Blockchain: Information Tracking

AFCEA C4I, George Mason University – 21 May 2018 Sean T Manion PhD CEO, Science Distributed Vice President, American College of Military Public Health

My Background

- Academia (Neuroscience)
 - 13 years
 - Economics, Biochemistry (BS), Psychology, Psychiatry, Neuroscience (PhD)
 - Temple University, Uniformed Services University of the Health Sciences, DoD, NIH
- Government Research Administration (Bureauscience)
 - 8 years
 - Deputy Chief of Staff, Research Activities Chief
 - Defense & Veterans Brain Injury Center, w/ DoD, VA, ED, HHS (NIH, CDC, FDA)
 - 17 sites, 60+ clinical studies, 100+ clinical researchers, 300+ publications
- American College of Military Public Health Non-profit/Volunteer (Vice President)
- Startup Science Distributed (Platform for Scientists, Blockchain for Trust)
 - < 1 year (feels like a lot more)

What is a Blockchain?

A <u>Blockchain</u>, a type of distributed ledger technology, is a system of <u>distributed</u> <u>databases</u> that enables the development of a permanent, tamper proof longitudinal record, irrefutable audit trail, more sophisticated data queries, and better data compiling from and data sharing among multiple parties.

It is:

<u>Safe</u> – Encryption plus public and private keys; distributed nature prevents corruption or physical disruption; no single point of failure

Inexpensive – Distributed across existing system; automatic back-up; automatic data management via smart contracts; lower maintenance and 3rd party costs

<u>Efficient</u> – Peer-to-peer data exchange; allows for sophisticated data queries; broader permissioned access to information

Blockchain is not bitcoin

- Blockchain is multi-purpose type of platform/system, like Windows OS or Mac OS
- Bitcoin is one application that can be run on that system
- There are an infinite number of different applications for blockchain beyond digital currency



