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

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

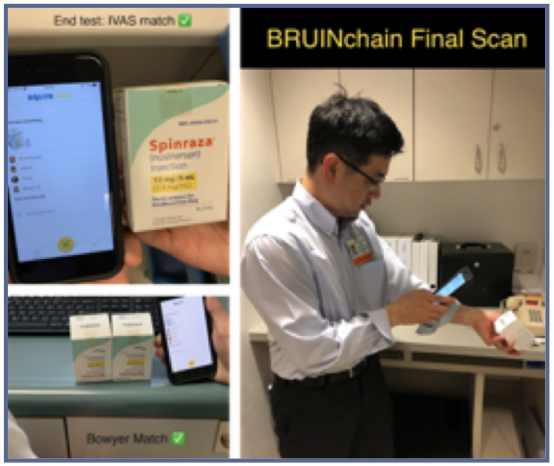
PDG FDA Pilot Program Round Robin, July 2020

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

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Partnership for DSCSA Governance

KitChain

Built KitChain for Clinical Supply Blockchain Working Group

Pfizer · IQVIA · UPS · MERCK · ThermoFisher Scientific · gsk

Member, Hyperledger Project

HYPERLEDGER FABRIC

FDA Naloxone Challenge

fda.gov/NewsEvents/PublicHealthFocus/ucm533711.htm

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THE TEAM

Sponsor: Ben Taylor (LedgerDomain LLC)
Submission by TeamMIT

GS1 US GS1 Healthcare US® Initiative

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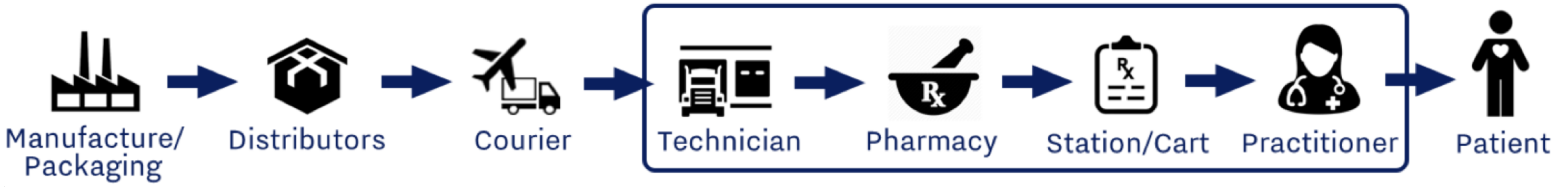
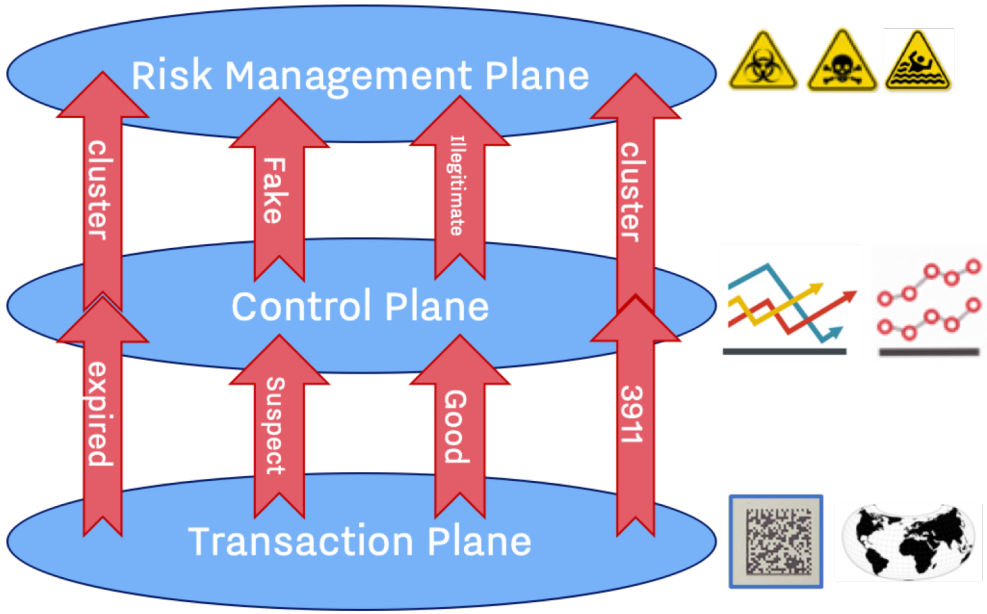
Last Mile DSCSA Objectives



- 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



BRUINchain Video

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

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BRUINchain

SUBMITTED TO FDA, JANUARY 2020

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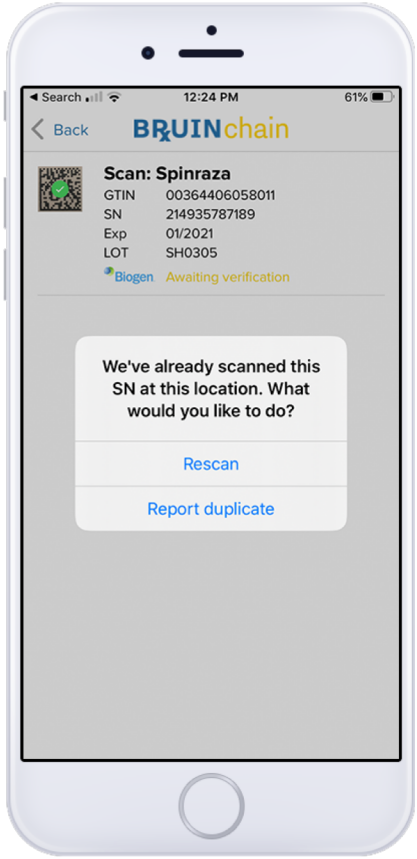
Foundations for Interoperability



- 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?

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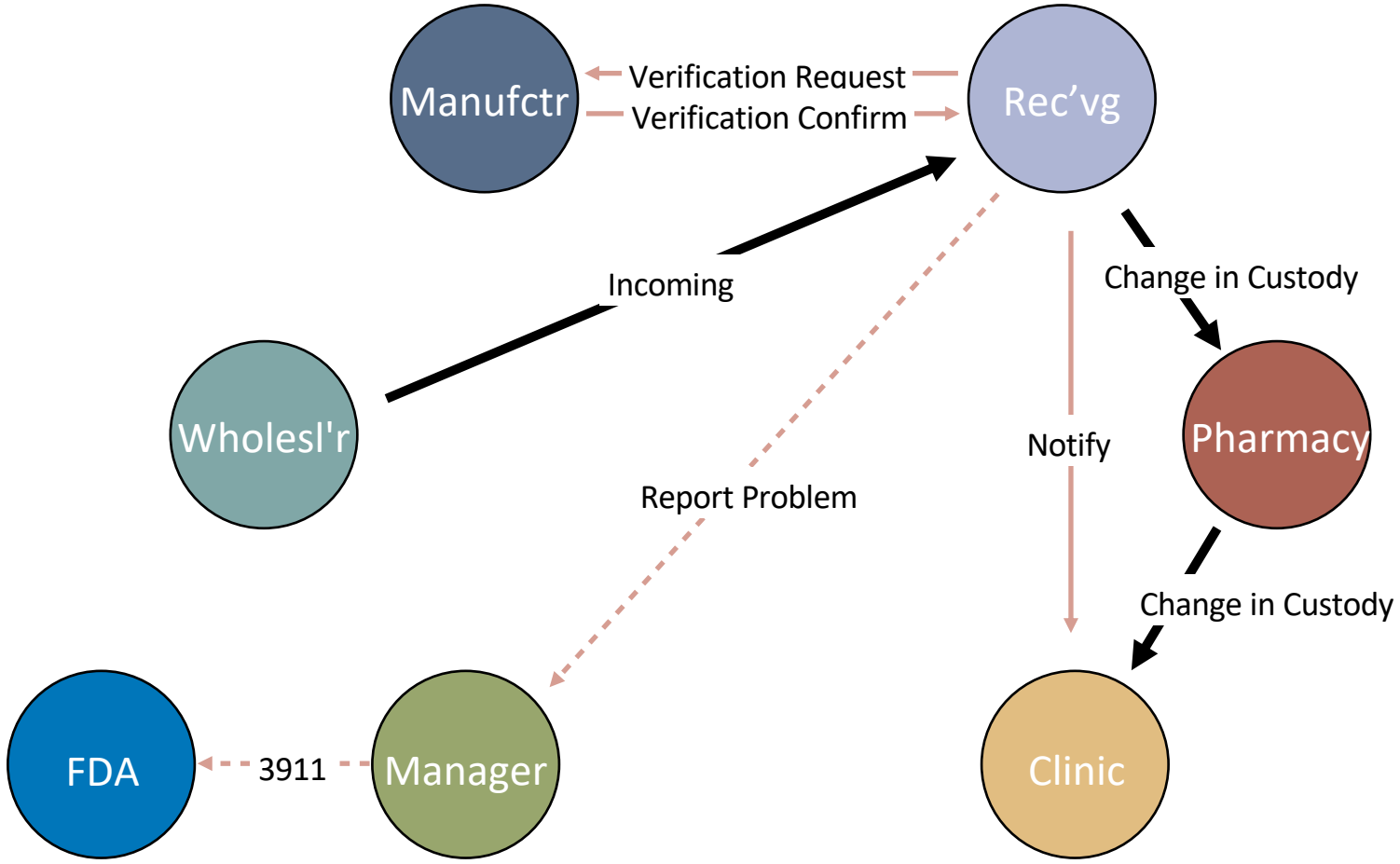
Last Mile DSCSA Process Map

Receiving, “Happy Path”, Manufacturer Verification



P2P blockchain supplemented with department & location info

Privacy & role-based privileges preserved

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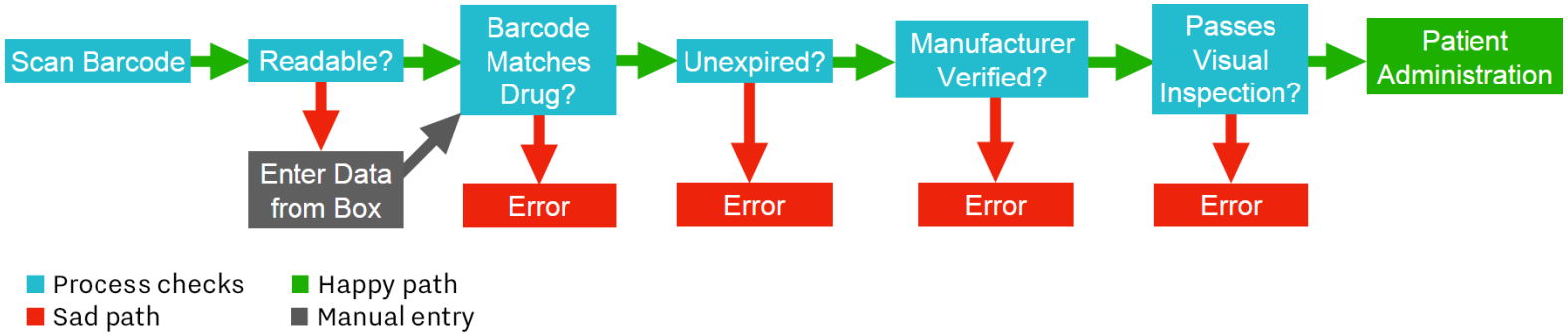
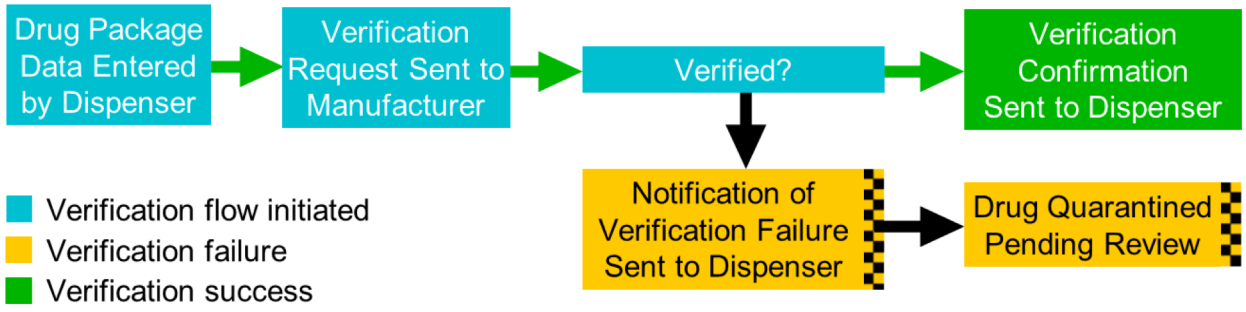
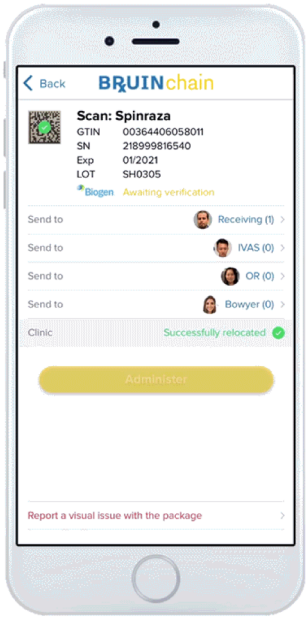
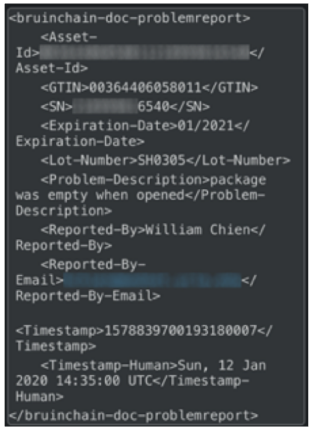
Last Mile DSCSA “Sad Paths”









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    <SN>[redacted]6540</SN>
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    <Lot-Number>SH0305</Lot-Number>
    <Problem-Description>package was empty when opened</Problem-Description>
    <Reported-By>William Chien</Reported-By>
    <Reported-By-Email>[redacted]</Reported-By-Email>

