

# Disclaimer

*The findings, conclusions, or recommendations in this presentation are those of the authors and do not represent the U.S. Food and Drug Administration's position on any compliance requirement or endorsement of any particular technology or approach.*

*Reference herein to any specific commercial products, process, or service by trade name, trademark, manufacturer, or otherwise, does not constitute or imply its endorsement, recommendation, or favoring by the U.S. Food and Drug Administration. The views and opinions of authors should not be misconstrued as advertising products nor for endorsement purposes.*

# DSCSA Pilot Project Program

## Participant Results (2)

Program Participant/Speaker <i>(All partnering entities are not listed)</i>	Pilot Project
Providence Health Technologies/Todd Barrett	Small Dispenser Pilot Study
Franciscan Missionaries of Our Lady Health System/Chris Chandler	DSCSA Verification to Improve Product Traceability at FMOL Health System
AmerisourceBergen/Xavier Health/Matt Sample	End-to-End 2023 Proof of Concept Pilot
UCLA/LedgerDomain Ben Taylor	UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology
MediLedger Eric Garvin	MediLedger DSCSA Pilot

**We will have a Participant Panel Q&A after the above presentations.**

# Small Dispenser Pilot Study

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

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?

## 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

## 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.

## 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. Some products were even 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

## 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)



# Conclusions & Recommendations

1. Encourage suppliers to provide data in an electronic format to dispenser customers
2. Work with suppliers and manufacturers to standardize data elements within ASNs (EDI 856 formatted data)
3. FDA to instruct wholesale distributors that were unresponsive to requests for data submission comply by providing a way to track data submissions
4. Development of a GTIN to NDC crosswalk data index is imperative
5. Alternatives to scanning the incoming prescription product shipments should be evaluated to meet product lot level validation

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

---

Chris Chandler, PharmD

December 08, 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/>
- 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](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 5-16<sup>th</sup> 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?**

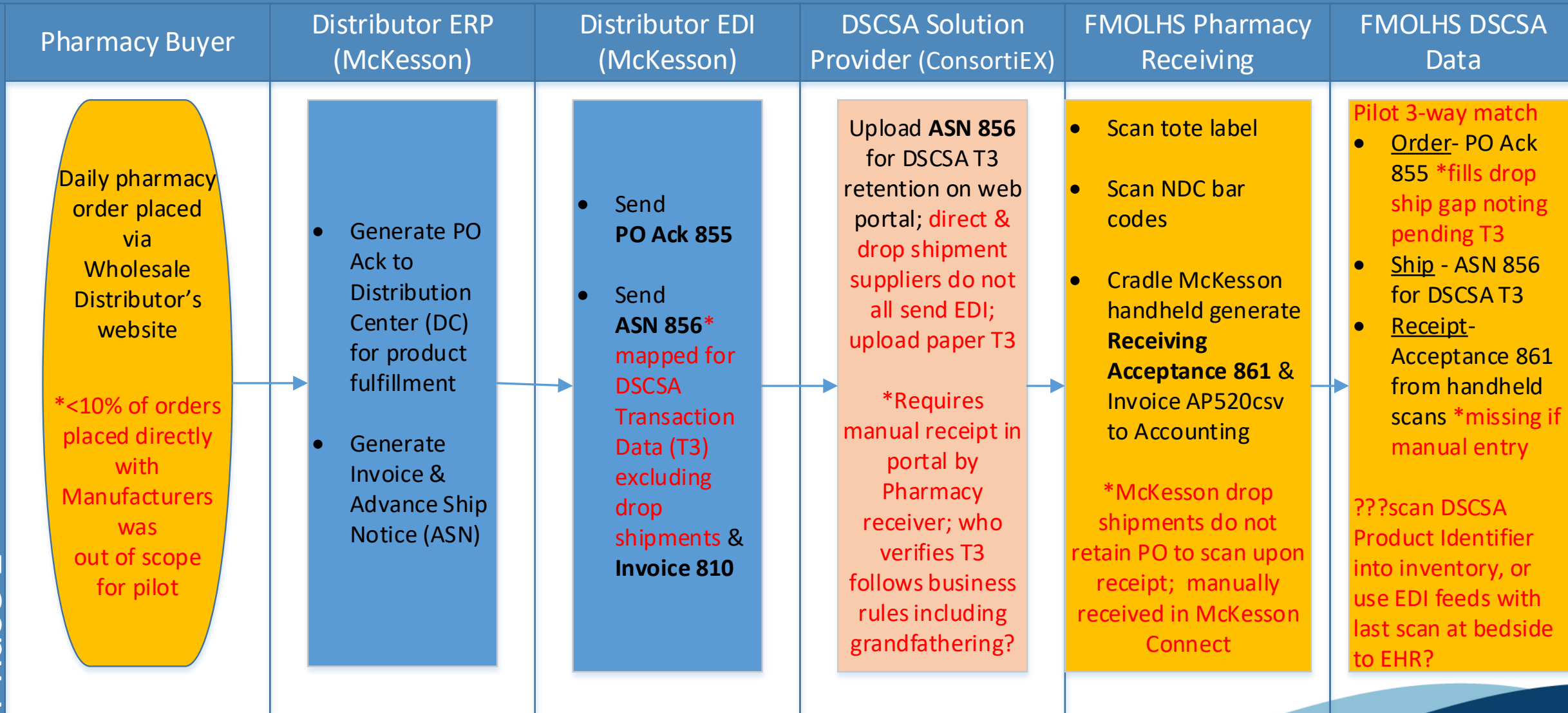


# Additional Reference Slides



# FDA Pilot Project- DSCSA Verification to Improve Product Traceability

Phase 1



# AmerisourceBergen & Xavier Health

## 2023 End-to-End Interoperability Pilot



# End-to-End Interoperability Pilot

## 2023 Regulatory Focus

- Manufacturers, re-packagers and wholesale drug distributors shall **include product identifier** in the Transaction Information.
- Trading partners shall exchange, or share, required transactional information in a secure, **interoperable**, electronic system.
- Trading partners **shall not accept ownership of a product** unless the previous owner provides transaction information, and the transaction statement for the product.

Use of GS1 Standards for Encoding Product Identifier on the product and in the transaction statement.

Implementation of GS1 EPCIS 1.2 standards for the exchange of Transaction Information and Statement

Evaluation of processes and system changes to ensure Transaction Information received.

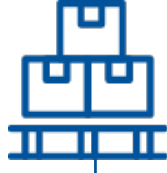
# End-to-End Interoperability Pilot

## Industry Participants



### Manufacturers:

- Amag
- Apotex
- Amgen
- Eli Lilly
- EMD Serono
- Genentech
- J&J
- Mylan
- Pfizer



### Distributors / 3PL:

- AmerisourceBergen
- ICS 3PL



### Dispensers:

- The Chris Hospital
- Walgreens

# End-to-End Interoperability Pilot

## Scope of the Pilot



- Send serialized products to AmerisourceBergen.
- Transmit serialized GS1 EPCIS 1.2 files along with, or prior to, shipment of product (TI, TS exchange).

- Receive serialized products and GS1 EPCIS 1.2 files; confirm receipt of TI, TS.
- Scan & aggregate at outbound shipments.
- Build customer capabilities for DSCSA: Send GS1 EPCIS 1.2, enhance customer portal, update customer handhelds, etc.

- Receive serialized products and GS1 EPCIS 1.2 data (TI, TS) into customer solution.
- Receive serialized products & data (TI, TS) using ABC solutions.
- Implementation processes to confirm receipt of TI, TS.



# End-to-End Interoperability Pilot

Tested two different dispenser processes and technologies

## ■ The Christ Hospital

- Audited 100% of all items received
- Utilized ABC's portal and DSCSA system to run a full TI report

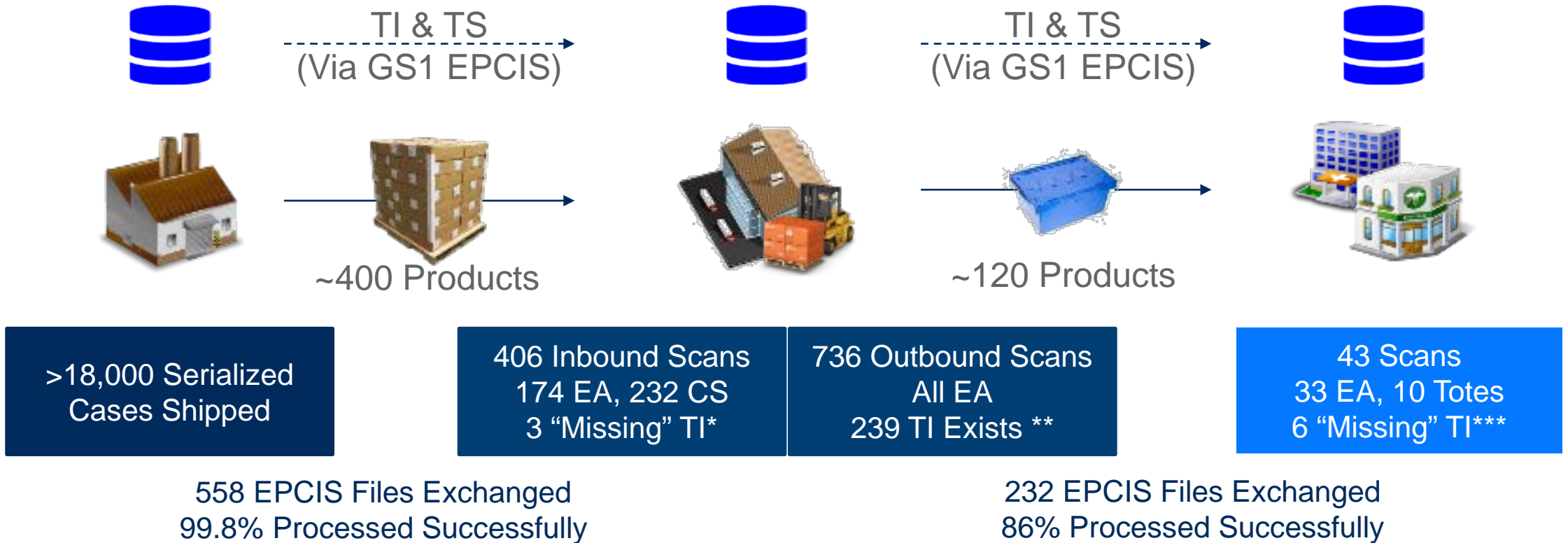
## ■ Walgreens

- Sampled/Audited items via scanning Totes and/or individual items
- Utilized third party (rfXcel) application for receiving EPCIS and auditing



# End-to-End Interoperability Pilot

What were the results?



\* Product arrived before data

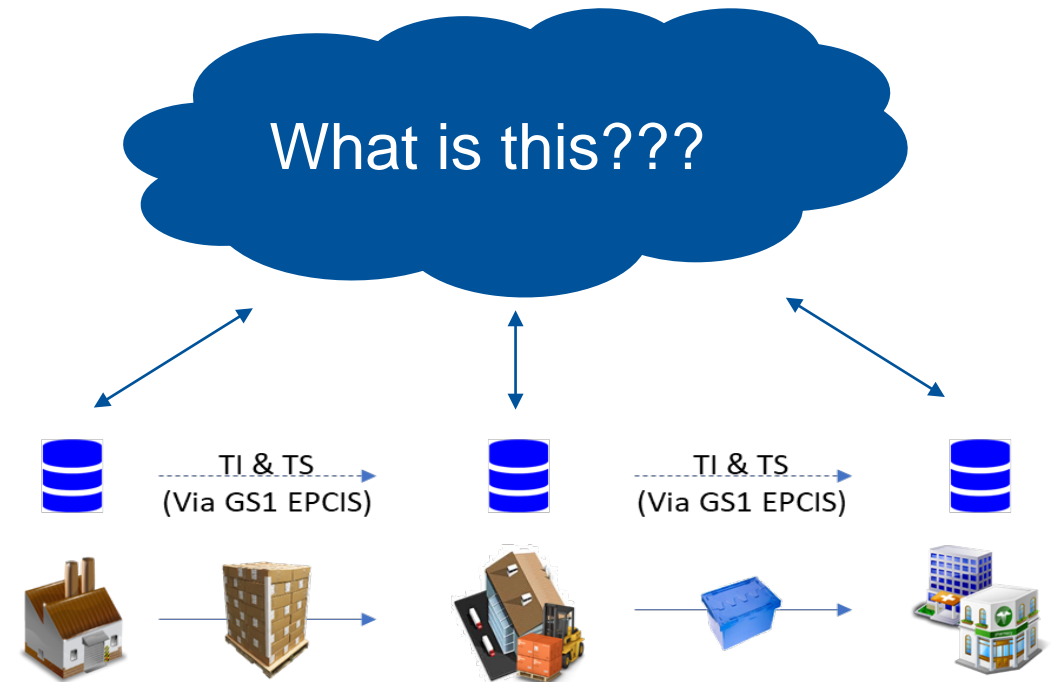
\*\* Product in inventory prior to pilot execution

\*\*\* 1 manually entered serial number type, 5 with mis-match expiration date.

# End-to-End Interoperability Pilot

## Closing Thoughts

- GS1 EPCIS 1.2 meets need for interoperable TI Exchange
  - The industry needs more robust master data sharing; and
  - The industry must test performance and capabilities on 2023 scale
- Dispensers can continue technologies that exist today
  - Wholesaler portals and tools; or
  - 3<sup>rd</sup> party integrated solutions
- Barcode and data issues will stop products!
- There's still an incremental 2023 need??
  - Promptly facilitate gathering the information





AmerisourceBergen®

Where knowledge,  
reach and partnership  
shape healthcare delivery.

## UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology

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

Submitter: [Han-Lian William Chien](#), PharmD, MBA  
Chief Pharmacy Officer: Josenor “Jess” DeJesus, PharmD, MBA, FACHE  
Senior Supervising Dispenser: Jennifer Colon, PharmD  
Prescriber: Prof. Perry B. Shieh, MD, PhD  
Ronald Reagan UCLA Medical Center

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

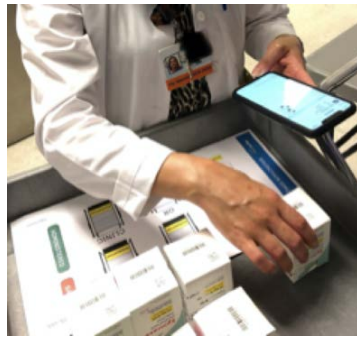
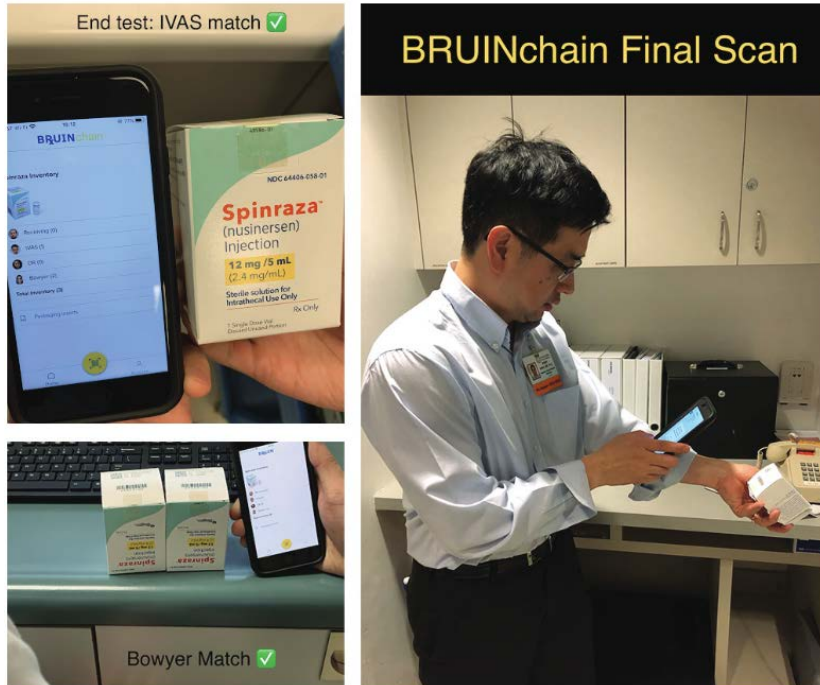