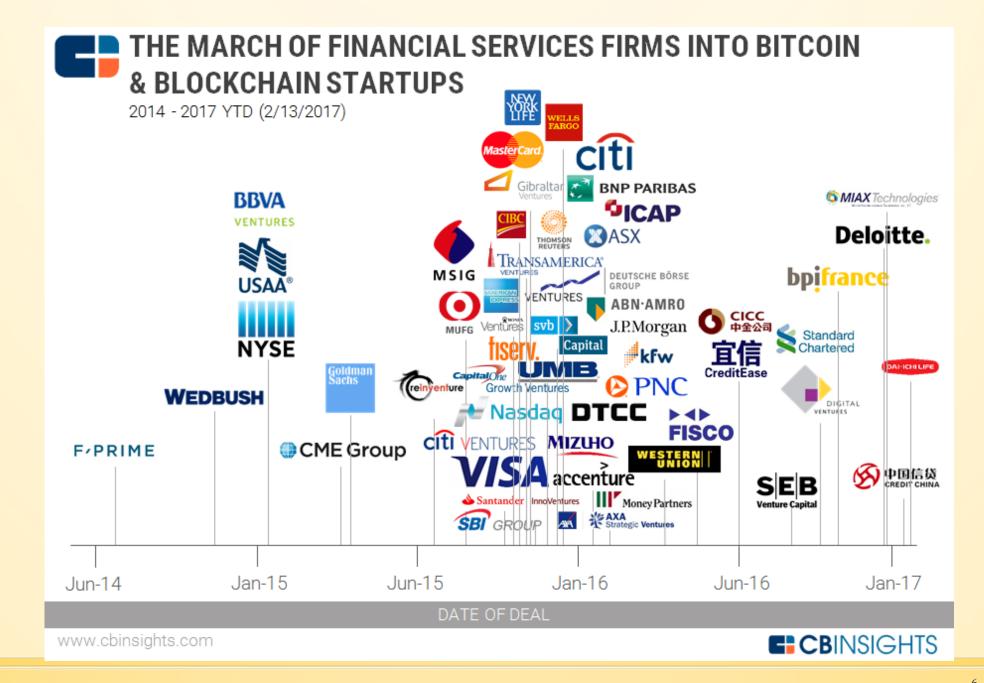
Blockchain is not hot sauce

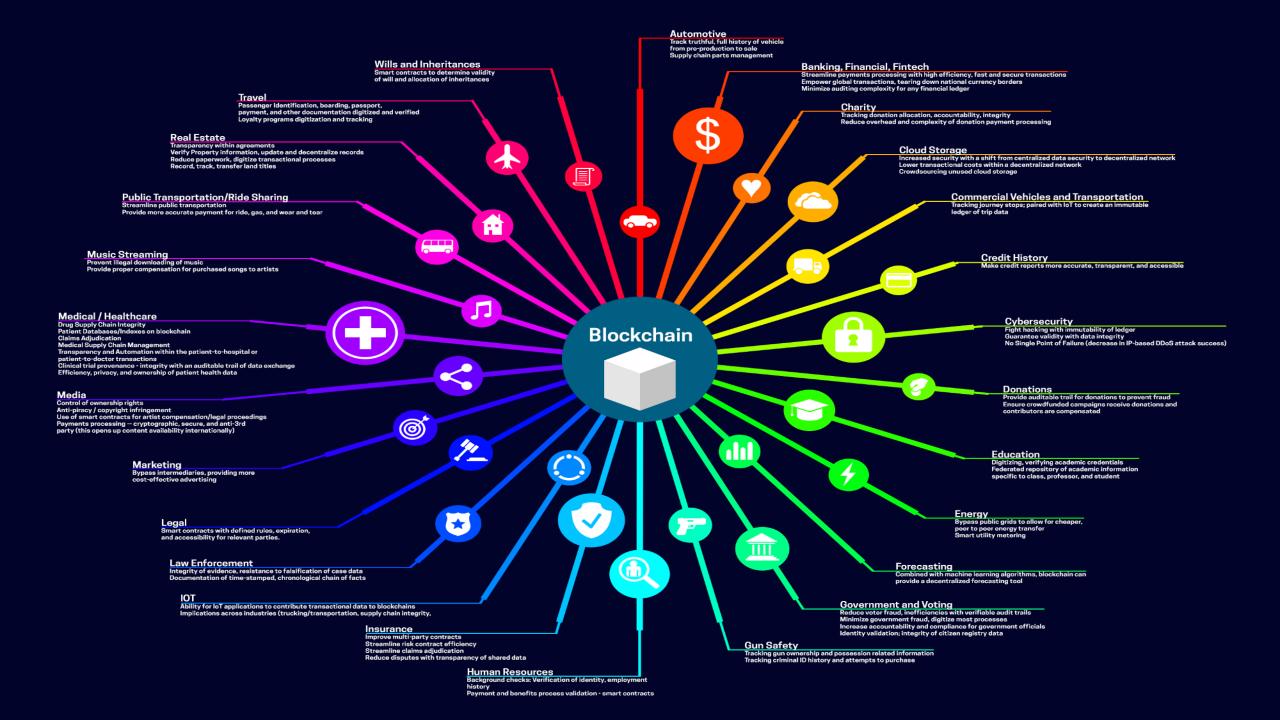


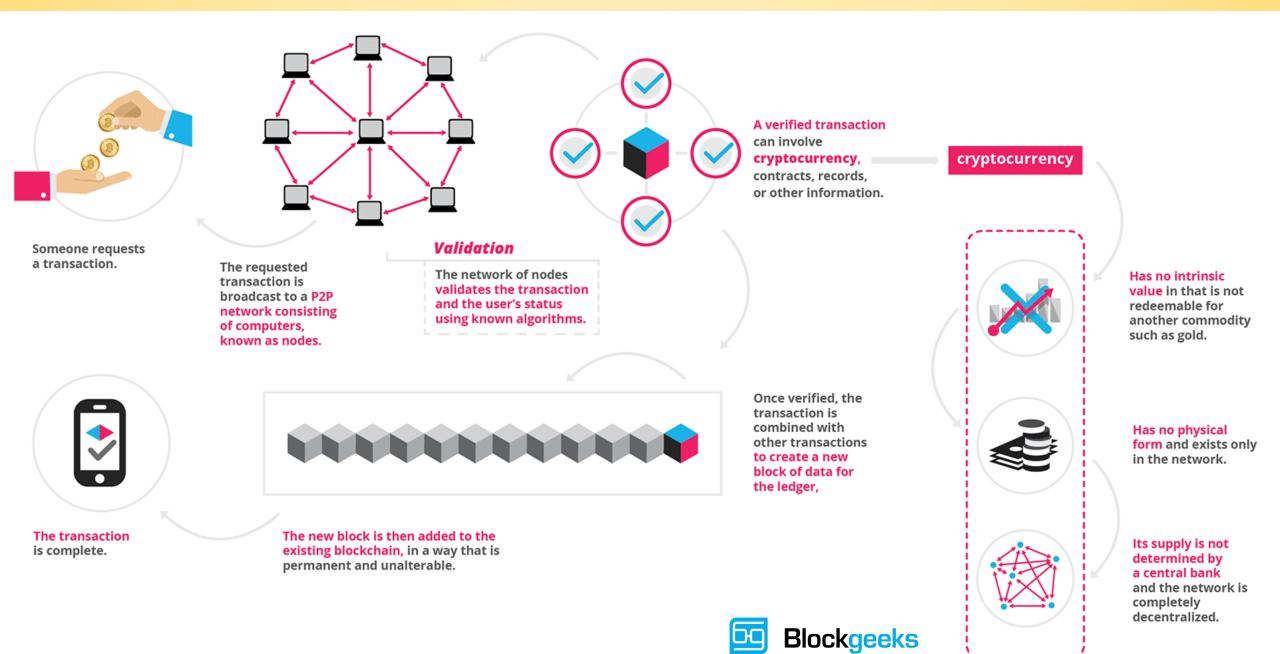
 "Blockchain isn't hot sauce, you can't just put that s*!t on everything" – Samson Williams

