HIMSS18 The leading health information and technology conference

WHERE THE WORLD CONNECTS FOR HEALTH

Blockchain 4 Healthcare: Fit for Purpose?

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Agenda

1. Introduction to Program and Speakers
2. Blockchain for Healthcare 101
3. Examining Blockchain Healthcare Use Cases
4. Final Thoughts and Future Challenges

Much of the promise of blockchain comes with its potential to disrupt and change how healthcare works, a position leading to questions and concerns among the healthcare community – including HIMSS members - on what blockchain-driven disruption might look like. With that in mind, HIMSS has recently established a work group to examine blockchain distributed ledger technology and its potential implications for the healthcare information and technology community. The work group, composed of payers, providers, vendors, and other interested parties, has set out to visualize the effects of that disruption.

Learning Objectives

- Discuss attributes of blockchain technology
- Identify key design elements of blockchain for healthcare
- Apply design elements and choose right tool for use cases in healthcare
- Assess policy challenges and opportunities that can inhibit or enable adoption

Conflict of Interest

Tim K. Mackey, PhD

Tim K. Mackey is a member of the Advisory Board for the company FarmaTrust a blockchain company developing technology for the pharmaceutical supply chain. He has not been compensated for activities associated with his advisory board membership.

Conflict of Interest

Robert Barkovich, Ph.D.

Founder, part-owner and employee of Health Linkages Inc., a C-corporation focused on data provenance, governance and analytics in healthcare.

IEEE-SA

IEEE (Institute of Electrical and Electronics Engineers)

- World largest technology association
- A non-profit with 423,000 members in 160 countries
- More than 100 years old

Standards Association

- Build standards for technology through consensus
- Develop protocol and policy recommendation guidelines for effective use of technology
- Building consistent protocols that can be universally understood
- Most notable Standards: 802.11 (Wi-Fi) and 802.3-2015 (Standards of Ethernet)

Full list of standards at http://standards.ieee.org

Why IEEE in Blockchain?

The viability of blockchain in critical industrial use cases will lead to better outcomes (ie. security, safety, care, etc) for end-users.

Blockchain/Distributed Ledger Technologies (DLTs) affords the platform to build a digital trusted framework that will enable “protected” execution of the next generation of digital interactions amongst digital citizens.

IEEE in Blockchain & Emerging Technology

- The ideal protagonist to convene all vested stakeholders and technologists to effectively valuate viability of industrial use cases in emerging technologies
- Present a balanced perspective on opportunities, benefits and challenges when adopting emerging technologies
- Do not advocate any one solution for an industry challenge nor advocate one technology for every industry challenge
- Bridge the gap from industry to end-user, from industry to regulatory and from regulatory to end-user
- Educate on technologies that have the potential to solve a problem and aligns with our mission to “advance technology for humanity”

Where Standards Can Help

Standards can mitigate or nominalize some of the barriers to implementation:

- Alleviate the questions of interoperability with other platforms
- Establish credibility in the technology application by aligning the name of a reputable neutral organization creating, approving, and protecting the standard
- Minimizing the uncertainty of the cost where the standard provides the blueprint to integration and interoperability
- Through the development of a consensus-driven standards (all stakeholders represented in the process) resistance of user buy-in is mitigated

Supply Chain/Clinical Trials Technology Implementations Industry Connections Program

- **Areas of Focus**– Pharma Supply Chain, Medical Devices, **Clinical Trials**, Food Safety/Supply Chain, Smart Contracts for Supply Chain

- Hybrid Groups – Pharma /Health Executives, Regulators, Academia, Technologists and Patient Advocacy Groups (in the case of Clinical Trials)

- Outcomes: Framework for technical standards and/or recommended policy & protocol guidelines **http://bit.ly/SC-CTIC**

Work Streams in Progress and Currently Recruiting

- Smart Contracts for e-Consent in Clinical Trials
- "Patient Health Data" Validation Scoring System
- *Clinical IoTs Data Validation and Integration in Blockchain for Patient Recruitment and Clinical Research*
- Techno-Legal Standards for Smart Contracts for Supply Chain
- Blockchain for compliance of US FDA DSCSA (Drug Supply Chain Security Act)
- *Blockchain, IoT and Cold Chain Logistics*

What is a blockchain?

- Blockchain is not bitcoin
- It is the underlying technology in bitcoin and other cryptocurrencies
- It can be used for many use cases
- We will describe what makes up a blockchain and what it can be used for

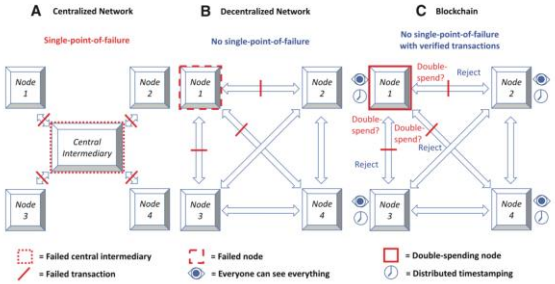


Figure 2. Comparison of the distributed network topologies. (**A**) Centralized network topology, which creates a single-point-of-failure (the central intermediary). If the central intermediary is down or attacked, the entire network stops working. (**B**) Decentralized network topology, which does not contain single-point-of-failure. If one of the nodes, such as *Node 1*, is down or attacked, the rest of the network can still operate normally. (**C**) Blockchain. If "everyone can see everything" and there exists a distributed timestamp mechanism, the double-spending problem can be solved on such a decentralized network. In the example illustrated in Figure 1, if everyone (ie, Alice, Bob, Charlie, and all other people in the same network) knows that Alice (*Node 1* in this example) sent 10 coins to Charlie yesterday, the transaction to send the same 10 coins to Bob today can thus be rejected through a verification process without consulting a bank.

