




Importance of Ensuring Blockchain Compliance for your Institution



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HCCA[™]
Health Care Compliance
Association
Research Compliance Conference



DISCLAIMER

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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



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But Bitcoin operates on the bitcoin blockchain

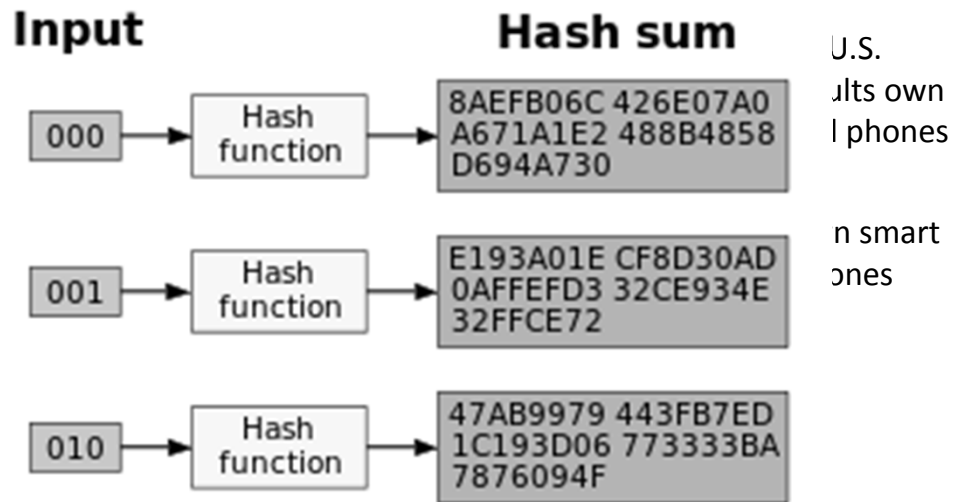
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BLOCKCHAIN IS A LEDGER

SHEET NO. <u>1</u>					ACCOUNT NO. <u>101</u>				
TERMS.					NAME <u>W. A. Brooks</u>				
RATING.					ADDRESS				
CREDIT LIMIT.									
DATE	ITEMS	Folio	✓	DEBITS	DATE	ITEMS	Folio	✓	CREDITS
1915					1916				
Nov 12	Cash from E.H. Allen			158 70	Nov 13	Draft to Barten T1			59 75
13	" " Payroll	11		173 50	13	Bal.			272 45
				332 20					332 20
13	Bal.			272 45	20	Draft to Barten T2			160 65
20	Cash from Payroll	12		154 20	20	Bal.			266 10
				426 65					426 65
20	Bal.			266 00	27	Draft to Barten T3			154 35
27	Cash from Payroll T3			100 10	27	Bal.			211 75
				366 10					366 10
27	Bal.			211 75	Dec 4	Draft to Barten T4			146 20
Dec 4	Cash from Payroll T4			126 30	11	Bal.			266 90

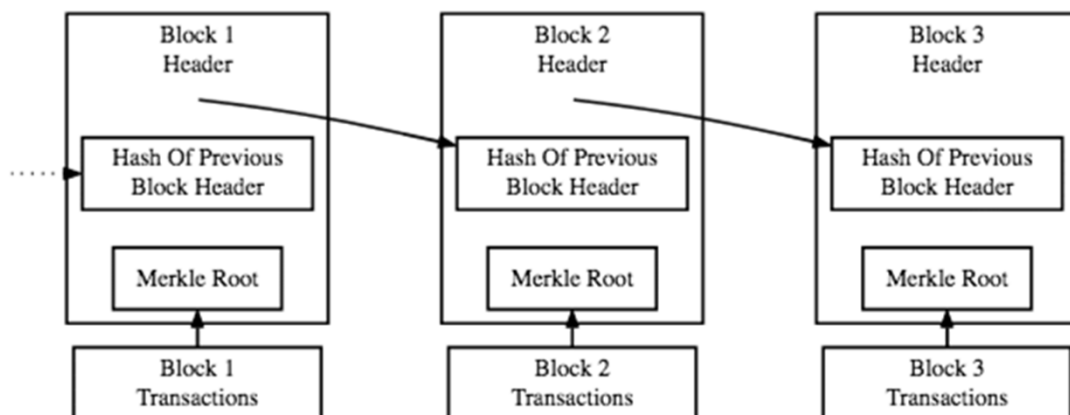
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BLOCKCHAIN USES CRYPTOGRAPHY (HASHES)



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BLOCKCHAIN USES HASHES TO CONNECT BLOCKS



This technology makes the information immutable / very resistant to change.

