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Blockchain: oportunidades en salud para la prestación de servicios, el aseguramiento, la industria farmacéutica y de dispositivos

Tim K. Mackey, MAS, PhD
Associate Professor, UC San Diego – School of Medicine

Organizan:

VIRREY SOLIS I. P. S.

ROZO ASOCIADOS

Aliado estratégico:

América economía Media Group

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Disclaimer

Las opiniones aquí presentadas son a título personal y no comprometen las posiciones de las entidades con las cuales tengo algún vínculo laboral o profesional.

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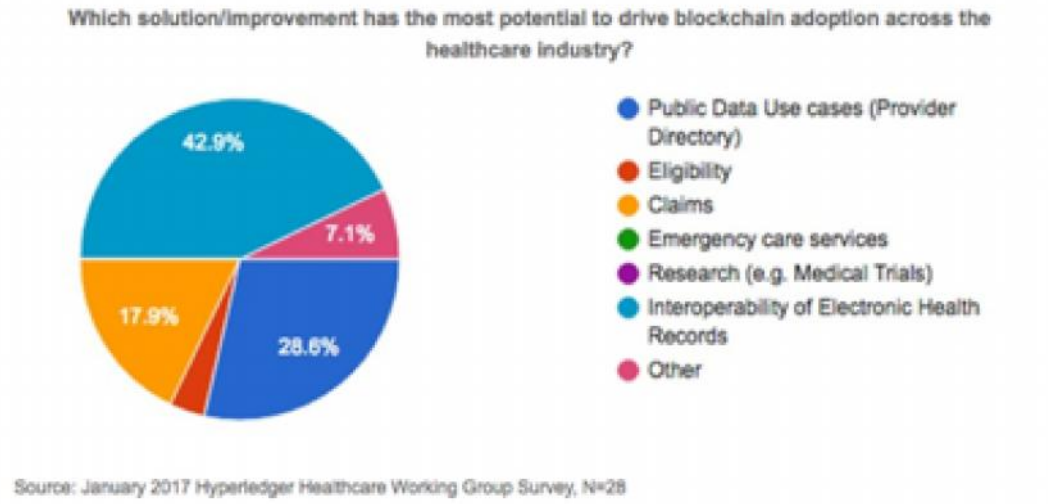
Blockchain Fundamentals

What is Blockchain?

- Blockchain is <u>not</u> bitcoin
- It is the underlying technology in bitcoin and other cryptocurrencies
- It can be used for many use cases (e.g. fintech, digital identify, asset management, supply chain)
- Lots of discussion about different use cases in healthcare



What is a blockchain made of?

-Distributed ledger (distributed network of nodes/computers)

-Hash Chain (hash function, pointers, merkle trees)

-Consensus (different consensus mechanism)

