HYPERLEDGER
FABRIC

LedgerDomain

Blockchain and Drug Supply Assurance in the Coronavirus Era

Ben Taylor, CEO

LedgerDomain

- Built KitChain for the Clinical Supply Blockchain Working Group
- Member of the Linux Foundation, Hyperledger Project, and GS1 US Healthcare

FDA Naloxone Challenge

www.fda.gov/NewsEvents/PublicHealthFocus/ucm533711.htm

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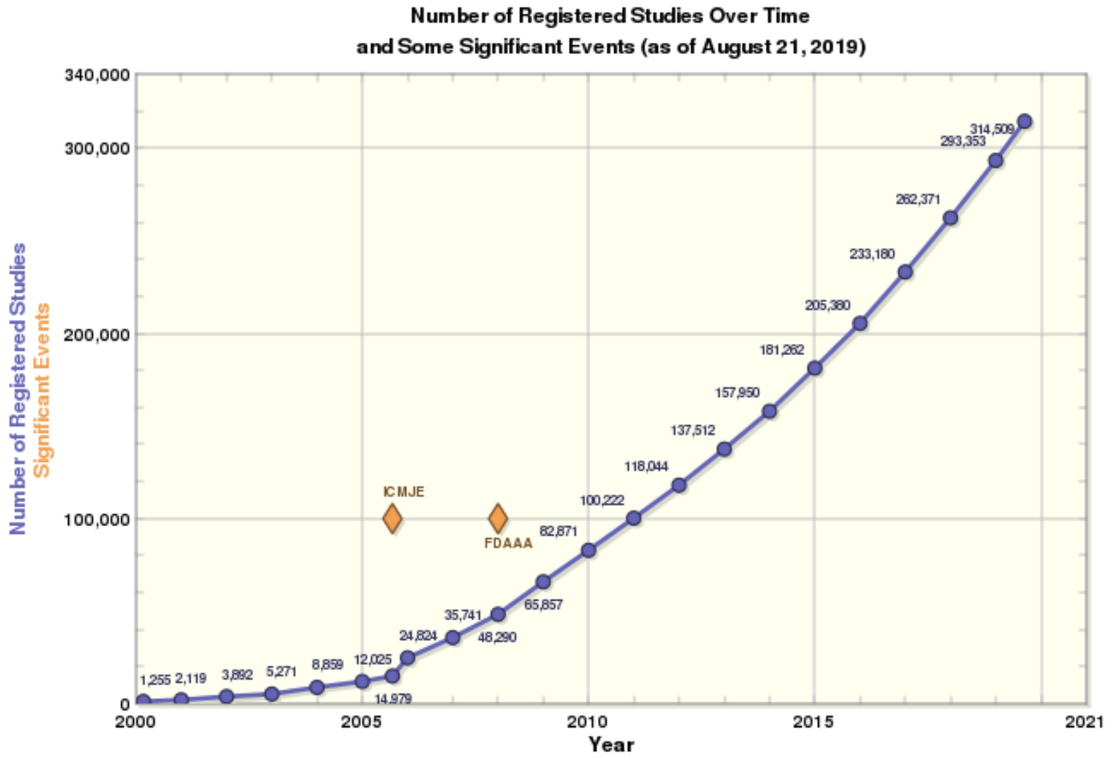
KitChain
A CSBWG Project

Clinical Supply: KitChain Pilot

- Active clinical studies have doubled over last 10 years, and clinical pharmacies are bursting at the seams
- In 2018, as part of a landmark pilot program, our working group with broad industry participation scoped, developed, and tested a GS1-compliant collaborative blockchain solution aimed at delivering a win for patients awaiting new medicines



Source: https://ClinicalTrials.gov

Pfizer IQVIA ups MERCK UCLA gsk ThermoFisher SCIENTIFIC Biogen LedgerDomain

BRxUINchain

- With personalized medicine and the increase in cold chain specifications, digital solutions are now more important than ever.
- The need for supply chain assurance has always been present, but accelerated with the rise of COVID-19.
- **LedgerDomain and UCLA Health partnered on a joint case study** in response to a call for pilots from the US FDA, launched to help develop the interoperable system that will track the vast majority drugs through the United States by 2023
- Features an iOS client running on DocuSeal framework & Selvedge app server, all on top of Hyperledger Fabric, interoperating with Oraculous Notification Service

