Update on IEEE SA P2418.6 Standards Development Working Group: Blockchain in Healthcare

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Chair, P2418.6 Standards Development Working Group, IEEE SA
Chair, Blockchain in Healthcare Global (BiHG), IEEE ISTO
Chair, Enterprise Ethereum Alliance (EEA) Healthcare SIG
Co-Chair, HIMSS Global Blockchain Task Force
Agenda

• 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

Stage One
- Supply Chain
- Provider Directory
- Contracting
- Credentialing
- Non-PHI Use-Cases

Stage Two
1. “Walled Garden” Paradigm
2. Advancing Ethical and Scientific Values

Stage Three
- Fully-Identified, Biometrically Attested, Sensitive PHI Use-Cases
  - Care Coordination Across Org Boundaries
  - Precision Medicine
  - APMs: Value-Based Reimbursement
  - Ultra-Secure Incentivized Digital Therapeutics

Population Health Impact

All Forms of IRB-Overseen Health Research

Stage Three use-cases can be brought into the Stage Two time interval when under an IRB-overseen research protocol.

Time & PHI Involvement
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

1. Improving Clinical Trials using Blockchain and Tokenization
2. Impact of Blockchain and Tokenization as Secondary End-Points

- 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”

New models for real-world evidence accelerate guidelines optimization and support rapid translation into practice.

Value-based reimbursement facilitated via the digital therapeutic, self-sovereign medical records and EHR integration (FHIR standard, restful APIs).

Specific value created can now flow to both investors and original data subjects.

Indications paired with ultra-secure and incentivized digital therapeutics.

STOs and “Precision Finance”

New alternatives to established data brokerage market; multi-use self-sovereign data and zero knowledge proofs.

Rethinking “Bench to Bedside”

Capital Formation

Market Research and Study Design

Participant Recruitment and Enrollment

Analysis, Publication, and Indication

Commercialization, Post-Market Surveillance, Compliance

Real-World Evidence and Value-Creation

Guidelines Optimization & Translation

New paradigm for opt-ins to be matched to inclusion criteria; accelerating e-consent, incenting protocol adherence.

Regulatory review processes accelerated with real-time analytics; transparency radically improved, compliance burden reduced.

Advancing Technology for the Benefit of Humanity
Barriers to Adoption

Presented in no order:

- Education
- Policy, Regulation, and Legislation
- Compliance
- Governance
- Ethics
- Trust
- Capital Formation
- Financial Forecasting
- Standards and Certifications
- Cybersecurity
- Heuristics
- Interoperability
- Scalability
- Identity
- Offchain Data
- Access

Advancing Technology for the Benefit of Humanity
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/](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/](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: 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.”
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
Internet of Medical Things (IoMT)
Cybersecurity
Harmonization

Clinical Trials
Provider Directory
Intellectual Property
Development Finance for Global Health

Next Actions

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

<table>
<thead>
<tr>
<th>Industry Advocacy and Organization</th>
<th>Develop and Advocate for Policy, Regulation, and Legislation</th>
<th>Initiate and Organize Industry Self-Regulation</th>
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<tbody>
<tr>
<td>Industry Education and Advancement</td>
<td>Deliver Healthcare Focused Professional Education</td>
<td>Propagate Emerging Standards and Administer Certifications</td>
</tr>
<tr>
<td>Consortia-Specific Professional and Technical Services</td>
<td>Administer Multiple Categories of Sector-Wide Research</td>
<td>Administer Consortia-Specific Governance Operations</td>
</tr>
<tr>
<td>Services are available only to organizational members; separate, fully-customized agreements with distinct scope and pricing are required.</td>
<td>Manage Consortia-Specific Platforms and Products</td>
<td>Operate and Secure Consortia-Specific Infrastructure</td>
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</table>
Activity Areas

• BiHG is not a standards *development* 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 Open 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
Blockchain in Healthcare: Innovations that Empower Patients, Connect Professionals and Improve Care (HIMSS Book Series) 1st Edition

by Vikram Dhillon (Author), John Bass (Author), Max Hooper (Author), David Metcalf (Author), Alex Cahana (Author)

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Group Discussion: EMBS Engagement

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