 Blockchain can be overkill in some applications, and may not be cost effective to implement.

 Blockchain won't solve problems with humans (e.g. lack of data standardization).







Centralized Decentralized Distributed Ledgers Image: Centralized Image: Centralized Image: Centralized

The New Networks

Distributed ledgers can be public or private and vary in their structure and size.

Public blockchains

Require computer processing power to confirm transactions ("mining")

- Users (•) are anonymous

- Each user has a copy of the legder and partipates in confirming transactions independently - Users (•) are not anonymous

- Permision is required for users to have a copy of the legder and participate in confirming transactions



BLOCKCHAIN FOR DRUG TRACEABILITY

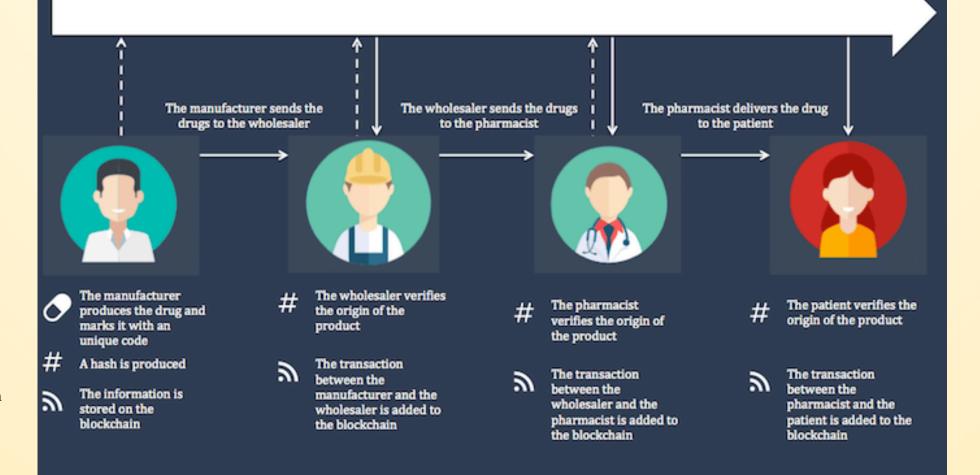


Image source: Anca Petre, http://www.anca petre.com/

Advantages

- Distributive version control: data recorded on a blockchain ledger is extremely difficult to change or remove as doing so would require changing the record on many computers
- Trust users establish their identities with one another in a secure, verified way
- Transparency
- Scaled information sharing
- Smart contract execution; data management
- Patient/end user will be in control of their data including health data via a data layer focused secure blockchain digital platform