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BLOCKCHAIN USES DISTRIBUTION OF HOSTS (NODES)

Centralized



Decentralized



Distributed Ledgers



- Users (●) are anonymous

- Users (●) are not anonymous

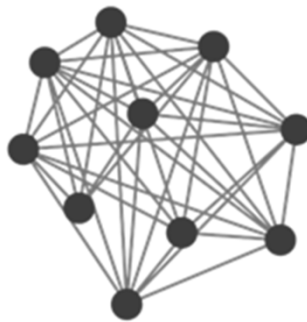
What happens when the server is down?

A copy of the information is distributed to the entire network. There is no single source of failure.

Block Geeks (2018)

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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.
altcoins own
I phones

Block Geeks (2018)

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EXAMPLES OF BLOCKCHAIN PLATFORMS

- | | | |
|--------------|---------------|------------------------------------|
| ✓ Bitcoin | ✓ Hyperledger | 95% of U.S. adults own cell phones |
| ✓ Ethereum | ✓ Multichain | |
| ✓ Monero | ✓ Credits | 77% own smart phones |
| ✓ Dash | ✓ Stellar | |
| ✓ Corda | ✓ Hydrachain | |
| ✓ BigChainDB | ✓ Iota | |

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SMART CONTRACTS ON THE BLOCKCHAIN

Programs that execute a code-based agreement. Offer:

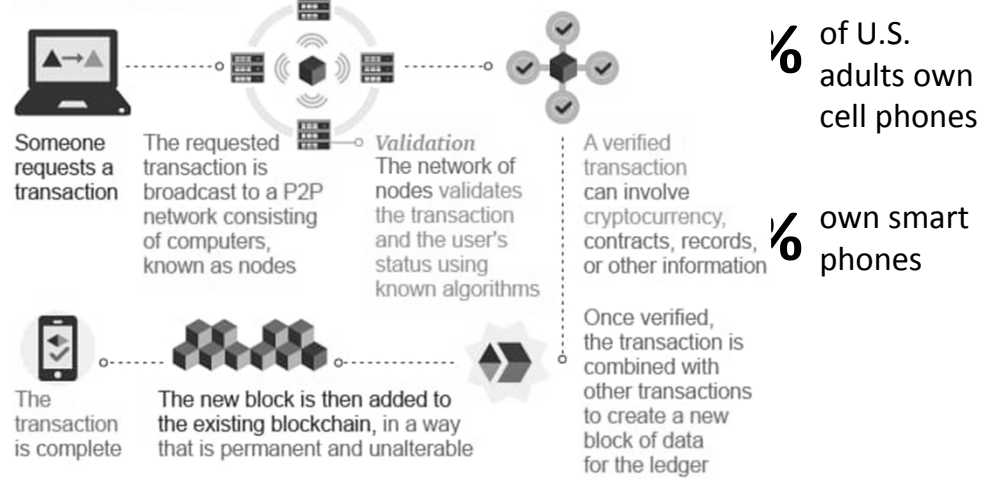
- ✓ Automation
- ✓ Accuracy
- ✓ Transparency
- ✓ Security
- ✓ Speed



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BLOCKCHAIN PROCESS FOR HEALTHCARE

How it works



PriceWaterhouseCooper (2018)

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USE CASES for CLINICAL RESEARCH

