HYPERLEDGER
Healthcare
SPECIAL INTEREST GROUP

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Pharmaceutical supply (block)chain

Ben Taylor, CEO

Why Hyperledger?

	ethereum	HYPERLEDGER FABRIC	bitcoin
Positioning	Visionary	Enterprise-grade	Classic
Governance	Ethereum Foundation?	Linux Foundation	Hmmmm
Participation	Open with Velvet Ropes	Permissioned, private	Open
Consensus	PoW → PoS?	Pluggable consensus	PoW Mining
Smart contracts	Yes, typically Solidity	Yes, typically Go or Java	More basic
Currency	ether, gas, altcoins	None in native form	bitcoin

Hyperledger is the blockchain platform of choice for global enterprises concerned with data security and access to information regulations.

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Blockchain’s Potential for Privacy & Compliance

GDPR – HIPAA – CalPrivacy – New York Privacy Act?

“Skate to where the puck is going” –Gretzky

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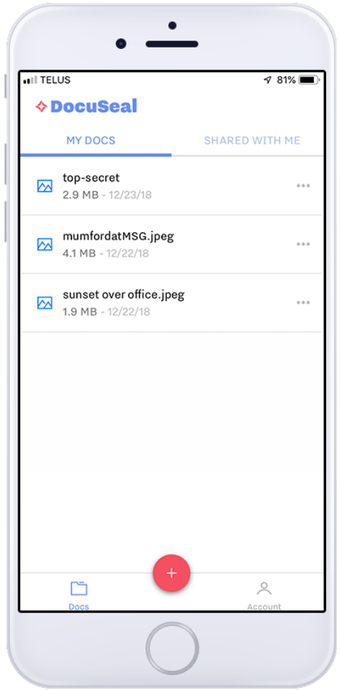
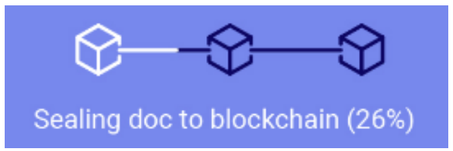
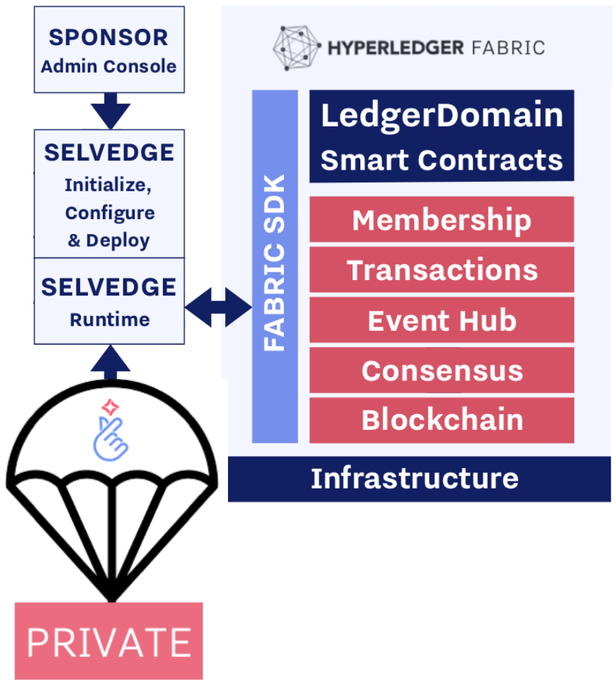
DocuSeal Framework

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.