    <Timestamp>1578839700193180007</Timestamp>
    <Timestamp-Human>Sun, 12 Jan 2020 14:35:00 UTC</Timestamp-Human>
</bruinchain-doc-problemreport>
```

3911 Flow

Auditable “Sad Path” Escalates to Generation of 3911

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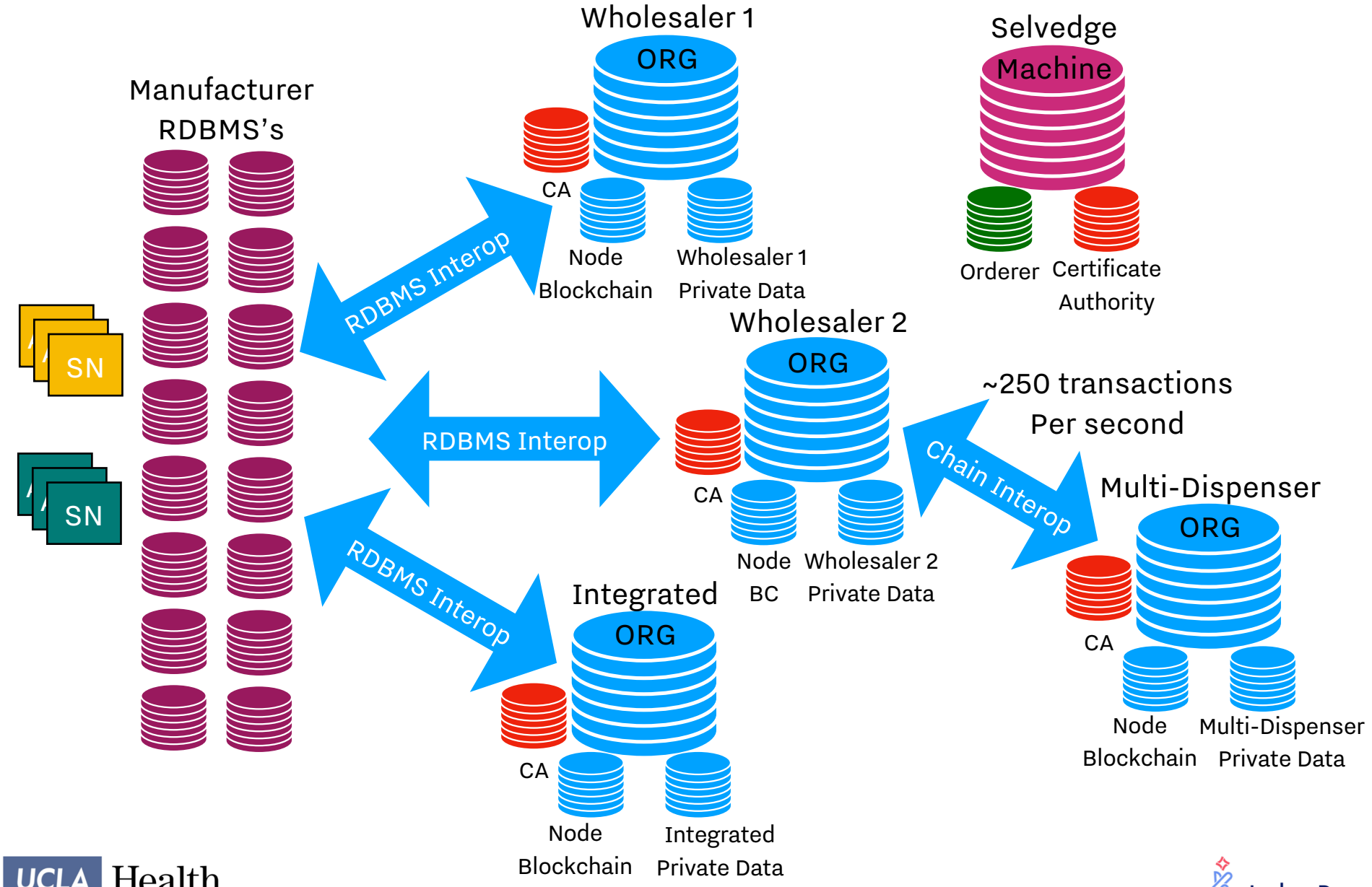
Framework for Multi-stakeholder Platform

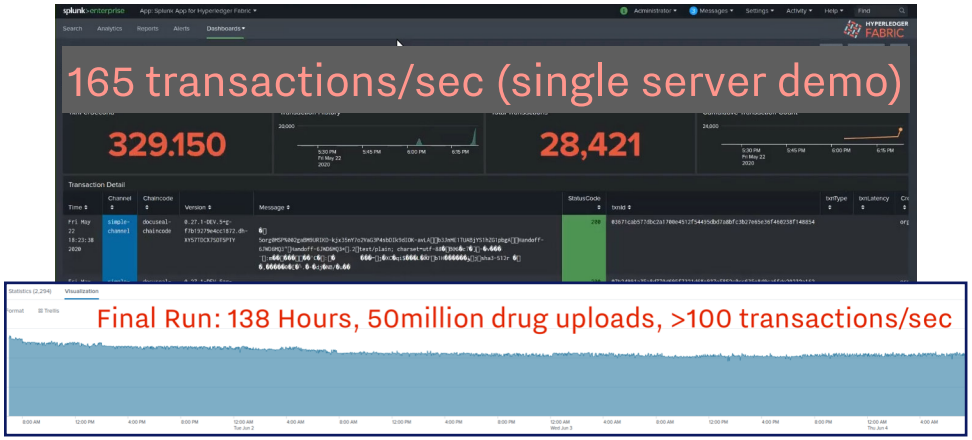
All blockchain nodes agree on single version of truth



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”

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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

Appendix 1.

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

The Last Mile: DSCSA Solution Through Blockchain Technology: Drug Tracking, Tracing, and Verification at the Last Mile of the Pharmaceutical Supply Chain with BRUINchain

BLOCKCHAIN IN HEALTHCARE TODAY

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XML

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Abstract

Purpose: As part of the FDA's DSCSA Pilot Project Program, UCLA and its solution partner, LedgerDomain (collectively referred to as the team hereafter), focused on building a complete, working blockchain-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 (COTS) technology.

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)

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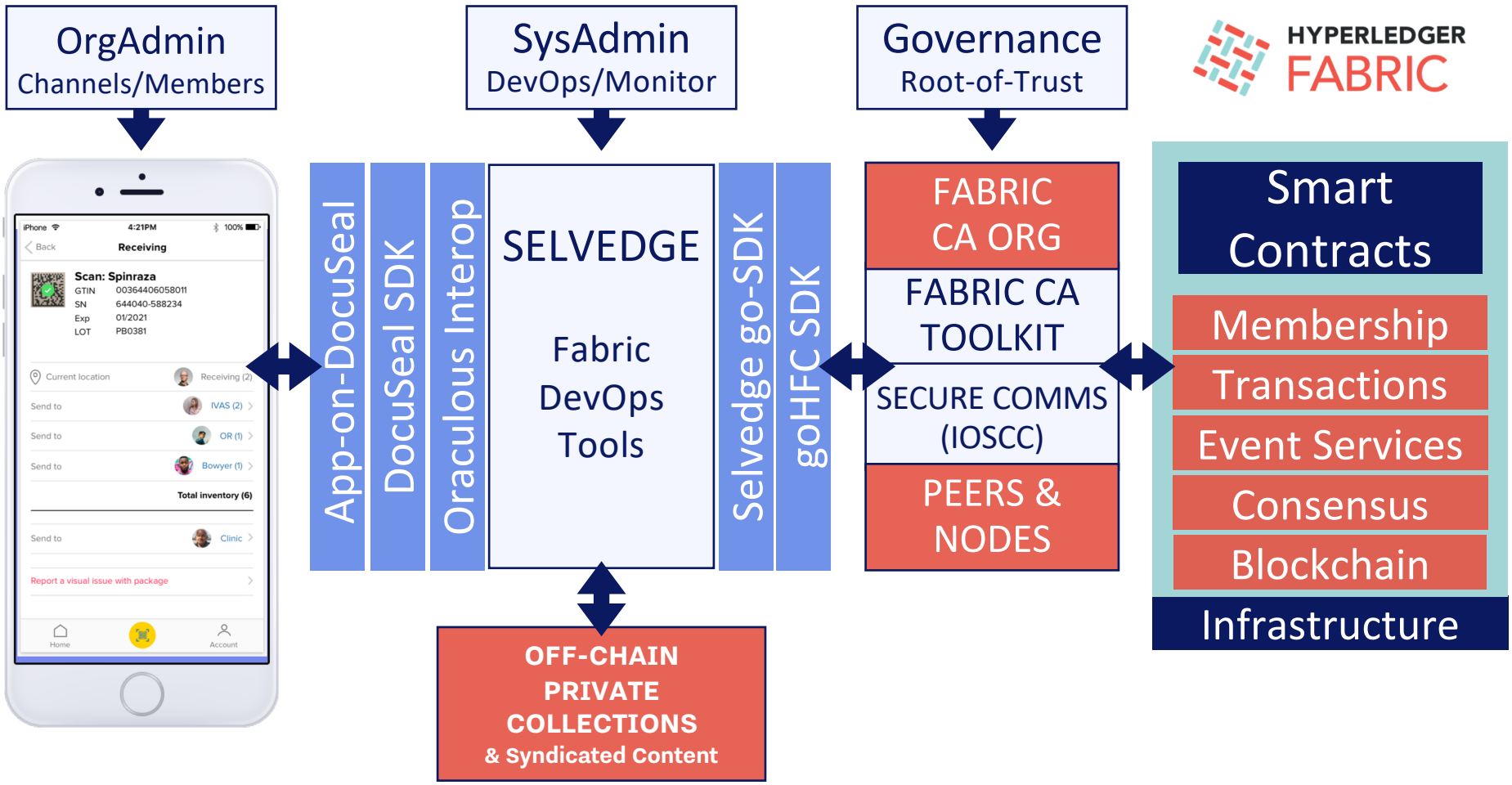
Appendix 2.

BRUINCHAIN Architecture



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The Global Language of Business

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.

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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.

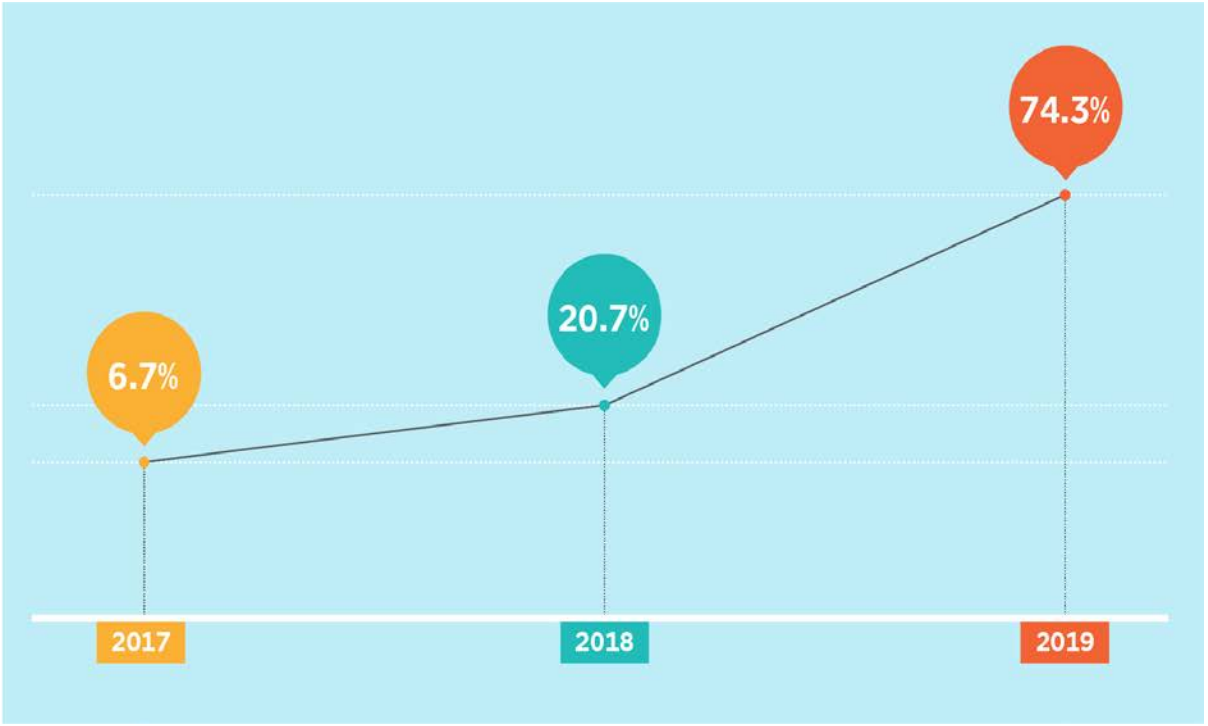
- Cardinal Health and GS1 US conducted the barcode assessment of "**homogeneous cases**" from pharmaceutical manufacturers with **linear or 2D barcodes** for the 2nd year.

- 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



Exceeding Expectations

Readable 2D GS1 DataMatrix Barcode With All Four DSCSA Data Elements

2019 Specialty Products	71.9% scanned at AmerisourceBergen	Compared to 2018: 20.4%	Compared to 2017: 7.2%
2019 Homogeneous Cases	78.7% scanned at Cardinal Health with 2D (GS1 DataMatrix) barcodes & 73.3% scanned at Cardinal Health with linear (GS1-128) barcodes		Compared to 2018: 15.1%
2019 Rx Products	71% scanned at McKesson	Compared to 2018: 20.8%	Compared to 2017: 6.5%

"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

2017-2019

Packages scanned

Packages 2017
16,618

Packages 2018
21,209

Packages 2019
17,859

Readable barcodes with all four DSCSA data elements

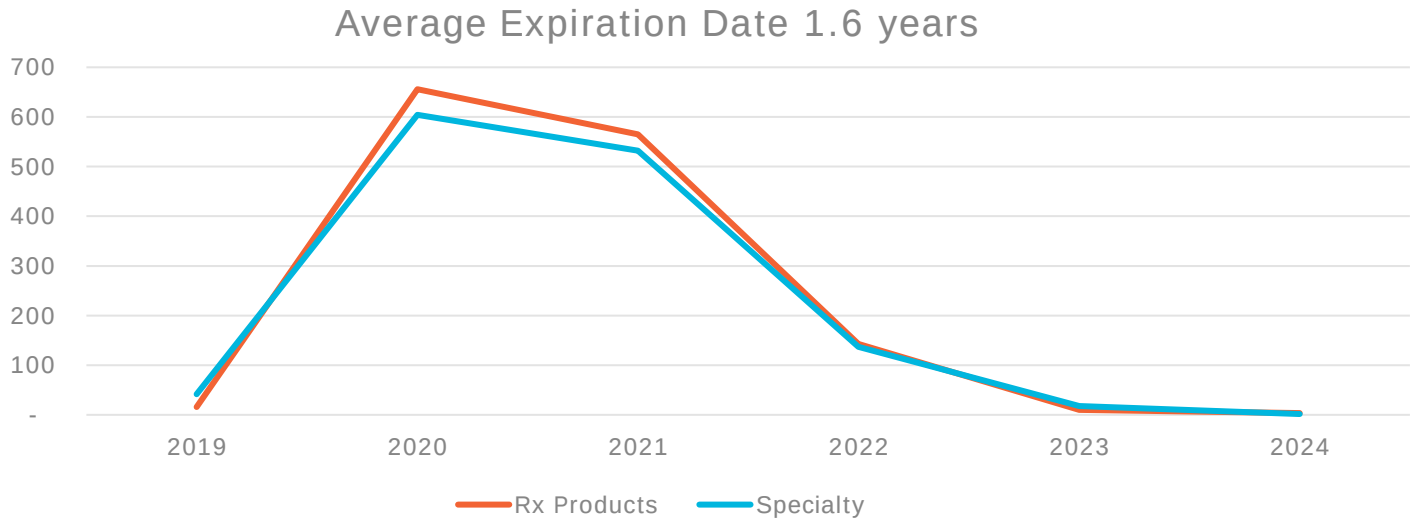
Packages 2017
6.6%

Packages 2018
20.7%

Packages 2019
72.5%

Source: AmerisourceBergen, Cardinal Health, and McKesson barcode assessments

2019 Packages Expiration Date Results



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		
BEST	NEXT BEST	NEXT BEST
		
NO	NO	NO
		

SPACES		
BEST	NEXT BEST	NEXT BEST
		
NO	NO	NO
		

Homogeneous Case Results Over Two Years

Progress in 2D Barcode Adoption With DSCSA Requirements
Cardinal Health

2018-2019

Cases scanned

Homogeneous Cases 2018
6,481

Homogeneous Cases 2019
7,996

Readable barcodes with all four DSCSA data elements

Homogeneous Cases 2018
15.1%

Homogeneous Cases 2019
78.7%
(readable 2D barcodes)

73.3%
(readable linear barcodes)

Source: AmerisourceBergen, Cardinal Health, and McKesson barcode assessments

Homogeneous Case Results

"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.

