond Use” Dates
- Refrigerated example

Recalls
- Closed loop with manufacturer
- Positive progression tracking
- Partial batches
- Notifications (manufacturer & crowdsourced)

Suspect/Illegitimate Product
- Manufacturer notifications
- Automatic detection (TID & implausible occurrences)
Key Outcomes

Manufacturer Aggregation & Packaging

Combining RFID Tags and 2D code increased cost by an average of 5-7 cents

Using RFID improved SC efficiency because the data carrier not line of site

Cost-neutral, overall

👍🏻 Tags are more expensive than barcodes
👍🏻 SC Efficiency
👍🏻 Reduced aggregation errors
Conclusion

FDA should allow RFID
• As a data carrier for DSCSA data
• So long as it is accompanied by a serialized barcode

FDA should avoid selecting specific technologies & implementations
• For example, dictating how data gets exchanged
• Allow for simplicity and flexibility
Conclusion

Manufacturers should consider:

“Are RFID-based aggregation workflows right for me, my products, and my customers?”

For many, this would be beneficial

- Reduce the effort of gathering SN data for an investigation
- Address data integrity gaps for aggregation
- Enables downstream workflows & technologies
Conclusion

Unit-dose Serialization + MDR
- Benefits that customers are willing to pay for
- Is already proven

Helps with
- Inventory Management
- Recalls
- Suspect/Illegitimate Product
- Automation
- Data for manufacturers and FDA
Conclusion

DSCSA ≠ full supply chain security

That serial number [in the salable-unit barcode] is only good until it encounters a pair of scissors.

The real goal is full supply chain security, which means the combination of:

- unit-dose serialization
- a centralized master data repository
Next Steps

1. Sandoz is launching 6 RFID-tagged products in Q4
2. Kit Check is bringing other pharmaceutical manufacturers live
3. Pilots with other service providers to show inoperability
   • Digital recalls
   • Efficiency of gathering data for investigations
   • Verifications using RFID technology as a data carrier
     (small increase in cost addresses many of the data errors and gaps)
4. Thinking Beyond 2023
   • Interoperable platform
   • Tools for high-speed manufacturing lines
Thank You
01 Objectives

Supply Chain Provenance

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.

Patient Safety

**Improve patient safety** by triggering product alerts and increasing visibility to relevant supply chain partners in the event of a product investigation or recall.

Pilot

The Pilot was successful in demonstrating **both stated objectives**.
02 Key Features

Integrated manufacturer enterprise system to private permissioned blockchain and enabled post of product commissioning transaction.

Recorded subsequent receive, ship and dispense actions from manufacturer, distributor and dispenser on the blockchain ledger including established order and one up / one down privacy of information sharing.

Created product query function to verify product data.

Enabled alerts to be sent to product holders in the event of an investigation.

Enabled product recall communications to be sent in a targeted manner.
With a digital record following product movement, new opportunities to solve key challenges can be explored:

**Cold Chain Logistics**
Add data collected from IoT sensors to create an environmental history for each serialized product.

**Drug Shortages**
Analyze aggregated data across the platform to identify and address product shortages before they occur.

**Inventory Management**
Streamline processes to introduce a lean supply chain with optimized inventory management.
To foster industry adoption, an egalitarian, inclusive, open-sourced commercial solution should be considered to help launch a blockchain network intended for information exchange of the pharmaceutical product transactions in the United States.
To foster industry adoption, an egalitarian, inclusive, open-sourced commercial solution should be considered to help launch a blockchain network intended for information exchange of the pharmaceutical product transactions in the United States.

**DSCSA**

1. Accelerate the formation of supporting **policies**
2. Assisting the pharmaceutical supply chain stakeholders with **guidelines** to help extend existing industry standards to support this solution
3. Establish a **communication channel** with industry players who are developing similar solutions to share findings, received guidance, and actively collaborate

**Beyond DSCSA**

1. The number of **cold chain products** is rapidly expanding and visibility to temperature control and inventory levels will be paramount to reduce shortages and protect patients in the event of a recall
2. Expanded capabilities may require **cross agency collaboration**
3. A **platform centric approach** that meets the needs of many agencies on the backbone of a blockchain enabled DSCSA will accelerate deployment and adherence
Thank you!
FDA Pilot Project- DSCSA Verification to Improve Product Traceability at FMOL Health System

Chris Chandler, PharmD

July 31, 2020
DSCSA Verification to Improve Product Traceability Pilot

Participants

• Submitter Chris Chandler, PharmD and William Mosser, VP Franciscan Missionaries of our Lady (FMOL) Health System - Logistics One 12100 Little Cayman Ave Baton Rouge LA 70898
  – FMOLHS 22 Pharmacies located within our 11 hospitals and associated surgical centers, outpatient clinics, infusion centers and retail locations
  – Member of the Healthcare Transformation Group to SHARE best practices, DRIVE standards and TRANSFORM healthcare [https://www.healthcaretransformationgroup.com/](https://www.healthcaretransformationgroup.com/)

• Partners
  – ConsortiEX 3rd party DSCSA Service Provider 1000 N Water St Suite 950 Milwaukee WI 53202
    • Neal Long, CEO
    • Jim Brunner, Software Engineer - EDI Implementation Specialist
  – McKesson Pharma Wholesale Distributor - 6555 State Hwy 161 Irving TX 75039
    • Scott Mooney, VP Operations - Pharmaceutical Solutions and Services
    • David Pugh, B2B Customer Integration - EDI Specialist
DSCSA Verification Pilot to Improve Product Traceability