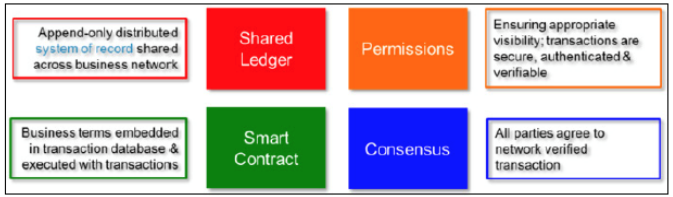
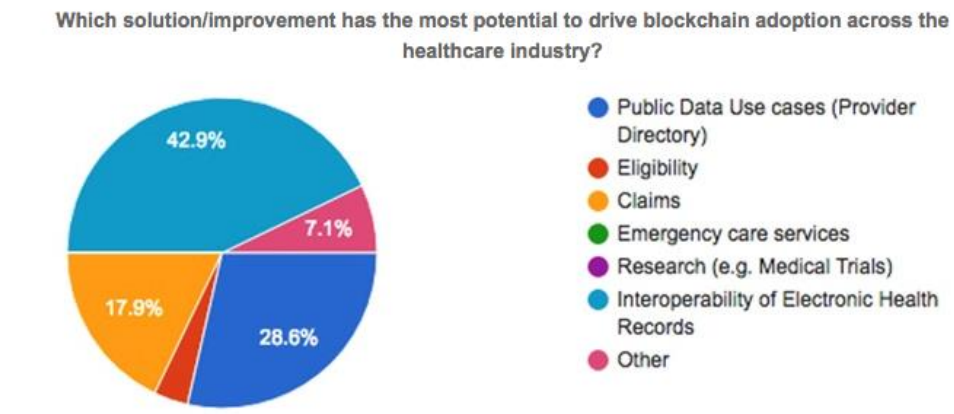


FIGURE 2-2: The key concepts of blockchain for business.

What problem does a blockchain solve?

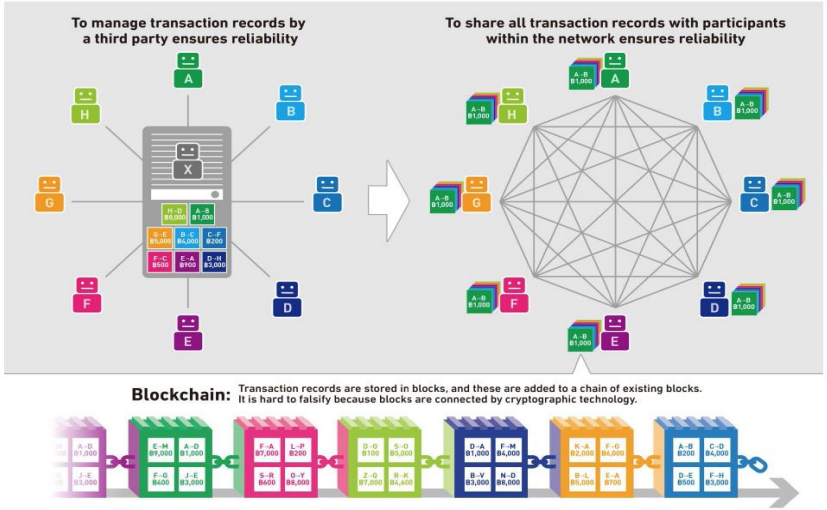
- A blockchain lets us agree on history, even if we don't all trust each other
  - This allows us to agree on the state of the system
- There is no need for a trusted third party



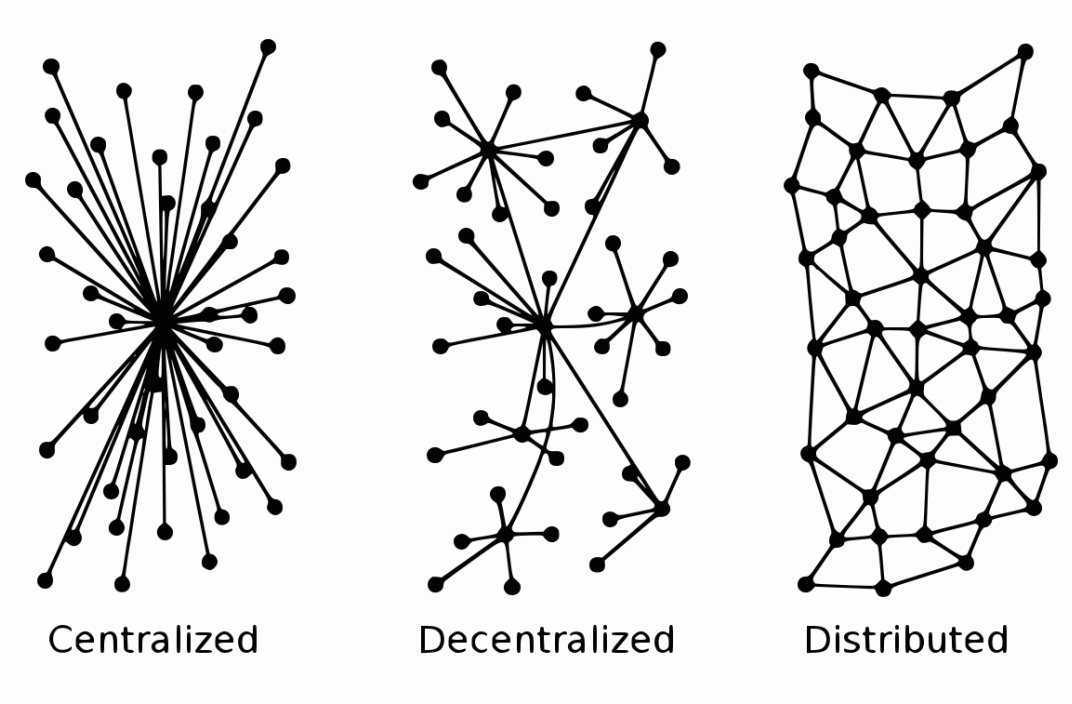
Source: January 2017 Hyperledger Healthcare Working Group Survey, N=28

What makes up a blockchain?

- Distributed Ledger
  - Distributed network of nodes (computers)
- Hash Chain
  - Hash function
  - Hash pointers
  - Merkle trees
- Consensus