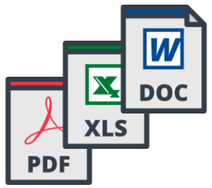


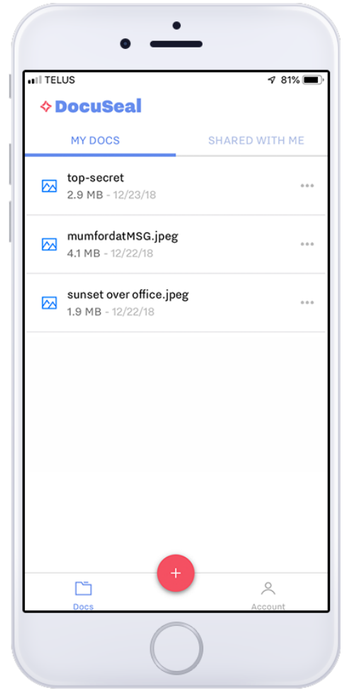
SERVER SIDE
WITH SELVEDGE & HYPERLEDGER FABRIC



Share

Revoke





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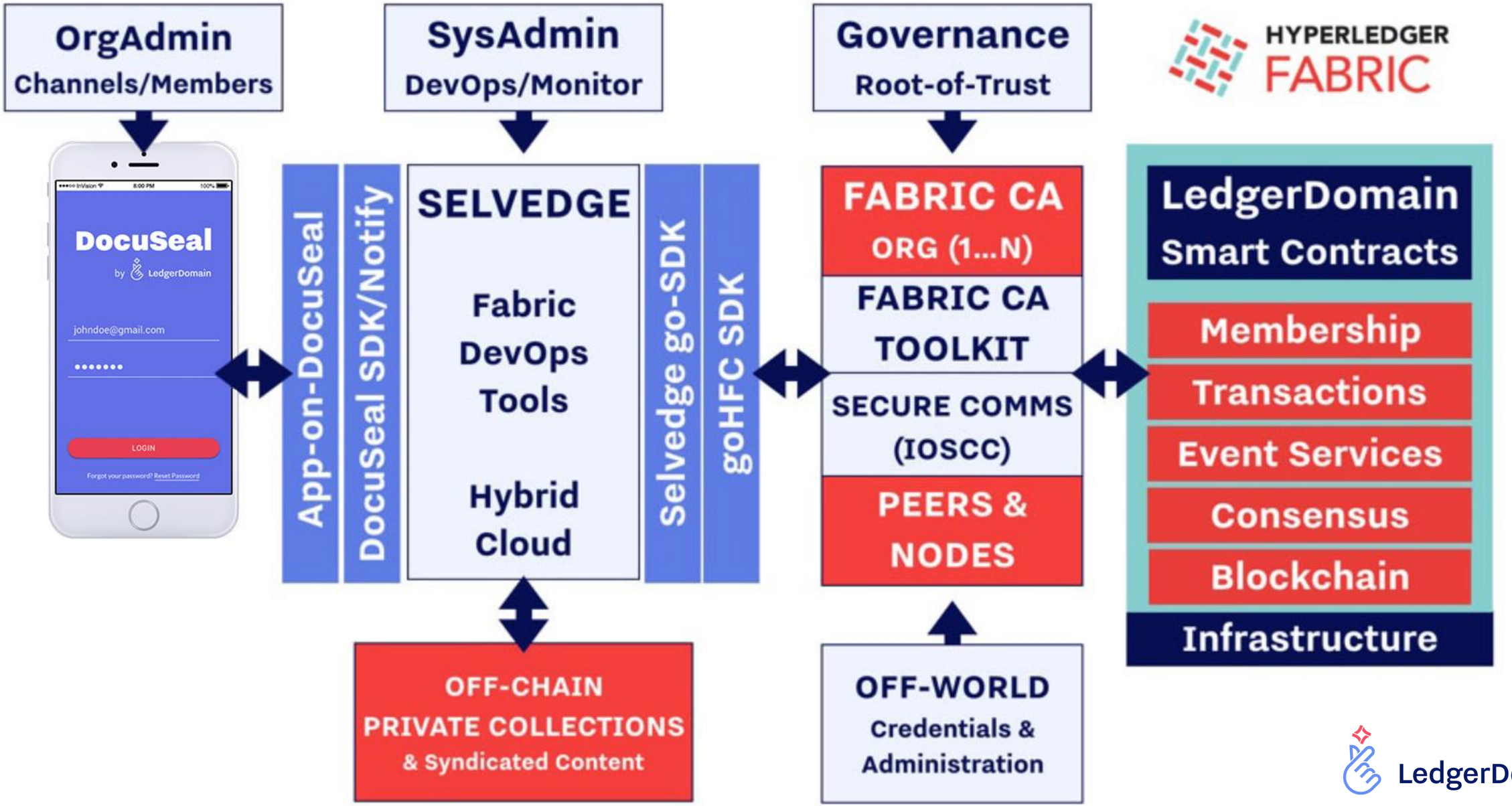
LedgerDomain Blockchain Application Architecture



