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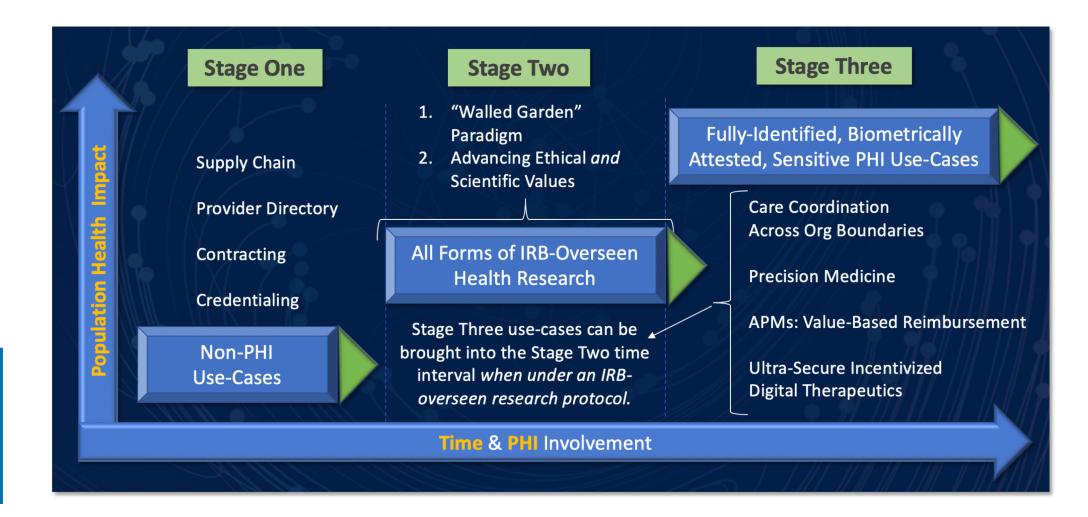




- Industry Context: Blockchain in Healthcare and Life Sciences
- Overview and Introduction: IEEE SA P2418.6 Standard Development Working Group, EMBS-Sponsored
- Overview and Introduction: Blockchain in Healthcare Global ("BiHG"),
 IEEE ISTO
- Educational Resources to Learn about Blockchain in Healthcare
- Group Discussion: EMBS Engagement and Collaboration w/P2418.6 and BiHG



Industry Context: PHI Readiness Framework





Clinical Trials: Two Contexts of Value Creation



- Incentivizing and Facilitating Participant Recruitment
- Enrollment and Consents
- Incentivizing Protocol Adherence
- Radically Improve Data Integrity, Reproducibility / Replicability
- Diminish Compliance Burden and Improve Regulatory Relations
- Real-Time Study Data Analytics
- Potential to Remunerate Investors and Data Subjects

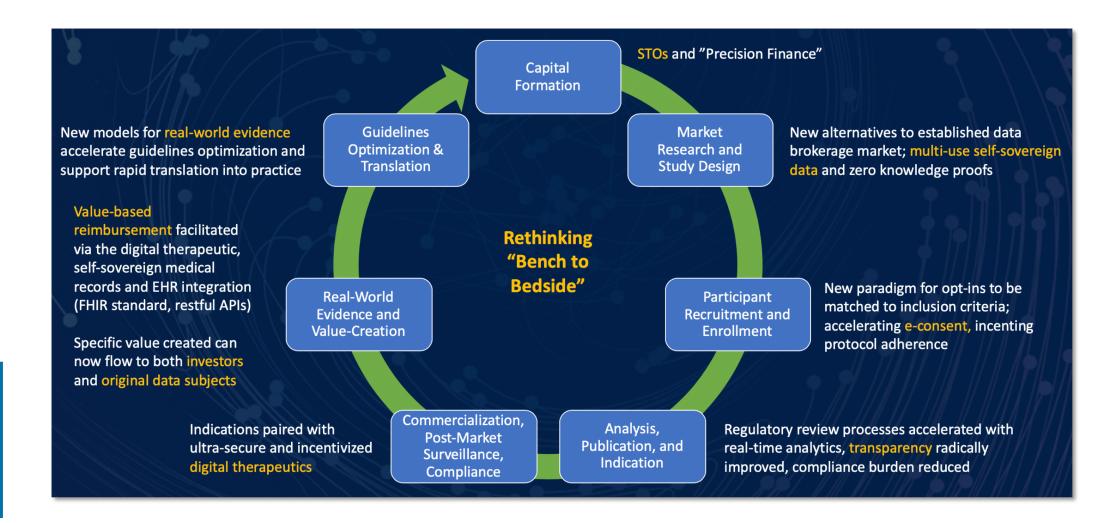
Improving Clinical Trials using Blockchain and Tokenization as Secondary End-Points

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- Answer critical Stage Three research questions, while including impact measures of blockchain and tokenization in study designs as secondary and tertiary end-points
- Gain understanding of impact and justification of use of this technology through classic empirical methods



Industry Context: Rethinking "Bench to Bedside"





Barriers to Adoption





P2419.6 Standards Dev Working Group – IEEE SA

- Prestandards and standards (P2418 family) development activities are underway in healthcare in the IEEE Standards Association (IEEE SA), including blockchain for clinical trials, blockchain and IoMT, etc. https://blockchain.ieee.org/
- P2418.6 has received internal IEEE sponsorship from the IEEE Engineering in Medicine and Biology Society (EMBS), https://www.embs.org/about-embs/ → THANK YOU!
- Harmonization with current standards and standards in development a top priority (NIST, ISO/IEC JTC 1/SC 31/WG 8, FHIR Foundation, W3C, DIF, etc.)