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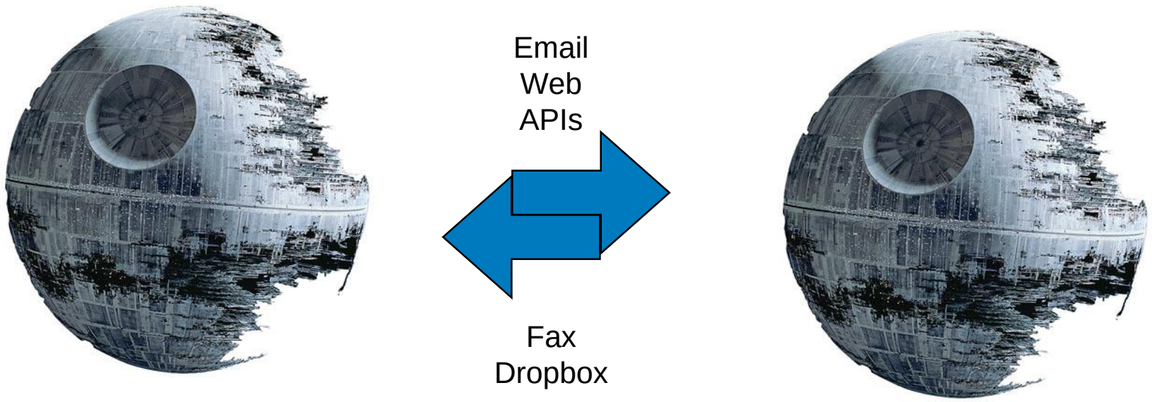
Challenge for the 2020s

Today's pharmaceutical supply chain is a patchwork of traditional databases and patients deserve better!

- With no shared global database, human error is harder to catch
- Criminals are able to use spoofing and **man-in-the-middle attacks** to introduce counterfeits
- More critical with rise of gene therapies and personalized medicine



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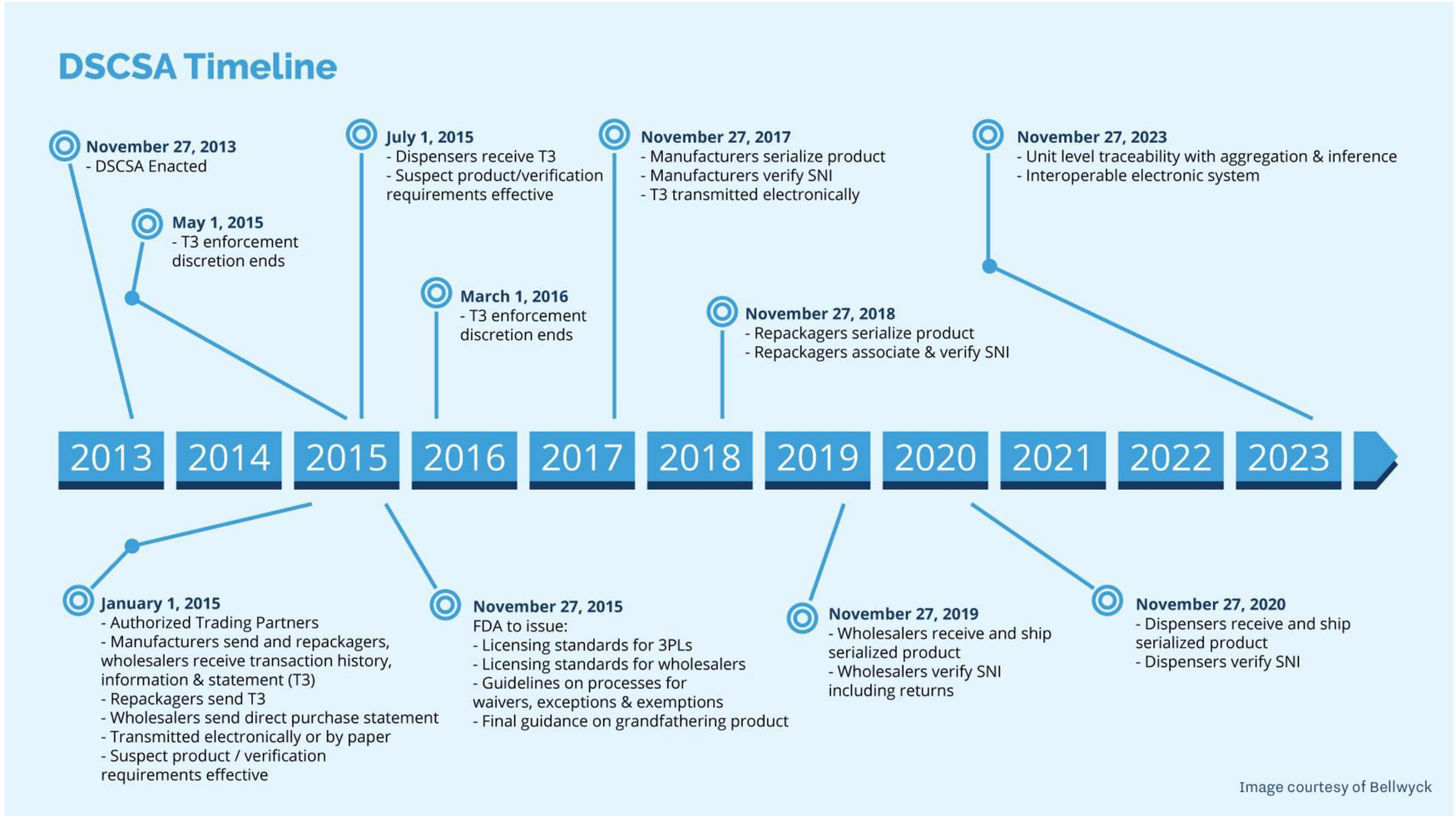
DSCSA



