

P2418.6

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Type of Project: New IEEE Standard

PAR Request Date: 27-Jul-2018

PAR Approval Date: 27-Sep-2018

PAR Expiration Date: 31-Dec-2022

Status: PAR for a New IEEE Standard

1.1 Project Number: P2418.6

1.2 Type of Document: Standard

1.3 Life Cycle: Full Use

2.1 Title: Standard for the Framework of Distributed Ledger Technology (DLT) Use in Healthcare and the Life and Social Sciences

3.1 Working Group: Blockchain and Distributed Ledger Technology(DLT) in Health (EMB/Std Com/BDLTH WG)

Contact Information for Working Group Chair

Name: Heather Flannery

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Contact Information for Working Group Vice-Chair

None

3.2 Sponsoring Society and Committee: IEEE Engineering in Medicine and Biology Society/Standards Committee (EMB/Std Com)

Contact Information for Sponsor Chair

Name: Carole Carey

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Contact Information for Standards Representative

None

4.1 Type of Ballot: Individual

4.2 Expected Date of submission of draft to the IEEE-SA for Initial Sponsor Ballot: 05/2019

4.3 Projected Completion Date for Submittal to RevCom

Note: Usual minimum time between initial sponsor ballot and submission to Revcom is 6 months.: 02/2020

5.1 Approximate number of people expected to be actively involved in the development of this project: 50

5.2 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.

5.3 Is the completion of this standard dependent upon the completion of another standard: No

5.4 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.

5.5 Need for the Project: Globally, healthcare and the life and social sciences are comprised of a highly diverse set of stakeholders characterized by divergent and often directly competing interests. These organizational and individual stakeholders function within an increasingly complex and technologically reliant system, with exponentially growing volumes of minimally-interoperable health data and rapidly increasing cybersecurity threat vectors, attack frequency, and severity. Profound disparities in access to healthcare, population health outcomes, and social determinants of health are well established in the literature both qualitatively and quantitatively. While standards alone cannot resolve the full scope of these challenges, they can meaningfully mitigate a number of risks and barriers to adoption of blockchain and DLT in this sector, and accelerate incremental progress.

5.6 Stakeholders for the Standard: Stakeholders to the standard are in several macro-level categories, all of which are global. First, all

organizations and individuals involved in healthcare delivery (all health systems, hospitals, clinics, providers, health administrators, everyone involved in health information technology, health policy, healthcare law and compliance, etc.) are stakeholders. Second, all entities and individuals, public and private, that pay for healthcare services, and for public services that influence social determinants of health and therefore healthcare costs (every government of the world, all philanthropic donors supporting healthcare delivery causes, all health insurance companies, all employers who pay for the costs of healthcare for their employees, every taxpayer whose contributions cover healthcare expenditures), are stakeholders. Third, all entities, public and private, that research, discover, develop, translate, regulate, commercialize, and distribute, pharmaceuticals, medical devices, and other medical technologies, are stakeholders. Fourth, all established and emerging information technology corporations producing products, services, solutions, platforms, and tools targeted at the blockchain space and utilizable or appropriate for healthcare and the life and social sciences are stakeholders. Last, but most definitely not least: every human being is a patient, and most are loved ones or caregivers to other patients at some point. The healthcare delivery infrastructure to which we have meaningful access impacts all of us - our friends, families, and communities -- both positively and negatively through its unique acts and omissions.

Intellectual Property

6.1.a. Is the Sponsor aware of any copyright permissions needed for this project?: No

6.1.b. Is the Sponsor aware of possible registration activity related to this project?: No

7.1 Are there other standards or projects with a similar scope?: No

7.2 Joint Development

Is it the intent to develop this document jointly with another organization?: No

8.1 Additional Explanatory Notes: