Pharmaceutical supply (block)chain

Ben Taylor, CEO
# Why Hyperledger?

<table>
<thead>
<tr>
<th>Positioning</th>
<th>Visionary</th>
<th>Enterprise-grade</th>
<th>Classic</th>
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<tbody>
<tr>
<td>Governance</td>
<td>Ethereum Foundation?</td>
<td>Linux Foundation</td>
<td>Hmmm</td>
</tr>
<tr>
<td>Participation</td>
<td>Open with Velvet Ropes</td>
<td>Permissioned, private</td>
<td>Open</td>
</tr>
<tr>
<td>Consensus</td>
<td>PoW → PoS?</td>
<td>Pluggable consensus</td>
<td>PoW Mining</td>
</tr>
<tr>
<td>Smart contracts</td>
<td>Yes, typically Solidity</td>
<td>Yes, typically Go or Java</td>
<td>More basic</td>
</tr>
<tr>
<td>Currency</td>
<td>ether, gas, altcoins</td>
<td>None in native form</td>
<td>bitcoin</td>
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Hyperledger is the blockchain platform of choice for global enterprises concerned with data security and access to information regulations.
Blockchain’s Potential for Privacy & Compliance

GDPR – HIPAA – CalPrivacy – New York Privacy Act?

“Skate to where the puck is going” – Gretzky
DocuSeal Framework

Uploaded documents are sealed in private storage, tied to unique hash that’s immutably stored on private blockchain. The authenticity of medical documents and patient data is verified each time it’s accessed.
LedgerDomain Blockchain Application Architecture
Patient Registry
Harnessing Power of Intermediary Model

INFO HUB

Patient ➔ Pharma
Provider ➔ Researcher
Provider ➔ Care Provider
Provider ➔ Patient Advocate

FDA and EMA have both advanced similar concepts for clinical studies
Patient Registry: Key Components

- Unique & anonymized identifier scheme
- Links to family, caregiver, doctor
- Core structured data fields & sources
- Off-chain data types, encryption & access
- Maintaining compliance with HIPAA and GDPR?
- Registry scheme: re-consent; outreach; registration
Clinical Supply: KitChain Pilot

- Active clinical studies have doubled over last 10 years, and clinical pharmacies are bursting at the seams.
- In 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.

Number of Registered Studies Over Time
and Some Significant Events (as of August 21, 2019)

Source: https://ClinicalTrials.gov
Clinical Supply Blockchain Working Group Charter

WHAT TOPIC?
What challenge(s) do you want to address?

- Disparate group of parties involved in a chain of custody (CROs, sites, etc)
- Comparator products purchased via third party vendors
- Adaptive trial design and ensuring product quality
- Regulatory reporting, drug accountability and reconciliation
- Site storage constraints
- Multiple systems and product lines
- GMP/GCP handoffs and compliance
- Incorporation of IoT devices
- Facilitation of payments (e.g. orders, shipments, VAT/Duty, etc.)

IMAGINE A WORLD
If this vision came true, what would the world look like?

- Amazon-like user experience for supply chain managers, clinical sites and patients to track and trace investigational products from point of manufacture to acknowledgement of consumption by patients
- Fully auditable and transparent system, that allows all stakeholders to have direct access to a trusted source of validated data

THINK ON THE FRINGE
What ecosystem would be needed? Which internal and external stakeholders would we need to engage?

- API Manufactures, CROs, CMOs, Couriers, Sites, Patients, Study Teams, Sourcing Groups, Customs, MOH

START SMALL, REALLY SMALL
What might we do together over the next few months to turn this vision into a real experiment?

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<th>Explore</th>
<th>Evaluate</th>
<th>Advance</th>
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<tbody>
<tr>
<td>• Evaluate opportunities for cross-industry alignment</td>
<td>• Determine what makes the most sense to try to standardize</td>
<td>• Good understanding of use cases in the clinical supply space</td>
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<tr>
<td></td>
<td>• Attend education sessions and share learnings with working group</td>
<td>• Gather requirements to support an industry POC</td>
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“Bringing an Amazon-like Experience to Clinical Supply”
KitChain Demo Video

“Bringing an Amazon-like Experience to Clinical Supply”

KitChain

An immutable digital inventory and event tracking model for the pharmaceutical clinical supply chain

See the video at kitchain.org/video
Supply Chain Systems

- Unique identifiers for physical objects
- Flag & categorize bad transactions
  - Root-cause analysis
  - Pro-actively query users

- Risk Management
- Control + Analytics
- Transactions
Next Generation Pharma Supply Chain?

- Personalized medicine & enhanced privacy
- Internet-of-things (IoT) all the way to patient
- FDA & DSCSA 2023 rollout
- Tracing vs tracking
- Value-added services
Commercial Supply: FDA & DSCSA

- As part of the FDA DSCSA Pilot Project Program, we’ve partnered with UCLA to build and test a last-mile blockchain-based system with an iPhone client.
- This application, BRUINchain, aims to demonstrate a successful implementation where product tracing notifications are sent automatically to key stakeholders.
- UCLA Health will test it in a live environment as a way to help deliver life-saving medications to babies.
Product tracing and verification

GTIN*  Standardized Numerical Identifier (SNI or SN)  Expiration date (YY-MM-DD)  Lot number

010036440605801121213740531660{GS}1719093010SH0284
UCLA Pilot

BRUINCHAIN

Distributors
Courier
Technician
Manager
Pharmacy
Manufacture/ Packaging
Sponsor
Patient
Prescriber
Station/ Cart
Admin

UCLA
Roadmap to 2023

• 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
• Designing for compliance with privacy laws (e.g. HIPAA, GDPR)

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