Drug Supply Chain Security Act (DSCSA): US federal law requiring an interoperable system that will track prescription drugs through the United States by 2023

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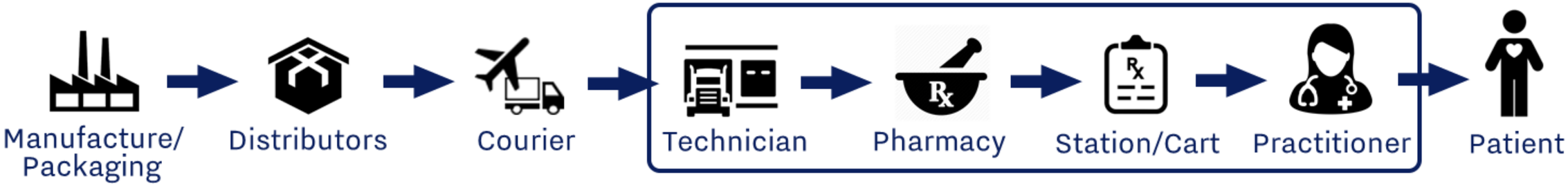
Last-Mile DSCSA Objectives



- FDA's DSCSA Pilot Project Program: opportunity to test technologies and methods for enhanced DSCSA requirements
- UCLA and LedgerDomain focused on the last mile, pharmacist to patient:
  - 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

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Common Data Model

We found that FDA's DSCSA-required 2D barcode could serve as the foundational information building block for a common data model

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EXP: JAN 31 2021
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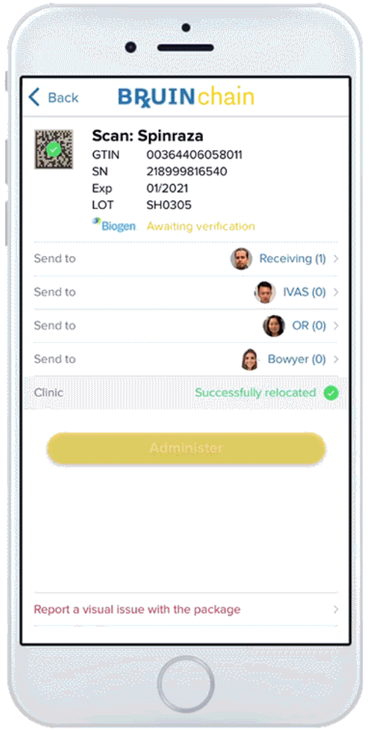

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Video: https://www.youtube.com/watch?v=eonwH5dHb60