Partner & Presenter: [Ben Taylor](#), CEO, LedgerDomain

**FDA DSCSA Pilot Project Program and Enhanced Drug Distribution Security  
Public Meeting, December 2020**

# UCLA Health

- ❖ 5 facilities, >200 clinics, 600,000 unique patients yearly
- ❖ 300+ pharmacy 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

Product names & trademarks property of their respective owners. Use of names, trademarks and brands does NOT imply endorsement. SPINRAZA is a Biogen trademark. UCLA, University of California Los Angeles and all related trademarks are property of Regents of the University of California. Hyperledger & Hyperledger Fabric are trademarks of Linux Foundation. The DocuSeal, Selvedge & Oraculous software programs and accompanying procedures, functions, and documentation described herein are sold under license agreement by LedgerDomain Inc. Use, duplication & disclosure are subject to the restrictions stated in the license agreements. XATP & QuaRxantine property of LedgerDomain Inc.



# LedgerDomain Solution Partner

 **Built KitChain for Clinical Supply Blockchain Working Group**

**FDA Naloxone Challenge**  
[fda.gov/NewsEvents/PublicHealthFocus/ucm533711.htm](https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm533711.htm)

**THE NALOXONE APP COMPETITION**

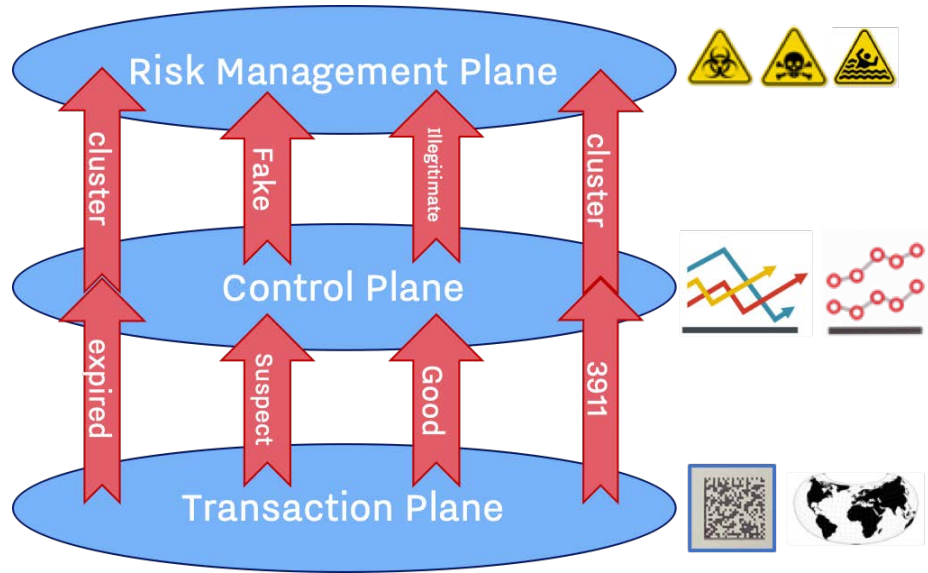
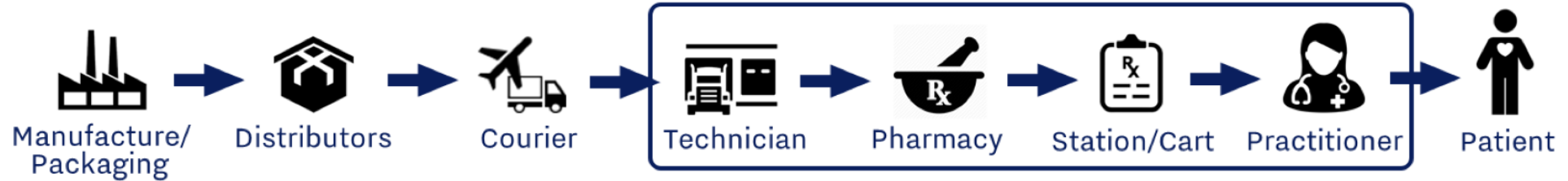


Hattie Chung (Lead)  
Rodrigo Ipince  
Emily Zhao  
Sinchan Banerjee  
Grace C. Young

THE TEAM  
Sponsor: Ben Taylor (LedgerDomain LLC)  
Submission by TeamMIT



# Last Mile DSCSA Objectives

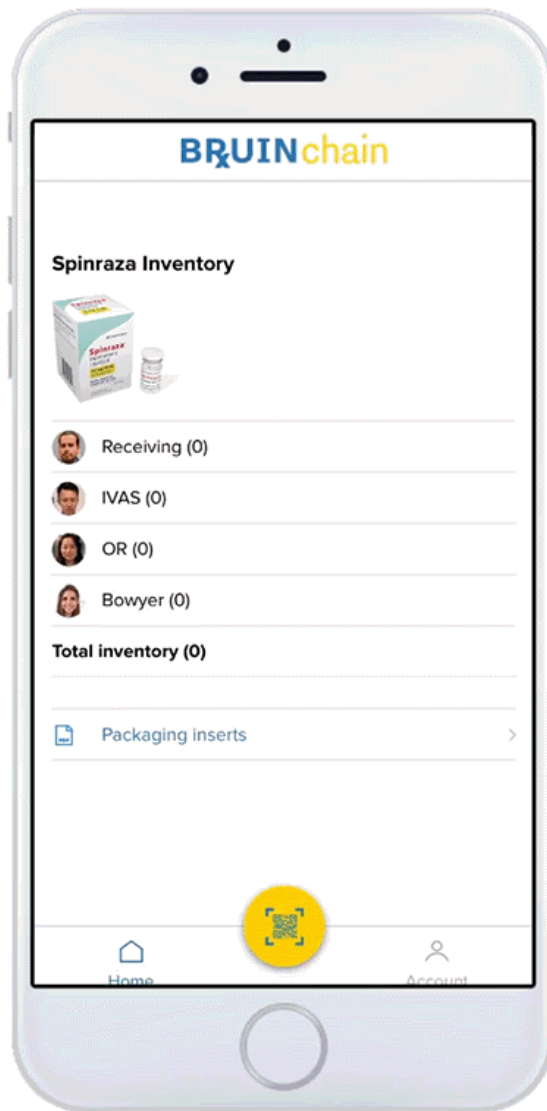


- ❖ Robust DSCSA checks & verification
- ❖ Flag double-counts & surface suspect transactions
- ❖ Exception handling; escalate to 3911
- ❖ Real-time inventory & quarantine at refrigerator level
- ❖ Real-time availability & verification notifications