Goals & Objectives

• Automate delivery and confirmation the Dispenser has valid T3 for each product received from trading partners to the last mile

• Capture and achieve perfect order via electronic data interchange (EDI) and automatic identification and data capture (AIDC) for a touch-less process from trading partners through pharmacy receiving areas
DSCSA Verification Pilot to Improve Product Traceability

Process Studied

• Validation via DSCSA business rules running in the background of established supply chain practices to compare wholesaler T3 (EDI 856) with the bar code scanning data captured by the Dispenser upon receipt of the shipment

• We (FMOLHS, McKesson, ConsortiEX) acknowledge the FDA’s request for unit-level traceability, however lot and serial numbers are not electronically shared from the Wholesaler to Dispenser at this time
DSCSA Verification to Improve Product Traceability Pilot

Evaluation Methods

- Success rate of EDI 856 shipment T3 matching EDI 861 product receipt via dispenser bar code scans; can match to EPCIS if sent by suppliers*

- Identification of data, system, or process challenges to automating validation of DSCSA transaction data requirements

- For the full intent of DSCSA to improve the recall process via a secondary objective- in future pilots to carry the traceability to the patient record at administration or dispense or final decommission via return or destruction with a mock recall as proof of concept*

*previously studied by https://www.gs1.org/docs/healthcare/12h05_Traceability_put_into_praxis_MAGER_BONE_DREES_CHANDLER_eng.pdf
DSCSA Verification to Improve Product Traceability Pilot

Timeline and Results to-date

• Pilot Team weekly calls began in April 2019
  – Testing McKesson Connect Handheld Scanner Use, Remapping EDI, Aligning data (UoM), Adding unique identifier to link/match McKesson EDI
    • From Sep 5-16th 2019 we matched all 1017 lines of T3 (EDI 856) from McKesson at one of our Medical Centers with 994 NDC Receipt scan lines (EDI 861) with a 98% match; 2% (23) T3 lines did not have a receiving scan match due to item mismatch or failed scans resulting in manual receiving via McKesson Connect software program.

• Inventory Software Enhancements (*delayed by unforeseeable disruptions in 2020*)
  – Perfect order touchless 3-way match with bar code scanning at receipt (Advance Ship Notice EDI 856 plus PO Ack EDI 855 drop shipments match pharmacy barcode scans creating Order Receipt EDI 861)
  – Push scan of DSCSA Product Identifier, Lot Number, Expiration Date and Serial Number to inventory system and point-of-care cabinets
• EDI process flow for perfect order in pharmacy is complex!

• Use of McKesson Connect mobile handhelds
  – Main use is currently for accounts payable processes, look to Next Gen upgrade
  – 861 Order Receipt exceptions require a process for manual T3 matching

• EDI connections for drop shipment and direct supplier T3
  – Suppliers are still not 100% electronic, sending paper and/or directed to portals
  – Drop shipments have a different invoice number and require another field to match or SNI
  – Lack of a standard listing of products exempted from providing DSCSA T3
DSCSA Verification to Improve Product Traceability Pilot

Lessons Learned – ConsortiEX and McKesson

• Manual Intervention
  — Matching required customization to EDI transactions which needs to be maintained and replicated if expanded to other trading partners
  — Products or cases when the barcode scanner is not used for receiving (drop shipments and non-McKesson orders)
  — The process occurs after product receipt and accepted into inventory versus catching suspect/missing T3s prior to receipt
  — The linear scanners do not capture Lot/Expiration to automatically add to the T3 record for search ability; future enhancements with Next Gen McKesson Connect to begin in Fall 2020.

• Future Opportunity - unforeseen circumstances delayed Phase 2 to develop a comprehensive solution:
  — Incorporate 855 Order data to proactively identify drop shipments
  — Handle all received shipments, non-EDI records and new trading partners
  — Capture Lot # and Expiration date directly from 2D barcodes on delivered drugs
  — Check for T3 at receiving and prevent inventory without valid T3
Questions?
Additional Reference Slides
<table>
<thead>
<tr>
<th>Pharmacy Buyer</th>
<th>Distributor ERP (McKesson)</th>
<th>Distributor EDI (McKesson)</th>
<th>DSCSA Solution Provider (ConsortiEX)</th>
<th>FMOLHS Pharmacy Receiving</th>
<th>FMOLHS DSCSA Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily pharmacy order placed via Wholesale Distributor’s website</td>
<td>• Generate PO Ack to Distribution Center (DC) for product fulfillment</td>
<td>• Send PO Ack 855</td>
<td>Upload ASN 856 for DSCSA T3 retention on web portal; direct &amp; drop shipment suppliers do not all send EDI; upload paper T3 *Requires manual receipt in portal by Pharmacy receiver; who verifies T3 follows business rules including grandfathering?</td>
<td>• Scan tote label</td>
<td>Pilot 3-way match</td>
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<tr>
<td>*&lt;10% of orders placed directly with Manufacturers was out of scope for pilot</td>
<td>• Generate Invoice &amp; Advance Ship Notice (ASN)</td>
<td>• Send ASN 856* mapped for DSCSA Transaction Data (T3) excluding drop shipments &amp; Invoice 810</td>
<td></td>
<td>• Scan NDC bar codes</td>
<td>*Order - PO Ack 855 *fills drop ship gap noting pending T3</td>
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<td>• Cradle McKesson handheld generate Receiving Acceptance 861 &amp; Invoice AP520csv to Accounting</td>
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<td>*McKesson drop shipments do not retain PO to scan upon receipt; manually received in McKesson Connect</td>
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