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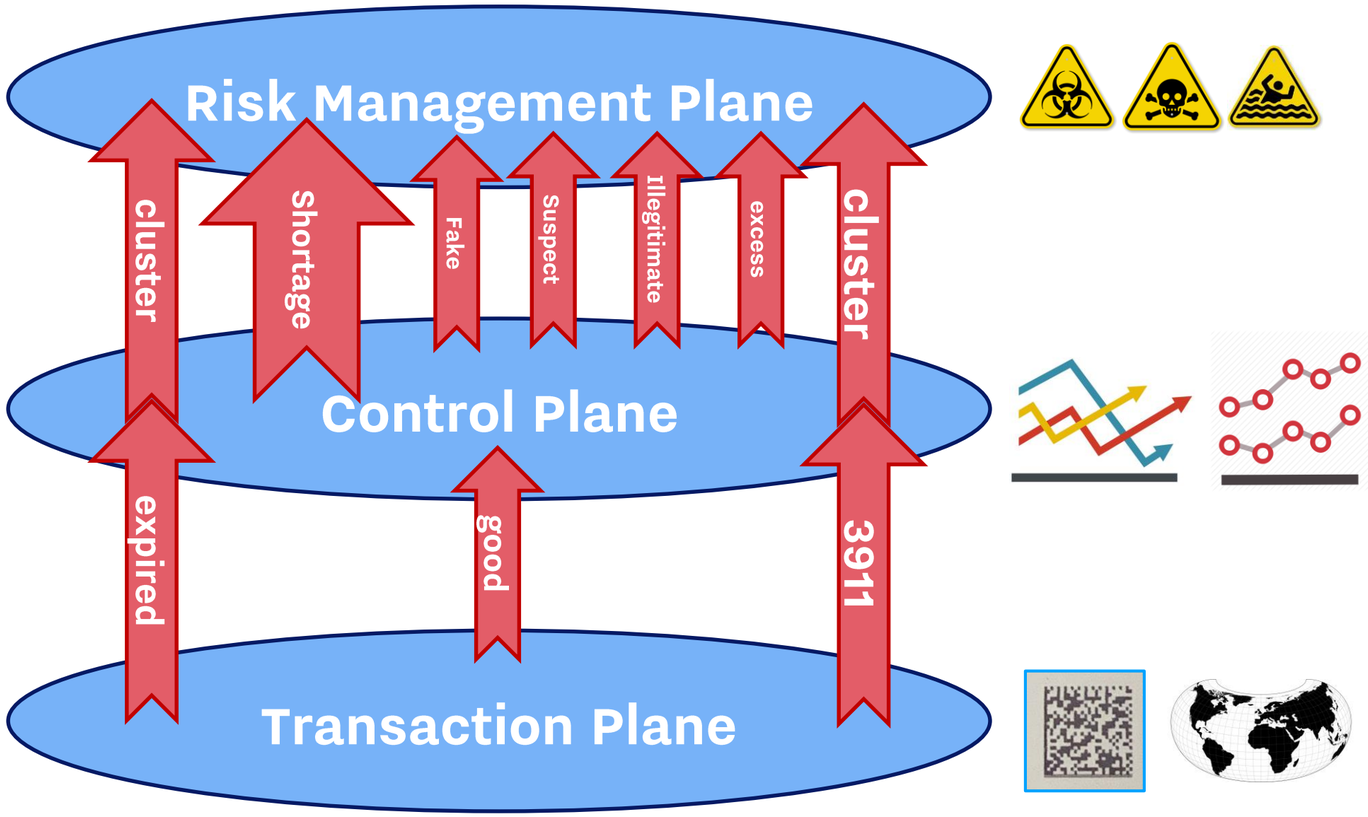
BRUINchain

SUBMITTED TO FDA, JANUARY 2020

Enhance Blockchain with Deep Learning & Notifications

🗣 Marco 👂 Polo

- Tracks barcodes
- Connectivity to legacy systems
- Countable (integrable) data
- Block & remedy bad transactions
- Flag out-of-spec aggregates
- Machine learning robots
- Multi-faceted client perspectives
- Private/escalating notifications



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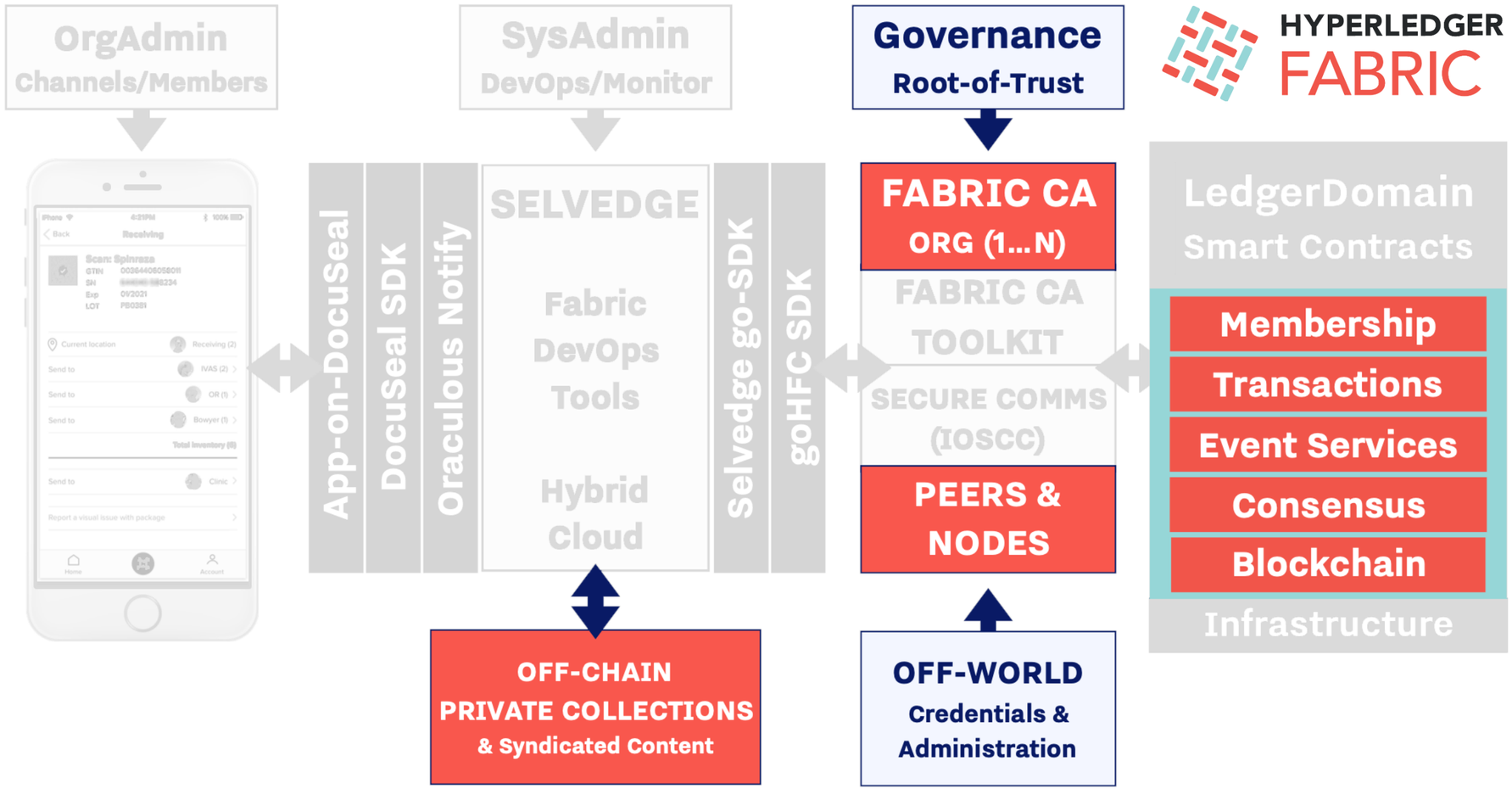
Hyperledger Fabric Architecture