# BRUINchain Pilot

BRUIN  
chain



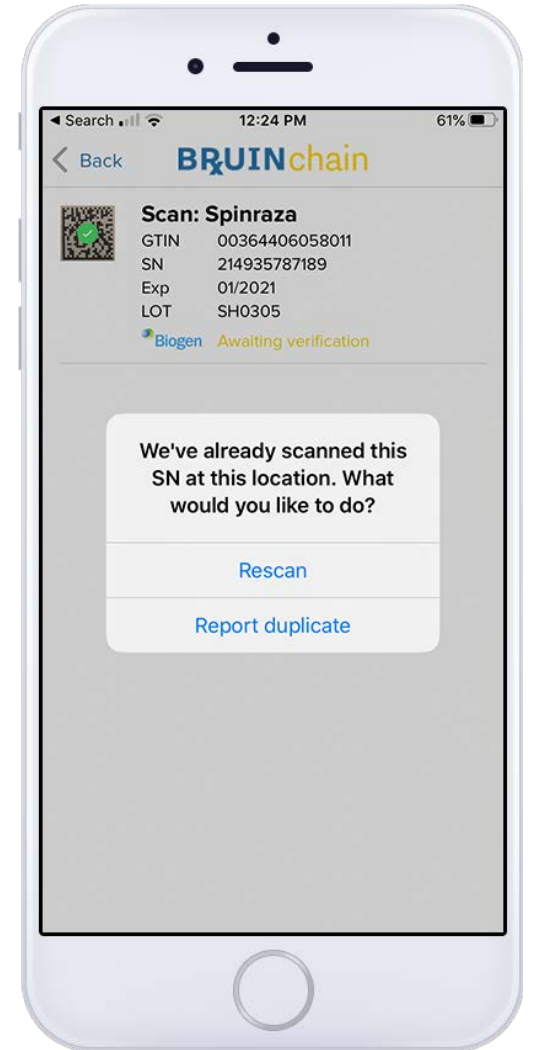
- ❖ Scanning 2D barcodes, not “paper-pushing” (>8% error)
- ❖ Tracks changes in drug custody with guaranteed auditability and security
- ❖ Expiration flagging & suspect product quarantining
- ❖ Manufacturer verification & real-time notifications

*Real data; real caregivers; life-saving medication; in real-time*

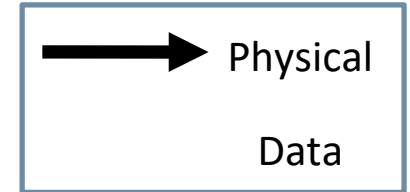
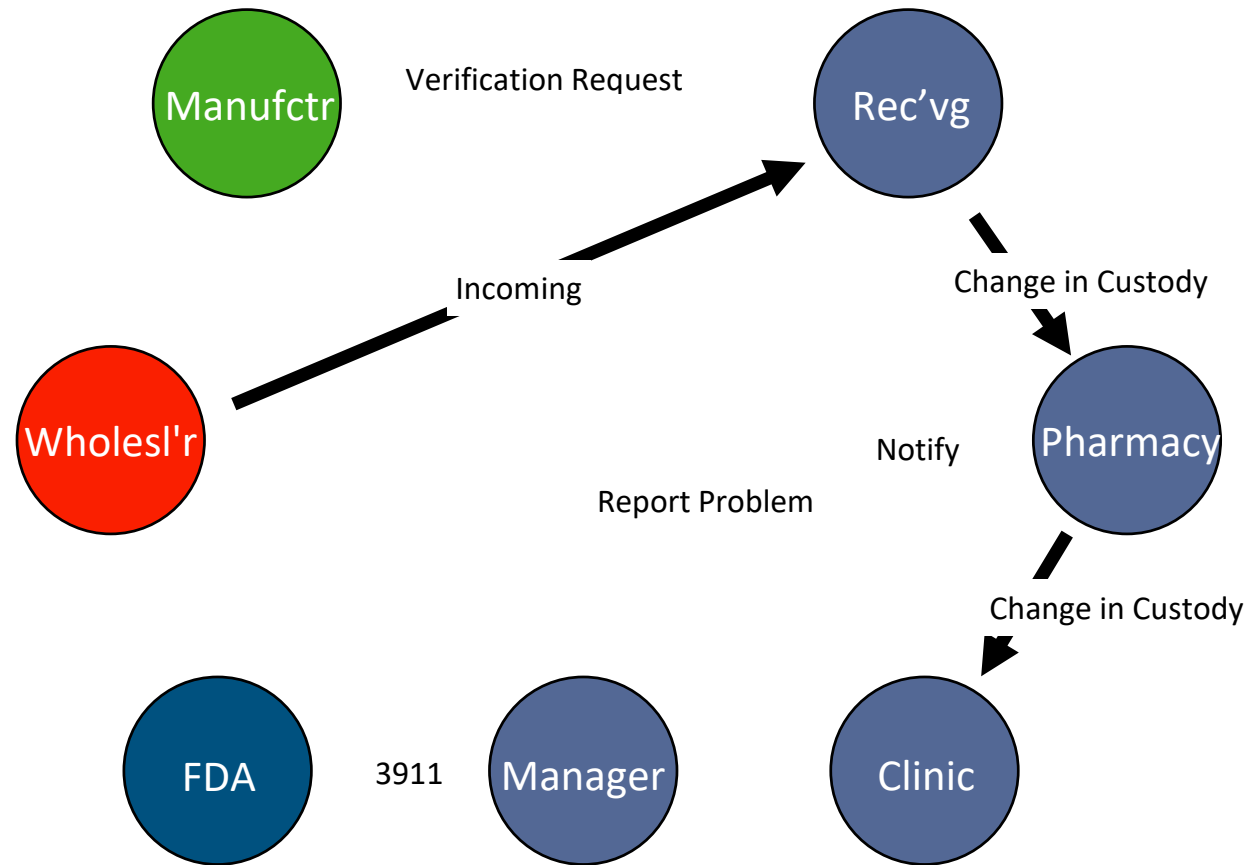
# Foundations for Interoperability

- ❖ DATA SCIENCE: GS1-compliant salable units
- ❖ IDENTITY: Capture entities, members & locations
- ❖ SOURCE: Relational & blockchain interoperability
- ❖ HISTORY: Audit-readiness through immutable time-stamps
- ❖ LEDGER: Real-time persistent data to query quickly & reliably

*If counterfeit duplicate scanned,  
must be flagged in real-time*

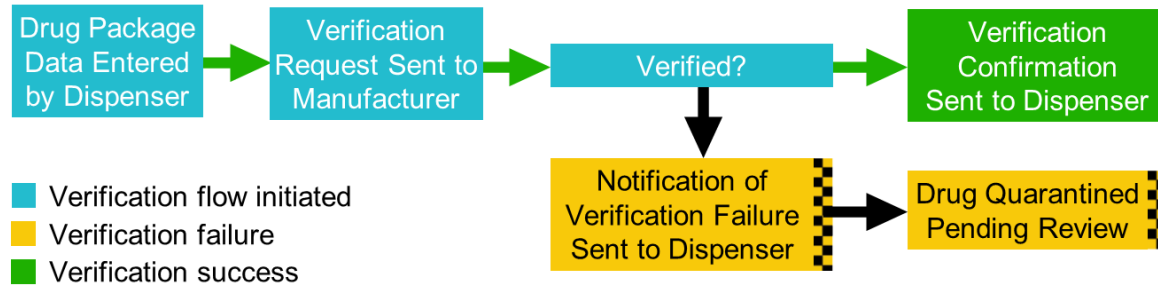
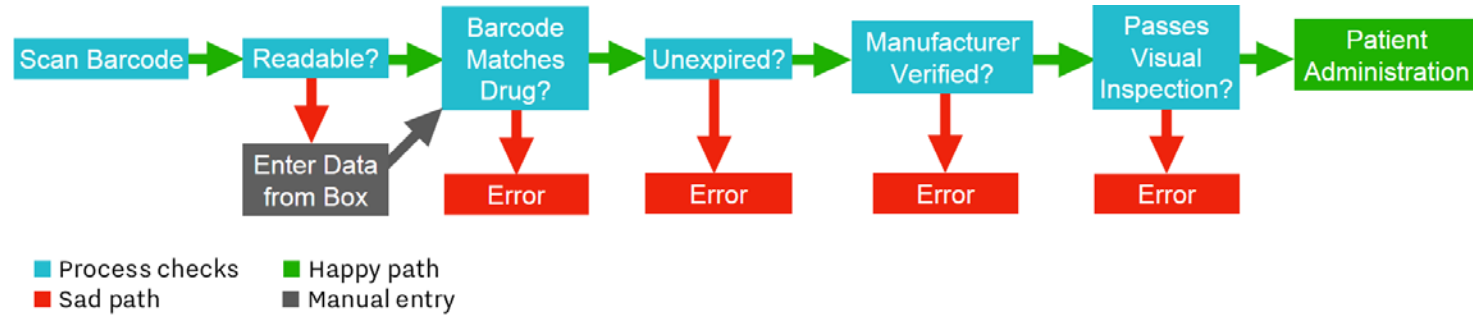


# Last Mile DSCSA Role-based Happy Path



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

# Last Mile DSCSA “Sad Paths”

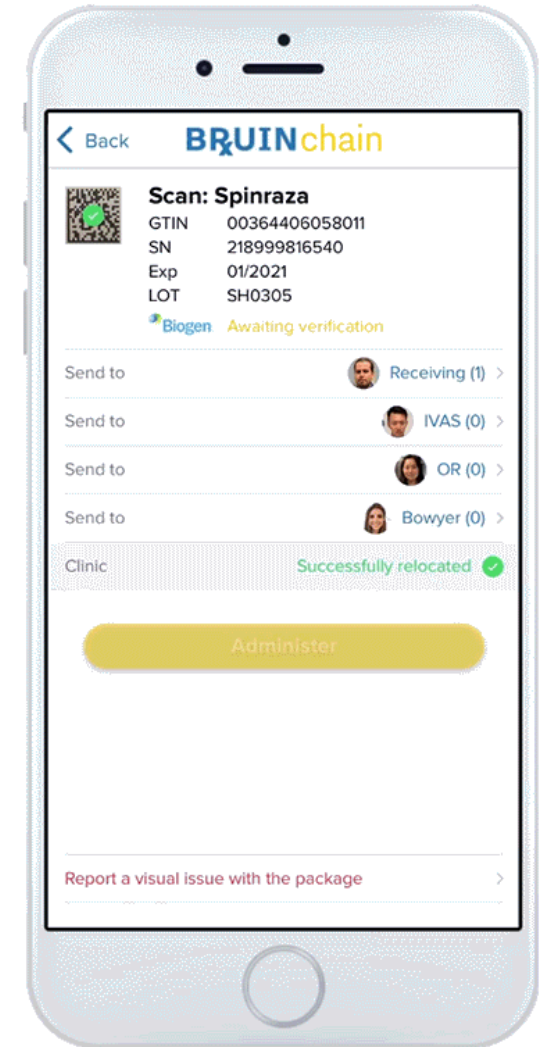


```

    <bruinchain-doc-problemreport>
    <Asset-
    Id-
    Asset-Id-
    <GTIN>00364406058011</GTIN>
    <SN> 6540</SN>
    <Expiration-Date>01/2021</
    Expiration-Date>
    <Lot-Number>SH0305</Lot-Number>
    <Problem-Description>package
    was empty when opened</Problem-
    Description>
    <Reported-By>William Chien</
    Reported-By>
    <Reported-By-
    Email>
    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

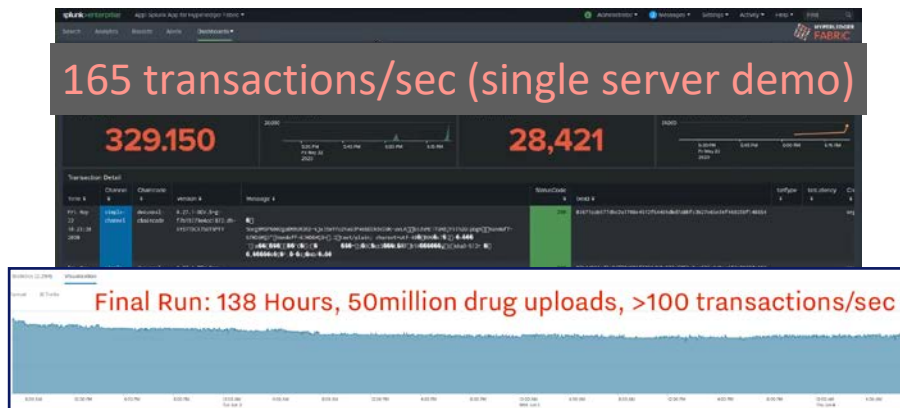


# Content, Scalability & XATP



## COMPLETE DRUG CONTENT

- ❖ >100,000 drugs; >200,000 packages
- ❖ Expiration extensions & recalls
- ❖ Building block for flagging & 3911s



## TRANSACTIONS ON SINGLE SERVER

- ❖ ~5Bn Rx/year = ~87 saleable units/sec
- ❖ 2024 US Target ~250 per second

Final hurdle: fading “human-in-the-loop”

# Last Mile Learnings & Perspectives



## LEARNINGS

- ❖ App barcode scanning 100% on iPhone
- ❖ Expiration, verification & inspection targets achieved
- ❖ Interoperating with upstream manufacturer database
- ❖ Refrigerator-level inventory tracking & soft quarantine
- ❖ Quarantine stickers & trays
- ❖ 3911 reports can be generated automatically
- ❖ >17¢/unit cost borne by dispenser (not including safety stock)

## DISPENSER PERSPECTIVES

- ❖ Barcode size, quality & placement
- ❖ Quick verifications reduce safety stock
- ❖ Crisp guidance(s) for white bagging, 3911s, inspection
- ❖ Reward compliance “bottle bill”?

## Resources

Peer-reviewed study in BHTY  
[doi.org/10.30953/bhty.v3.134](https://doi.org/10.30953/bhty.v3.134)

Hyperledger case study  
<https://www.hyperledger.org/learn/publications/ledgerdomain-case-study>

XATP Pilot  
[xatp.io](https://xatp.io)

## 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)

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



Volume 3, 2020

- PDF
- HTML
- XML

Published Mar 12, 2020

DOI  
<https://doi.org/10.30953/bhty.v3.134>