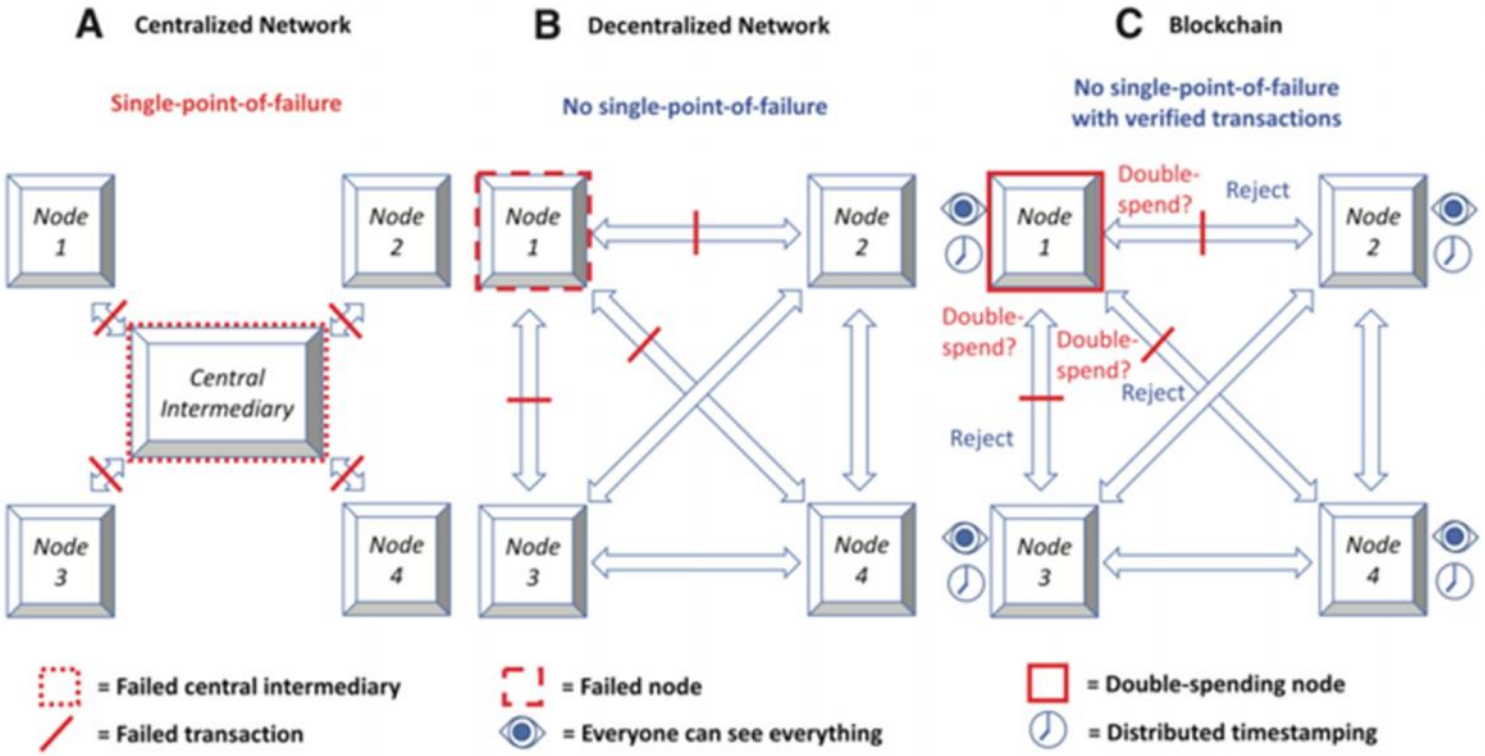


Figure 2. Comparison of the distributed network topologies. (**A**) Centralized network topology, which creates a single-point-of-failure (the central intermediary). If the central intermediary is down or attacked, the entire network stops working. (**B**) Decentralized network topology, which does not 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.

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“Fit-for-Purpose” for Healthcare?

Blockchain for Healthcare?

Core Principles and Design Element Considerations

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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?

Blockchain Fit-for-Purpose

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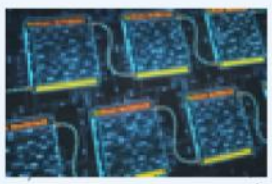
1. Design Type

Decide whether your blockchain will be a public (permission-less), private, or hybrid blockchain. These design characteristics should map to your healthcare challenge and your users and peers.

3. Governance

Who will be users and nodes of your blockchain? Do you want only select partners, consortium (a group of selected partners), regulators, and/or the public to be users, peers, and/or validators? Is this a patient-centric or process-centric bc?

Who is your community and how will they govern the bc?



What data & design elements are needed to solve the challenge?

2. Data Sharing?

What levels of permission (if any) do you need for data that may be part of the blockchain. Will you store it off-chain, on-chain? What regulatory and legal considerations might lead you to assess data governance.

X. Ultimate Goal

What is your ultimate goal for your blockchain solution, to improve a healthcare process, to enhance safety and quality, incentivize data sharing, drive revenue, ensure better compliance? Do you need a **token** to incentivize participation?