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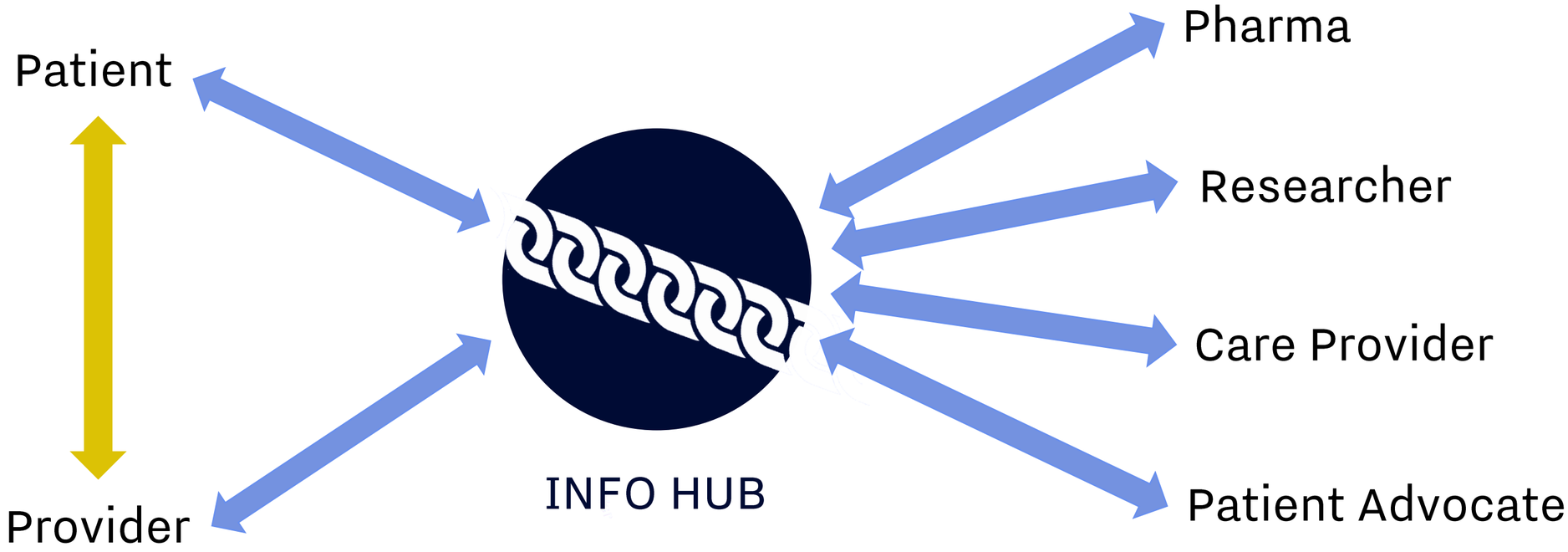
Patient Registry

Harnessing Power of Intermediary Model



FDA and EMA have both advanced similar concepts for clinical studies

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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