Vision Towards the Future

"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

NETWORK FOR GREATER GOOD





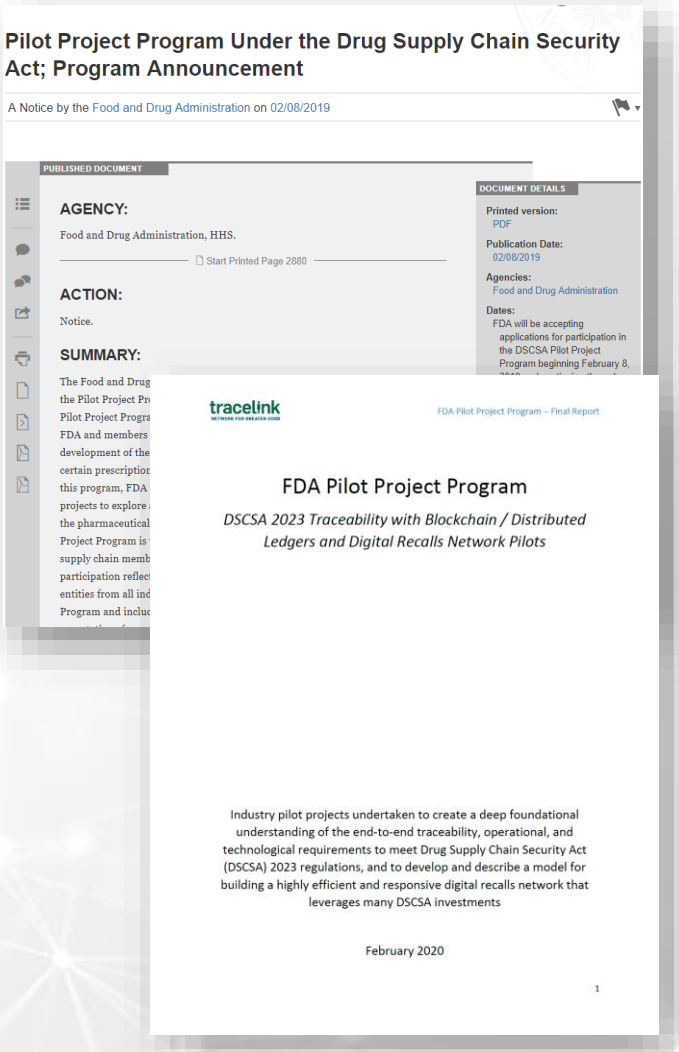



TraceLink FDA Pilot Project
DSCSA Trace Histories and Digital Recalls Network

Brian Daleiden, TraceLink Inc.

July 23, 2020

TraceLink's FDA Pilot Project Vision and Approach



- 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	Digital Recalls
Interoperable information sharing and "gather upon request" model for DSCSA 2023 compliance leveraging a blockchain-based tool	Electronic tracing, verification, and notification for patient safety by enabling a digital recalls network

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The FDA Pilot Project was an Industry-Led Collaboration

Cross-Industry, Cross-Archetype Discussion was Critical in Understanding Challenges/Opportunities

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

Digital Recalls Workstream

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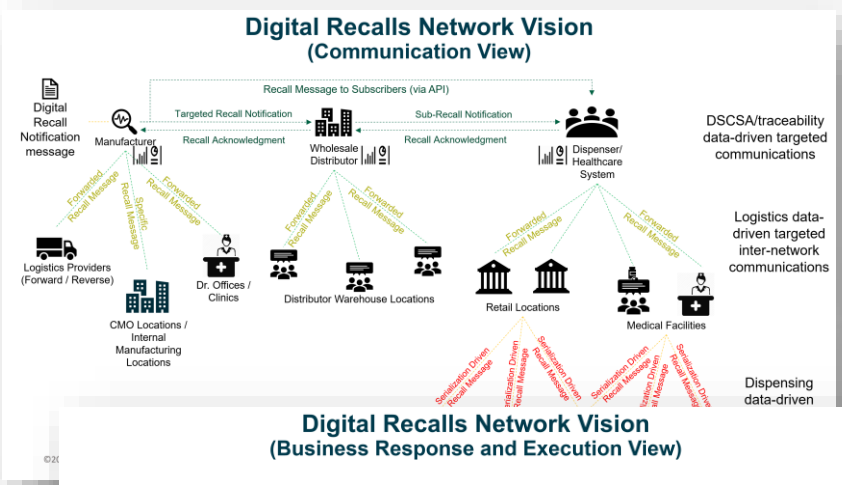
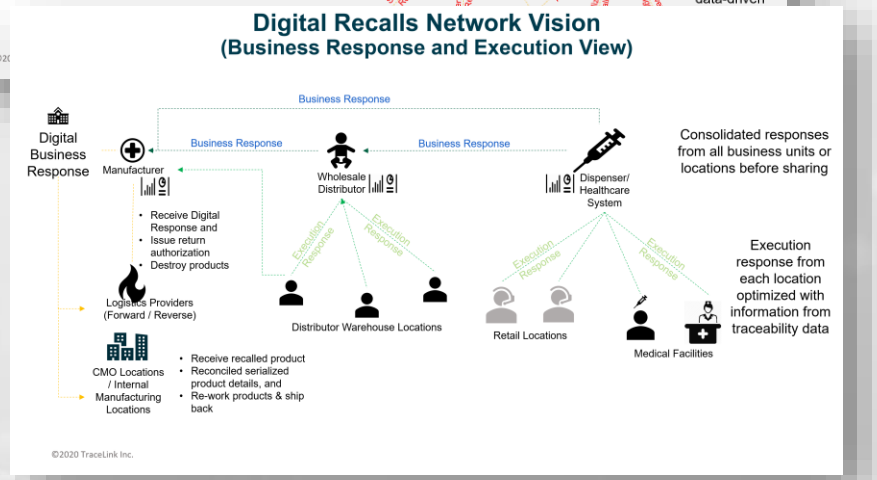
Digital Recalls Workstream





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

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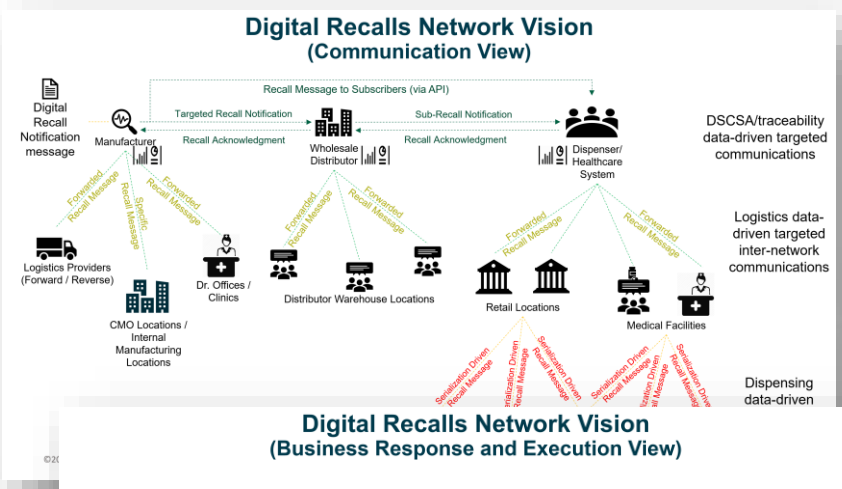
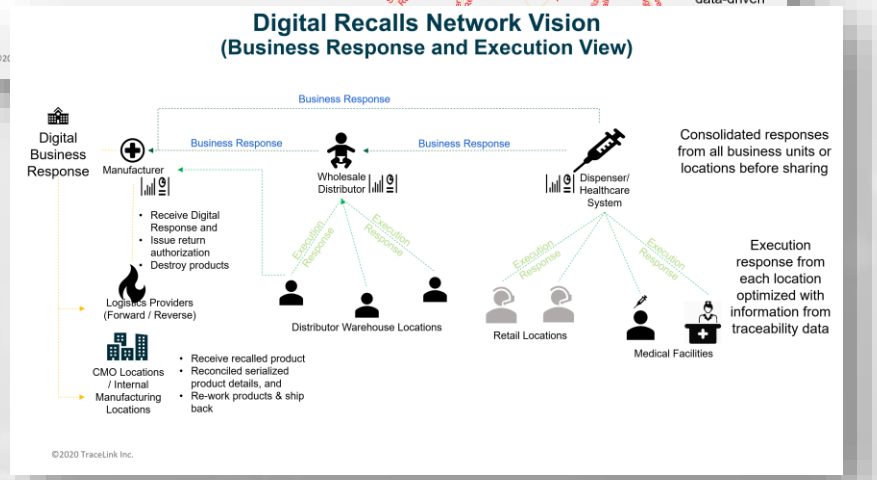
Digital Recalls Workstream





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.

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Trace Histories Workstream

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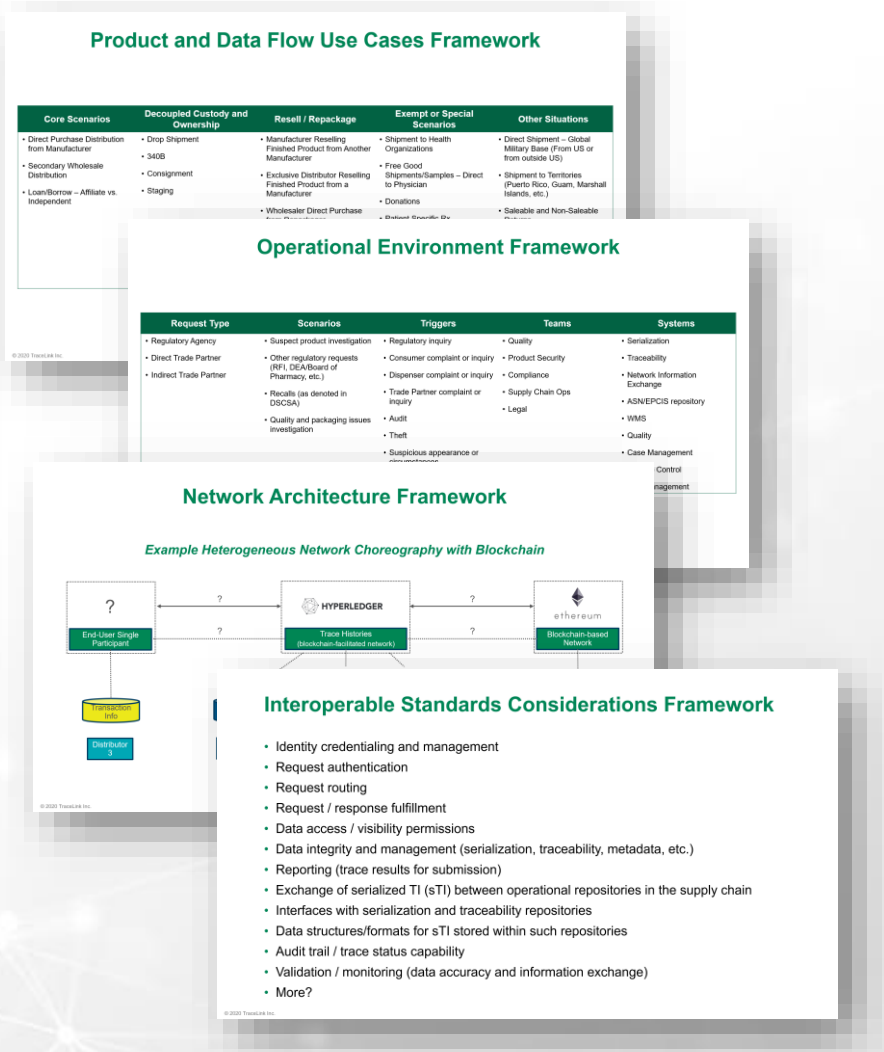
Trace Histories Workstream



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

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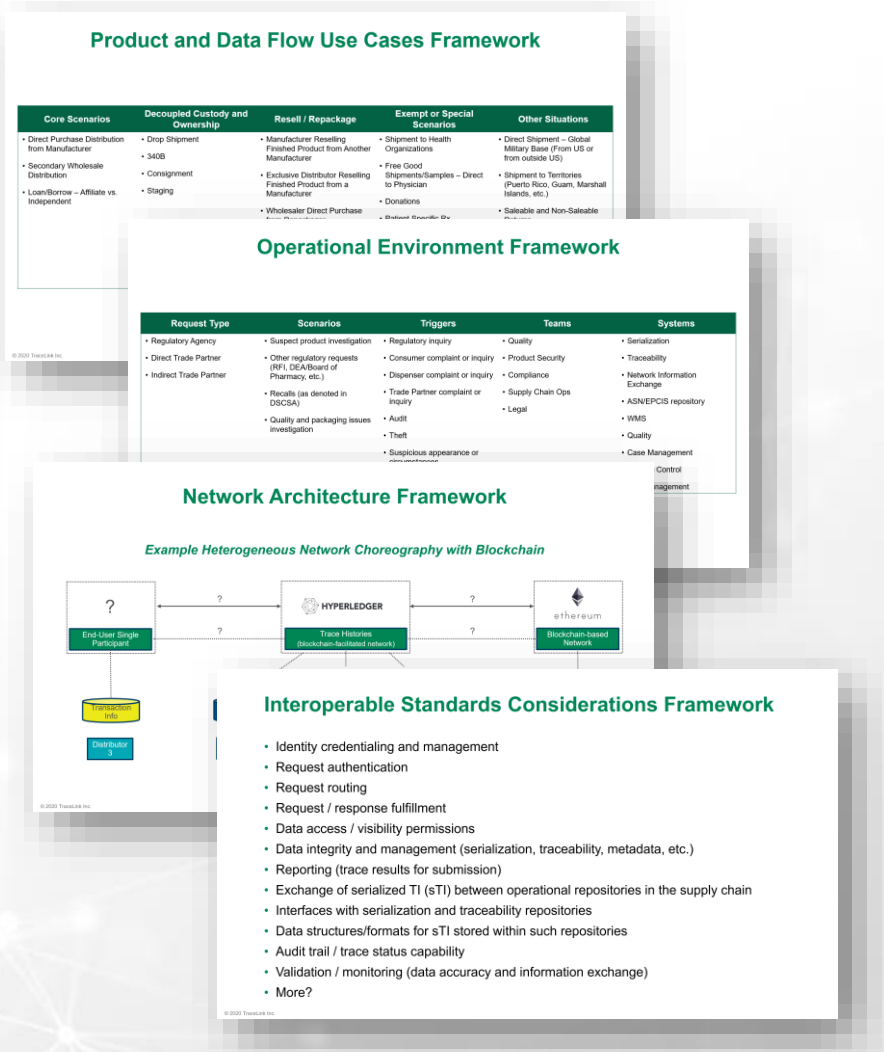
Trace Histories Workstream



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.

tracelink

Questions?

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

Brian Daleiden
bdaleiden@tracelink.com

tracelink

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

providence health technologies

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?

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Partners

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

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Participants

- Long Term Care Pharmacies (3)
- Specialty Pharmacies (2)
- Hospital Pharmacies (2)
- Independent Retail Pharmacies (10)

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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

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

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Product Compliance

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

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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.

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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.

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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

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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

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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)

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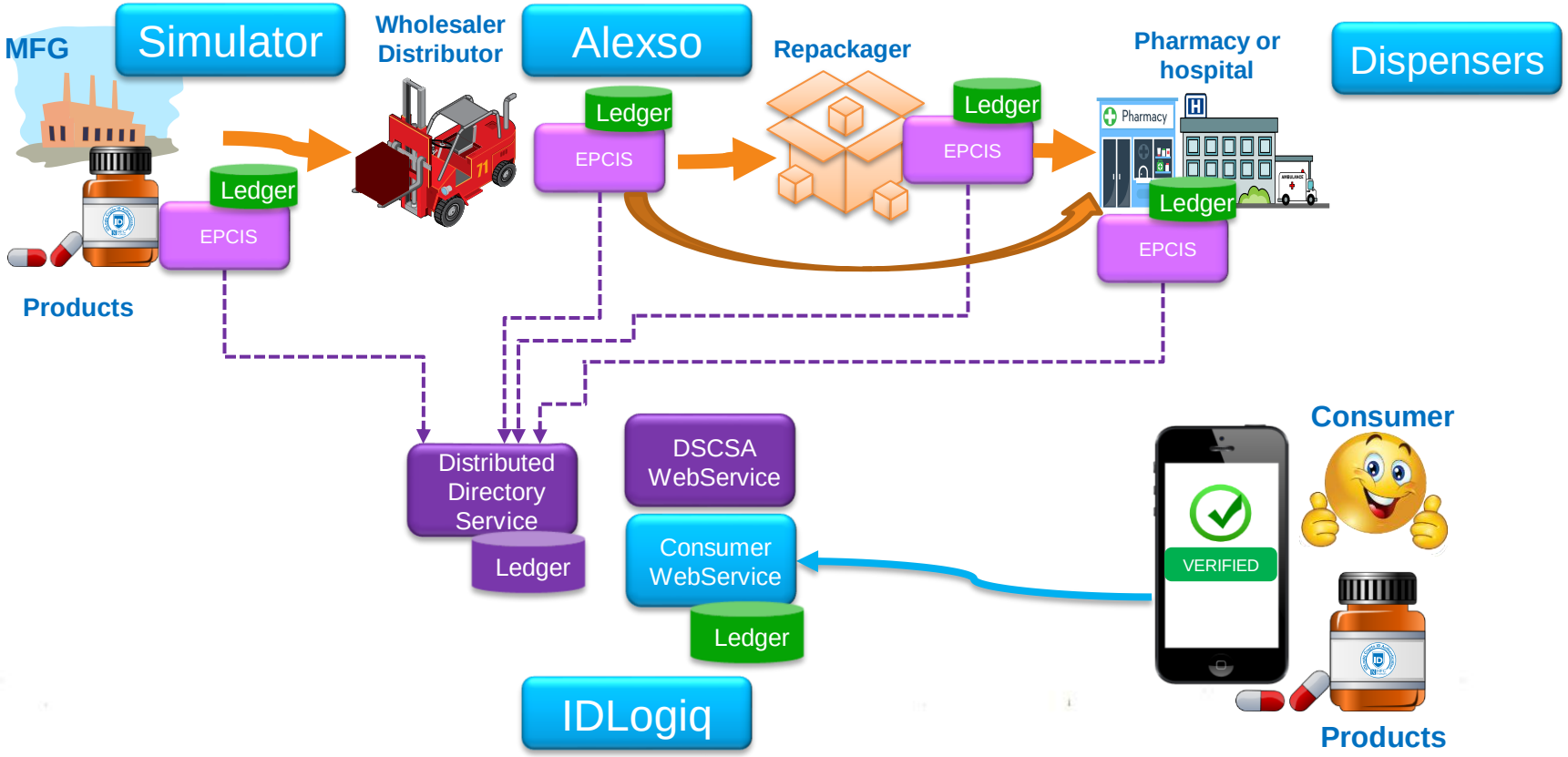
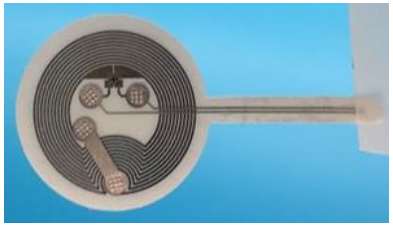
Cryptographic Identity Authentication (CIA)

IDLogiq Inc.
FDA DSCSA Pilot

Introduction – Workflows of Entities Participated in the Pilot

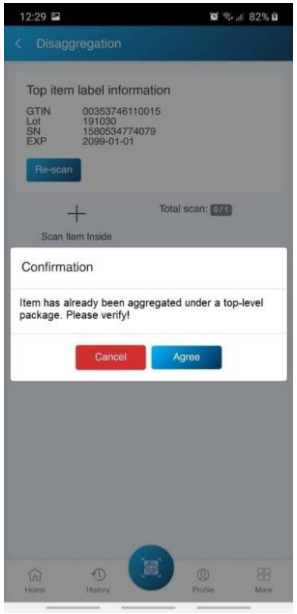


Examples / Demo