P2418.6 Standards Dev Working Group – IEEE SA

P2418.6: Standard for the Framework of Distributed Ledger Technology (DLT) Use in Healthcare and the Life and Social Sciences

Scope: "This standard provides a **common framework** for distributed ledger technology (DLT) usage, implementation, and interaction in healthcare and the life and social sciences, addressing scalability, security and privacy challenges. DLT tokens, smart contracts, transactions, assets, networks, off-chain data storage and access architectural patterns, and both permissioned and permission-less DLT are included in the framework."

Purpose: "The purpose of this standard is two-fold. First, it is to provide a common semantic model and framework for the usage of blockchain and DLT in healthcare and the life and social sciences, under which a body of detailed, complementary standards specific to myriad niche use-cases can be subsequently developed. Second, it is to clarify and rationalize the use of DLT in healthcare and the life and social science in concert with converging innovations relevant to the sector, including, but not limited to, the family of Artificial Intelligence (AI) and the Internet of Medical Things (IoMT), delivering healthcare-specific coordination of these adjacent standards activities."



P2419.6 Standards Dev Working Group – IEEE SA

Sub-Groups

Sub-Groups have distinct leadership (Chairs and Co-Chairs)

Sub-Groups, as their work progresses, may elect to submit their work as Sub-Standards (P2418.6.X)

Current Sub-Groups

Identity Clinical Trials

Internet of Medical Things (IoMT) Provider Directory

Cybersecurity Intellectual Property

Harmonization Development Finance for Global

Next Actions Health

Single presentation outlining the objectives, approach, deliverables, and timelines of each sub-group



Blockchain in Healthcare Global - IEEE ISTO

- Who is IEEE ISTO? Industry Standards and Technology Organization
- Who is Blockchain in Healthcare Global ("BiHG")?
 https://www.blockchaininhealthcare.global/



- Mission: to address the barriers to adoption of blockchain and converging innovations in healthcare and life sciences while advancing progress in scientific reproducibility, medical ethics, human rights, and global inclusion.
- Corporate, Academic, Government, Non-Profit Affiliate, and Individual Membership Categories



Blockchain in Healthcare Global - IEEE ISTO



Activity Areas



Industry Advocacy and Organization

Develop and Advocate for Policy, Regulation, and Legislation

Initiate and Organize Industry Self-Regulation

Industry
Education and
Advancement

Deliver Healthcare Focused Professional Education Propagate Emerging
Standards and
Administer Certifications

Consortia-Specific Professional and Technical Services

Services are available only to organizational members; separate, fully-customized agreements with distinct scope and pricing are required.

Administer
Multiple Categories of
Sector-Wide Research

Manage
Consortia-Specific
Platforms and Products

Administer
Consortia-Specific
Governance Operations

Operate and Secure Consortia-Specific Infrastructure

Blockchain in Healthcare Global - IEEE ISTO



Activity Areas



- BiHG is not a standards <u>development</u> organization.
- · BiHG will support the
 - propagation of standards,
 - develop certifications and attestations of conformity to standards,
 - provide education on standards, and
 - develop and advocate for health policy that incorporates standards.

Educational Resource

- HIMSS Task Force Collaboration: Nine Co-Authors
- Published March 23rd 2018
- Peer-Reviewed <u>Open</u> Journal Publication in the journal *Blockchain in Healthcare Today*
 - https://blockchainhealthcaretoday.com
- Highest download rate to date among all articles in the journal
- New publications in production by Task Force





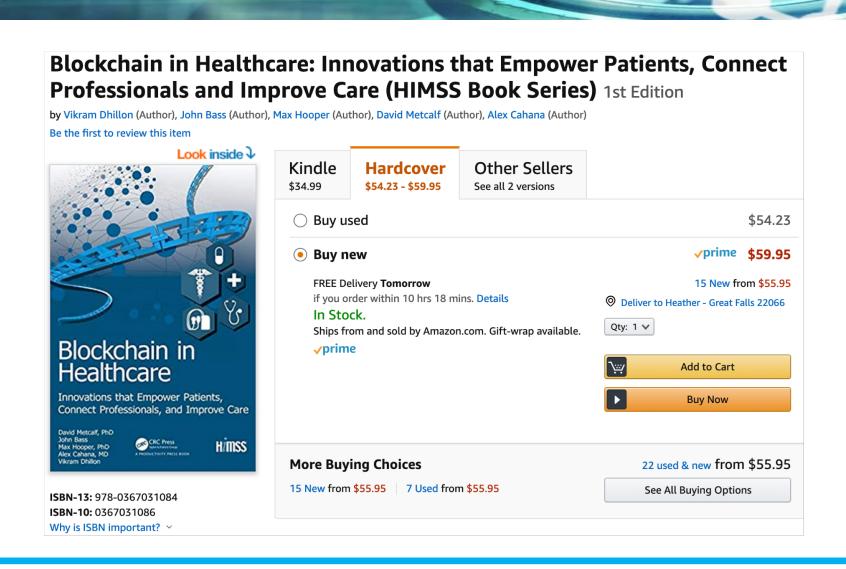
https://doi.org/10.30953/bhty.v1.24

Educational Resource

Published Feb 2019

Chapter 16 (Standards) contributed by Heather Flannery





Group Discussion: EMBS Engagement





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