We use Hyperledger Fabric 1.4 out of the box, and focus our efforts to leverage Golang to meet enterprise expectations

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State of Hyperledger

- Hyperledger has a flexible modular design, backing of major industry players, healthy developer community, great documentation, and a plethora of tutorials and ‘hello world’ code samples
- Challenging to develop an end-to-end understanding of the platform, create custom deployments, and develop real-world user-facing applications backed by smart contracts
- Governance and orchestration questions still unsettled

Our Work

- Hyperledger is a great starting point for enterprise communities. LedgerDomain added four additional components:
  - FDOT (Fabric DevOps Toolkit) for orchestration of Fabric networks
  - Selvedge SDK for the generic legwork of the blockchain app backend
  - DocuSeal as a reusable framework for secure off-chain file storage and authentication
  - Oraculous for interoperability between Fabric blockchain apps and the outside world (M2H or M2M)
- These create a framework for high-performance high-security supply chains, 100% in Golang and with extensive use of private collections.

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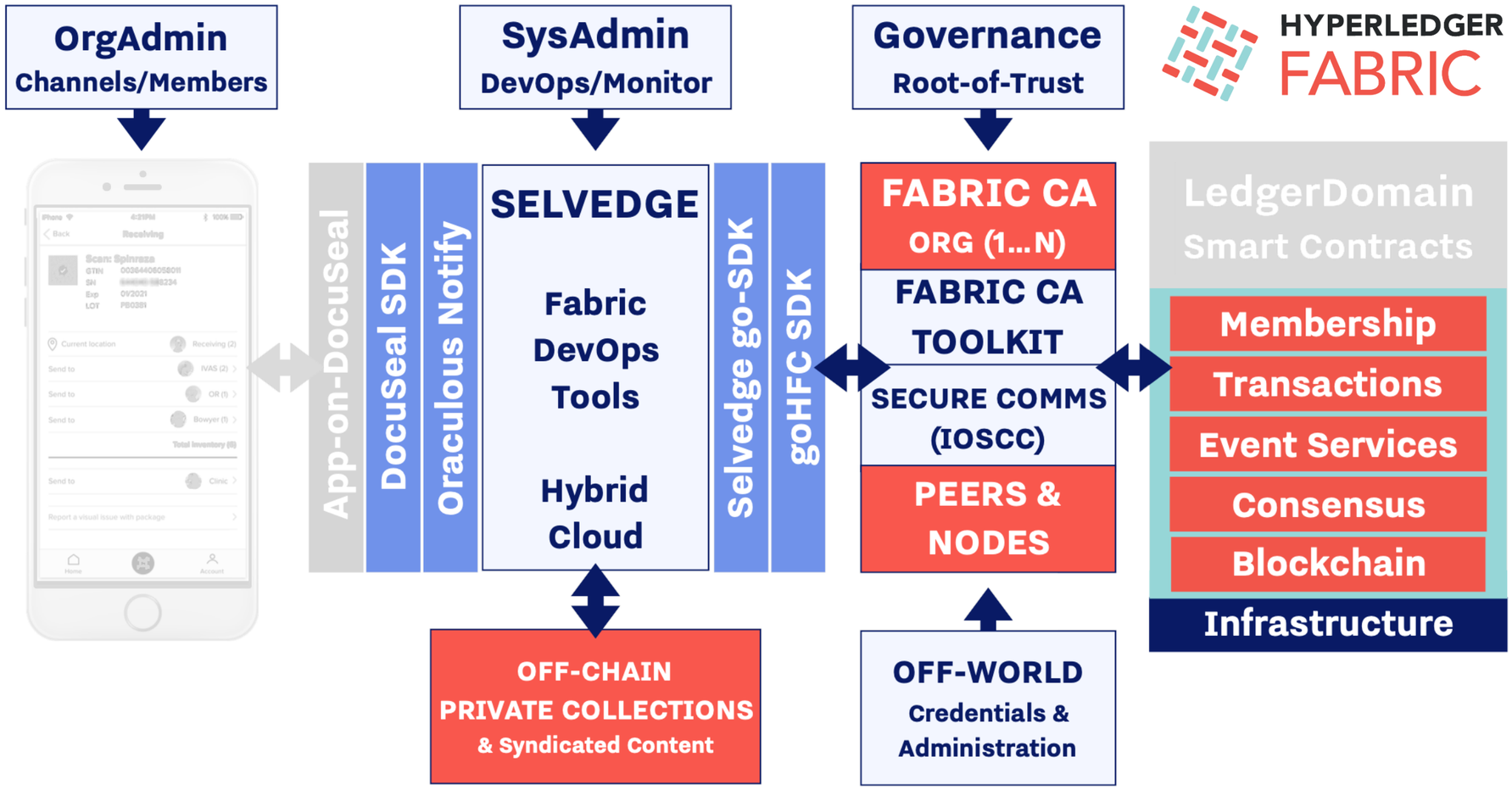
LedgerDomain Architecture