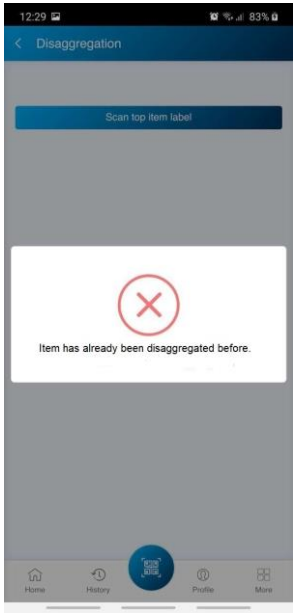


Example Screenshots of Errors, Exception Condition

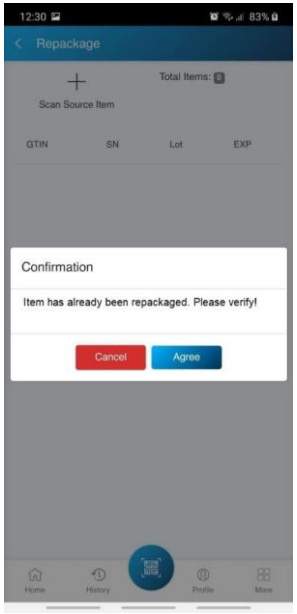
Repackaging: Invalid ownership of product



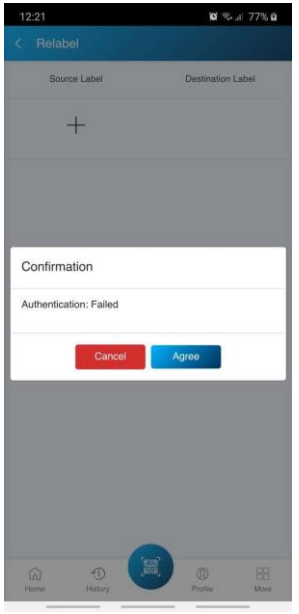
Aggregation: Items has already been aggregated



Dis-aggregation: Item has already been disaggregated

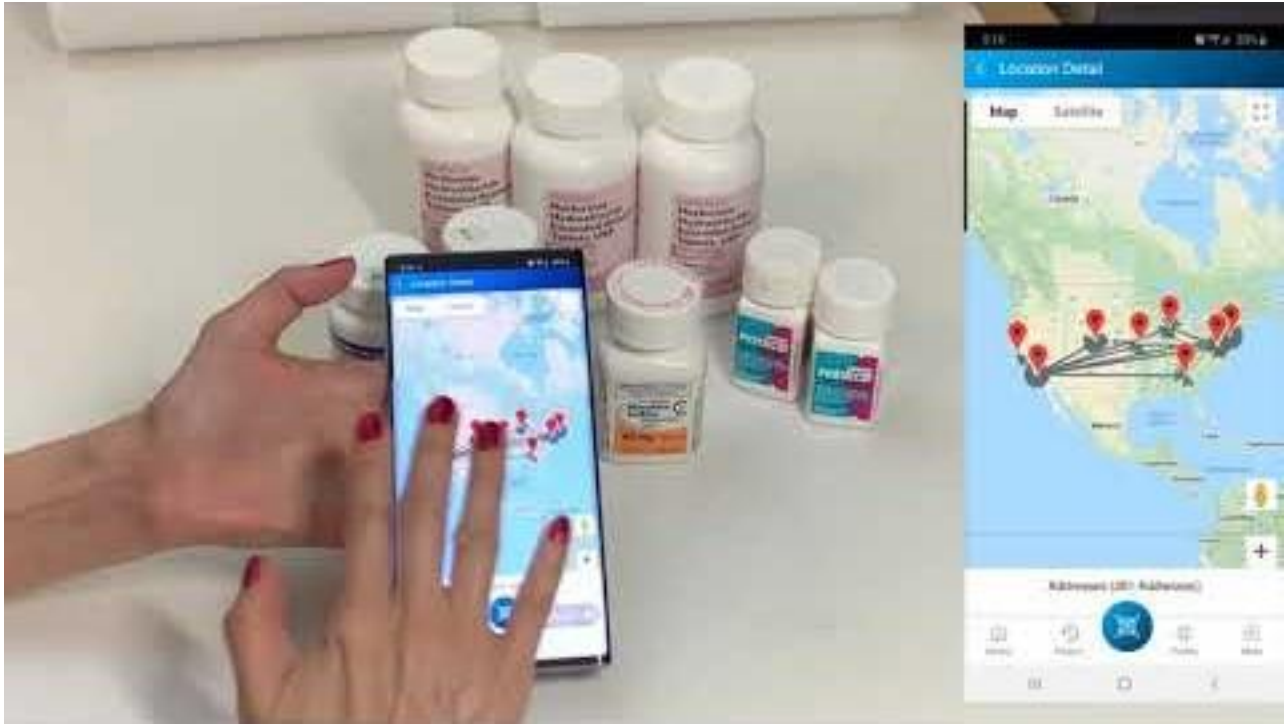


Repackaging: Item has already been repackaged



Counterfeit detected via Cryptographic ID Authentication

Video Track and Trace of a Product Life Cycle



Example: TI Reports

Shipping Information											
Shipped Date	2019-11-19T22:19:41.000Z										
Shipped From	SA3, LLC										
Shipped To	Alpha Medical Pharmacy Inc Gabriel Blvd										
(TI) Item Shipped											
ID	Shipped Date	Product	NDC	UPC	Dosage Form	Strength	Container Size	MFG	Qty	Lot	Serial Number
488c53b4-65a4-43c2-b2c6-a4f853e41646	2019-11-19T22:19:41.000Z	Naproxen Sodium	69420-1375-1	"00369420137513"	TABLET, FILM COATED, EXTENDED RELEASE	"375 mg/1"	100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1)	SA3, LLC	1	191113	3606440918495544
488c53b4-65a4-43c2-b2c6-a4f853e41646	2019-11-19T22:19:41.000Z	Naproxen Sodium	69420-1375-1	"00369420137513"	TABLET, FILM COATED, EXTENDED RELEASE	"375 mg/1"	100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1)	SA3, LLC	1	191113	3616870985969605
488c53b4-65a4-43c2-b2c6-a4f853e41646	2019-11-19T22:19:41.000Z	Naproxen Sodium	69420-1375-1	"00369420137513"	TABLET, FILM COATED, EXTENDED RELEASE	"375 mg/1"	100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1)	SA3, LLC	1	191113	3661003717595213
488c53b4-65a4-43c2-b2c6-a4f853e41646	2019-11-19T22:19:41.000Z	Naproxen Sodium	69420-1375-1	"00369420137513"	TABLET, FILM COATED, EXTENDED RELEASE	"375 mg/1"	100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1)	SA3, LLC	1	191113	3682584920443046
488c53b4-65a4-43c2-b2c6-a4f853e41646	2019-11-19T22:19:41.000Z	Naproxen Sodium	69420-1375-1	"00369420137513"	TABLET, FILM COATED, EXTENDED RELEASE	"375 mg/1"	100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1)	SA3, LLC	1	191113	3753489221457785
488c53b4-65a4-43c2-b2c6-a4f853e41646	2019-11-19T22:19:41.000Z	Naproxen Sodium	69420-1375-1	"00369420137513"	TABLET, FILM COATED, EXTENDED RELEASE	"375 mg/1"	100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1)	SA3, LLC	1	191113	3781595217834361
488c53b4-65a4-43c2-b2c6-a4f853e41646	2019-11-19T22:19:41.000Z	Naproxen Sodium	69420-1375-1	"00369420137513"	TABLET, FILM COATED, EXTENDED RELEASE	"375 mg/1"	100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1)	SA3, LLC	1	191113	3781763940180028

Example: TH Reports

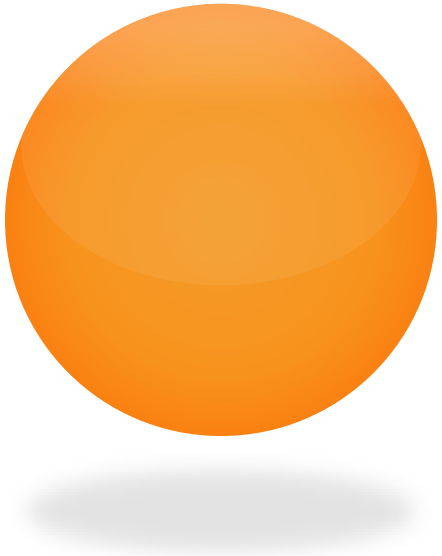
GTIN	Serial Number	Timestamp	Transaction Type	Lot Number	EXP	Description
"00369420137513"	3606440918495544	2019-11-19T22:19:41.000Z	SHIPPING	191113	8/30/2021	Shipping from SA3 to Alpha Medical Pharmacy Inc Gabriel Blvd
"00347781153014"	4689415182531103	2019-11-19T21:19:15.000Z	Repackage	191113	8/30/2021	SA3 repackaged from 00347781153014.4689415182531103 to 00369420137513.3606440918495544
"00347781153014"	4689415182531103	2019-11-15T10:18:02.934Z	SHIPPING	191113	8/30/2021	SHIPPING from Alvogen Manufacturer to SA3
"00369420137513"	3616870985969605	2019-11-19T22:19:41.000Z	SHIPPING	191113	8/30/2021	Shipping from SA3 to Alpha Medical Pharmacy Inc Gabriel Blvd
"00347781153014"	3623183817940961	2019-11-19T21:19:15.000Z	Repackage	191113	8/30/2021	SA3 repackaged from 00347781153014.3623183817940961 to 00369420137513.3616870985969605
"00347781153014"	3623183817940961	2019-11-15T10:18:02.934Z	SHIPPING	191113	8/30/2021	SHIPPING from Alvogen Manufacturer to SA3