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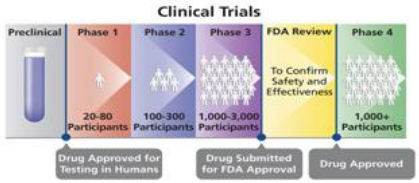
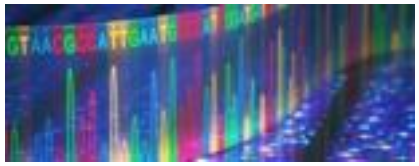
Mapping to Blockchain Healthcare Use Cases

Healthcare Use Cases

Supply chain: Ensuring the integrity and trust in the pharmaceutical and health commodity supply chain, such as a blockchain-enabled track and trace system across disparate trading partners



Clinical Trials: Ensuring trust and provenance of data in clinical trial and protocol management and better enabling e-consent and other functions through smart contracts



Genomics: Incentivizing users to share their sequencing data for population health analysis, precision medicine, drug discovery, and clinical research

Medical Device: Leveraging IoT, health informatics, and patient engagement for medical device blockchains. This includes using smart contracts for device maintenance.

Pharmaceutical Supply Chain

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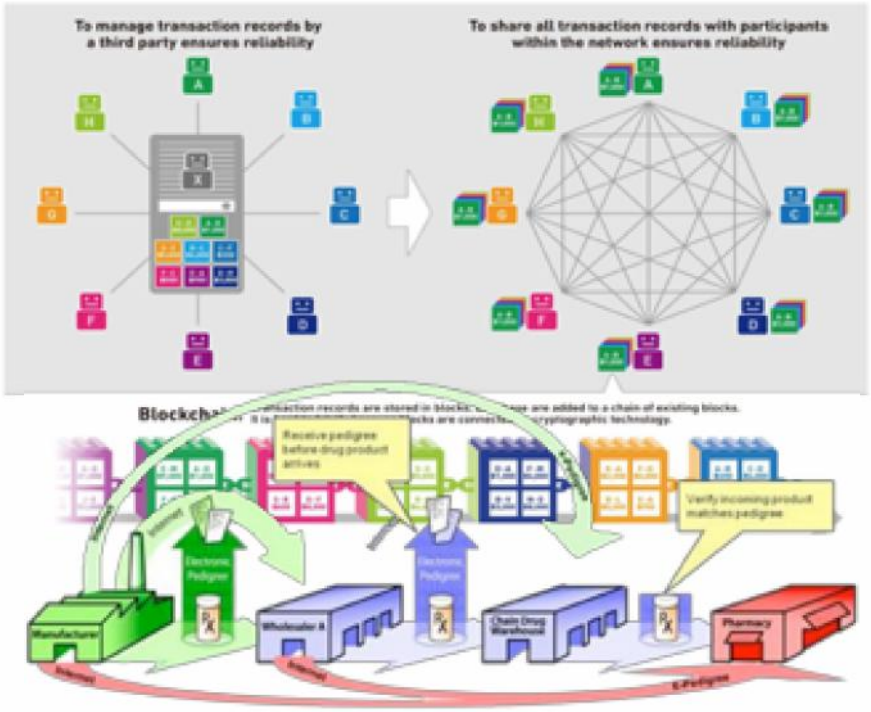
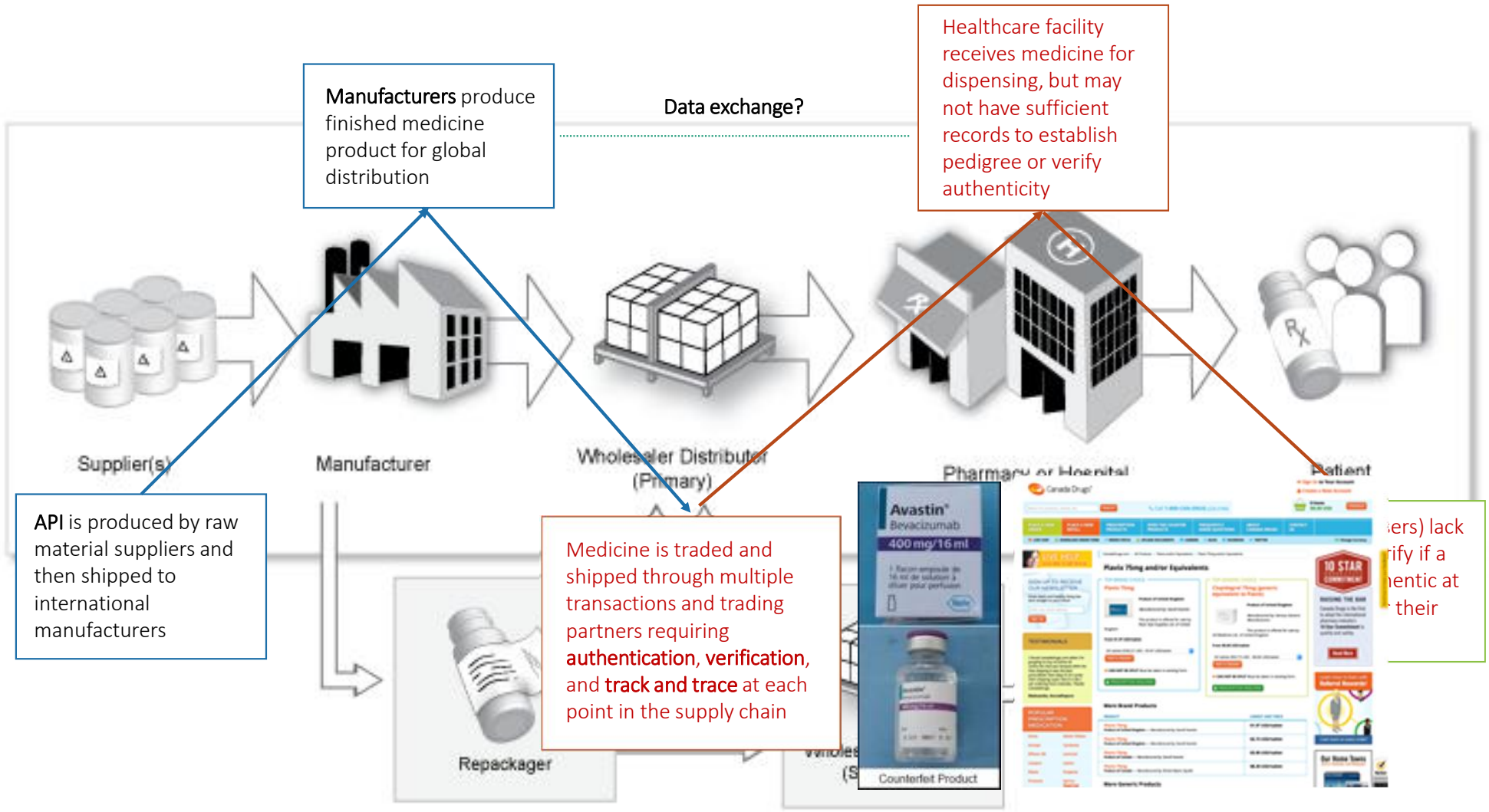