- William Chien**  
UCLA Health
- Josenor de Jesus**  
UCLA Health
- Ben Taylor**  
LedgerDomain
- Victor Dods**  
LedgerDomain
- Leo Alekseyev**  
LedgerDomain
- Diane Shoda**  
LedgerDomain
- Perry B. Shieh**  
UCLA Health



#### 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.



# Pharma Enabled Blockchain Platform

FDA Pilot Overview

December 2020





# MediLedger Pilot Leads

Matthew Sample

VP, Manufacturer Operations, AmerisourceBergen

1300 Morris Drive

Chesterbrook, PA 19087

[MSample@amerisourcebergen.com](mailto:MSample@amerisourcebergen.com)

414-374-6504



Eric Garvin

Head of Pharma Solutions, Chronicled

121 Minna Street

San Francisco, CA 94105

[eric@chronicled.com](mailto:eric@chronicled.com)

773-858-4998



# FDA Pilot Overview



# MediLedger FDA Pilot Report - Published February, 2020

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

## Manufacturers



AMGEN

Genentech  
A Member of the Roche Group



GILEAD

hikma.

Dermira<sup>o</sup>

Lilly



## Wholesalers

MCKESSON



## Dispensers

MAXOR<sup>®</sup>  
NATIONAL PHARMACY SERVICES COMPANY

Walmart

Walgreens

## Others



FedEx



CENTER  
for Supply Chain Studies™

# Pilot 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

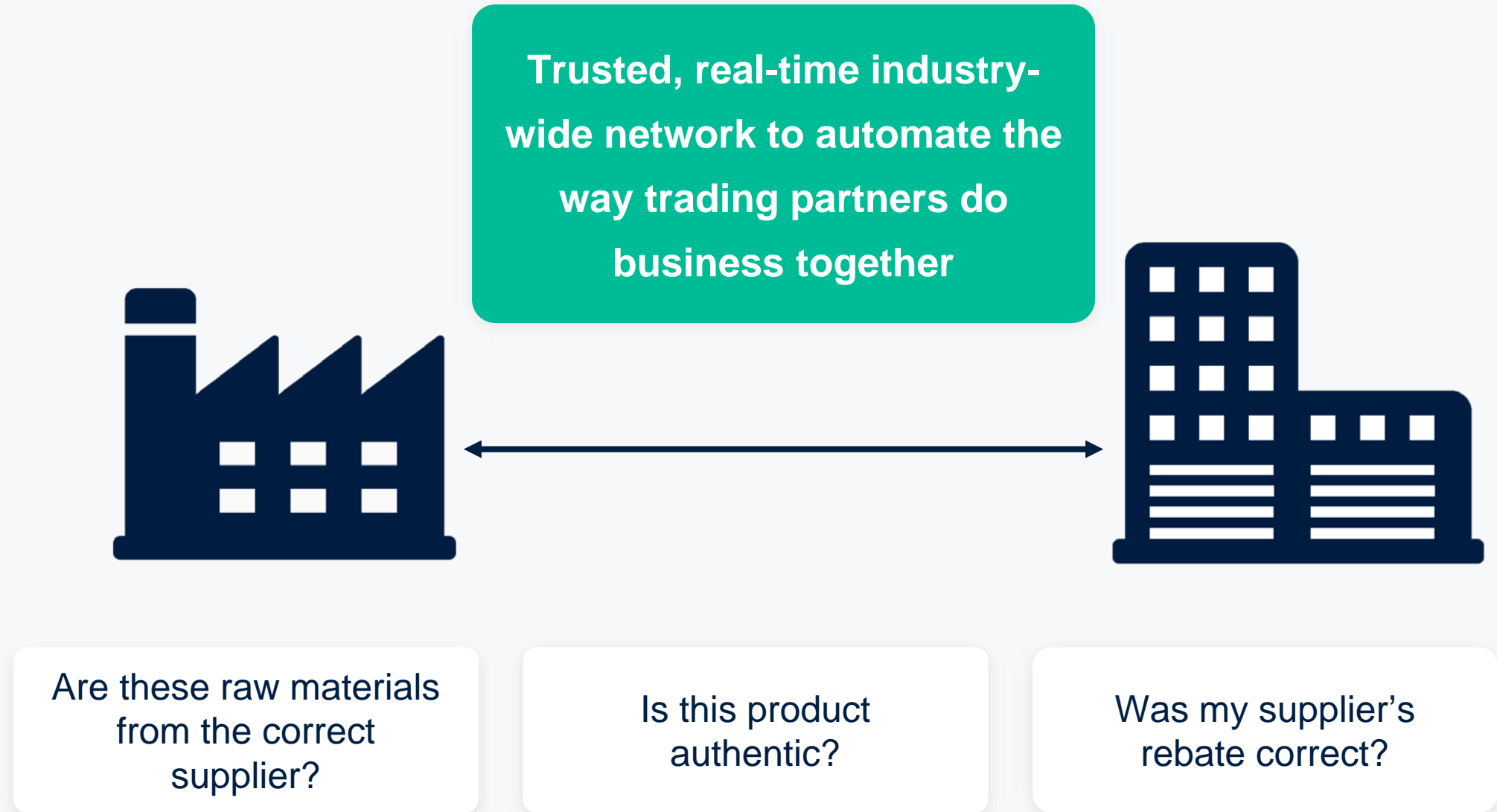
Without appropriate standards, it is unlikely that disparate track and trace systems can be interoperable.

# MediLedger

## How it could work

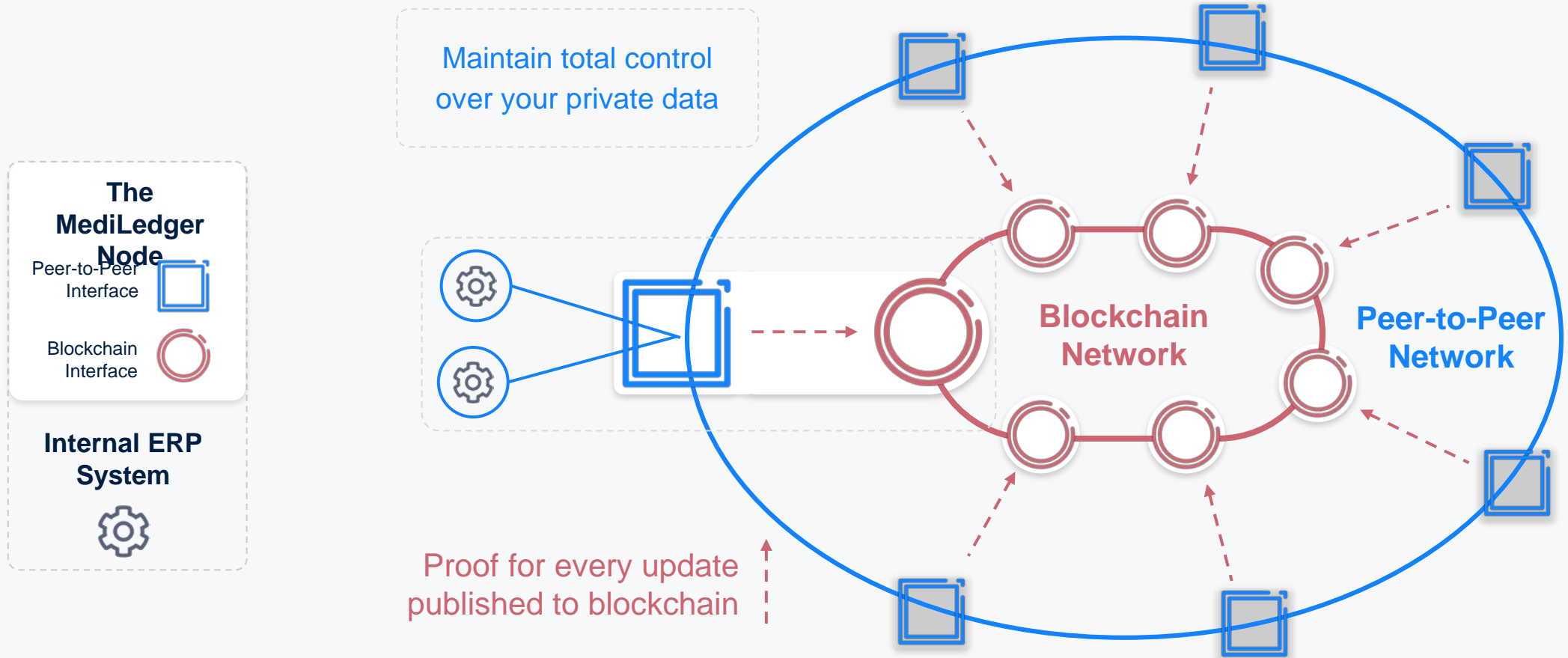


# MediLedger Basics

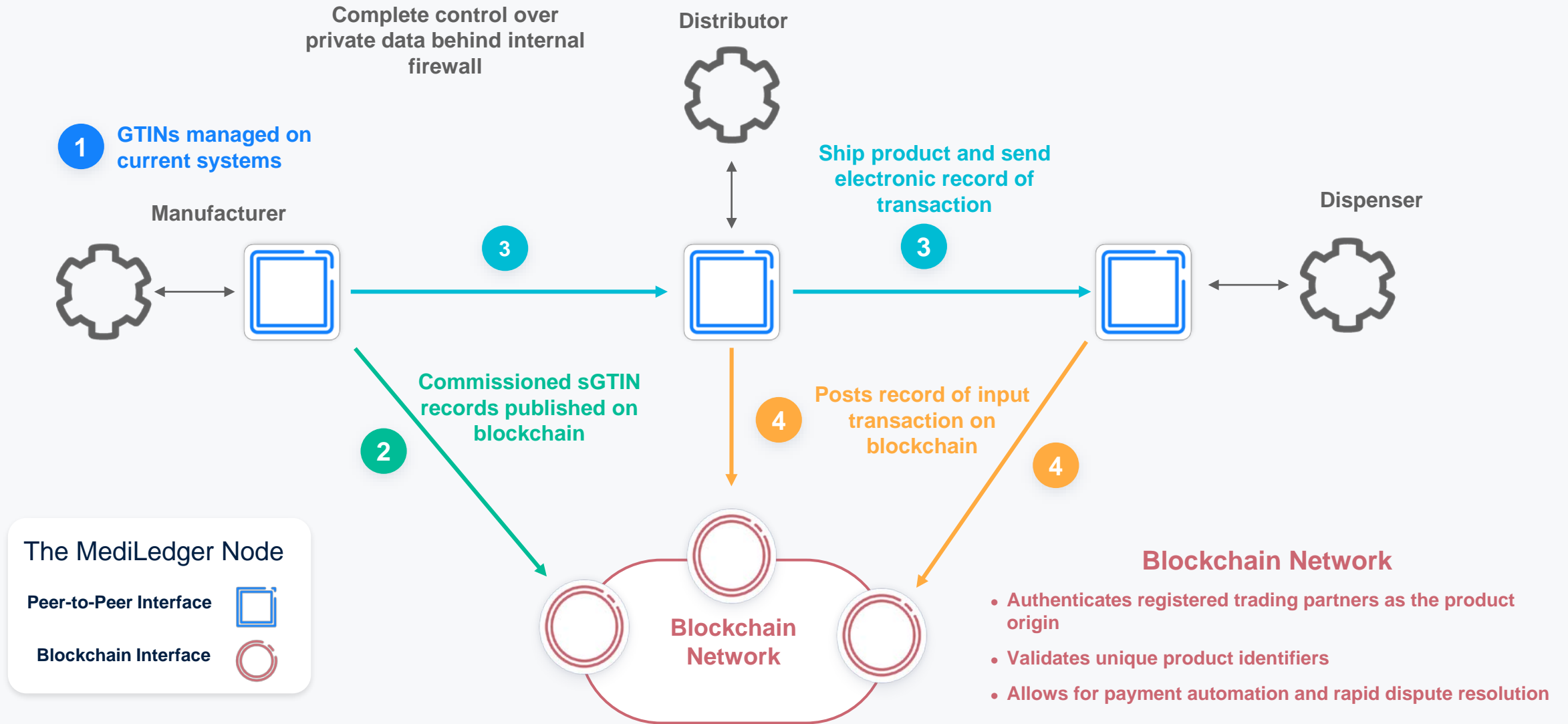


# The MediLedger Network

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





# Appendix



# FDA Pilot Report



# MediLedger FDA Pilot Report - Contents

[Table of Contents](#)

[FDA Pilot Request: Drug Supply Chain Security Act, 2023](#)

[Table of Participants](#)

[Acronyms](#)

[Pilot Description and Report Overview](#)

[Executive summary](#)

[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](#)

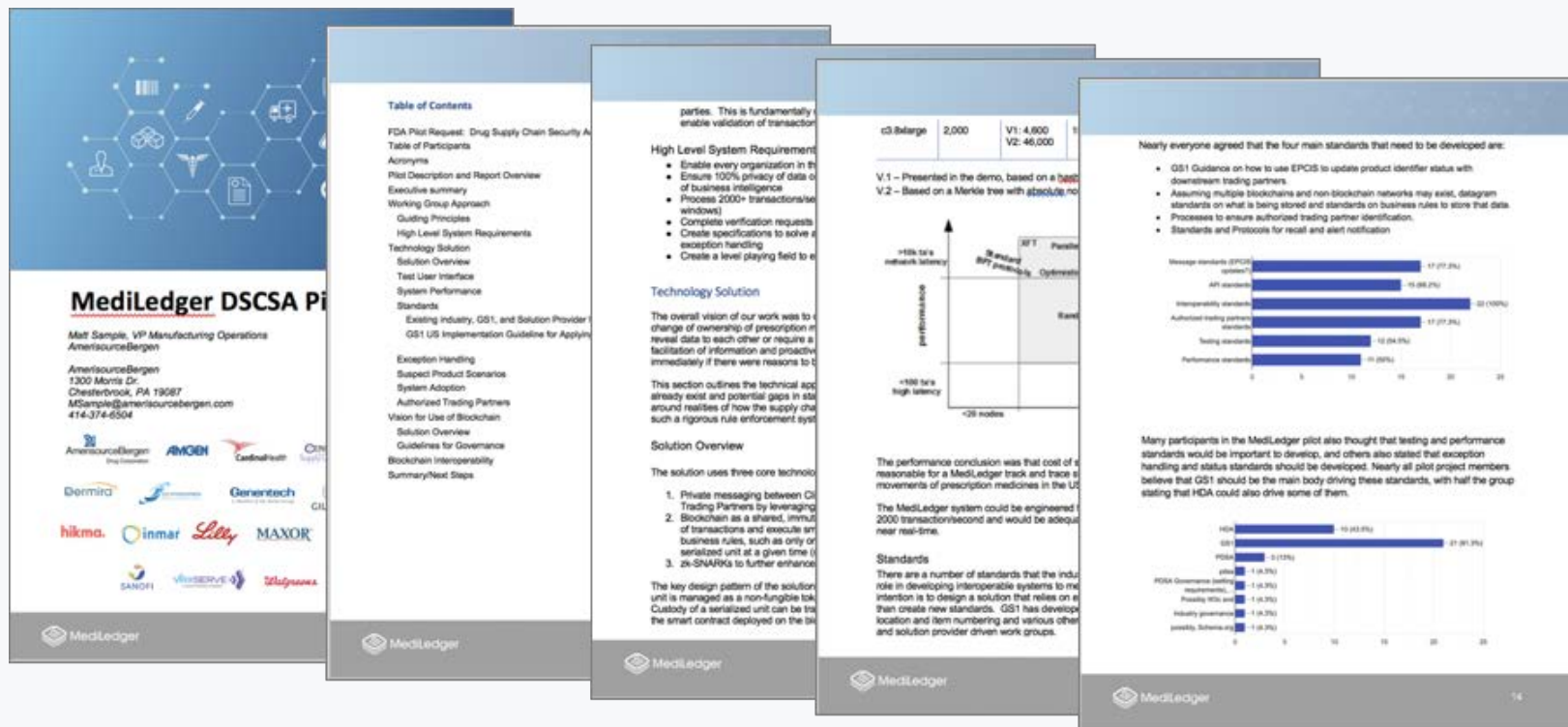
[Vision for Use of Blockchain](#)

[Solution Overview](#)

[Guidelines for Governance](#)