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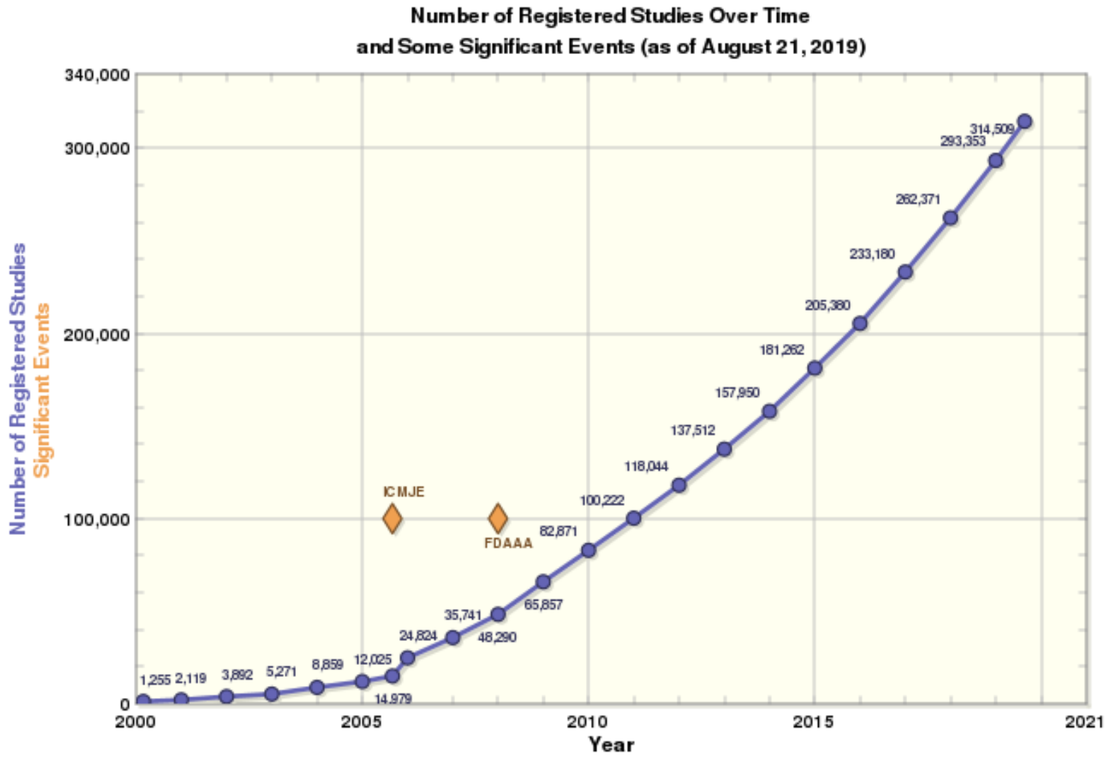
A CSBWG Project

Clinical Supply: KitChain Pilot

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

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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.)

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

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

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

Explore	*Evaluate*	*Advance*
• **Evaluate opportunities for cross-industry alignment**	• **Determine what makes the most sense to try to standardize** • **Attend education sessions and share learnings with working group**	• **Good understanding of use cases in the clinical supply space** • **Gather requirements to support an industry POC**

"Bringing an Amazon-like Experience to Clinical Supply"