Healthcare Problem: The security of the drug supply chain has been compromised by infiltration of fake, falsified and substandard medicines. Complexity and lack of data sharing

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

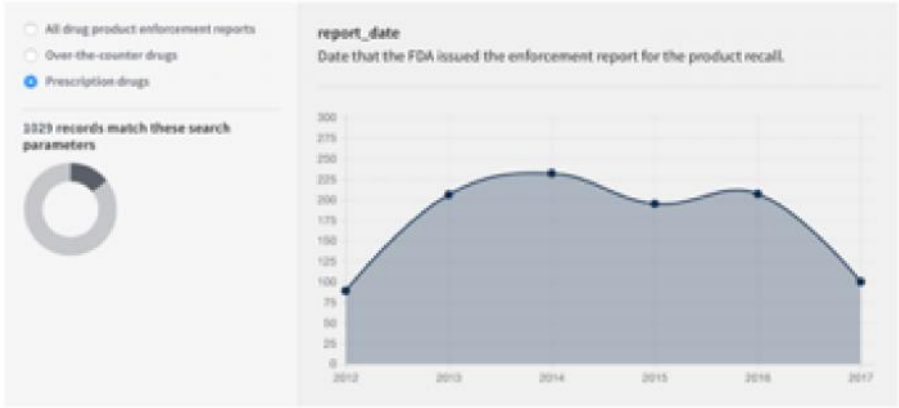
Design?: Given industry needs, a permissions-based blockchain that is private and extends to select trusted partners is being explored by several companies