Challenges

- Integrating blockchain within existing system
 - Higher value by integrating end to end and avoiding blockchain silos
 - Majority/monopoly risk: A majority (not 100%) of 'nodes' can confirm that a transaction is valid i.e. matches the blockchain history - the new transaction will be approved and added to the chain.
- Need to develop effective governance models among stakeholders
 - Blockchain requires new rules of participation and operation, new procedures for decision making and new decentralized governance framework
 - Regulatory development and enforcement
 - File size limitations, mitigating solutions available (e.g. side chains)
 - Conflicting commercial interests need to balanced via technology transfer agreements
- Lack of maturity of blockchain technology
 - While technology has constraints, adopting a specific approach helps to selectively implement
 - Experimental and currently slow because of verifying contracts and cross---contract communication
 - Nascent recognition as legal documentation
 - Competing platforms

Science will be Blockchained by 2025

Sean Manion - Published on January 16, 2017 (LinkedIn Pulse) https://www.linkedin.com/pulse/science-blockchained-2025-sean-manion



Distributed Science Value Proposition

- Better Science (for Scientists)
 - Problem: Reproducibility Issues
 - Solution: Improved reproducibility through transparency and immutable audit trail for research data; better quality data from standardization; improved materials; increased meta-analysis capabilities
- Cheaper Research (for Funders)
 - Problem: Expensive; decreasing ROI
 - Solution: Increased return on investment for research dollars spent; reduced data management costs through blockchain/smart contracts, amplified with machine learning/AI
- Faster Miracles (for Everyone)
 - Problem: 17 years from bench to bedside
 - Solution: Moving more quickly from bench to bedside and improved outcomes with accelerated research and higher quality data; improved tracking of individual contribution will allow for expanded permissioned access of data to more brilliant minds for faster findings; assisting with administrative applications for blockchain (e.g. IRB file process)

U.S. Investments in Medical and Health Research and Development (2015)

Breakdown by source:

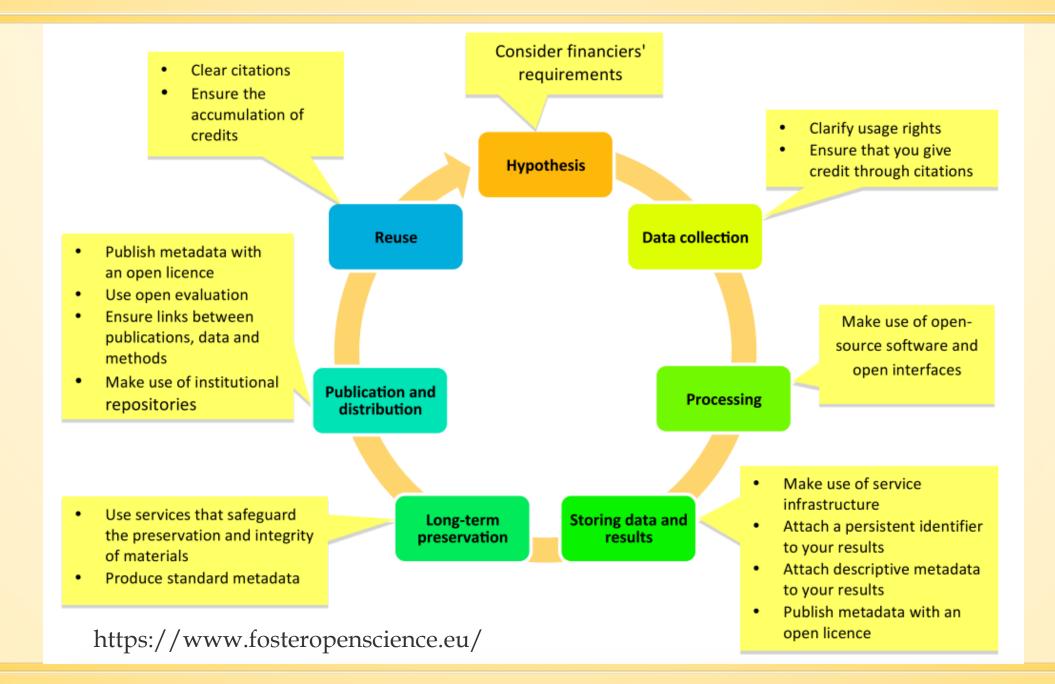
- Industry invested more in R&D than any other sector, totaling \$102.7 billion.
- Federal agencies invested a total of \$35.9 billion, with the National Institutes of Health accounting for \$29.6 billion.
- Research institutions, including universities and independent research institutes (IRIs), dedicated more than \$12.5 billion to R&D.
- Foundations contributed **\$4.7 billion** to U.S. medical and health R&D.
- Voluntary health associations, professional societies, and state and local governments invested nearly \$3 billion in medical and health R&D.