"00369420137513"	3661003717595213	2019-11-19T22:19:41.000Z	SHIPPING	191113	8/30/2021	Shipping from SA3 to Alpha Medical Pharmacy Inc Gabriel Blvd
"00347781153014"	5661445665230668	2019-11-19T21:25:11.000Z	Repackage	191113	8/30/2021	SA3 repackaged from 00347781153014.5661445665230668 to 00369420137513.3661003717595213
"00347781153014"	5661445665230668	2019-11-15T10:18:02.934Z	SHIPPING	191113	8/30/2021	SHIPPING from Alvogen Manufacturer to SA3
"00369420137513"	3682584920443046	2019-11-19T22:19:41.000Z	SHIPPING	191113	8/30/2021	Shipping from SA3 to Alpha Medical Pharmacy Inc Gabriel Blvd
"00347781153014"	7170071169111973	2019-11-19T21:30:36.000Z	Repackage	191113	8/30/2021	SA3 repackaged from 00347781153014.7170071169111973 to 00369420137513.3682584920443046
"00347781153014"	7170071169111973	2019-11-15T10:18:02.934Z	SHIPPING	191113	8/30/2021	SHIPPING from Alvogen Manufacturer to SA3

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,

SANOFI

Product Identifier Verifications by a CMO on behalf of MAH

Pilot Results ,July 23rd 2020

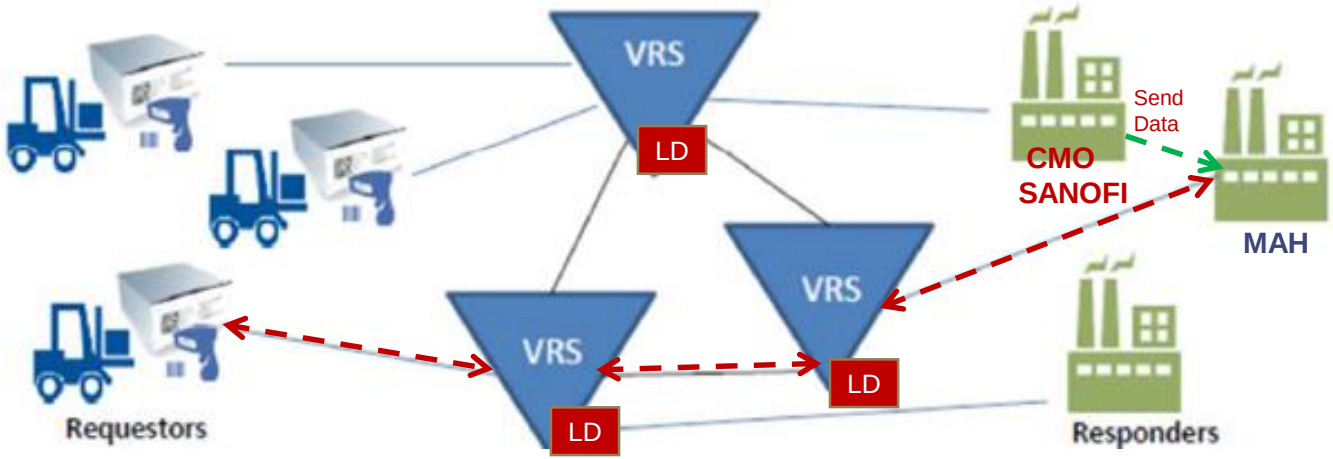
Agenda

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

Objective and Introduction

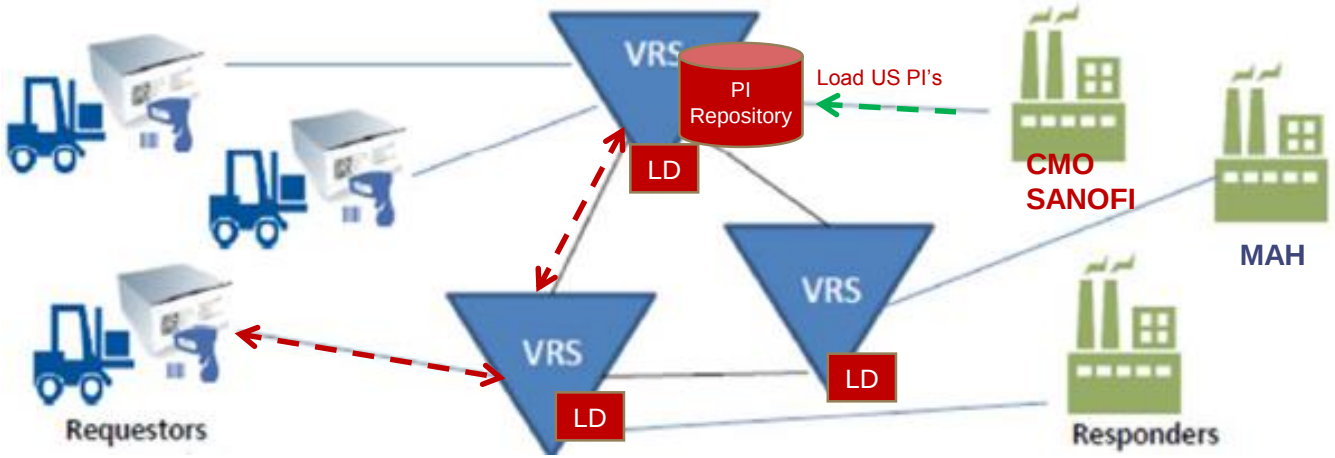
Traditional

All SNs in MAH VRS Repository



Verification Delegation:

All SNs in CMO VRS Repository



Pilot Project Participants

Company	Type	Contact	Size: Number of employees
Sanofi	Manufacturer	Arthi Nagaraj Arthi.Nagaraj@sanofi.com Reid Graves Reid.Graves@sanofi.com	110,000
McKesson	Wholesale Distributor	Scott Mooney Scott.Mooney@McKesson.com Vinod Vedire Vinod.Vedire@McKesson.com	80,000
Advanz Pharma	Virtual Manufacturer	Chris Humphrey Chris.Humphrey@advanzpharma.com	400
Adents	Service Provider	Saad Achouri sachouri@adents.com	100

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

SANOFI

pdg Partnership for DSCSA Governance

Advancing Collaborative, Timely Implementation of DSCSA Interoperability

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 Partnership for DSCSA Governance

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

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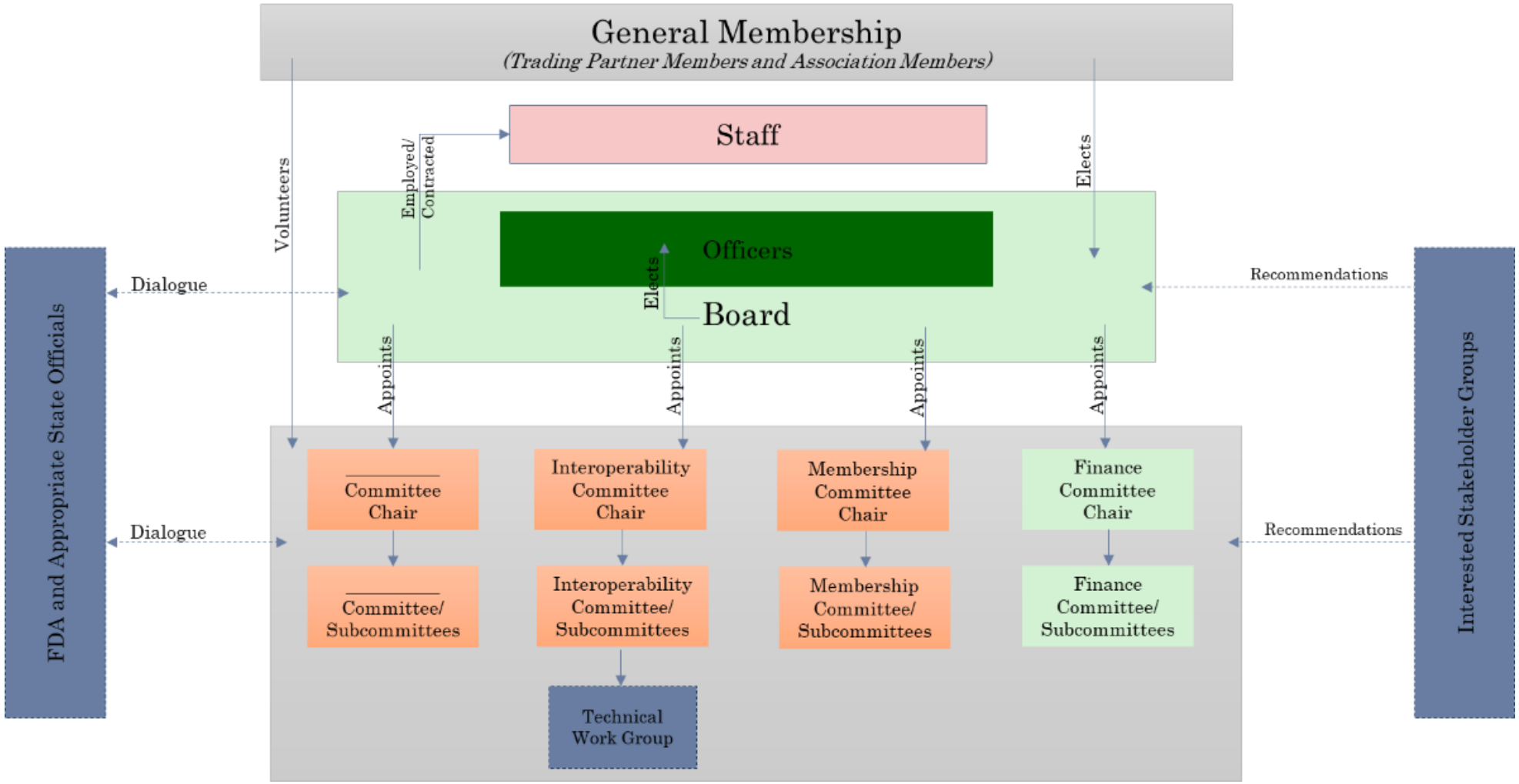
PDG Structure



pdg Partnership for DSCSA Governance

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.

pdg Partnership for DSCSA Governance

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

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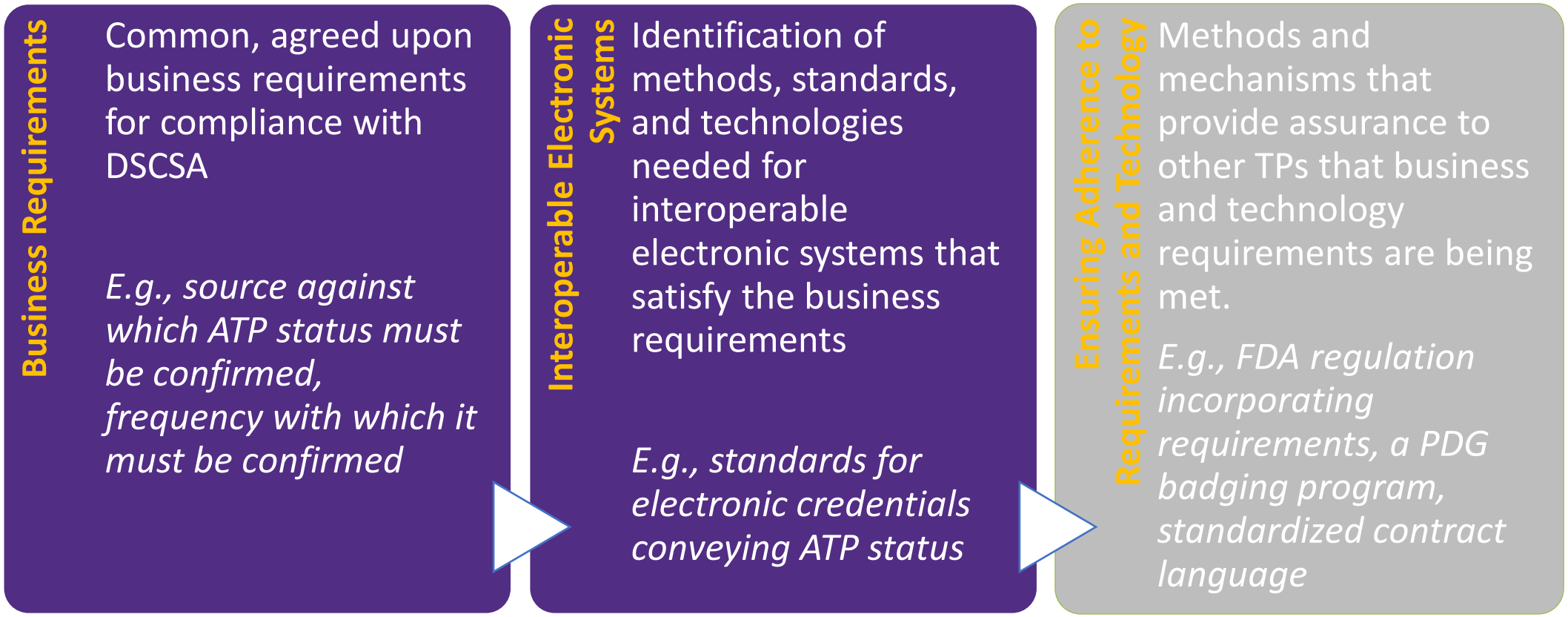
Pilot Scope

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.



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Metrics to Evaluate Governance Structures & Processes

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

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Key Findings

PDG Formation	Sufficient Membership
	Successful Formation
	Sufficient Financial Commitments
Notable Pilot Successes	Meaningful technical participation
	Valuable FDA presence
	Effective use of prior work
	Prior work not seen as binding
	Fair and equal participation
	Fair and balanced decision making
	No major process issues

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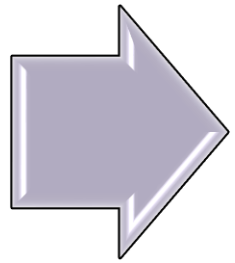
Conclusions & Recommendations

Lesson 1: Ensuring Respect for Output



Recommendation:
Define consensus and determine appropriate input

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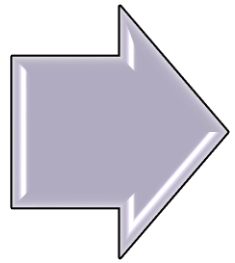
Conclusions & Recommendations

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