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



Solutions exist largely in isolation at each point to authenticate and verify, but there is no unifying legal or systems-based framework to ensure the integrity of the global supply chain

Pharmacovigilance



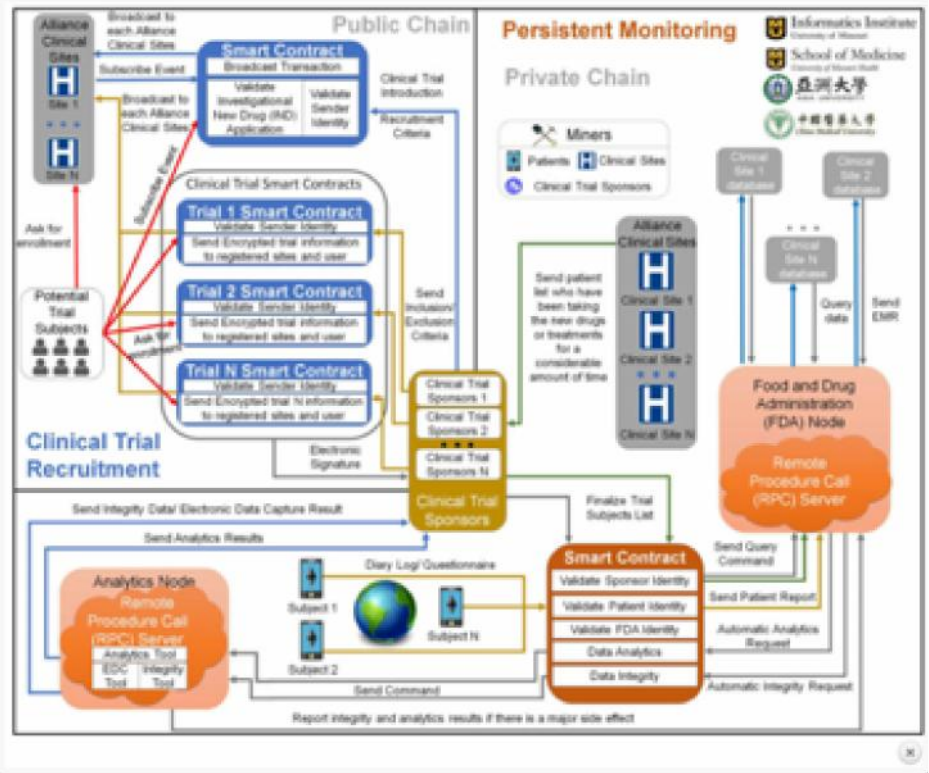
Problem: Product recalls (removal and correction) are expensive and time consuming. Ensuring compliance to FDA recall monitoring and auditing can be difficult

Blockchain?: A ”recall” BC could ensure trustworthiness of data to accurately identify product subject to recall. Could enable ”strategic removals” and better audit records

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.

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

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 Devices

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

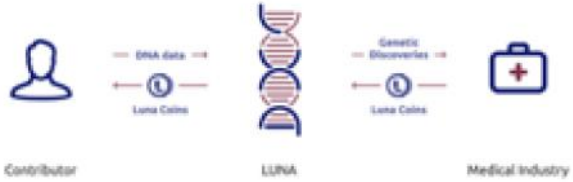
Design?: Many models envision some interaction with patient/end use, so hybrid (public and private) might be the most common approach.