Selvedge and DocuSeal together make it possible for members to share and authenticate supply chain messages

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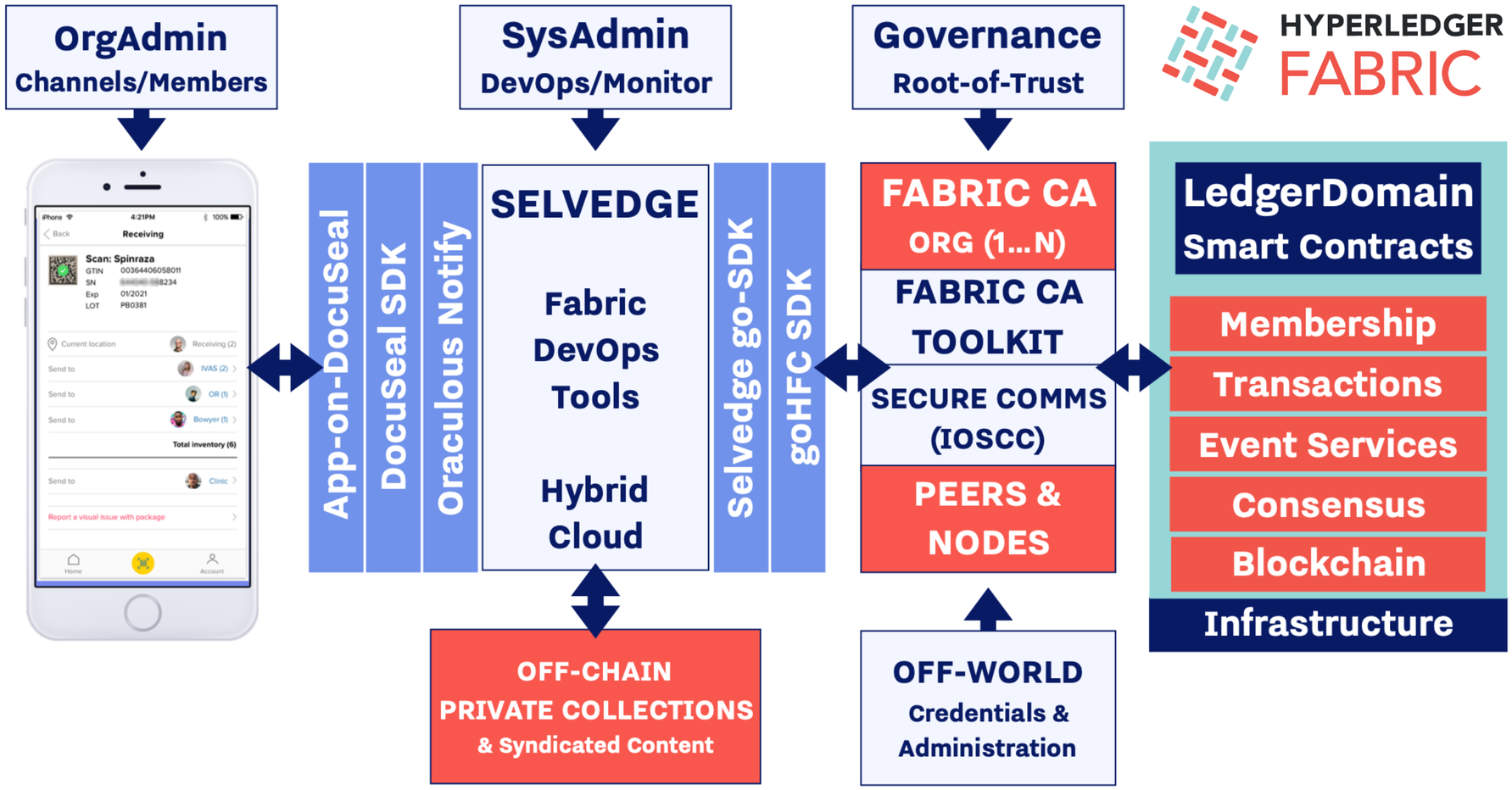
Application-Specific Architecture