- DATA INTEGRITY
- MEDICAL RECORDS
- PAYMENTS

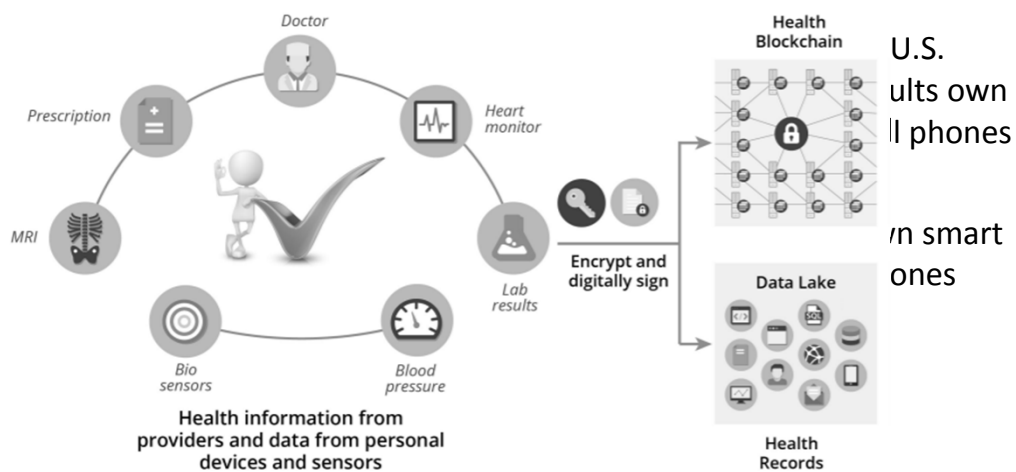
DATA INTEGRITY – PROOF OF EXISTENCE



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

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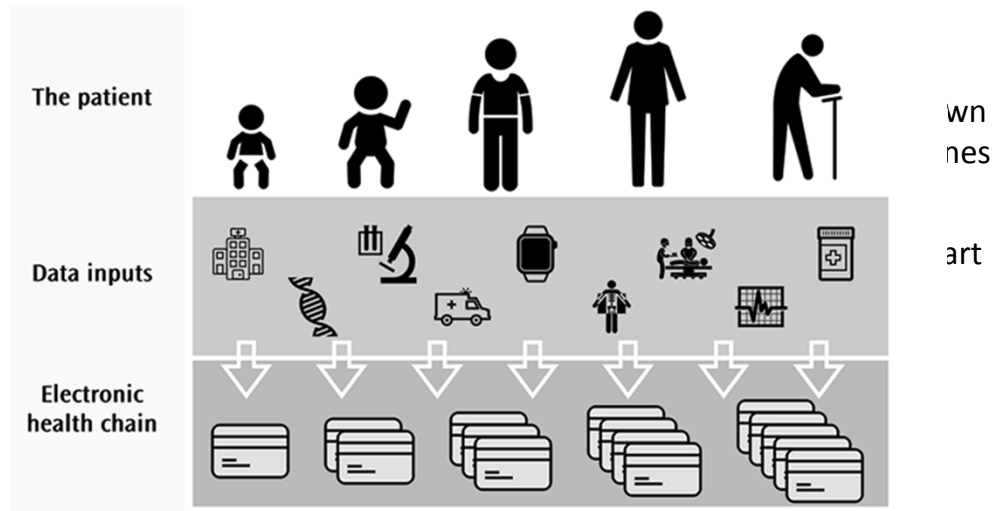
SECURING RESEARCH RECORDS



Linn & Koo (2018)

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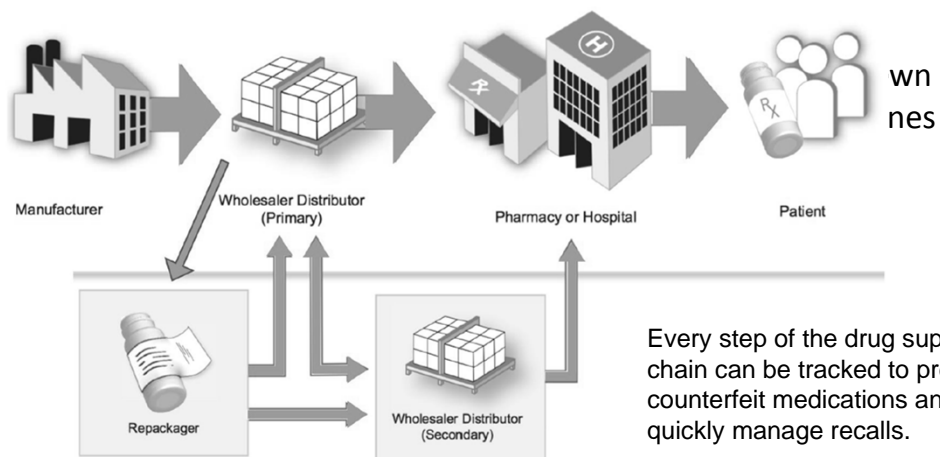
STORING HEALTHCARE DATA



American College of Surgeons (2017)

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MEDICATION SUPPLY CHAIN TRACKING