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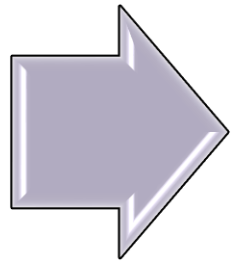
Conclusions & Recommendations

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

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Appendix

PDG Formation Activities

September 30, 2019	Non-binding Membership Commitments Due*
October 4, 2019	Entity Officially Incorporated
October 11, 2019	Expression of Intent to Run for Board Seats Due
October 14, 2019	Governance Body Kick-Off Meeting
October 15 – October 30, 2019	Board Elections
November 13, 2019	Board Officially Seated; Entity Officially Named the Partnership for DSCSA Governance (PDG)
November 21, 2019	Board Meeting; Committee Chairs Appointed
December 12, 2019	Board Meeting
December 13, 2019	PDG Membership & Prospects Meeting
December 16, 2019	Public Rollout of PDG
January 2020	Committee Activity Begins

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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?*

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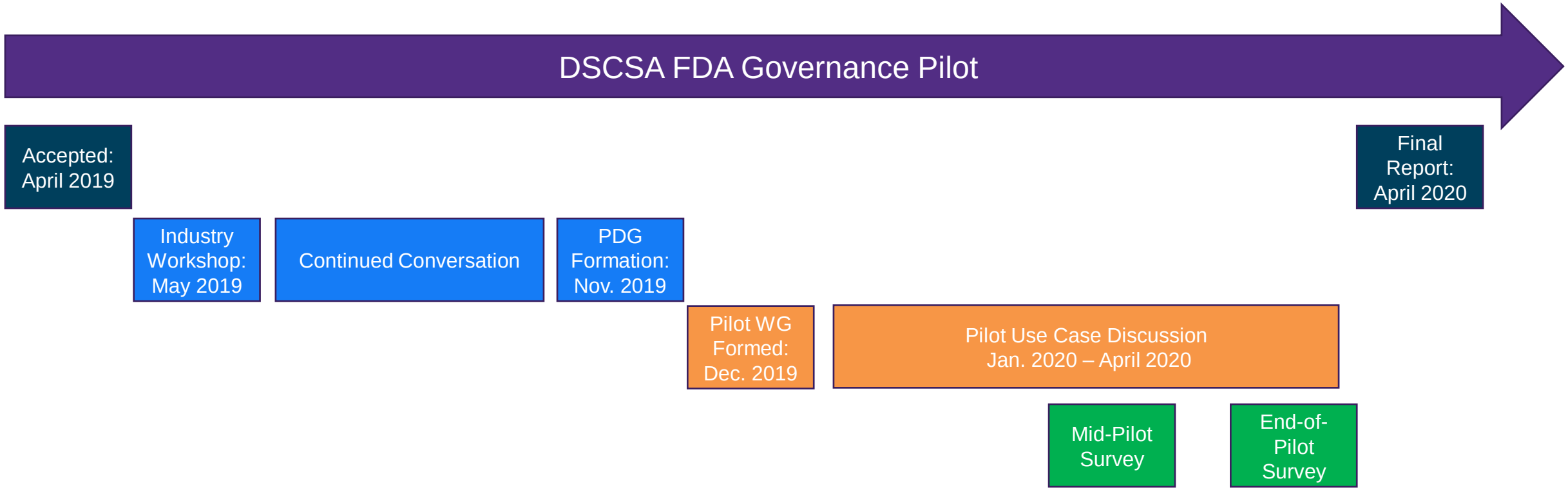
Methods



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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

pdg Partnership for DSCSA Governance

Appendix

SANOFI

Lexicon

Terms	Description
MAH	Marketing Authorization Holder
CMO	Contract Manufacturer
PI	Product Identifier. This consists of the GTIN, Serial number, Lot and Expiry
GTIN	Global Trade Identification Number. This is part of the GS1 standards that can be used by companies to identify their Trade items
DSCSA	Drug Supply Chain Security Act
VRS	Verification Router Service. This is interoperable solution used to primarily address DSCSA verification requirements for the Saleable returns' regulation
HDA	Healthcare Distribution Alliance. HDA is a national organization representing primary pharmaceutical distributors
LD	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
GLN	Global Location Number. This is part of the GS1 standards that can be used by companies to identify their locations
Pilot	A small-scale study to evaluate feasibility of a concept

Interoperability Data Exchange Errors & Exception Handling DSCSA Pilot Project

Darlene Bond

6/25/2020

CardinalHealth
Essential to care™

Agenda

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

Introductions

- John “Quentin” Dittman - Director, Deployment Leader

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- 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
  - file structure format
  - data element format
  - event sequencing
  - EPC event chronology
  - late transmissions
  - 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

Exception Type	Data Samples Collected	Exception Percentage
Late Data Arrival	114	31%
EPC Event Chronology	44	12%
Master Data Missing	40	11%
EPCIS Structure Issues	40	11%
XML Structure Issues	40	11%
AS2 Setup/Transmission	26	7%
Incorrect Data Format	26	7%
Missing Required Data Element	18	5%
Master Data Setup	6	2%
Serial Number Configuration	4	1%
No Error	3	<1%
MQ Issue	1	<1%
System Processing Exception	1	<1%
Total	**363**	**100%**

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:
  - **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

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

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
  - 150 manufacturers, repackagers, CMOs, wholesale distributors and Cardinal Health business units.
  - 11 EPCIS providers
- Documentation
  - 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.
  - Systematic exchange master data between Cardinal ERPs and the event management systems.