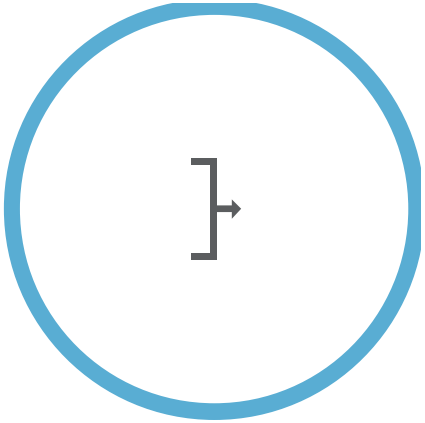


System Types

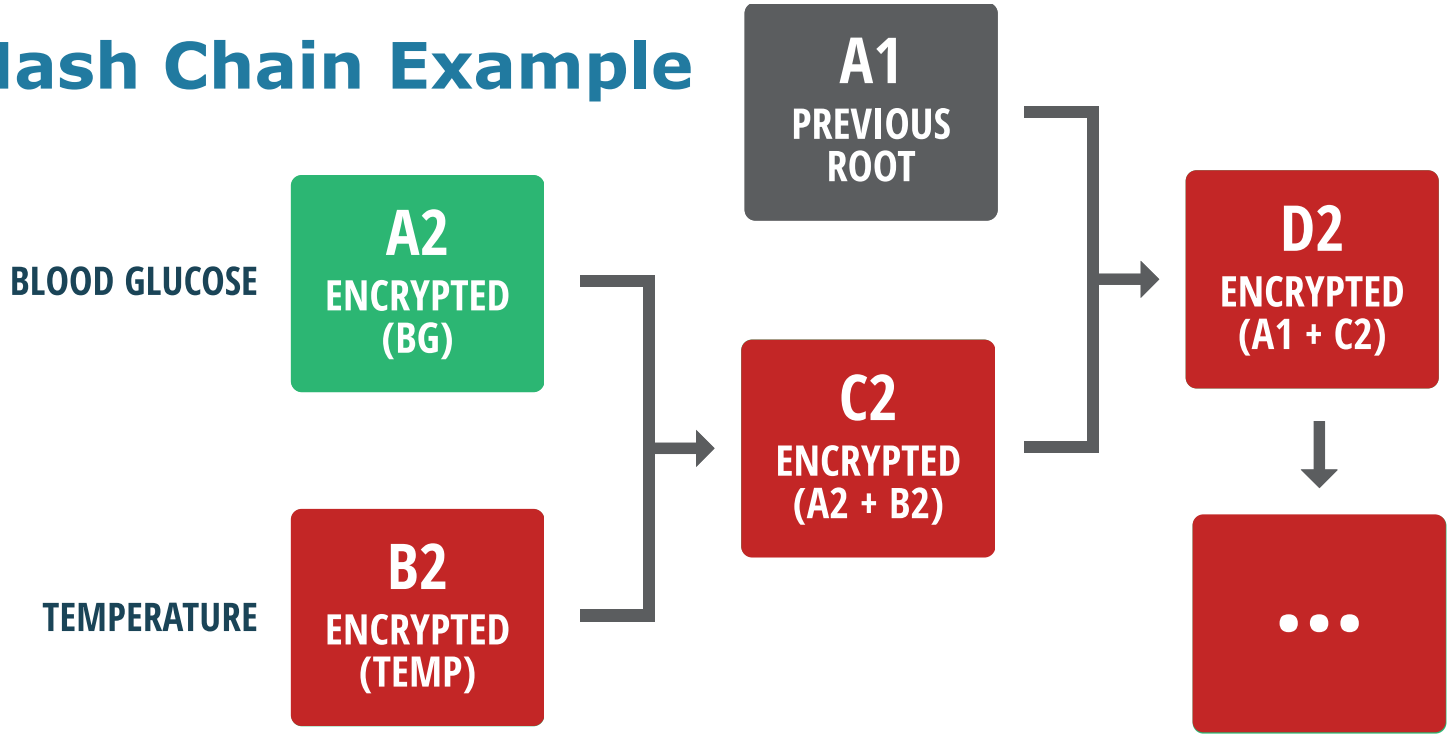


Hash Chains

- A successive application of a cryptographic hash function to a piece of data
  - From Wikipedia



Hash Chain Example



Consensus

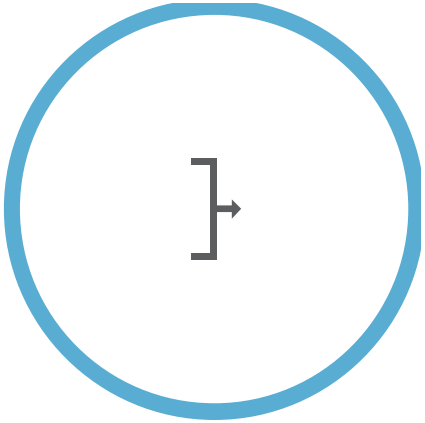
- Why do we need consensus
  - Need to decide what blocks are valid on the chain
  - Need to decide whether we are using the current chain

Different Consensus Algorithms

- Proof of Work
- Proof of Stake
- Practical Byzantine Fault Tolerance (PBFT)
- Proof of Elapsed Time (PoET)
- Many others

Types of Blockchains

- Public
- Private
- Hybrid
- Permissioned



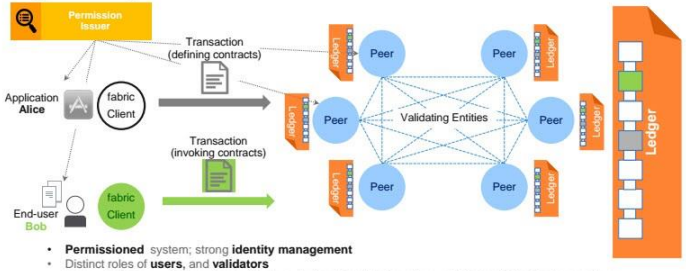
Most Common Blockchain Frameworks

- Bitcoin Blockchain
- Ethereum
- Hyperledger projects
  - Fabric
  - Sawtooth Lake
  - others
- So many more…only listing publically available chains that are most applicable to healthcare.
  - Apologies to any left out!

HYPERLEDGER

ethereum

Hyperledger-fabric model



- **Permissioned** system; strong **identity management**
- Distinct roles of **users**, and **validators**
- Users **deploy** new pieces of code (chaincodes) and **invoke** them through **deploy & invoke** transactions
- Validators evaluate the effect of a transaction and reach consensus over the new version of the **ledger**
- **Ledger** = total order of transactions + hash (global state)
- **Pluggable consensus** protocol, currently PBFT & Sieve

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IBM

How do you know what to use?

- What is your application/use case?
- What blockchains are available to you?
  - Know the strengths and limitations of these frameworks
- Make sure you don't try to fit a "square peg into a round hole"

How does blockchain apply to health?