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



luna

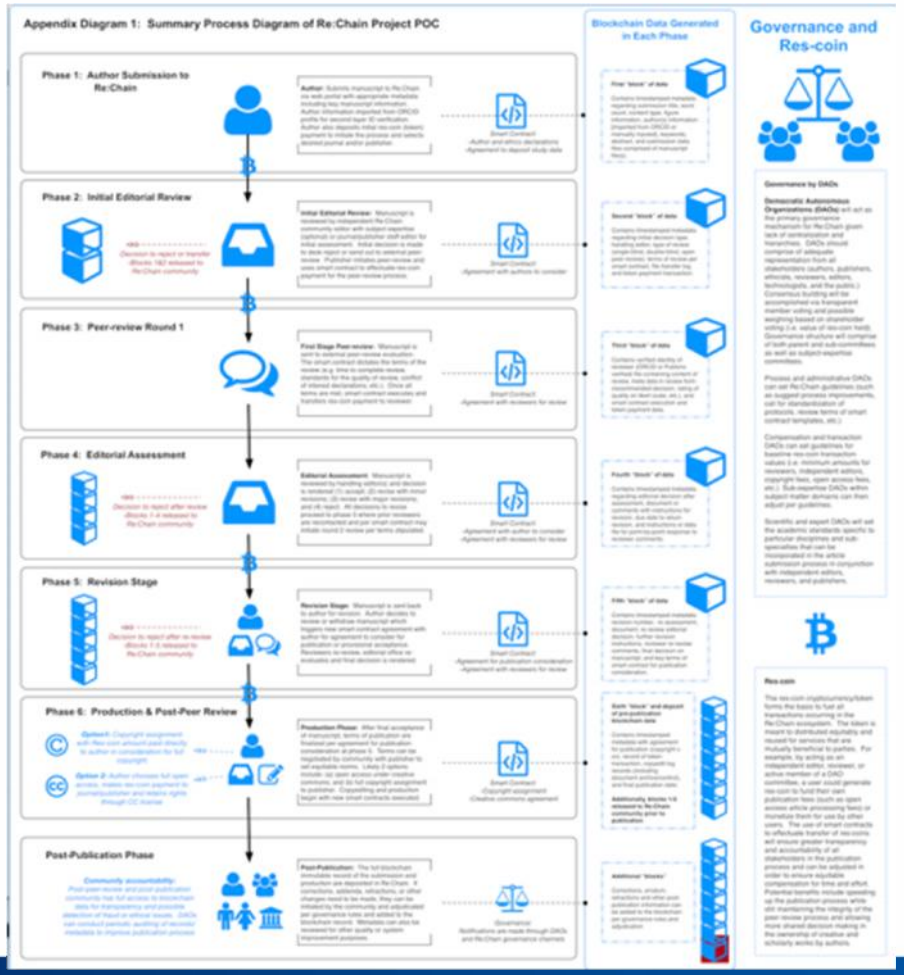
Problem: The field of genomics and precision medicine is rapidly expanding along with the ability to generate large volumes of sequencing data (including DTC sequencing).

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

Academic Publishing



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Health Blockchain Education

Educational Workshop Format

UC San Diego EXTENSION

UC San Diego SCHOOL OF MEDICINE

May 2018 1.5 day workshop hosted by UCSD through partnership between UCSD – Extension, UCSD – School of Medicine, San Diego IEEE Section, and IEEE Standards Association. The workshop was meant to be different than your typical blockchain conference by focusing on **education, knowledge application,** and **open discussion** about the potential challenges *and* opportunities for blockchain to transform healthcare. Speakers came from industry, academia, IEEE, and the technology startup and investment communities.

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Design Workshop Learning Objectives

- Conceptualize a framework for thinking about blockchain as a data structure/architecture
- Apply technical framework to “fit-for-purpose” to healthcare challenges
- Develop framework and ”fit” for specific healthcare vertical use cases (medical device, clinical trials, supply chain)

Workshop Format

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9:00-11:15am
"Healthchain" Vertical Breakout Design Sessions

On day 2, attendees will self-select to participate into one of three healthcare vertical breakout design sessions applying design approaches learned on day 1 to address critical challenges in healthcare. Breakout sessions will be led by a technical framework developed by an IEEE Fellow and a healthcare vertical content expert. Breakout groups will present later in the afternoon.

Technical Framework Speaker:
Ephraim Feig, IEEE, Life Fellow (Nautilus B)

Pharmaceutical Supply Chain
Content Expert Lead: Tim K. Mackey, UCSD
Location: Nautilus C

Medical Device Industry
Content Expert Lead: Kevin Clauson, Lipscomb Univ
Location: Nautilus D

Clinical Research
Content Expert Lead: Basker Gummadi, IEEE-SA
Location: Nautilus B




5:15pm
Blockchain and STEM Education Spotlight

Presentation from Canyon Crest Academy teachers and students on potential for blockchain to integrate into STEM education.