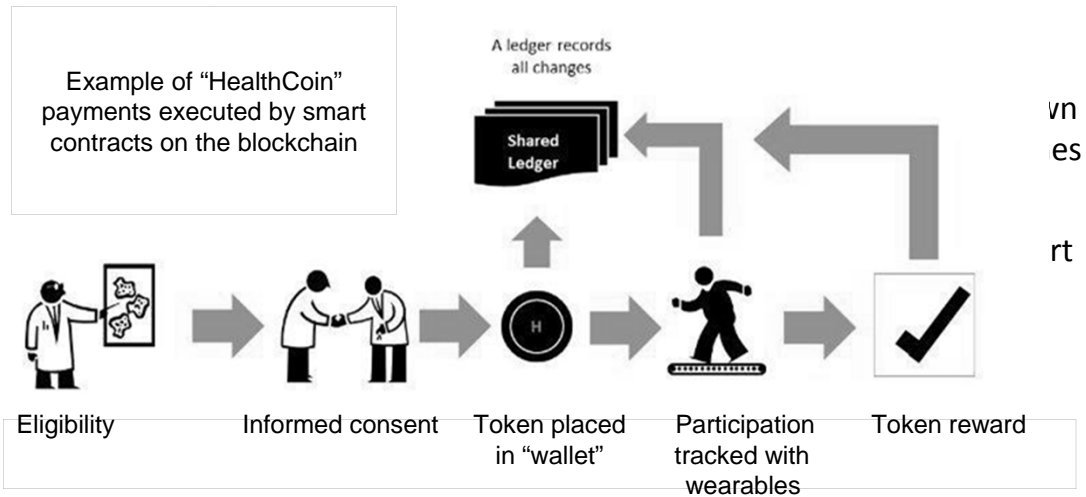


Every step of the drug supply chain can be tracked to prevent counterfeit medications and quickly manage recalls.

Sandner (2017)

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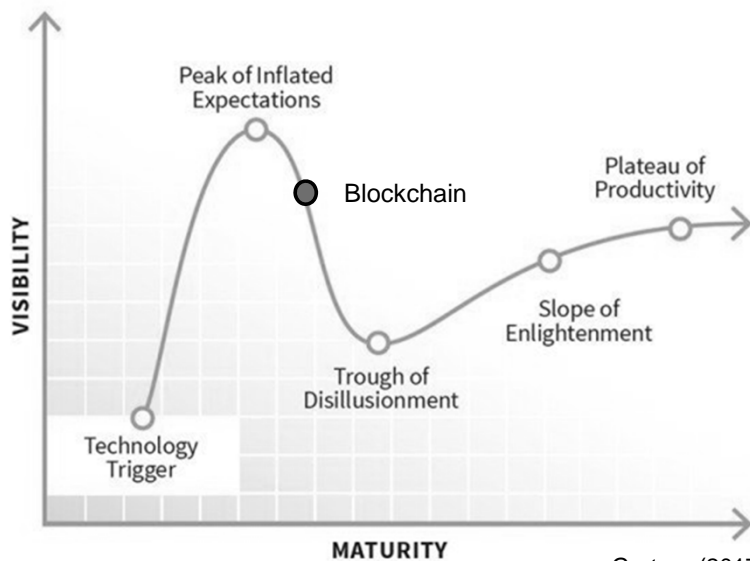
SMART CONTRACTS FOR RESEARCH PAYMENTS



IBM (2018)

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HOW MUCH IS HYPE AND HOW MUCH IS REALITY?



Gartner (2017)

15% Hospitals ready to deploy blockchain

45% Looking into blockchain

Healthcare IT News (2018)

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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)

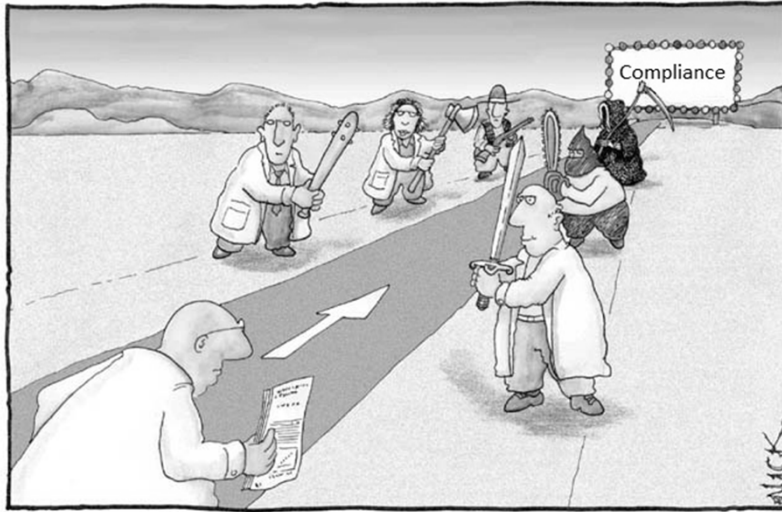
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RISKS and CHALLENGES