- By its very nature, blockchain is well positioned to be part of a solution to many problems in healthcare:
  - Data Provenance
  - Pharma Supply Chain and Medical Device Supply Chain
  - Clinical Trials Patient Recruitment
  - Security and Interoperability of IoMT Data
  - Security and Privacy of Genomic Data
  - Many others…

"Health" Blockchain

Core Principles: At its core, a BC is an immutable distributed ledger that can better ensure the resilience, provenance, traceability, and management of healthcare data

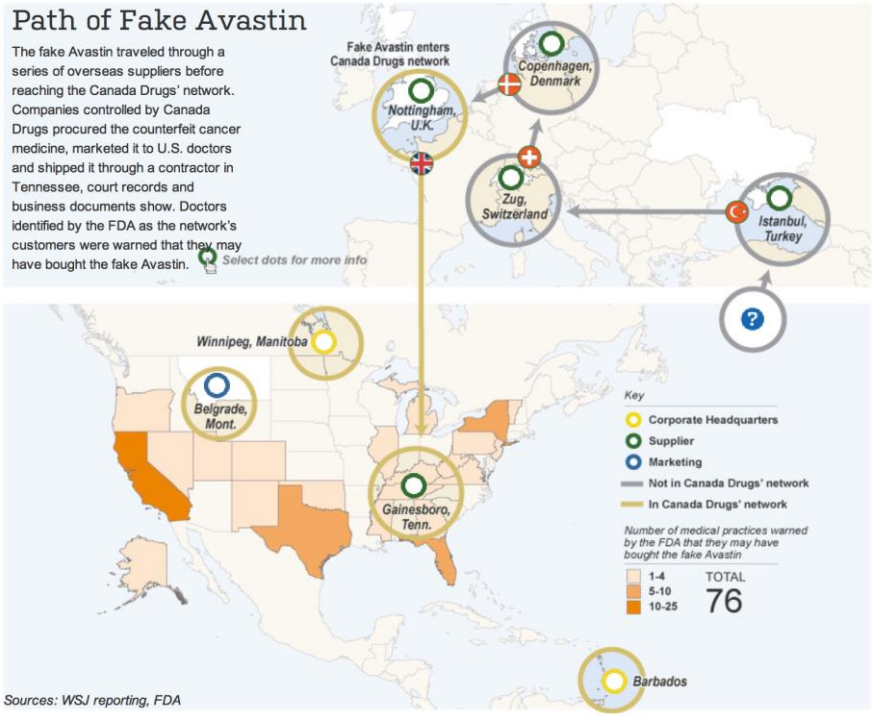
Design Decisions: **Three** primary design elements: (1) private models; (2) public models; and (3) hybrid (also consortium-based models.) These design choices should map to healthcare industry specific challenges and characteristics (→)

Beyond Blockchain: Beyond the design elements and core principles, what "added value" does a health blockchain have to offer? Examples include added compliance, audit, enabling aggregation/data sharing, incentivizing participation (tokens), etc.

Other characteristics for consideration

1. Data sharing, what is shared what is not? (levels of permissions)
2. Offchain storage vs. onchain storage
3. Governance of a BC, p2p networks, roles for regulators?
4. Use of smart contracts, and types of consensus mechanisms?

Pharma Supply Chain



Healthcare Problem: The security of the drug supply chain has been compromised by infiltration of fake, falsified and substandard medicines. Complexity and lack of data sharing

Why Blockchain?: Enables provenance of supply chain data across multiple partners and better ensures integrity of the supply chain against fake medicine penetration

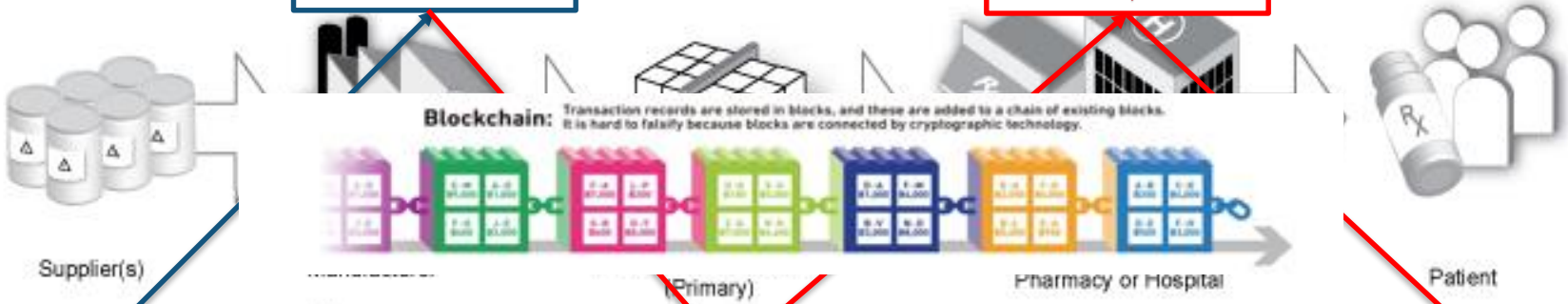
Design?: Given industry needs, a permissions-based blockchain that is private and extends to select trusted partners is being explored by several companies

Additional meta-data (e.g. e-pedigree) in BC on supply chain attributes could help identify risks of counterfeiting and can also be augmented with other verification technologies

Manufacturers produce finished medicine product for global distribution

Data exchange?

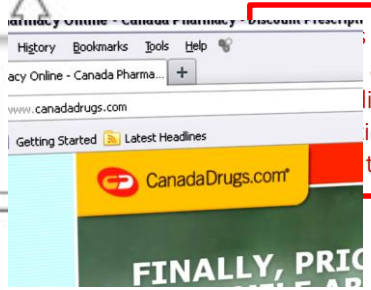
Healthcare facility receives medicine for dispensing, but may not have sufficient records to establish pedigree or verify authenticity



API is produced by raw material suppliers and then shipped to international manufacturers

