Blockchain and Drug Supply Assurance in the Coronavirus Era

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- Built KitChain for the Clinical Supply Blockchain Working Group
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FDA Naloxone Challenge
www.fda.gov/NewsEvents/PublicHealthFocus/ucm533711.htm
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.
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.
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
Drug Supply Chain Security Act (DSCSA): US federal law requiring an interoperable system that will track prescription drugs through the United States by 2023.
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
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.
Video: https://www.youtube.com/watch?v=eonwH5dHb60

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BRUINchain

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Enhance Blockchain with Deep Learning & Notifications

- 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
Hyperledger Fabric Architecture

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

Selvedge and DocuSeal together make it possible for members to share and authenticate supply chain messages.
Application-Specific Architecture

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

Next Steps
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- Manufacturer RDBMS's
- Selvedge Machine
- ~250 transactions per second
- Multi-Dispenser

Interoperability:
- RDBMS Interop
- Blockchain Interop
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.
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