  - Trading partners to include the product and location master data within the EPCIS documents
- Success Criteria
  - Third party engagement to onboard trading partners
    - Generating appropriate EPCIS documents before vendor onboarding activities.
  - 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
  - Barcodes from randomly selected pallets, cases and items of serialized products
    - Scanned during receiving
    - Compared to the serialized EPCIS data
- Documentation
  - Reporting: EPCIS Reliability Report to track aggregation issues by repackager or by NDC.
  - Monitoring serial numbers allocated to repackagers of the Cardinal Health owned products.
- Success Criteria
  - As manufacturer, CMO and repackager packaging line processes mature, we expect to see fewer aggregation errors.
  - 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
  - Analyzing the need for document or process changes to support them.
- Investigating the use of a web-based portal
  - Allows dispensers to access serialization data
  - Avoids sending of EPCIS documents.

Aggregation Exceptions

- Exploring an internal “trusted” vendor process
  - Make receiving serialized products more efficient
- Creating tools to allow product flow
  - Align disposition of serial numbers with product movement.

Questions?

MEDILEDGER

Pharma Enabled Blockchain Platform

FDA Pilot Overview

July 2020

CHRONICLED

Agenda

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

MediLedger Pilot Leads

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MediLedger Basics

MEDILEDGER

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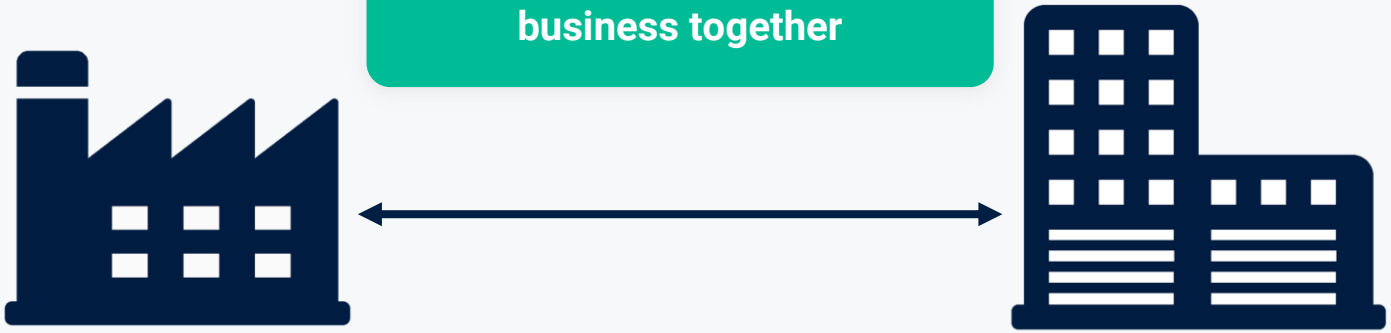
MediLedger Basics

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



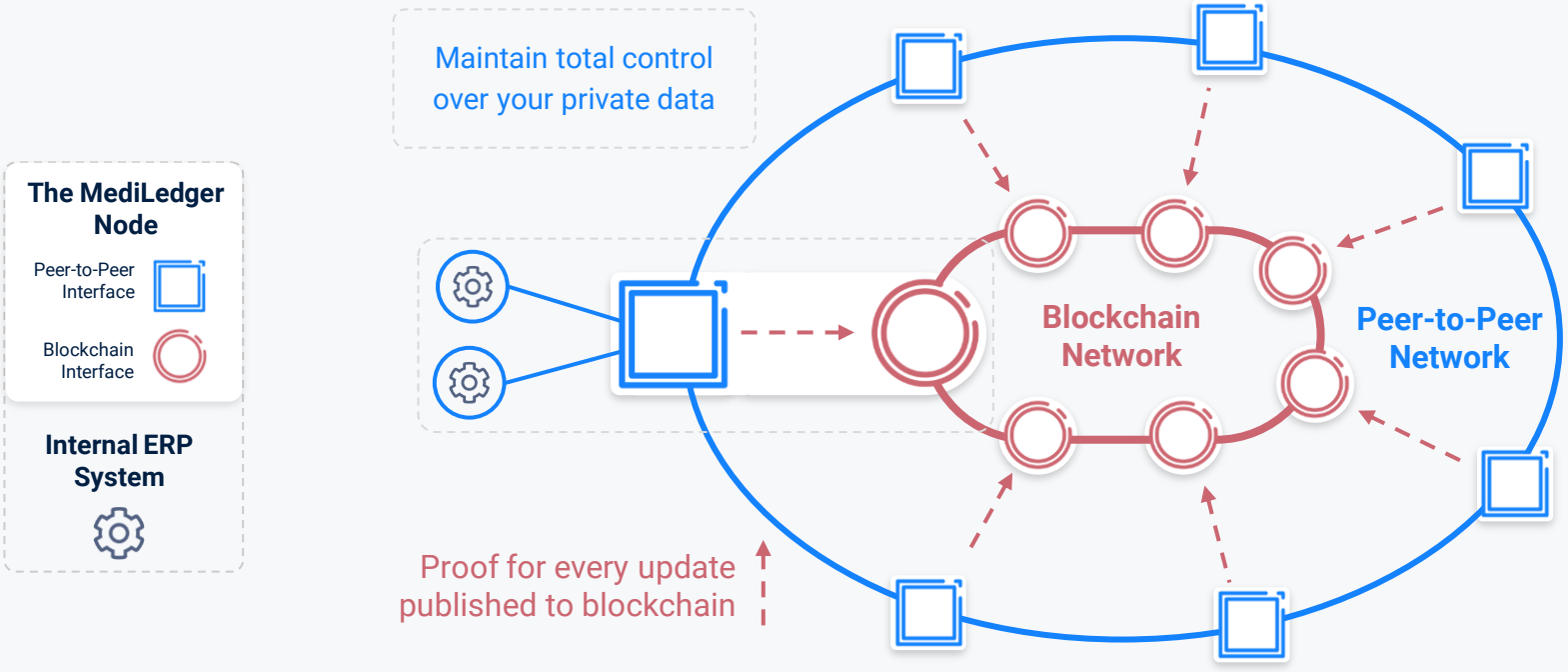
Are these raw materials from the correct supplier?

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



FDA Pilot Overview

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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
A Member of the Roche Group
NOVARTIS
GILEAD
hikma.
Dermira
Lilly
gsk
SANOFI

Wholesalers

McKESSON
AmerisourceBergen
CardinalHealth
FFF enterprises
Helping Healthcare Care
VAXSERVE
A SANOFI PASTEUR COMPANY

Dispensers

MAXOR
NATIONAL PHARMACY SERVICES COMPANY
Walmart
Walgreens

Others

CHRONICLED
GS1 US
FedEx
INMAR intelligence
CENTER for 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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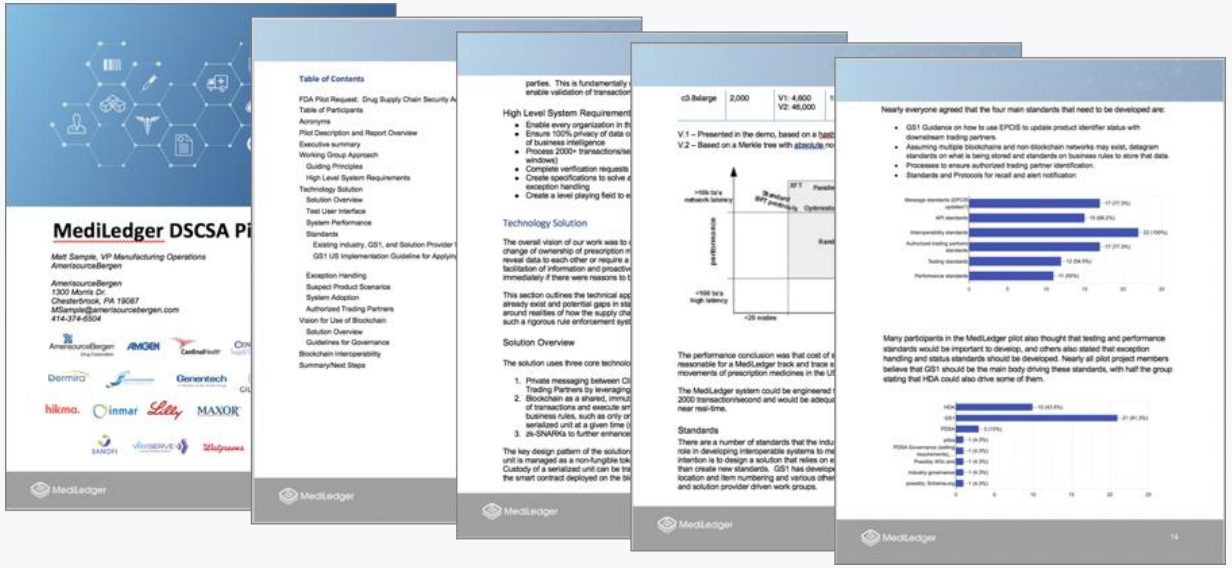
MediLedger FDA Pilot Report - Contents

Table of Contents

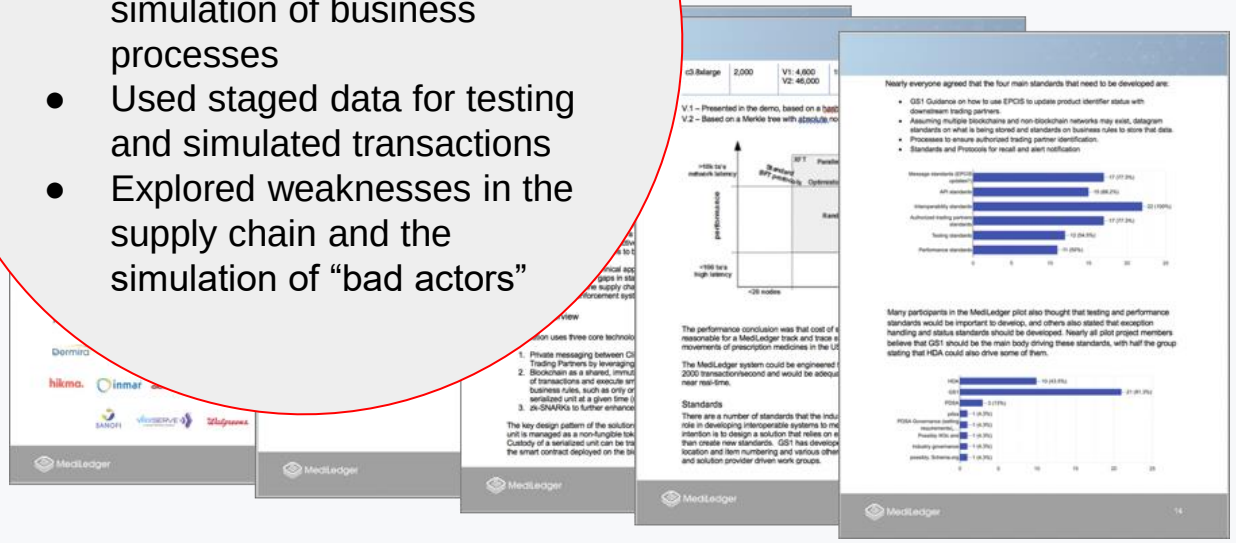


https://www.mediledger.com/fda-pilot-project

MediLedger FDA Pilot Report - Highlights

Table of Contents

- 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”

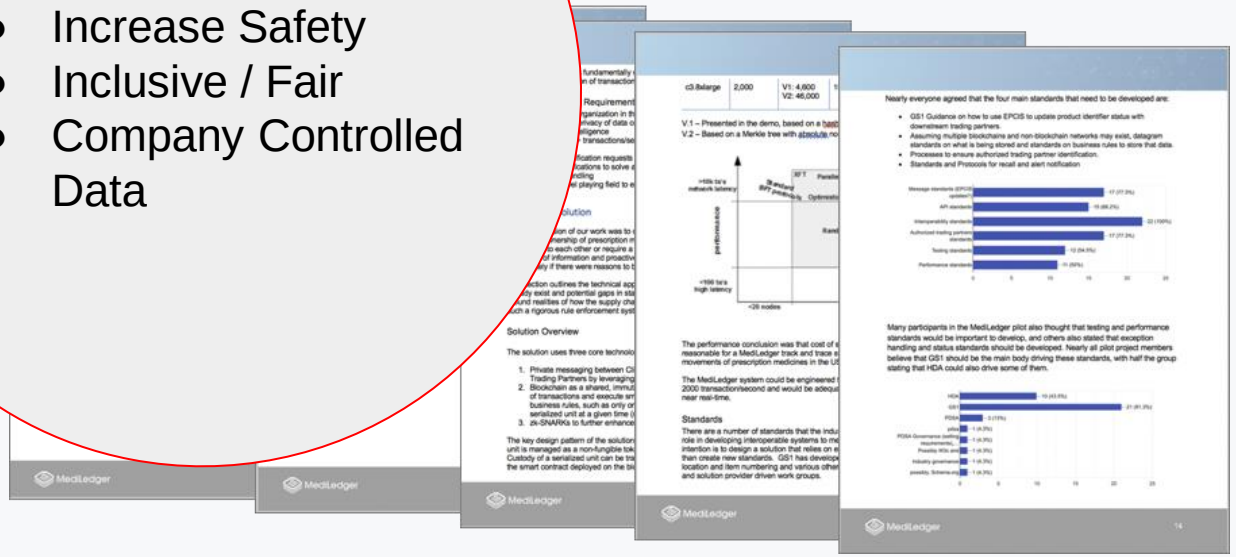


https://www.mediledger.com/fda-pilot-project

MediLedger FDA Pilot Report - Highlights

Table of Contents

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

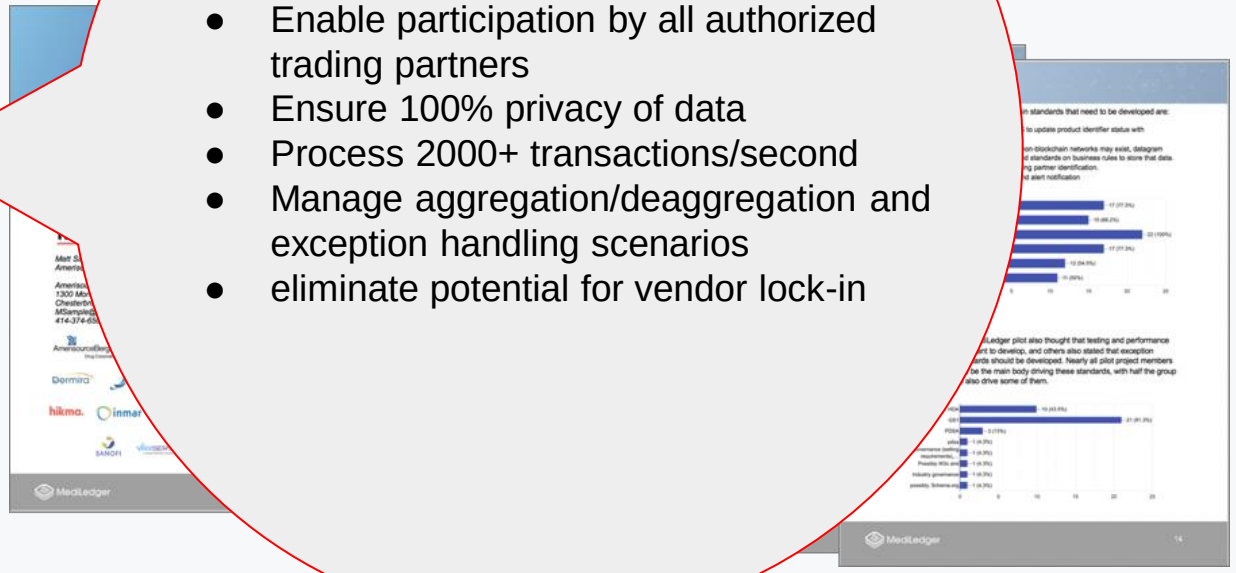


https://www.mediledger.com/fda-pilot-project

MediLedger FDA Pilot Report - Highlights

Table of Contents

- 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

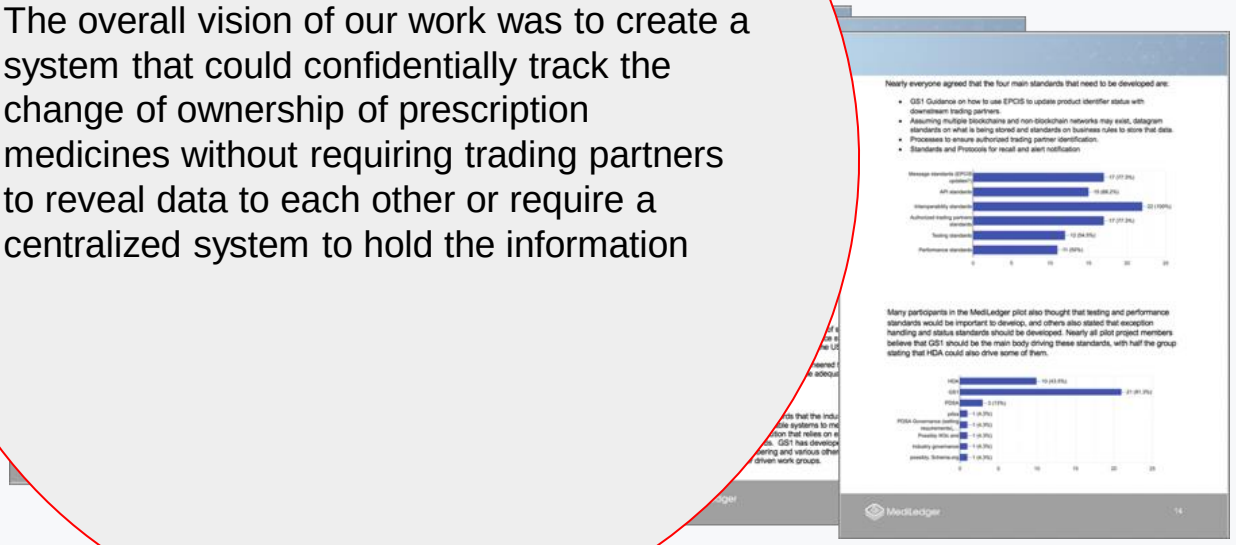


https://www.mediledger.com/fda-pilot-project

MediLedger FDA Pilot Report - Highlights

Table of Contents

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

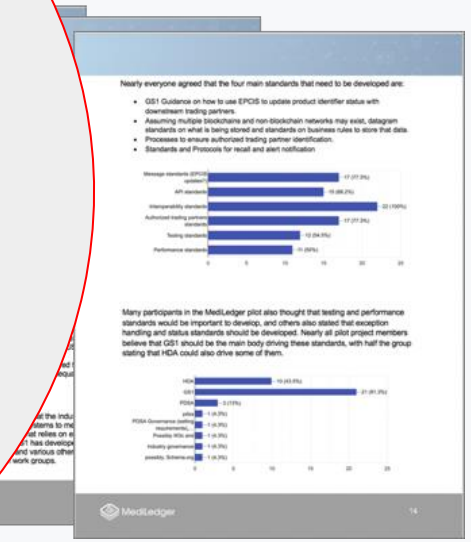


https://www.mediledger.com/fda-pilot-project

MediLedger FDA Pilot Report - Highlights

Table of Contents