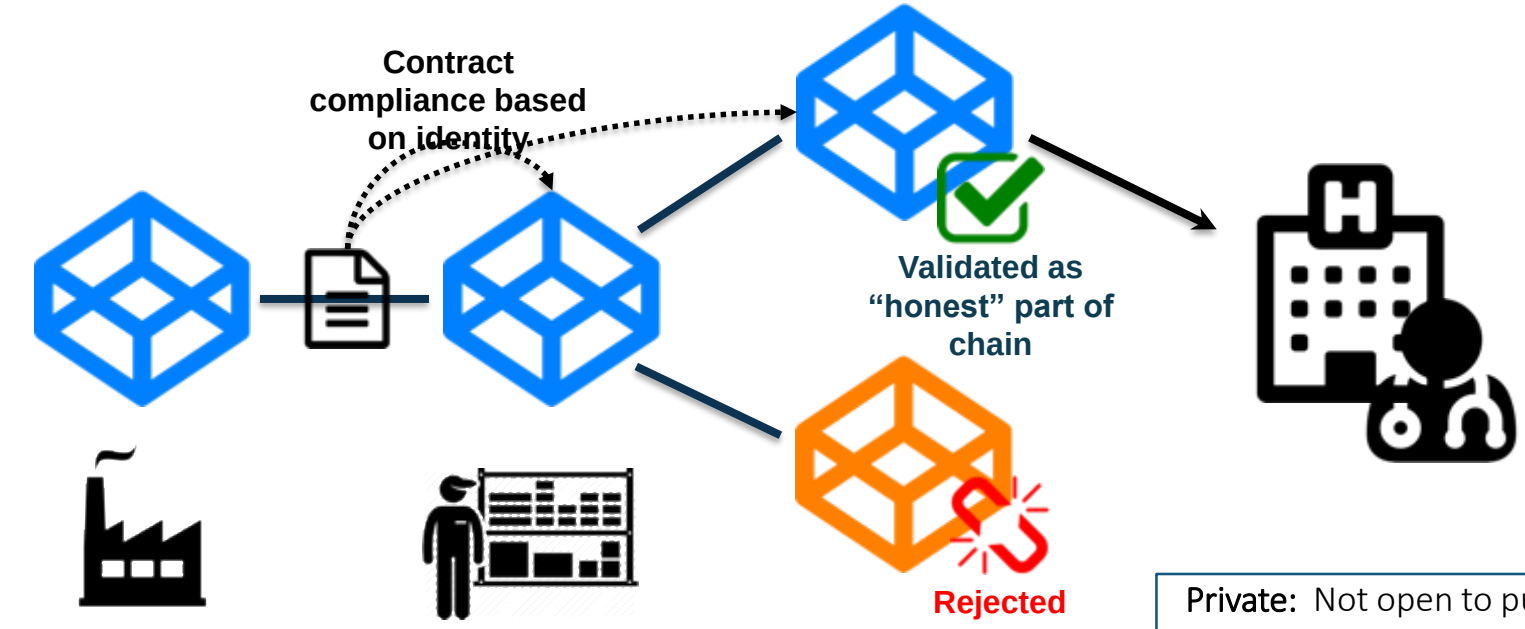
Medicine is traded and shipped through multiple transactions and trading partners requiring **authentication**, **verification**, and **track and trace** at each point in the supply chain