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COMPLIANCE IS CHALLENGING – MOSTLY UNKNOWN



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BLOCKCHAIN: LEGAL RISKS

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



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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



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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"?

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BLOCKCHAIN: FDA 21 CFR, PART 11

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



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COMPLIANCE SOLUTIONS

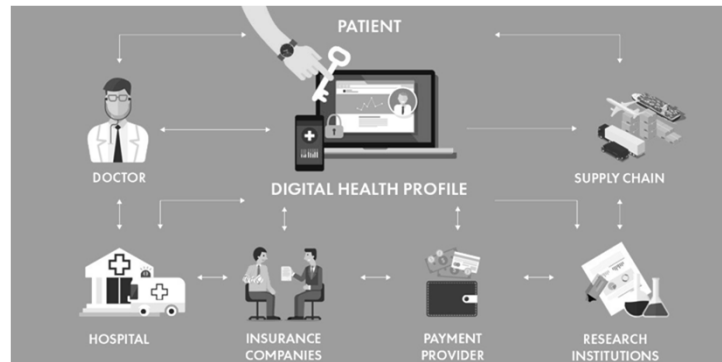


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LEGAL CONSIDERATIONS

ASK the Sponsor or Vendor:

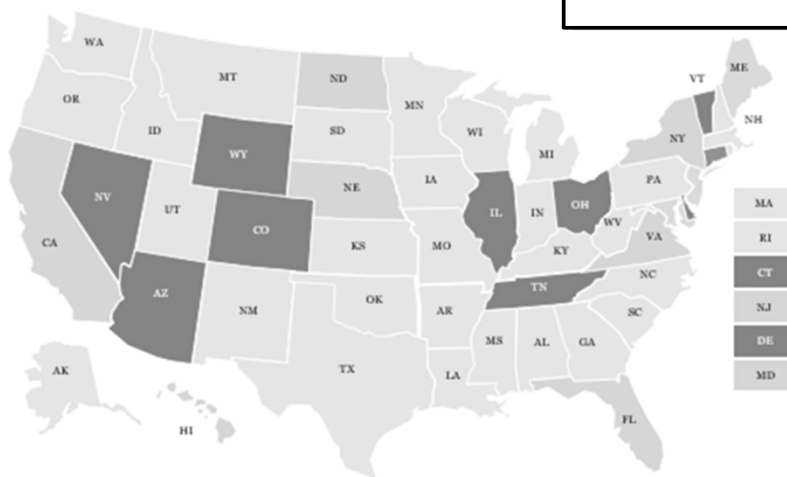
- ✓ Are there smart contracts?
- ✓ What is legality of smart contracts and authentication in your state?



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STATES THAT PASSED OR PROPOSED BLOCKCHAIN

■ Passed blockchain legislation ■ Proposed blockchain legislation



National Journal (2018)

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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

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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**



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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?

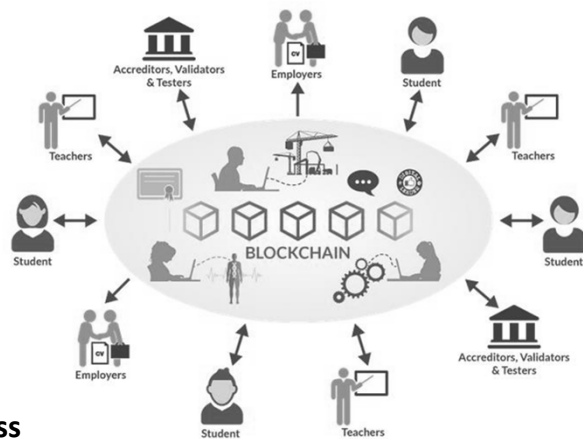


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SUBMITTING BLOCKCHAIN TECHNOLOGY TO IRB

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**



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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***

Questions?



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