Transforming for Digital Medicine
Industry Connections Activity Initiation Document (ICAID)
Version: 2.0, MAY 15, 2021
IC19-003-02 Approved by the IESS SMDC 14 June 2021

Name Change: TRANSFORMING FOR DIGITAL MEDICINE

We are in the midst of a true "digital transformation." The ICAID initial processes laid an important foundation for generating our future work. Via various new groups in the "Digital Medicine" space, we formed a "melting pot" of experts representing a very broad range of expertise – from clinical medicine, to cloud, to "AI," to medical imaging, to precision medicine, to health data policy, state-of-the-art database experts, and leading technologies for patient controls of personal health data. Along this journey, relationships and ideas were formed that lay an important foundation for our highly multi-disciplinary group. This group is a foundation for optimal and needed thought-leadership and education by the growing ICAID "Transforming for Digital Medicine" group.

Instructions

- Instructions on how to fill out this form are shown in red. It is recommended to leave the instructions in the final document and simply add the requested information where indicated.
- Shaded Text indicates a placeholder that should be replaced with information specific to this ICAID, and the shading removed.
- Completed forms, in Word format, or any questions should be sent to the IEEE Standards Association (IEEE SA) Industry Connections Committee (ICCom) Administrator at the following address: industryconnections@ieee.org.
- The version number above, along with the date, may be used by the submitter to distinguish successive updates of this document. A separate, unique Industry Connections (IC) Activity Number will be assigned when the document is submitted to the ICCom Administrator.

1. Contact
Provide the name and contact information of the primary contact person for this IC activity. Affiliation is any entity that provides the person financial or other substantive support, for which the person may feel an obligation. If necessary, a second/alternate contact person's information may also be provided.

Name: Moira Schieke
Email Address: moira@cubismi.com
Employer: Cubismi, Inc.
Affiliation: Cubismi, Inc.

IEEE collects personal data on this form, which is made publicly available, to allow communication by materially interested parties and with Activity Oversight Committee and Activity officers who are responsible for IEEE work items.

2. Participation and Voting Model
Specify whether this activity will be entity-based (participants are entities, which may have multiple representatives, one-entity-one-vote), or individual-based (participants represent themselves, one-person-one-vote).

3. Purpose

3.1 Motivation and Goal
Briefly explain the context and motivation for starting this IC activity, and the overall purpose or goal to be accomplished.

The "Transforming for Digital Medicine" (TFDM) group seeks to create a series of thought-leadership whitepapers on key topics for creating a patient-centric digital transformation that optimally protects and serves the interests of patients.   The group will seek consensus and intellectual contribution by collaborating with various public and private organizations, including leading digital medicine organizations, using a participatory design model. The specific organizations may change from paper to paper, but all of the work will be driven by the goals of the TFDM Group.

The potential impact of Digital Medicine is enormous and is advancing new interfaces between traditional medicine, technology, and engineering. High variety heath data can be now be collated in the Cloud and precision analytics can offer insights into the human body not possible before. This technology has the potential to solve massive current problems in our healthcare systems, such as high rates of diagnostic error as well as launch a leap forward for precision diagnostics for far earlier detection of disease and precision treatment choices personalized for each patient. New Cloud, Big Data, and "AI" technologies are a new frontier for medicine that are poised to propel a future of precision medicine and value-based care.

However, the potential economic power of the health data needed to power new Digital Medicine technologies is also massive. It now represents a $7.2 trillion dollar worldwide market and a $3.5 trillion US market. In many areas of the world, there is felt to be overrepresentation of industry on topics of ethical use of patient data. The impact of this imbalance is a misalignment of stakeholder interests with patient data being used in ways not in the interests of patients and healthcare providers. It is impeding the potential impact of new Digital Medicine technology for patients.

The Digital Medicine group seeks to "level the playing field" for all stakeholders in this important conversation on how to create an optimal ecosystem to serve the potential benefits for each individual patient, and thus global public health and society at large.

Given the demonstrated excellence of IEEE in successful participatory design systems and process, the TFDM group feels the IEEE is the perfect "anchor" upon which to build participation amongst multiple external and newer organizations around topics of Digital Medicine and Health Data. This creates the perfect conduit for creation of respected and credible global intellectual content on the topic of positive transformation for Digital Medicine and global economics to foster better alignment between the various stakeholders' interests and goals.

The goal of this consortium is to use a participatory design process to assist in the development of whitepapers on the general topic of creation of an optimal patient-centric technology ecosystem for the evolution of Digital Medicine technology. In this ecosystem, each and every individual will retain the ability to freely and knowingly participate and substantially contribute to the ecosystem. A key component for a fair ecosystem thus includes protection of core individual digital rights. Many new technologies are enabling patient-centric systems for patient data management and data sharing, a critical need for public health. Many additional important topics

could be explored by the TFDM group relevant to the topic of optimal transformation which the group feels to be potentially most impactful. Various potential topics could include the impact of improved patient journey experiences via use of new cloud-based technologies on patient care and digital medicine quality of care endpoints.