Counterfeit Product

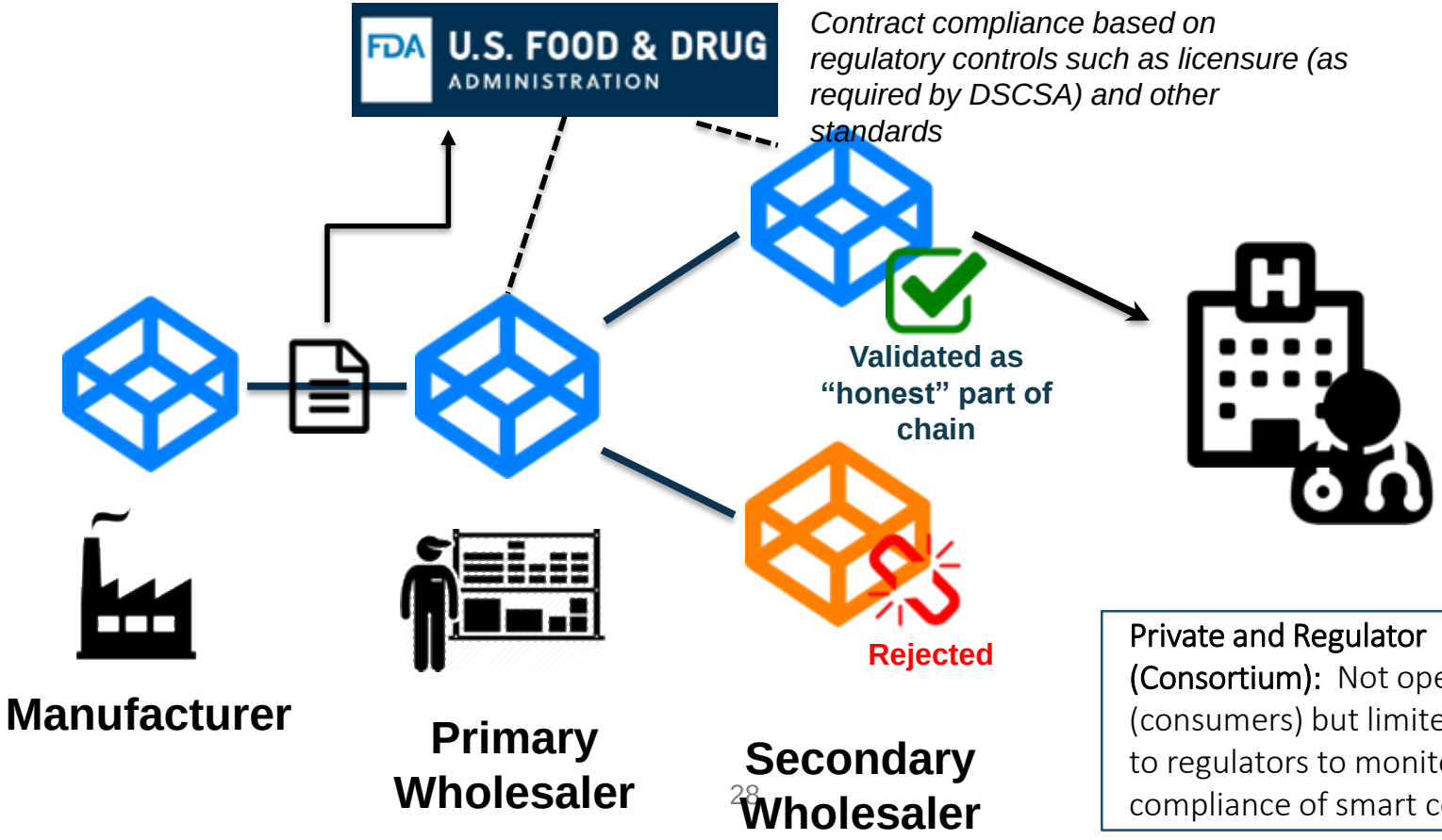


(end-users) ability to verify licine is ic at point-of-their own safety

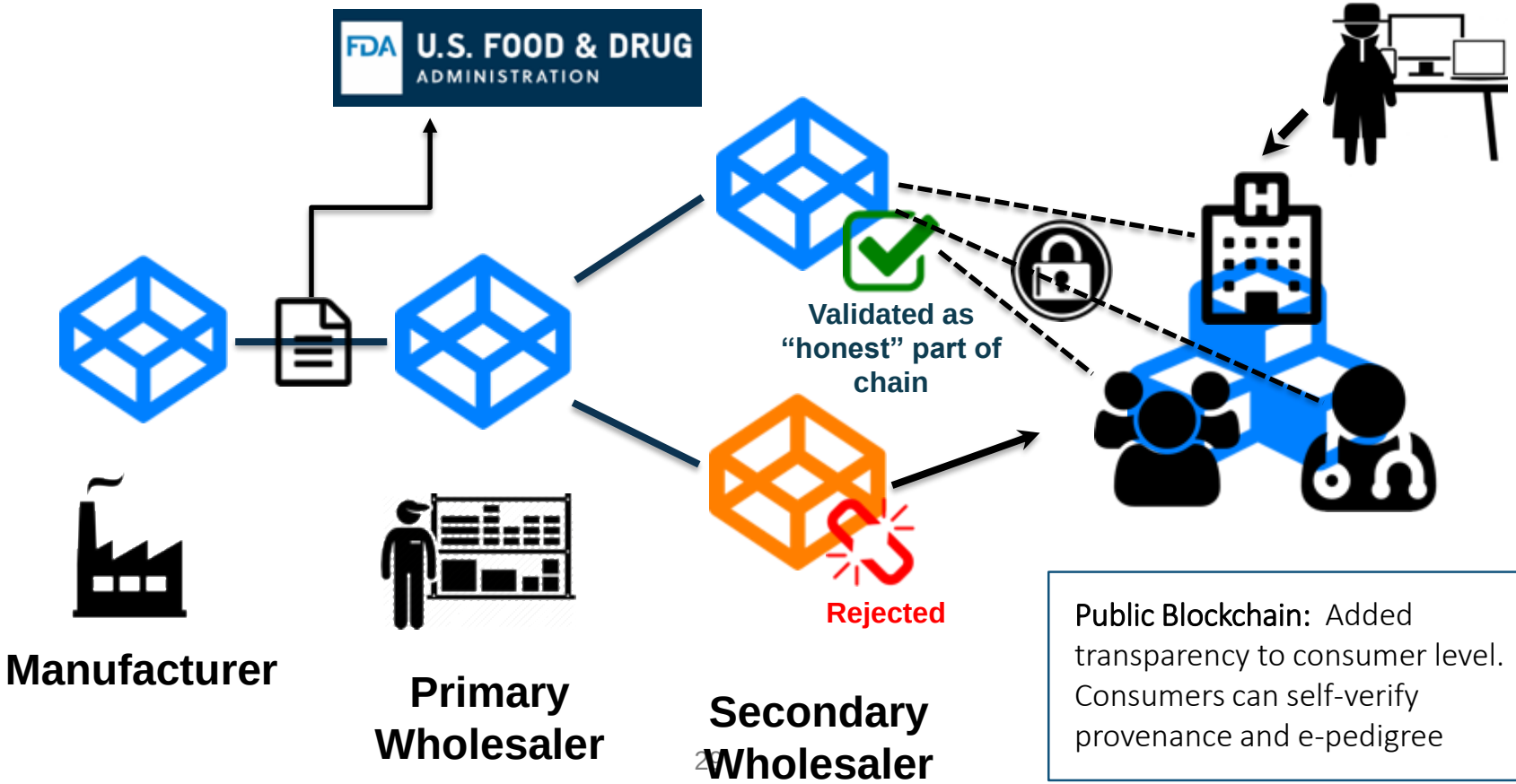
Solutions exist largely in isolation at each point to authenticate and verify, but there is no unifying framework to ensure a secure, immutable, shared ledger of supply chain transactions



Private: Not open to public (consumers) or regulators, focused on manufacturer's supplier networks. Compliance based on smart contracts

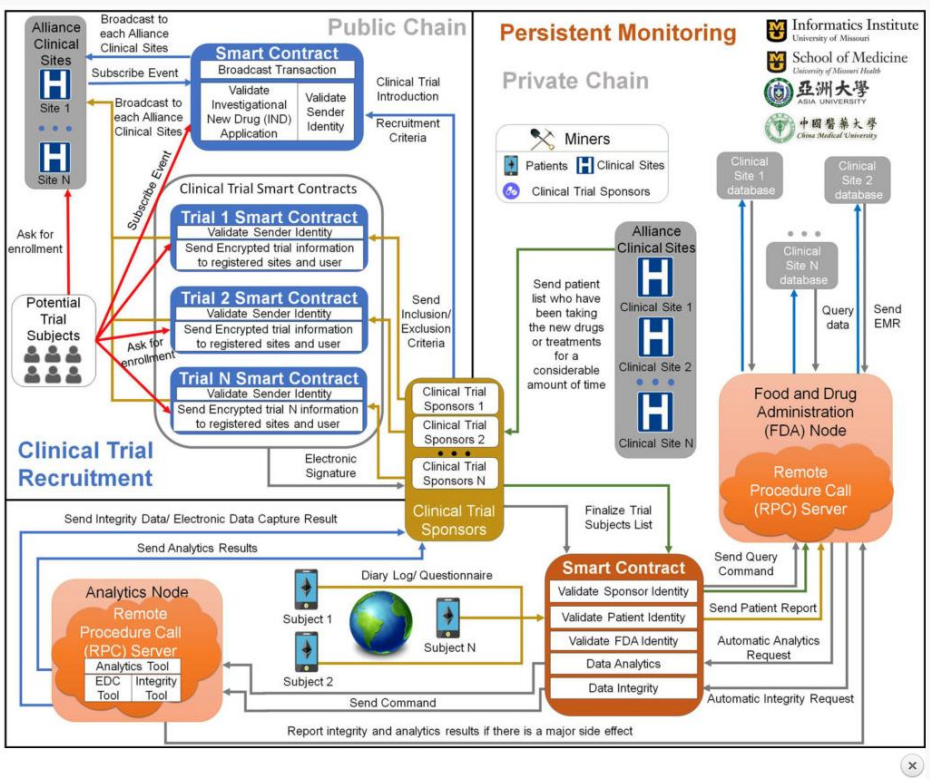


Private and Regulator (Consortium): Not open to public (consumers) but limited visibility to regulators to monitor compliance of smart contracts.



Public Blockchain: Added transparency to consumer level. Consumers can self-verify provenance and e-pedigree

Clinical Trials



Problem: Clinical trials recruitment is expensive and time consuming. Study data should be verifiable and also follow study protocol and data sharing plan to support outcomes

Why Blockchain?: Can enable patient matching and monitoring (e.g. matching with EHRs), can validate data, can incentivize patient participation, enable e-consent

Design?: Clinical trial BC can adopt hybrid design with public (enrollment) and private (clinical trial protocol) components. Smart contracts can enable trial steps.

Additional meta-data in BC clinical trial attributes could help create shared patient databases for future participation and enable better sharing of trial results with subjects.