U.S. Investments in Medical and Health Research and Development (2015)

- Worldwide \$2.5 trillion annually on scientific R&D (data.oecd.org)
- Total U.S. medical and health R&D was **\$158.7 billion**.

"U.S. Investments in Medical and Health Research and Development, 2013 – 2015," Research America!

- !!!!! U.S. biomedical research that can't be replicated <u>\$28 Billion per year !!!!!!</u>
 "Economics of reproducibility in Preclinical Research" Freedman et al, PLoS 13(6) e1002165, 2015
- What amount of *clinical research* can't be replicated?



U.S. Investments in Medical and Health Research and Development (2015)

- Worldwide **\$2.5 trillion** annually on scientific R&D (data.oecd.org)
- Total U.S. medical and health R&D was **\$158.7 billion**.

"U.S. Investments in Medical and Health Research and Development, 2013 – 2015," Research America!

- Industry invested more in R&D than any other sector, totaling **\$102.7 billion**.
- Federal agencies invested a total of \$35.9 billion, with the National Institutes of Health accounting for \$29.6 billion.
- Research institutions, including universities and independent research institutes (IRIs), dedicated more than \$12.5 billion to R&D.
- Foundations contributed **\$4.7 billion** to U.S. medical and health R&D.
- Voluntary health associations, professional societies, and state and local governments invested nearly \$3 billion in medical and health R&D.
- !!!!! U.S. biomedical research that can't be replicated <u>\$28 Billion per year !!!!!!</u>
 "Economics of reproducibility in Preclinical Research" Freedman et al, PLoS 13(6) e1002165, 2015

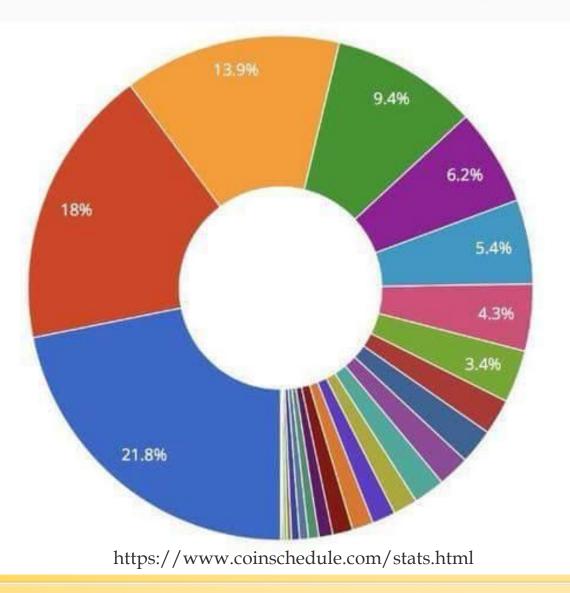


Blockchain Ecosystem

<u>Blockchain by Industry (\$500K+ ICOs 2014 – Oct 2017; Energy Collective – 135 total)</u>:

- Finance 42%
- Gaming 13
- Infrastructure 11
- Media 9
- Other 9
- Computer/Storage 5
- Browser/Social 4
- Identity/IoT 3
- Energy 2
- <u>Healthcare 2</u>

ICOs by Category 2018



Communications 21.8% (\$969,953,600) Finance 18.0% (\$799,701,539) Trading & Investing 13.9% (\$617,237,136) Gaming & VR 9.4% (\$416,049,113) Commerce & Advertising 6.2% (\$275,965,500) Payments 5.4% (\$240,025,329) Infrastructure 4.3% (\$190,628,000) Machine Learning & Al 3.4% (\$149,931,776) Energy & Utilities 2.3% (\$101,500,000) Mining 2.3% (\$100,000,000) Supply & Logistics 2.0% (\$90,166,668) Drugs & Healthcare 2.0% (\$89,178,011) Data Storage 1.6% (\$69,000,000) Privacy & Security 1.5% (\$66,793,221) Social Network 1.4% (\$60,057,000) Data Analytics 1.3% (\$57,017,078) Compliance & Security 0.9% (\$39,544,101) Transport 0.7% (\$29,500,000)

▲ 1/2 ▼



Blockchain Healthcare Ecosystem

Key Areas:

- Electronic health record, patient-centric
- Provider identity
- Payments
- Supply chain
- Pharma, Devices
- Clinical trials



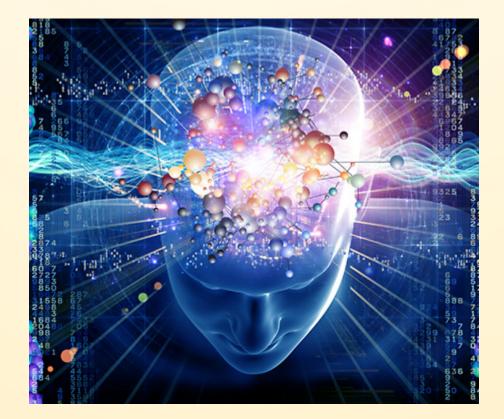
Blockchain Health Science Research Ecosystem

- Terraforming: Science Distributed
- Legacy: Nature/Digital Science/Katalysis; Wolfram Alpha (Pluto); IEEE
- Healthcare/Clin Research: Obesity PPM, Hashed Health, Genomics (Various), etc.
- Other: Atana, Co-Lab, ScienceRoot, Frankl, Ovium, Peerwith, Scientist.com
- **Journal:** Blockchain in Healthcare Today; IEEE; Ledger, Frontiers in Blockchain

Enhancing Federal Research: Traumatic Brain Injury & Blockchain Technology

By Sean Manion - March 3, 2018

http://www.fedhealthit.com/2018/03/enhancing-federal-research-traumatic-brain-injury-blockchain-technology-part-1-introduction/



Blockchain: Distributed Science Value Proposition

- Better Science (for Scientists)
 - Problem: Reproducibility Issues
 - Solution: Improved reproducibility through transparency and immutable audit trail for research data; better quality data from standardization; improved materials; increased meta-analysis capabilities
- Cheaper Research (for Funders)
 - Problem: Expensive; decreasing ROI
 - Solution: Increased return on investment for research dollars spent; reduced data management costs through blockchain/smart contracts, amplified with machine learning/AI
- Faster Miracles (for Everyone)
 - Problem: 17 years from bench to bedside
 - Solution: Faster from bench to bedside: improved outcomes, accelerated research and higher quality data; improved tracking of individual researcher contribution will allow for expanded permissioned access of data; assisting with administrative applications for blockchain (e.g. IRB file process)

Traumatic Brain Injury (TBI): Problem Area

- In 2013, about 2.8 million TBI-related emergency department (ED) visits, hospitalizations, and deaths occurred in the United States.
 - TBI contributed to the deaths of nearly 50,000 people.
 - TBI was a diagnosis in more than 282,000 hospitalizations and 2.5 million ED visits. These consisted of TBI alone or TBI in combination with other injuries.
- In 2012, an estimated 329,290 children (age 19 or younger) were treated in U.S. EDs for sports and recreation-related injuries that included a diagnosis of concussion or TBI.
 - From 2001 to 2012, the rate of ED visits for sports and recreation-related injuries with a diagnosis of concussion or TBI, alone or in combination with other injuries, more than doubled among children (age 19 or younger).

https://www.cdc.gov/traumaticbraininjury/get_the_facts.html

Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System

- FITBIR was developed to share data across the entire TBI research field
- Created in Jan 2013 by NIH, DoD
- 25 federal agencies partnered: NIH, DoD, and VA; along with One Mind
- Hosted by NIH (fitbir.nih.gov)
- Central repository for data
- Encourages data sharing, crossstudy comparison, and metaanalysis



TBI: Federal Research

- NIH <u>665 active studies</u>; **\$307 Million** (2018, NIH RePORTER)
- DoD ~300 active studies (est.); ~\$200 Million annually (est.*)

* "Report to Congress: On Expenditures for Activities on Traumatic Brain Injury and Psychological Health, Including Posttraumatic Stress Disorder, for Calendar Year 2012"

