Importance of Ensuring Blockchain Compliance for your Institution

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DISCLAIMER

The views expressed in this presentation are the views of the presenter and do not necessarily reflect the views or policies of her employer.

There are no known conflicts of interest.
Learning Points

Use Cases for Clinical Research

Blockchain technology is coming to your institution soon. It is important to learn the common research use cases of blockchain and understand why this technology will create advances in clinical research.

Risks

The blockchain itself is secure, but there are still legal and security risks to your institution, such as uses of smart contracts.

Compliance Solutions

This presentation will teach how to oversee blockchain technology with regard to IRB submissions, FDA and HIPAA Security Rule regulations and considerations for state statutes.

WHAT IS BLOCKCHAIN?
BLOCKCHAIN IS NOT BITCOIN

But Bitcoin operates on the bitcoin blockchain

BLOCKCHAIN IS A LEDGER
BLOCKCHAIN USES CRYPTOGRAPHY (HASHES)

This technology makes the information immutable / very resistant to change.
**BLOCKCHAIN USES DISTRIBUTION OF HOSTS (NODES)**

What happens when the server is down? A copy of the information is distributed to the entire network. There is no single source of failure.

- Users (●) are anonymous
- Users (▲) are not anonymous

Block Geeks (2018)

**BLOCKCHAIN CAN BE PUBLIC OR PRIVATE**

- **Public blockchain:**
  - Users manage nodes and transactions offer transparency.
  - Users can be anonymous.

- **Private blockchain:**
  - Users must be given permission.
  - Organizations often collaborate to support the blockchain.

U.S. adults own cell phones

Block Geeks (2018)
EXAMPLES OF BLOCKCHAIN PLATFORMS

- Bitcoin
- Ethereum
- Monero
- Dash
- Corda
- BigChainDB
- Hyperledger
- Multichain
- Credits
- Stellar
- Hydrachain
- Iota

95% of U.S. adults own cell phones
77% own smart phones

SMART CONTRACTS ON THE BLOCKCHAIN

Programs that execute a code-based agreement. Offer:
- Automation
- Accuracy
- Transparency
- Security
- Speed
BLOCKCHAIN PROCESS FOR HEALTHCARE

How it works

Someone requests a transaction

The requested transaction is broadcast to a P2P network consisting of computers, known as nodes

Validation: The network of nodes validates the transaction and the user’s status using known algorithms

A verified transaction can involve: cryptography, contracts, records, or other information

Once verified, the transaction is combined with other transactions to create a new block of data for the ledger

The transaction is complete

The new block is then added to the existing blockchain, in a way that is permanent and unalterable

60% of U.S. adults own cell phones

60% own smart phones

PriceWaterhouseCooper (2018)

USE CASES for CLINICAL RESEARCH

DATA INTEGRITY

MEDICAL RECORDS

PAYMENTS
DATA INTEGRITY – PROOF OF EXISTENCE

- Prevents data alteration (fraud)
- Locks the protocol or analysis plan
- Proof that consent forms exist
- Data transparency for ClinicalTrials.gov submissions

SECURING RESEARCH RECORDS

- U.S. adults own
  - 95% own cell phones
  - 77% own smart phones

Linn & Koo (2018)
STORING HEALTHCARE DATA

The patient

Data inputs

Electronic health chain

American College of Surgeons (2017)

MEDICATION SUPPLY CHAIN TRACKING

Every step of the drug supply chain can be tracked to prevent counterfeit medications and quickly manage recalls.

Sandner (2017)
RESEARCH REGISTRIES

Users agree to share health data. Health wallet creates pseudonymous address and stores as smart contract on Blockchain. Gives permission for certain releases under specific conditions.

Researchers wish to access data. For each record, they check conditions of smart contract to determine if the use is allowed. If so, access the data, record transaction on Blockchain, make micropayment (in this case) to individual's health wallet.

Patients can control access to their Healthcare data for use in research.

Health coin payment is made – can be converted to money used in HSA, or to purchase medical services. Could be Bitcoin.

IBM (2018)

SMART CONTRACTS FOR ENROLLMENT

https://f1000research.com/articles/6-66/v5
SMART CONTRACTS FOR RESEARCH PAYMENTS

Example of “HealthCoin” payments executed by smart contracts on the blockchain.

Eligibility | Informed consent | Token placed in “wallet” | Participation tracked with wearables | Token reward

IBM (2018)

HOW MUCH IS HYPE AND HOW MUCH IS REALITY?

15% Hospitals ready to deploy blockchain
45% Looking into blockchain

Healthcare IT News (2018)
EXAMPLE OF HOSPITAL INTEREST

Mayo Clinic looking to store health records on blockchain

Written by Julie Spitzer | June 19, 2018 | Print | Email

Rochester, Minn.-based Mayo Clinic is looking for ways to store patient data on blockchain, a decentralized, digital ledger that promises enhanced security, and the provider has signed a joint working agreement with the London-based startup Medicalchain.

Medicalchain uses blockchain to hold patient health records, which lets physicians from different organizations request access to an EHR and record that activity on a distributed ledger.

Under the agreement, Medicalchain and Mayo will explore various potential benefits of blockchain in healthcare.

"We are thrilled to be working with Mayo Clinic. Mayo Clinic will provide their world-class healthcare and health IT expertise, while Medicalchain will provide our knowledge of blockchain and crypto," said Dr. Abdullah Albeyatti, CEO of Medicalchain. "Together we will work on several use cases using blockchain based electronic health records. There’s a lot of opportunity out there, and we feel this working agreement will be of benefit to all healthcare stakeholders."

Becker's Hospital Review (2018)
COMPLIANCE IS CHALLENGING – MOSTLY UNKNOWN

BLOCKCHAIN: LEGAL RISKS

- Smart contracts may not be legal in all states
- Legal/regulatory jurisdictions
- Legal validity of documents as “evidence of proof”? 
BLOCKCHAIN: HIPAA

- HIPAA Security Rule does not allow mathematically-derived pseudonyms
- How to construct a blockchain for PHI access, use, and disclosure
  - Patients’ rights to withdraw authorization and correct inaccurate information in an immutable environment
- Uncertainty about future regulations

BLOCKCHAIN: GENERAL DATA PROTECTION REGULATION

If the blockchain is cannot be changed, how do you honor an EU resident’s GDPR “right to be forgotten”?
BLOCKCHAIN: FDA 21 CFR, PART 11

- Will FDA allow data stored in a blockchain?
- Smart contracts and digital identity for electronic signatures?
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LEGAL CONSIDERATIONS

ASK the Sponsor or Vendor:

- Are there smart contracts?
- What is legality of smart contracts and authentication in your state?

STATES THAT PASSED OR PROPOSED BLOCKCHAIN

COLORADO LEGAL CONSIDERATIONS

Passed:
- Senate Bill 19-023: securities laws for cryptocurrencies

Not Passed:
- House Bill 1426: virtual tokens

Governor’s Blockchain Council:
- Definition of Tokens
- Securities
- Taxation
- Exchanges
- Banking services
- Trust / custody
- Incorporation
- Smart Contracts
- Digital Identity
- Government Use
- General Regulatory Environment
- Debt Payments
- Higher Education

BLOCKCHAIN: HIPAA CONSIDERATIONS

ASK the Sponsor or Vendor:

✔ Hosting and storage
  - Who is hosting?

✔ HIPAA Security when PHI On-Chain
  - Technical specifications
  - Private key recovery
  - User authentication methods
  - Access, control, limitations
  - Monitoring security?

✔ DHHS may provide clarifications

Crowdsourcing for study design, analyses, Remote spirometry, vital signs, 6MWT, Remote monitoring

Hosting and storage
Remote monitoring
BLOCKCHAIN: FDA CONSIDERATIONS

ASK the Sponsor or Vendor:

- Data Capture and Integrity
  - Which variables are on-chain?
  - Is there real-time data capture?
  - How do we make changes to info?
  - What training will be provided?

- FDA 21 CFR Part 11 Compliance
  - Technical specifications?
  - Auditability / traceability?
  - Hashes for electronic signatures?
  - Methods of validation?

SUBMITTING BLOCKCHAIN TECHNOLOGY TO IRB

IRBs are still somewhat unfamiliar with blockchain. Provide:

- Blockchain host and platform
- Variables stored on-chain
- Smart contract terms (if any)
- Technical specifications
- Training and documentation
- Ongoing monitoring for security, access
**KEY TAKEAWAYS**

- Blockchain is coming to Healthcare
- Blockchain is still an immature technology for Healthcare
- Federal regulations are uncertain and evolving
- Start with pilots projects and ask many questions about compliance

“The old question ‘Is it in the database?’ will be replaced by ‘Is it on the blockchain?’”

- William Mougayar

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**Questions?**

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