Medical Device

How It Works

1. User provides a blood prick (similar to glucose test) or saliva sample
2. User inserts cartridge into the side of the device
3. Bowhead device uses computer vision to determine reagent strength and signal
4. Based on reading: licensed doctor offers recommendation and dispensing occurs
5. All signals monitored securely and stored using Blockchain technology
6. You can get paid for sharing your anonymous health data
   70% patients
   30% token holders

Prototypes Developed in Past 18 Months

Diagnostic cartridge app

Diagnostic reader & dispenser

Vegan spherical gels

Mobile app

Problem: Medical devices are becoming increasing enabled by wireless technology and reliant on health informatics for enhanced clinical decisionmaking. Security is key concern.

Why Blockchain?: Further enable devices beyond IoT to allow smart contracts for maintenance, can ensure tamper proof medical device logs, better validate insurance claims

Design?: A "recall" BC would likely need to be public and extend to the end-user (patient-level) but also could include visibility to regulator (consortium model.)

Meta-data collected from multiple medical devices in a BC could better enable complete digital health identify and better ensure continuity of care. Data could also better verify AEs and non-compliance

Genomics

Harvard University geneticist George Church has co-founded a new company to help individuals share and market their genomes. GRETCHEN ERTL/*The New York Times*

Q&A: George Church and company on genomic sequencing, blockchain, and better drugs

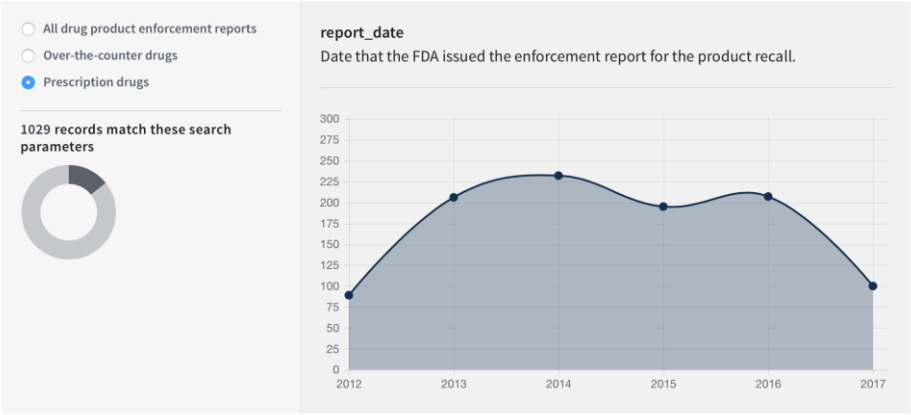
Problem: The field of genomics and precision medicine is rapidly expanding along with the ability to generate large volumes of sequencing data (including DTC sequencing).

Why Blockchain?: Verification of disparate sources of genomic data w/out centralization that could enable greater sharing for research, drug dev, pop health analysis.

Design?: Several companies in the genomic BC space focus on public models that use tokens to encourage sharing of genomic data. Privacy and security key issues.

Genomic data in the blockchain could be one attribute of many. For example, PMI ("All of Us"), collects environmental, lifestyle, and biologic data that can be added to genomic data in a bc enviornment

Pharmacovigilance



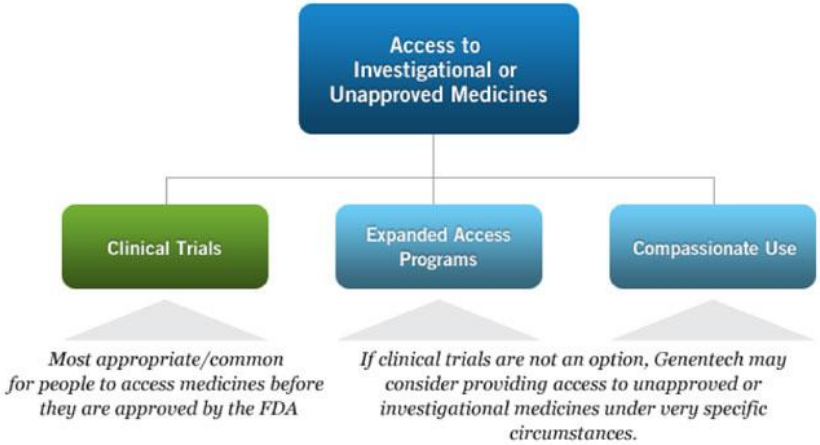
Problem: Product recalls (removal and correction) are expensive and time consuming. Ensuring compliance to FDA recall monitoring and auditing can be difficult

Why Blockchain?: Could ensure trustworthiness of data to accurately identify product subject to recall enabling "strategic removals" and establish immutable audit record

Design?: A "recall" BC would likely need to be public and extend to the end-user (patient-level) but also could include visibility to regulator (consortium model.)

Additional meta-data in BC on supply chain attributes or post-market surveillance could help identify causes of spoilage/ adulteration and clusters of AEs that lead to recall events

Patient Assistance



Problem: Patient Assistance Programs and EAPs lack standardization and are often difficult to match to eligible patients (rare disease, compassionate use, etc.)

Why Blockchain? A PAP and EAP BC could join with patient health wallet information and better verify identity and eligibility of patients seeking greater access

Design? A public BC model in partnership with patient advocacy groups and possible standardization of PAP and EAPs via smart contracts that transactions

Several pharmaceutical companies have come under fire for their policies on compassionate use. Patients have taken to social media to compel access even when eligibility and benefit are unclear.