[Blockchain Interoperability](#)

[Summary/Next Steps](#)



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

# MediLedger FDA Pilot Project Highlights

Table of Contents

FDA Pilot Request: Drug Supply Chain

Table of Participants

Acronyms

Pilot Description and Report Overview

Executive summary

**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

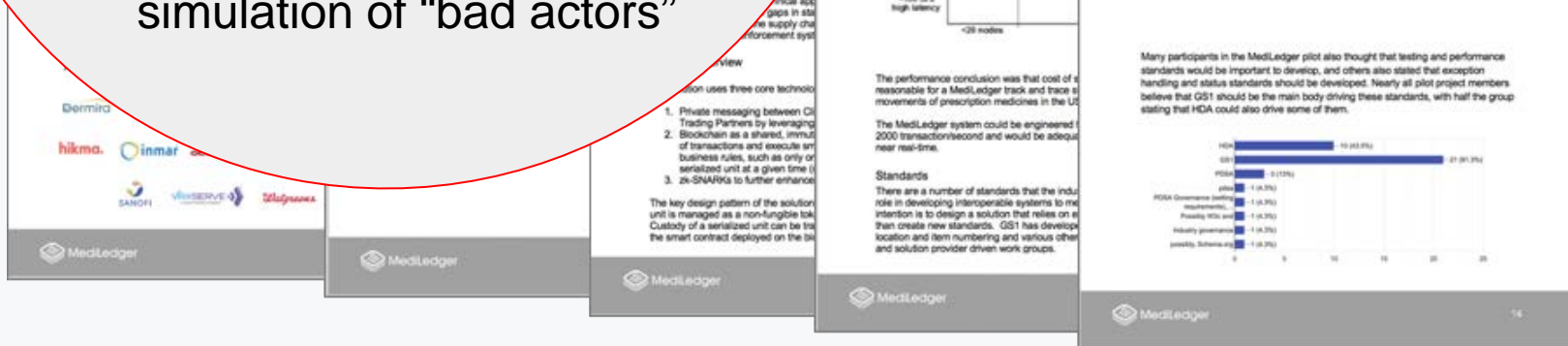
Solution Overview

Guidelines for Governance

Blockchain Interoperability

Summary/Next Steps

- 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](#)

[FDA Pilot Request: Drug Supply](#)

[Table of Participants](#)

[Acronyms](#)

[Pilot Description and Report Overview](#)

[Executive summary](#)

[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](#)

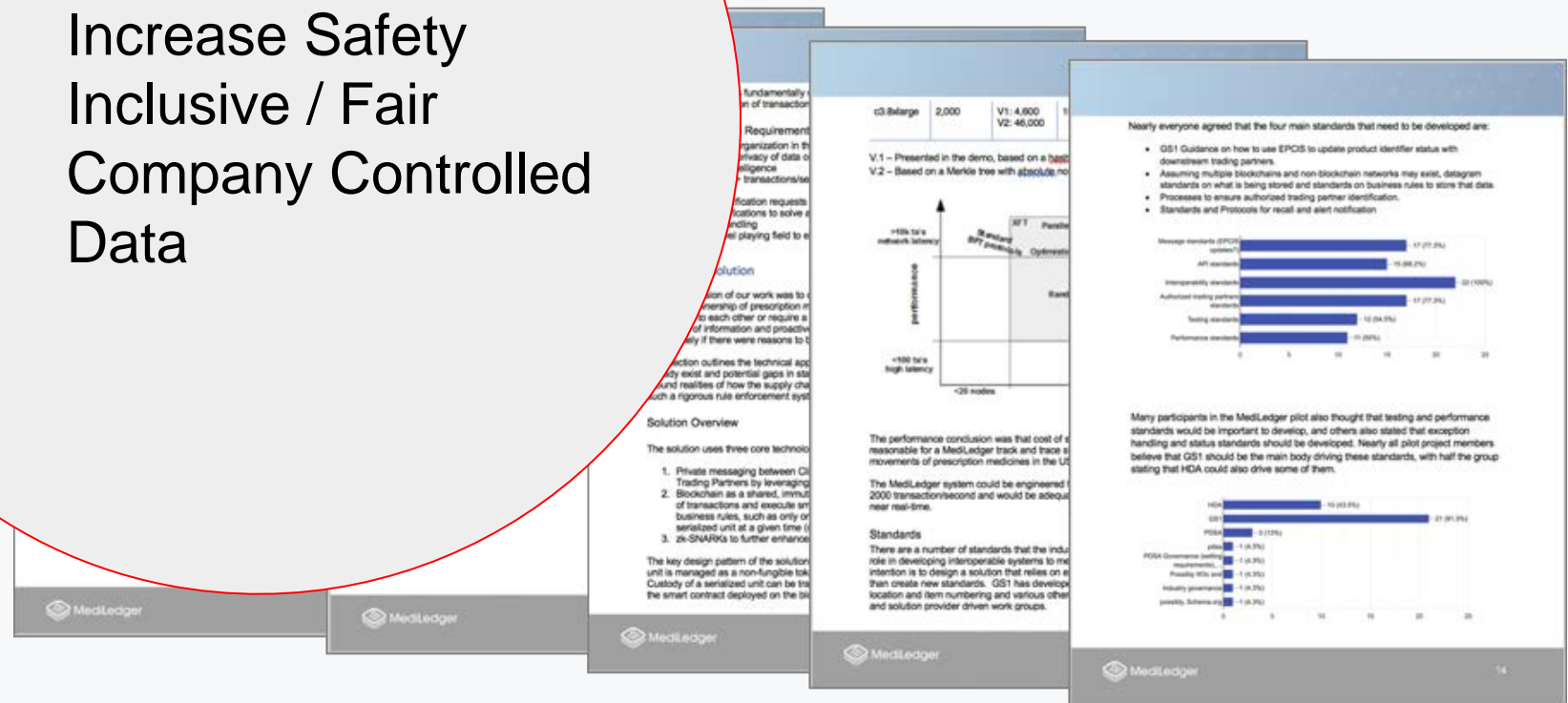
[Solution Overview](#)

[Guidelines for Governance](#)

[Blockchain Interoperability](#)

[Summary/Next Steps](#)

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



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

# MediLedger FDA Pilot Report - Highlights

## Table of Contents

FDA Pilot Request: Drug Supply Chain Security Act

Table of Participants

Acronyms

Pilot Description and Report Overview

Executive summary

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

- 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

FDA Pilot Request: Drug Supply Chain

Table of Participants

Acronyms

Pilot Description and Report Overview

Executive summary

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

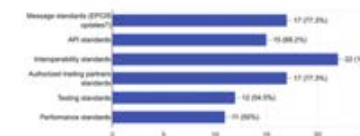
Blockchain Interoperability

Summary/Next Steps

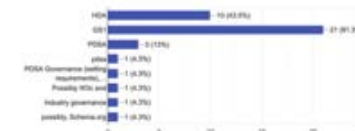
The overall vision of our work was to create a system that could confidentially track the change of ownership of prescription medicines without requiring trading partners to reveal data to each other or require a centralized system to hold the information

Nearly everyone agreed that the four main standards that need to be developed are:

- GSI Guidance on how to use EPCIS to update product identifier status with downstream trading partners.