11:30am
Blockchain Workforce Data Study

Presentation by UCSD Extension Center for Research on the Regional Economy on preliminary data from blockchain workforce market research.

11:45am - 12:30pm: Nautilus B
Design Session Vertical Presentations

Participants from Vertical Breakout design sessions will present their ideas, designs, and SWOT analysis to entire group and invited faculty judge.

Location: Green Acre Main Room
Guest Judge: Daniel Haders II, General Manager, Nex Cubed.

Workshop Use Cases

Supply chain: Ensuring the integrity and trust in the pharmaceutical and health commodity supply chain, such as a blockchain-enabled track and trace system across disparate trading partners

Clinical Trials: Ensuring trust and provenance of data in clinical trial and protocol management and better enabling e-consent and other functions through smart contracts

Medical Device: Leveraging IoT, health informatics, and patient engagement for medical device blockchains. This includes using smart contracts for device maintenance.

Healthcare-related Vertical: Open vertical for groups to determine what healthcare challenge they would like to address (no content lead).

A Framework for Blockchain

The Framework (Feig 2018)

1. Who are the users?
2. What data do users input?
3. ~~Are any inputs irreversible?~~
4. Who are the peers?
5. How do peers create blocks?
6. What do peers validate?
7. How do peers validate?
8. ~~How do peers reach consensus?~~
9. ~~Is the blockchain immutable?~~
10. ~~How are peers incentivized?~~

A Framework for Blockchain-Based Applications

Ephraim Feig
IEEE Life Fellow

Abstract

Blockchains have recently generated explosive interest from both academia and industry, with many proposed applications. But descriptions of many these proposals are more visionary projections than realizable proposals, and even basic definitions are often missing. We define "blockchain" and "blockchain network", and then discuss two very different, well known classes of blockchain networks: cryptocurrencies and Git repositories. We identify common primitive elements of both and use them to construct a framework for explicitly articulating what characterizes blockchain networks. The framework consists of a set of questions that every blockchain initiative should address at the very outset. It is intended to help one decide whether or not blockchain is an appropriate approach to a particular application, and if it is, to assist in its initial design stage.

1 Introduction

Blockchain has been heralded as "a foundational technology. It has the potential to create new foundations for our economic and social systems"[1]. People claim that blockchain will streamline the electronic health records process [2]; will "add greater visibility and efficiency across the entire supply chain to deliver higher value to your customers and trading relationships"[3]; will track ownership of real estate [4]; may "disrupt the insurance industry and change the way we share data, process claims and prevent fraud"[5]; "could revolutionize the Internet of Things" [6].

There are no explicit description of the blockchains in the cited applications. But the blockchains of cryptocurrencies are well understood. As Satoshi Nakamoto writes [7], they are needed to enable "electronic transactions without relying on trust." A complete, immutable public record of transactions is not a design goal in cryptocurrencies. Quite the contrary, cryptocurrency purists would prefer no record at all, to strengthen identity-hiding. Nakamoto wrote that, as was well known already [8], "To accomplish this without a trusted party, transactions must be publicly announced." The public ledger is the price to pay in order to enable cryptocurrency with integrity.

What exactly is the trust that Nakamoto was referring to in his paper? In an online forum [9] he writes, "The root problem with conventional currency is all the trust that's required to make it work. The central bank must be trusted not to debase the currency, but the history of fiat currencies is full of breaches of that trust. Banks must be trusted to hold our money and transfer it electronically, but they lend it out in waves of credit bubbles with barely a fraction in reserve. We have to trust them with our privacy, trust them not to let identity thieves drain our accounts."