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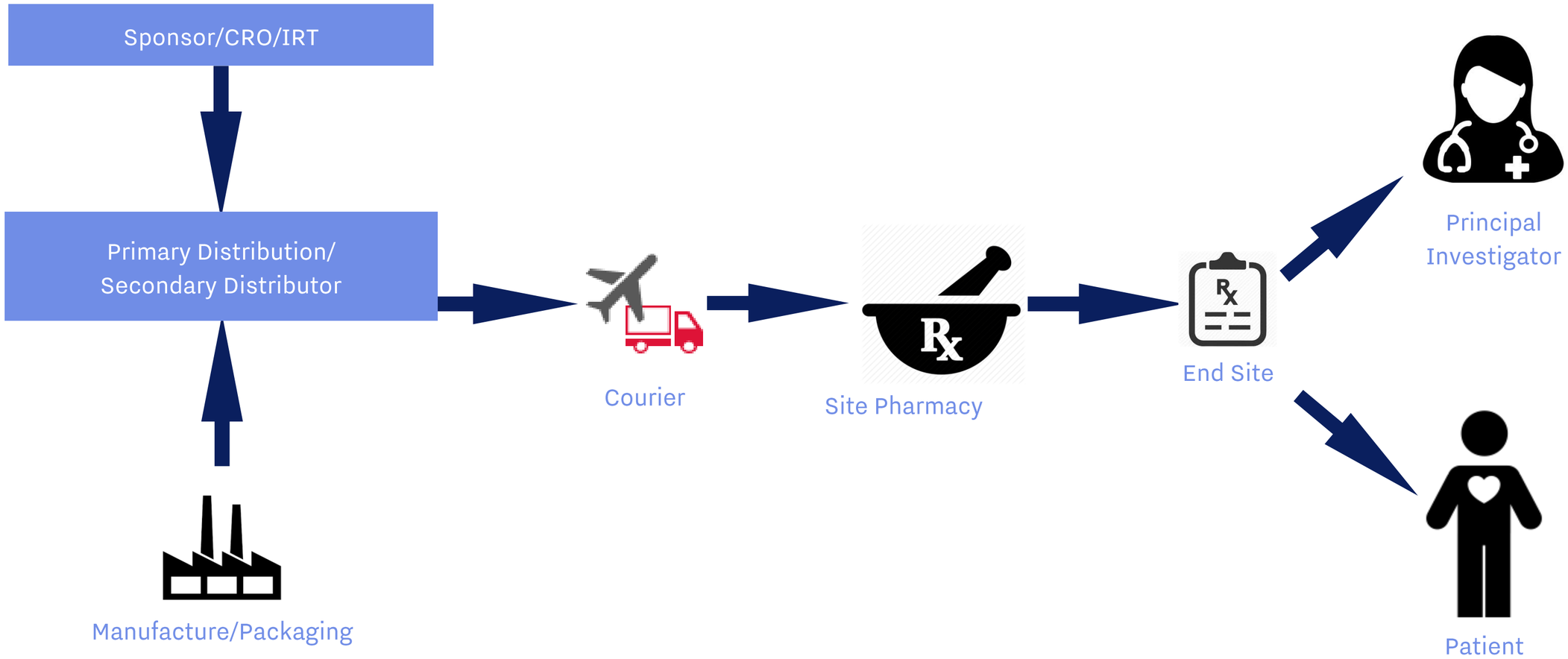
Clinical Supply Chain Roles



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KitChain Demo Video

"Bringing an Amazon-like Experience to Clinical Supply"

See the video at kitchain.org/video

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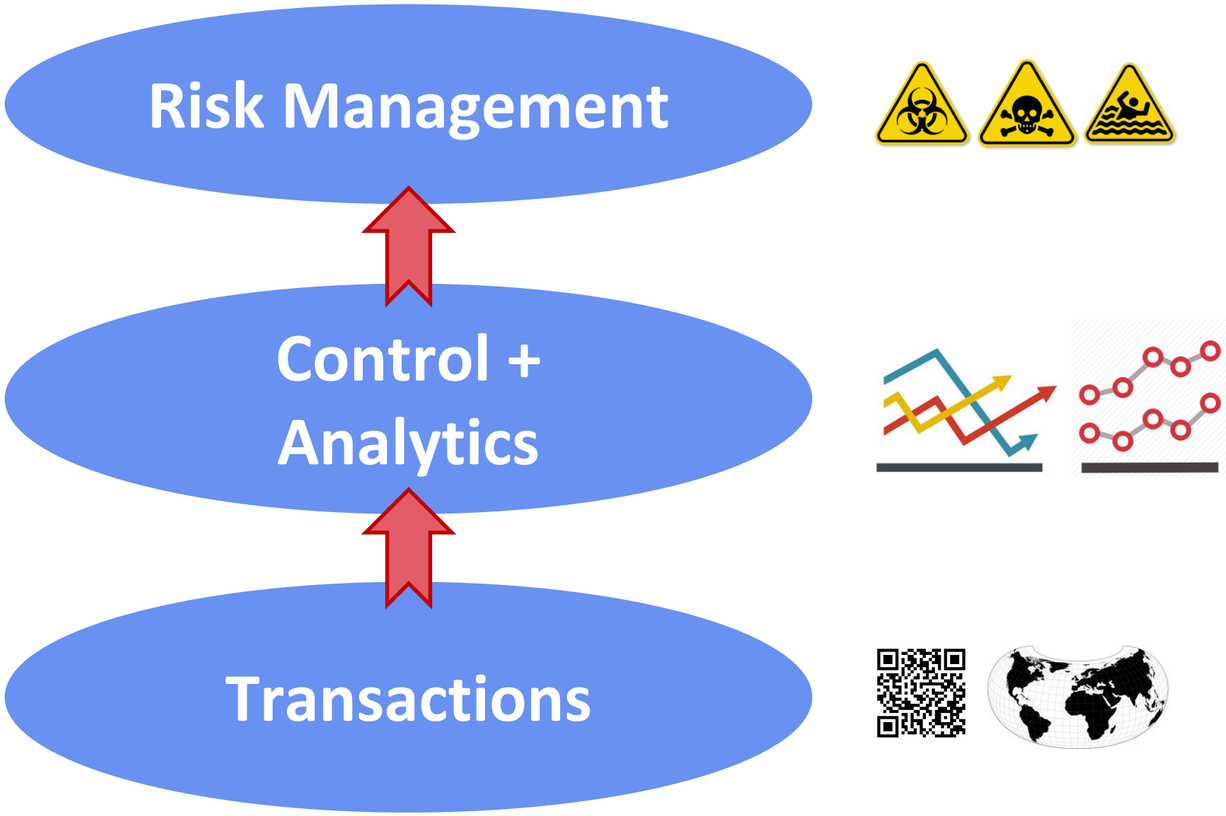
Supply Chain Systems