- Assuming multiple blockchains and non-blockchain networks may exist, datagram standards on what is being stored and standards on business rules to store that data.
- Processes to ensure authorized trading partner identification.
- Standards and Protocols for recall and alert notification



Many participants in the MediLedger pilot also thought that testing and performance standards would be important to develop, and others also stated that exception handling and status standards should be developed. Nearly all pilot project members believe that GSI should be the main body driving these standards, with half the group stating that FDA could also drive some of them.



[www.mediledger.com/fda-pilot-project](http://www.mediledger.com/fda-pilot-project)

# MediLedger FDA Pilot Report - Highlights

Table of Contents

FDA Pilot Request: Drug Supply Chain Sec

Table of Participants

Acronyms

Pilot Description and Report Overview

Executive summary

Working Group Approach

Guiding Principles

High Level System Requirement

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

- **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



[/www.mediledger.com/fda-pilot-project](http://www.mediledger.com/fda-pilot-project)



# Next Steps



# 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](mailto:eric@chronicled.com)



# DSCSA Pilot Project Program

## Participant Results (2)

Program Participant/Speaker <i>(All partnering entities are not listed)</i>	Pilot Project
Providence Health Technologies/Todd Barrett	Small Dispenser Pilot Study
Franciscan Missionaries of Our Lady Health System/Chris Chandler	DSCSA Verification to Improve Product Traceability at FMOL Health System
AmerisourceBergen/Xavier Health/Matt Sample	End-to-End 2023 Proof of Concept Pilot
UCLA/LedgerDomain Ben Taylor	UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology
MediLedger Eric Garvin	MediLedger DSCSA Pilot

### Participant Panel Q&A

- Please type in your question for the panel into the chat box.
- FDA will select and direct questions to the panel.