Real-world custody locations, advanced workflows, multiple roles, & exception handling, all on 50msec latency...

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BRUINchain Learnings and Outcomes

- Barcode scanning nearly 100% effective with **commercial off-the-shelf iPhone**
- Drugs can be tracked to the “refrigerator” level within a dispensing pharmacy **(not just ownership, but physical custody)**
- Tracked expiration dates, verified barcodes, inspected for problems
- Tracing and verifying by **interoperating with upstream relational database**
- Automatic removal of double-counts and flagging suspect transactions
- Notify colleagues about availability and verification in real-time
- Full study published in *Blockchain in Healthcare Today*

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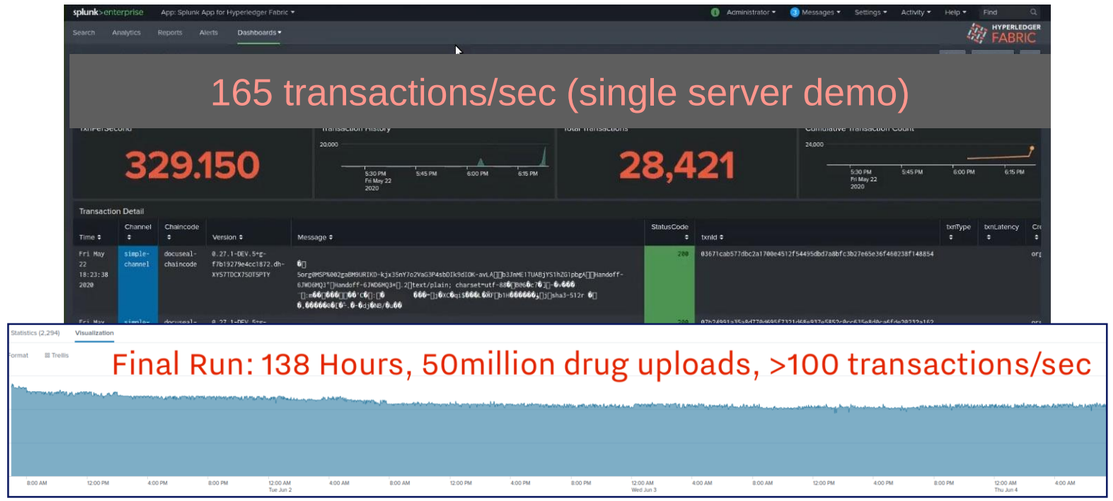
Next Steps