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



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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

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Commercial Supply: FDA & DSCSA

UCLA BRUINchain

- 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

DSCSA Timeline

November 27, 2013
- DSCSA Enacted

May 1, 2015
- T3 enforcement discretion ends

July 1, 2015
- Dispensers receive T3
- Suspect product/verification requirements effective

March 1, 2016
- T3 enforcement discretion ends

November 27, 2017
- Manufacturers serialize product
- Manufacturers verify SNI
- T3 transmitted electronically

November 27, 2018
- Repackagers serialize product
- Repackagers associate & verify SNI

November 27, 2023
- Unit level traceability with aggregation & inference
- Interoperable electronic system

2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023

January 1, 2015
- Authorized Trading Partners
- Manufacturers send and repackagers, wholesalers receive transaction history, information & statement (T3)
- Repackagers send T3
- Wholesalers send direct purchase statement
- Transmitted electronically or by paper
- Suspect product / verification requirements effective

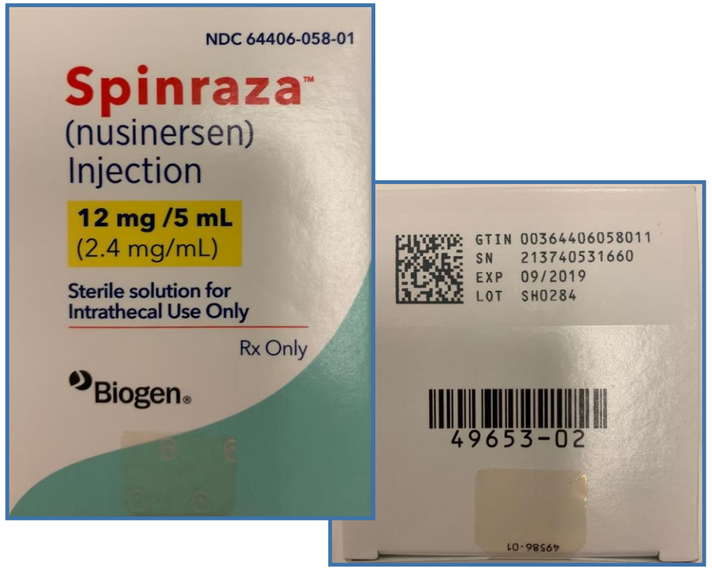
November 27, 2015
FDA to issue:
- Licensing standards for 3PLs
- Licensing standards for wholesalers
- Guidelines on processes for waivers, exceptions & exemptions
- Final guidance on grandfathering product

November 27, 2019
- Wholesalers receive and ship serialized product
- Wholesalers verify SNI including returns

November 27, 2020
- Dispensers receive and ship serialized product
- Dispensers verify SNI

Image courtesy of Bellwyck Package Solutions

Product tracing and verification



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

UCLA Pilot

UCLA

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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

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