- **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



ediledger.com/fda-pilot-project

Report Conclusions

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

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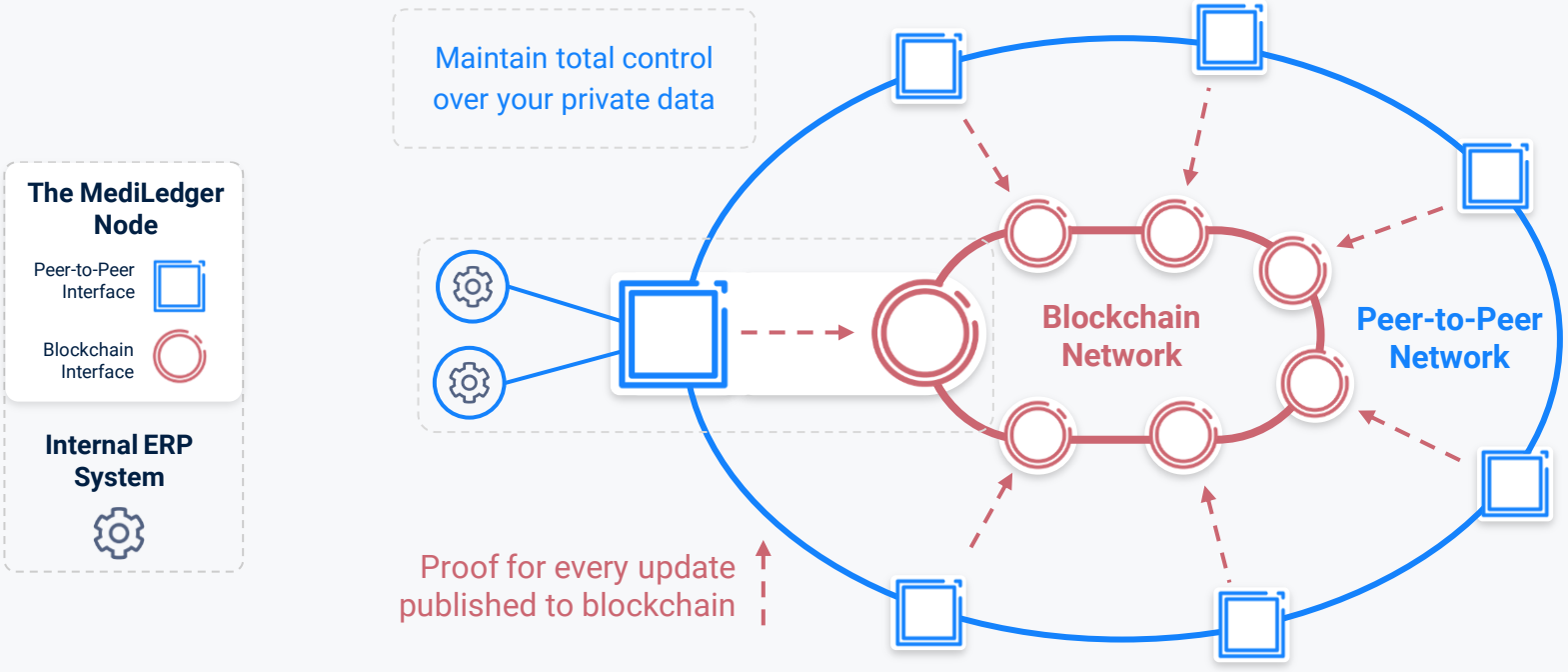
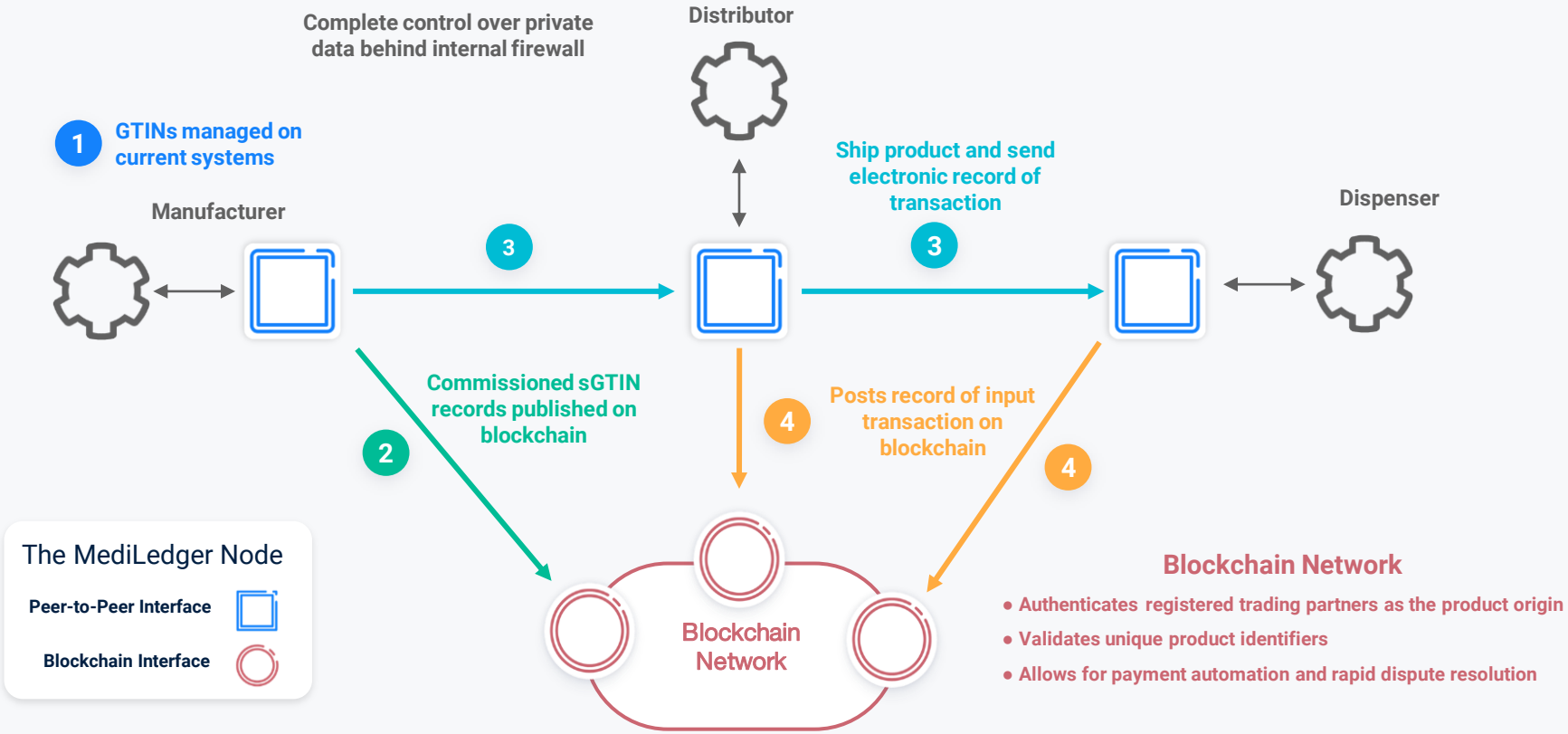
The MediLedger Network

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



Next Steps

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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

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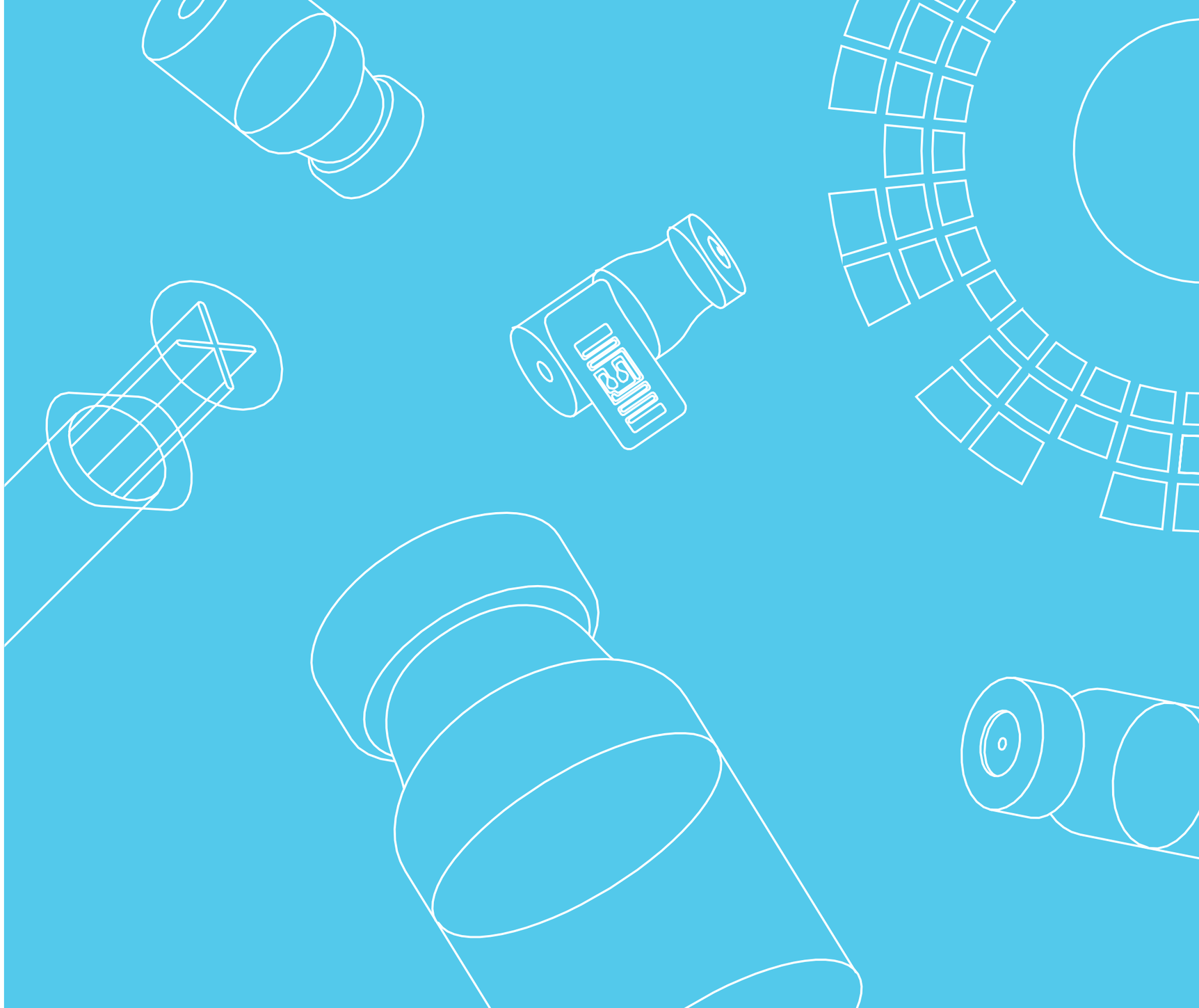
KITCHECK

POWERED BY BLUESIGHT

FDA Presentation

Kit Check / Sandoz
DSCSA Pilot




KITCHECK


SANDOZ
A Novartis
Division


CORAL GABLES
Hospital


HackensackUMC

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

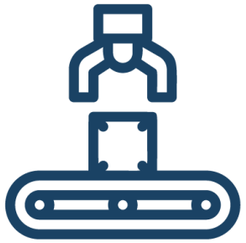
FDA should allow RFID

- 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

03

Conclusion

DSCSA ≠ full supply chain security

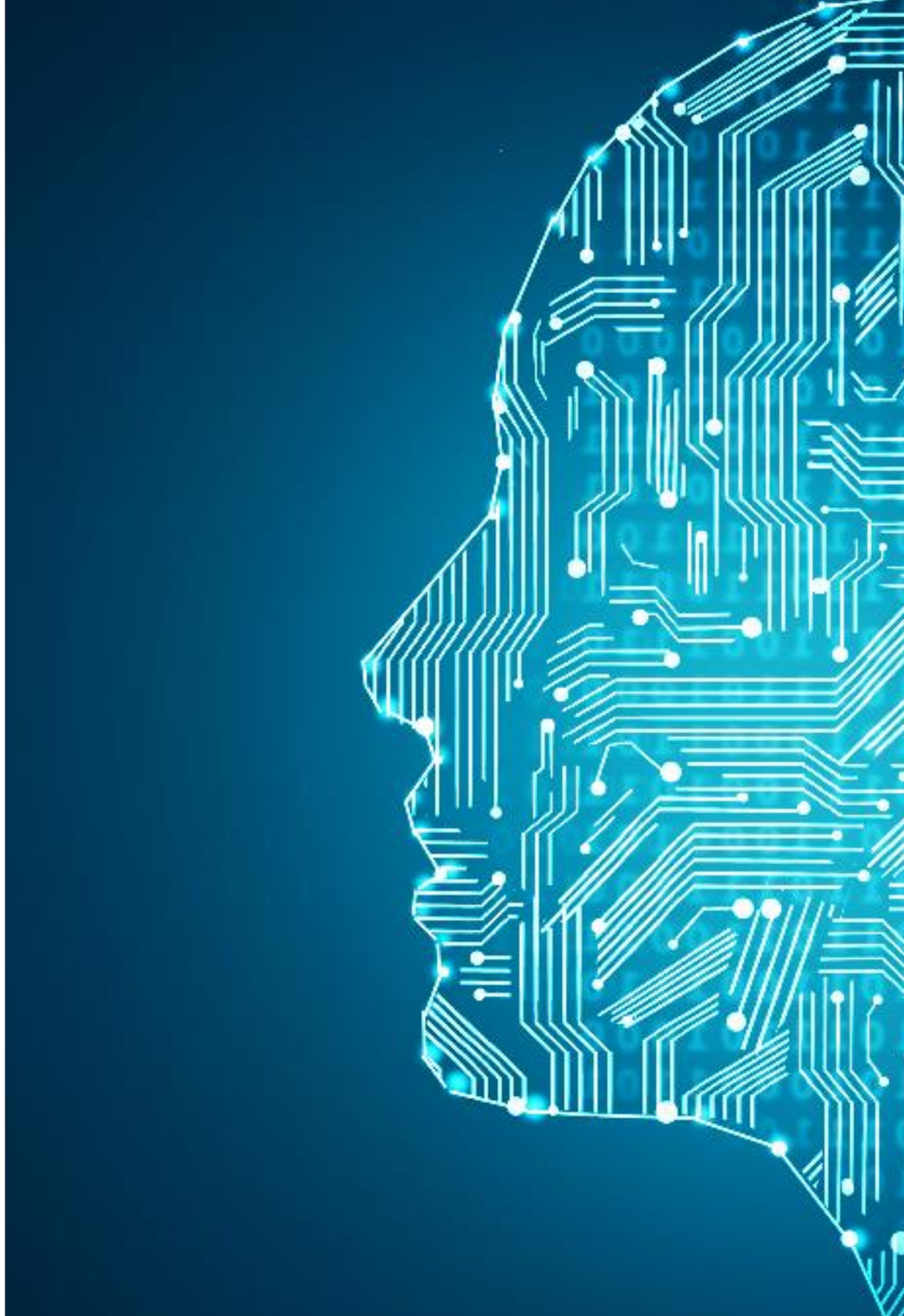
> **That serial number**
> **[in the salable-unit barcode]**
> **is only good**
> **until it encounters a pair of scissors.**

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

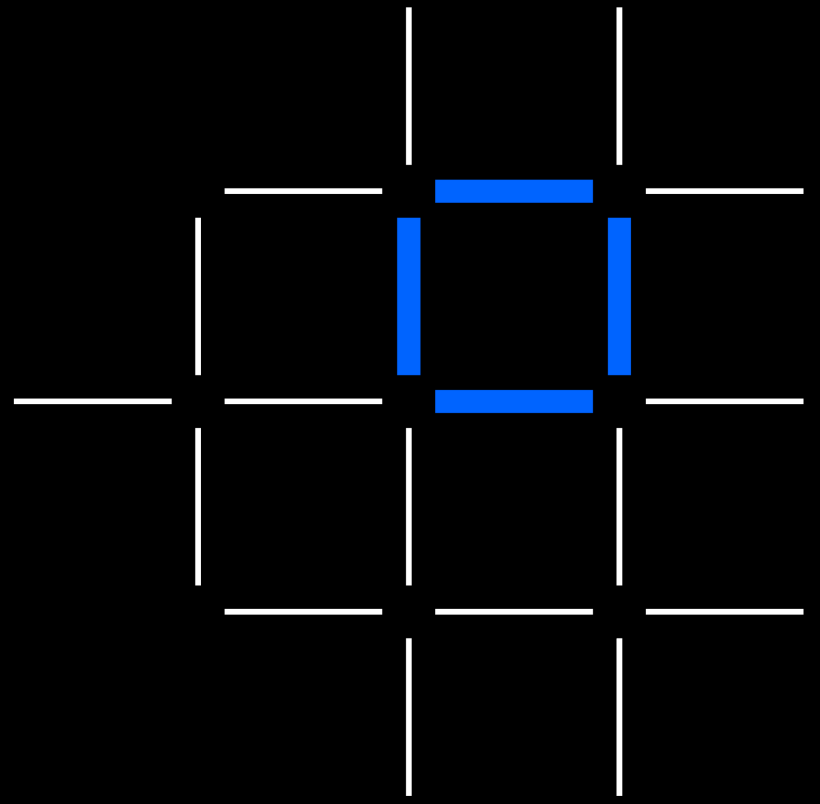
KITCHECK

Tim Kress-Spatz

tim@kitcheck.com

kitcheck.com

FDA DSCSA Blockchain Interoperability Pilot



PDG DSCSA Pilot Project
Program Round-Robin

July 31, 2020

KPMG MERCK Walmart IBM

00 Agenda

01 Objectives

02 Key Features

03 Value Beyond Compliance

04 Recommendation

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

03 Value Beyond Compliance

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

04 Opportunities

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.

04 Opportunities

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!

KPMG | MERCK | Walmart | IBM

FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM

FDA Pilot Project- DSCSA Verification to Improve Product Traceability at FMOL Health System

Chris Chandler, PharmD

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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/

- 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

DSCSA Verification to Improve Product Traceability Pilot

Lessons Learned - FMOLHS

- 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

FDA Pilot Project- DSCSA Verification to Improve Product Traceability

Phase 1

Pharmacy Buyer	Distributor ERP (McKesson)	Distributor EDI (McKesson)	DSCSA Solution Provider (ConsortiEX)	FMOLHS Pharmacy Receiving	FMOLHS DSCSA Data
Daily pharmacy order placed via Wholesale Distributor's website *<10% of orders placed directly with Manufacturers was out of scope for pilot	• Generate PO Ack to Distribution Center (DC) for product fulfillment • Generate Invoice & Advance Ship Notice (ASN)	• Send **PO Ack 855** • Send **ASN 856*** mapped for DSCSA Transaction Data (T3) excluding drop shipments & **Invoice 810**	Upload **ASN 856** for DSCSA T3 retention on web portal; direct & 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?	• Scan tote label • Scan NDC bar codes • Cradle McKesson handheld generate **Receiving Acceptance 861** & Invoice AP520csv to Accounting *McKesson drop shipments do not retain PO to scan upon receipt; manually received in McKesson Connect	Pilot 3-way match • Order- PO Ack 855 *fills drop ship gap noting pending T3 • Ship - ASN 856 for DSCSA T3 • Receipt- Acceptance 861 from handheld scans *missing if manual entry ???scan DSCSA Product Identifier into inventory, or use EDI feeds with last scan at bedside to EHR?