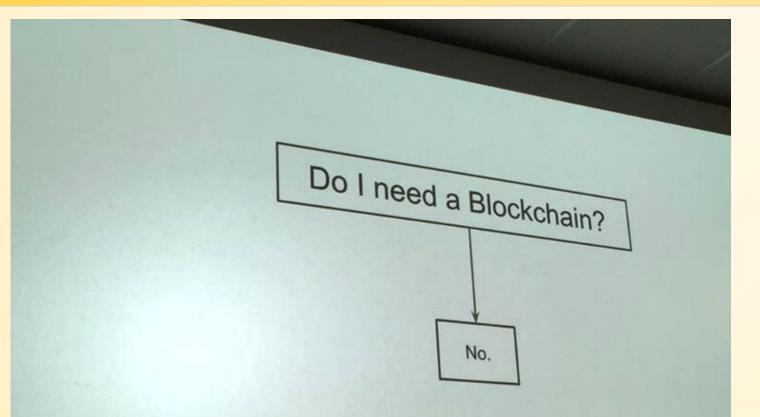
- VA <u>171 active studies</u> (2018, NIH RePORTER)
- Fed TBI Research <u>1,000+ studies</u>; **\$500+ Million annually**
- Studies in FITBIR (*https://fitbir.nih.gov/content/submitted-data*)
 - <u>125 studies committed to contribute data</u>
 - <u>78 studies submitted some data</u>
 - <u>15 studies have made data available</u> of more than 1000 federally funded TBI studies

FITBIR Challenges

- Researchers concerned with sharing data; "being scooped"
 - Limitations with tracking individual researcher contribution
- Costly for research groups to format data
 - Limitations of centralized data quality control
- Centralized access to data slow
 - Identity of requestors
 - Regulatory approval
- Limited number of Common Data Elements (CDE)
 - CDEs took 5+years to standardize by federal CDE working group
 - Additional data elements challenging to add/standardize
 - Limitations of centralized staff to approve new CDEs

How Blockchain Can Help

- Expanded data contribution tracking for individual researchers
- Auditable record of use of data by other researchers
- Data formatting automated by smart contracts
- Identity of users verifiable; automated speeding access
- Confirmation of regulatory approvals automated
- Consensus for additional data elements to facilitate expanded data elements
- Consensus for new standards driven by protocol development with experts and facilitated by automation/smart contracts and assistance by AI analysis of available literature



**Average federal scientist/ administrator perception on blockchain for research General Challenges for Blockchain in Federal Research

<u>Administrators are risk averse</u>

- Regulators are wary of the unknown
- Acquisition standards matter

Researchers are complex

- Science is a complex system
- Layered incentives; \$\$ only one
- Want input on protocols

• Developers assume simple, clean data

- Research data is messy, non-standardized
- Research partially centralized/distributed
- Central and single node intermediaries

Next Steps

For Administrators:

- Engage health regulators; sandbox approach successful in the UK
- Educate key stakeholders on the technology and processes

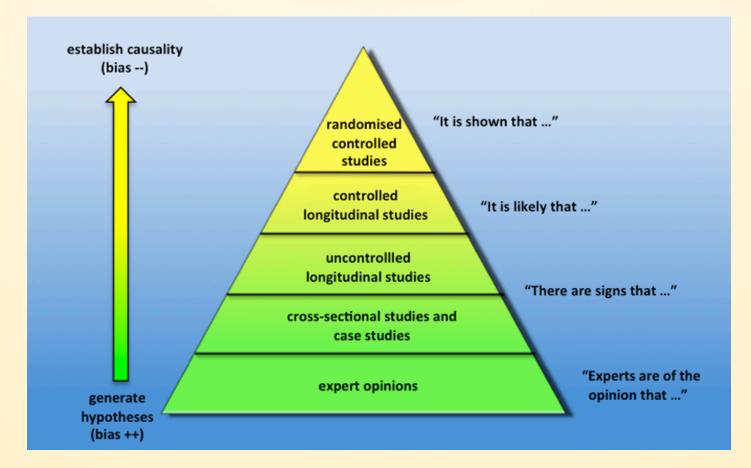
For Researchers:

- Create networks of early adopters
- Convene standards committees in key health areas

For Developers:

- Use UX design methodology to develop pilot governance protocol
- Understand complexities of health and research data

Levels of Evidence for Clinical Practice



Questions – Comments – Future Follow Up

Blockchain Healthcare Situation Report (BC/HC SITREP)

- Free weekly newsletter; curated news & events w/ commentary
- Email <u>stmanion@gmail.com</u>w/ "BC/HC SITREP" in subject line

Science Distributed Pilot Blockchain – in development

- Network, protocol, blockchain; in that order
- Email <u>stmanion@gmail.com</u> w/ statement of interest