DRUG FEATURES & SCALABILITY

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

MASTER DATA MANAGEMENT

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**

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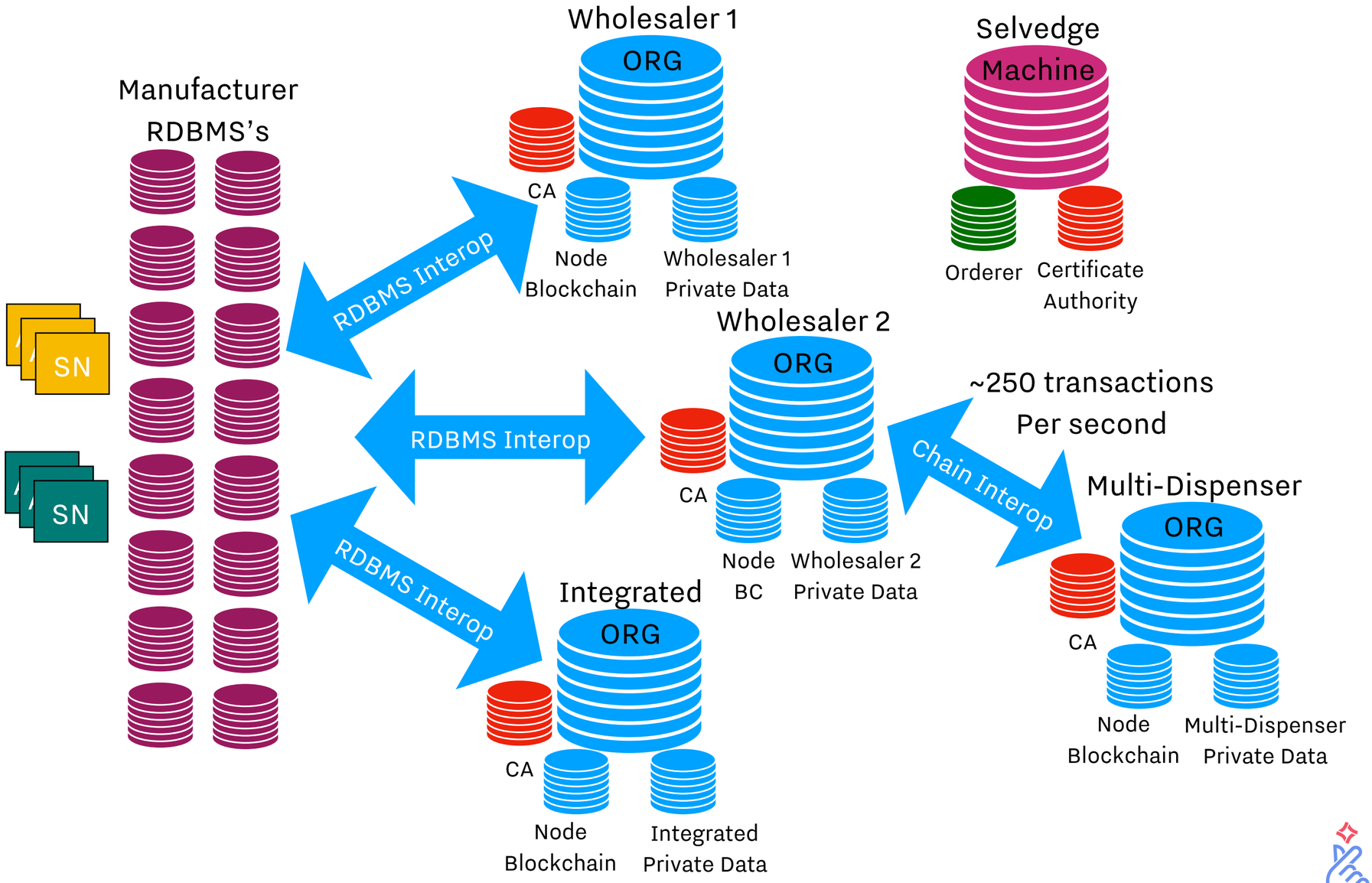
Next Steps



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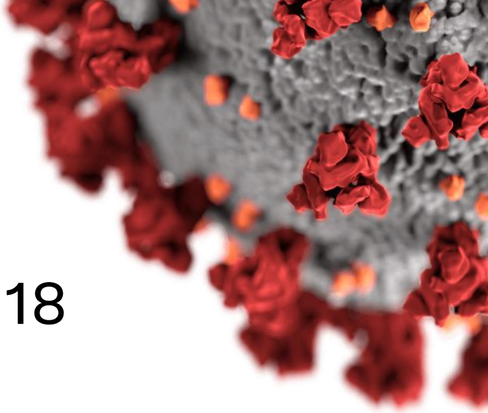
The COVID-19 Era



- COVID-19 will strain supply chain and health systems for the next 18 months, as stakeholders prepare for the next pandemic
- Blockchain providers must focus on COTS solutions and clear value add to stakeholders; in the case of our pilot with UCLA:
  - Dispenser: single-scan technique saves time and money ($183M/year in the US)
  - Manufacturer: nuanced real-time business intelligence
- Legacy relational systems capable of slow trace (↑) but only blockchain allows for fast trace + secure tracking down the supply chain (↑ ↓)
- Blockchain-based solution capable of tracking therapeutics, test kits, vaccines, and ventilators are necessary to accelerate the efforts of healthcare leaders and front-line workers to protect the public

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Ultimately…

- Chaincode portability, blockchain federation and integrability
- More robust models and standards for organizations and permissions
- Analytics on chain data
- Next-generation crypto and data models
- Integration with enterprise systems such as ERP & MES
- Ongoing enhancement for emerging regulations (e.g. HIPAA, GDPR)

Blockchain, artificial intelligence & IoT combine to make every transaction …instantaneous, confidential, unforgeable & trackable

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