Scientific Publishing

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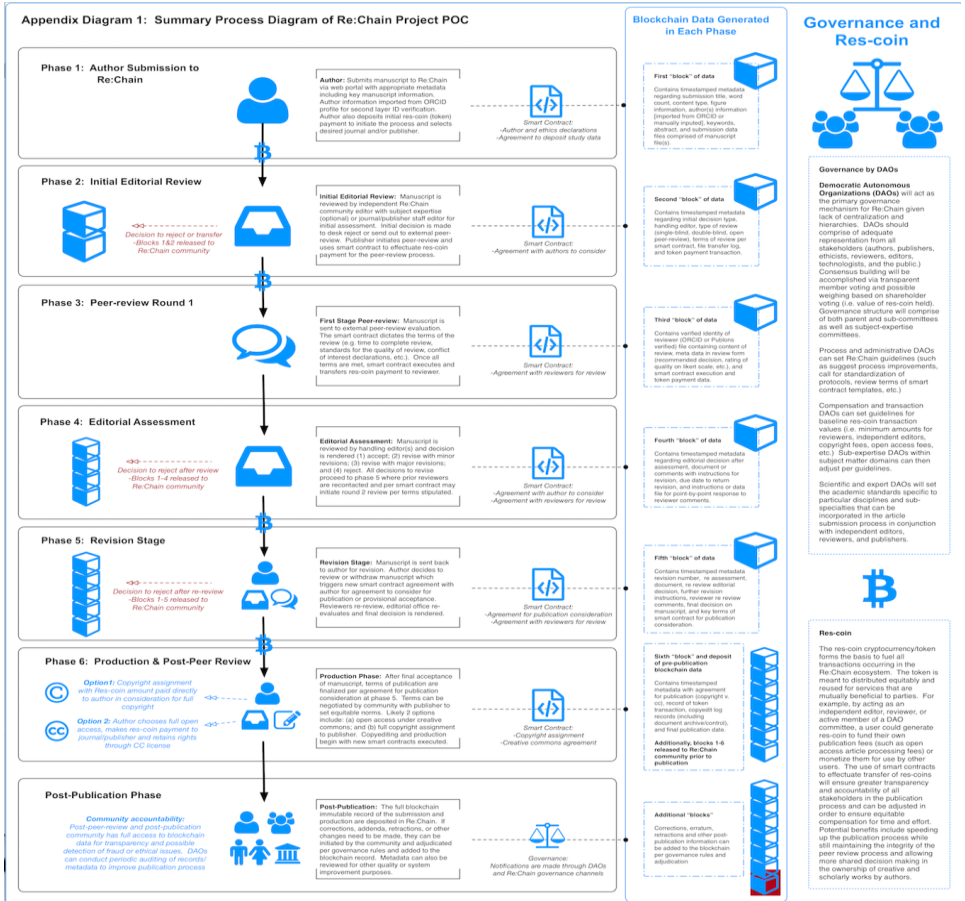
Re:Chain

Distributed ledger technology to power academic publishing

Problem: Academic publication process lacks transparency, is slow, and reviewers often have little incentive to peer-review papers.

Why Blockchain?: Could enable faster and more transparent peer-review process that is immutable and can also better incentivize participation through cryptocurrency (tokens)

Design?: A permissions-based blockchain open to public submission where access to manuscript and payment for services is enabled by smart contacts



Beyond Blockchain?

INTEGRATION

Ensuring BC integration into other solutions such as IoT, lab tests, EHRs QRC, RFID, NFC, scanning devices, mobile phones, cloud databases, etc.

SECURITY

Ensuring the security of a "shared" ledger particularly when public and private data (i.e. manufacturer → distributor → point of dispensing → patient)

INTEROPERABILITY AND ANALYSIS

Can open standards for BC enable greater interoperability between legacy systems and ERPs in order to further facilitate sharing and analysis of data

GLOBAL SOLUTION?

Can development of BC standards lead to regulatory harmonization across multiple countries/regulators by encouraging international data exchange?

POLICY RATIONALE

Is there a policy environment that either encourages or impedes blockchain adoption and how does that relate to design? (e.g. DSCSA, HIPAA, GDPR)

Policy Rationale - DSCSA

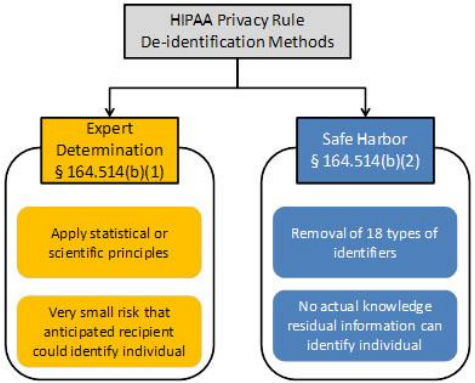
Key Requirements	Applicability	Compatible?
Product identification	Unique product identifier can be required contributed information validated as a side chain	✔
Product tracing	Allows manufacturers, distributors and dispensers to provide tracing information in shared ledger	✔
Product verification	Creates system and open solution to verify product identifier and other contributed information	✔
Detection and response	Allows public and private actors to report and detect drugs suspected as counterfeit, unapproved, or dangerous	✔
Notification	Creates shared system to notify FDA and other stakeholders if an illegitimate drug is found	✔
Information requirement	Can create shared ledger of product and transaction information including verification of licensure information	✔

U.S. Food and Drug Administration
Protecting and Promoting Public Health
DRUG SUPPLY CHAIN SECURITY ACT

Key		
	✔	Yes
	✖	No

Topics of Interest

- Blockchain Security
  - Is a blockchain secure?
- Should PHI be stored on a blockchain?
- What is the impact of GDPR for blockchain design/compliance?
- What about ICOs and Tokens?
- What is the role for standards settings?



Opportunities to Engage

UC San Diego EXTENSION

Healthcare

IEEE STANDARDS ASSOCIATION

Early bird registration: $399 by March 30; UC San Diego Affiliates: $399; IEEE Members: $399; Regular Registration: $499. Credit or non-credit

The "Healthchain"—Explore the Potential of Blockchain to Transform Health with UC San Diego and IEEE

Join us for a one-and-a-half day workshop conducted by UC San Diego, IEEE San Diego Chapter and IEEE Standards Association that will explore the potential for blockchain to transform healthcare. This educational workshop will feature a combination of lectures, use cases, applied skill learning and panel discussions from leading experts focused on key healthcare verticals including genomics, the health supply chain, clinical trials and medical devices.

- **IEEE Pharma Supply Chain/Clincial Trials/Medical Device Blockchain Industry Connections Program:** Exploring frameworks for standards of interoperability between blockchain, supplychain and clnical trials.
- **UCSD – IEEE SD/SA Blockchain in Healthcare Workshop:** May 24-25th at UCSD with focus on healthcare verticals. Topics bc healthcare 101, do you need bc?, healthcare veriticals, digital identity, legal/regulatory, design workshop.

Upcoming IEEE Blockchain Activities

- *Currently recruiting* – technologists, regulatory, pharma/health innovation professionals, patient advocacy groups – for participation in workstreams
- IEEE Wearables & Medical Interoperability Workshop (WAMI) – 25-26 April 2018, Washington DC – http://wami.ieee.org
- Health Blockchain Workshop – 25-25 May 2018, San Diego, CA
- Blockchain for Clinical Trials Forum Europe – November 2018, UK http://blockchain.ieee.org/clinicaltrials

Interested in Participating IEEE Initiatives?

- **Blockchain for Clinical Trials** – http://blockchain.ieee.org/clinicaltrials
- **Blockchain for Pharma/Supply Chain**– http://blockchain.ieee.org/supplychain
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