The central bank and fiat currencies issues that Nakamoto bemoans pale in comparison to their analogues in the cryptocurrency world. Anybody can create a cryptocurrency (there are over 1,500 of them [10]) and even the most established ones will fork at the whims of their creators [11]. As for banks' abuses, relative to total currency volume, they pale in comparison to Ponzi schemes by cryptocurrency exchanges [12]. As for draining accounts, cryptocurrencies lose by a wide margin [13]. The concern that we have to trust banks to hold and transfer funds is genuine, but mostly in cases where the transfer is prohibited by some legal authority. The big advantage cryptocurrencies offer is identity-hiding, and only to those who are able to cover their tracks [14]. To gain this advantage, Bitcoin needed

Design a Health Blockchain

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First Step: Based upon your selection on Day 1, you will be assigned the healthcare vertical of your choice. The technical lead and content lead will be your facilitators for the workshop.

Second Step: Pick a healthcare challenge in your vertical with consultation with your content lead faculty. What specific challenge do you want to solve with blockchain?

Third Step: Think of Feig Blockchain Design framework and first answer questions #1, 2, 4, 5, 6, 7, as a group.

Fourth Step: Apply the “fit-for-purpose” framework for healthcare to your challenge and conceptualize design.

Translation

1. Instructions for each healthcare vertical are available from content lead
2. Brainstorm and reach ”consensus” to second, third and fourth step
3. Conduct SWOT analysis of potential challenges and opporunities
4. Create a pitch deck (template provided) for your bc design solution


Blockchain Applications in Healthcare
Consent Management: Use Case for Using e-consent in Clinical Trials
Clinical Trials Vertical – Team 2
#ucsdeeBlockchain
ALEXANDRIA
PPP
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SIG

Future Blockchain Education

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Conducting "Fit-for-Purpose" workshop as a business school elective course with UCSD Rady School of Business. In-person short duration workshop with incubator follow-on. Conducted with UCSD Rady School of Management and UCSD - SOM faculty.

Rady School of Management
UNIVERSITY OF CALIFORNIA SAN DIEGO

UC San Diego
SCHOOL OF MEDICINE

Specialized four course online certificate in blockchain applications in healthcare offered through Coursera. Co-Directors Mackey and Clauson with core courses that can be taken together for certificate or alone. Introduction course, use case course, fit-for-purpose course, and applied blockchain design 101 course.

coursera
UC San Diego LIPSCOMB UNIVERSITY

Specialized certificate offered through UCSD – Extension. Same four core courses as Coursera offering with additional courses specific to healthcare verticals (supply chain, clinical trials, EHRs, etc.), electives in computer programming, and mentored capstone project.

UC San Diego EXTENSION
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SDSC SAN DIEGO SUPERCOMPUTER CENTER

IEEE - SA Industry Connections

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- **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

IEEE STANDARDS ASSOCIATION
IEEE

Supply Chain Workstream

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CHARTER: Exploring the use of blockchain and/or in combination with emerging technologies to optimize business operations that lead to a more inclusive and secure outcome for end-user consumption of food and medicine.

Areas of Focus

- Blockchain & AI for Clinical Trials/Research
- Smart Contracts for Supply Chain
- Blockchain for Pharmaceutical Drug Supply Chain
- Blockchain for Agriculture

Program Chairs:

Dr. Tim Mackey, UC San Diego, School of Medicine

Carole Carey, C3-Carey Consultants, LLC

Clinical Trial Workstream

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Pre-Standards Workstreams

- Health Data Quality Scoring System & Linking Patient Identity to Patient Data on the Public Blockchain
- Smart Contracts for Electronic Informed Consent
- Clinical IoT Data Validation and Interoperability with Blockchain

Initiative Lead: Basker Gummadi, Blockchain Enthusiast, Bayer Healthcare

BLOCKCHAIN FOR CLINICAL TRIALS

http://blockchain.ieee.org/standards/clinicaltrials

Interested in Participating

- **Pre-Standards activities are open and inclusive** (no membership or financial commitment)
- Collaborate with like-minded individuals to develop consensus on addressing pressing challenges

https://blockchain-ieee.slack.com

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http://blockchain.ieee.org
http://standards.ieee.org

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Co-Chair Supply Chain/Clinical Trials Technology Implementation Industry Connections Program
IEEE Standards Association

COLLABORATORS

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