Within this patient-centric framework, various stakeholder gains and benefits can be outlined, such as vast potential economic benefits from use of state-of-the-art self-sovereign identity technology. An ecosystem is possible that creates enormous economic windfall for stakeholders, while maintaining the integrity of patient-centric technology and systems. Given the excellence of both the IEEE participatory design processes, a consortium between these organizations provides excellent core processes and governance infrastructure to assure the integrity of a participatory design process for production of whitepapers on these topics and for these outlined purposes.

3.2 Related Work
Provide a brief comparison of this activity to existing, related efforts or standards of which you are aware (industry associations, consortia, standardization activities, etc.).

Recent and related work and achievements include:

- ○ Last-stage development of the IEEE 2673 standard for a patient-centric "Internet of Bodies" public database ecosystem for patient data.
- ○ Growth of a potential TFDM ICAID partner, MyData Health, to 182 members.
- ○ Traction for growth with other digital health not-for-profit organizations
- ○ On-going work in the Trust Over IP Foundation to create interoperable medical records, record verification techinques, and patient-centric ecosystems

3.3 Previously Published Material
Provide a list of any known previously published material intended for inclusion in the proposed deliverables of this activity.

3.4 Potential Markets Served
Indicate the main beneficiaries of this work, and what the potential impact might be.

The global healthcare economy is $7.2 trillion dollars, the US healthcare economy is $3.5 trillion dollars, and the European healthcare market is approximately $200 billion. The economic value of health data globally is massive. The Digital Health market is expected to reach $228B by 2025.

3.5 How will the activity benefit the IEEE, society, or humanity?

This activity supports IEEE's goal of advancing technology for humanity by addressing the digital rights and health interests of patients through an inclusive and participatory process that takes into consideration the voices of patients, practitioners, and technologists, as well as industry. Additionally, this work will help inform standards processes for smaller standards committees. It will generate thought leadership whitepapers to educate healthcare leadership on new technologies and to influence adoption of patient-centric designs to best support their goals and interests, as well as optimally align with larger societal inetrests.

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4. Estimated Timeframe

Indicate approximately how long you expect this activity to operate to achieve its proposed results (e.g., time to completion of all deliverables).

Expected Completion Date: 06/2023.

IC activities are chartered for two years at a time. Activities are eligible for extension upon request and review by ICCom and the responsible committee of the IEEE SA Board of Governors. Should an extension be required, please notify the ICCom Administrator prior to the two-year mark.

5. Proposed Deliverables

Outline the anticipated deliverables and output from this IC activity, such as documents (e.g., white papers, reports), proposals for standards, conferences and workshops, databases, computer code, etc., and indicate the expected timeframe for each.

Proposed whitepaper titles:

- Patient-Centric Digital Medicine: The potential value of technologically transformed experience from the perspective of Breast Cancers patients.
- Patient-Centric Digital Medicine: The potential financial return for healthcare systems for use of self-sovereign identity technology.
- Patient-Centric Digital Medicine: The potential financial return for healthcare systems from improved patient experience.
- Whitepaper titles will be determined through the TFDM group participatory design process.

Activities that result in prototypes or templates rather than papers:

Overlays Capture Architecture (OCA) overlays for each of the FHIR resources (Working group within the Trust Over IP Foundation)
Digital medicine ecosystem prototype (Working group within the Trust Over IP Foundation)

5.1 Open Source Software Development

Indicate whether this IC Activity will develop or incorporate open source software in the deliverables. All contributions of open source software for use in Industry Connections activities shall be accompanied by an approved IEEE Contributor License Agreement (CLA) appropriate for the open source license under which the Work Product will be made available.

CLAs, once accepted, are irrevocable. Industry Connections Activities shall comply with the IEEE SA open source policies and procedures and use the IEEE SA open source platform for development of open source software. Information on IEEE SA Open can be found at https://saopen.ieee.org/.

Will the activity develop or incorporate open source software (either normatively or informatively) in the deliverables?: No

The papers written as a result of this collaboration will be made available under the Creative Comments Attribution-Non-Commercial-ShareAlike (CC BY-NC-SA) license. This license allows other parties to use and derive from our work for non-commercial purposes, but forces them to licesnse any such derived work under the same terms as the original work.

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6. Funding Requirements

Outline any contracted services or other expenses that are currently anticipated, beyond the basic support services provided to all IC activities. Indicate how those funds are expected to be obtained (e.g., through participant fees, sponsorships, government or other grants, etc.). Activities needing substantial funding may require additional reviews and approvals beyond ICCom.

The TFDM group expects costs for scribes and proven professional writers to attend working group meetings and help build text from group edits and commentary, as well as PR work to recruit new members, projected to cost $500.00 per month.

The Activity will offset costs by seeking support from outside contributors via targeted sponsorships and events (https://www.mydatahealth.org/events-meetings).

In addition, we request support from the IEEE marketing arm to publicize and distribute the group-generated whitepapers.

7. Management and Procedures

7.1 Activity Oversight Committee

Indicate whether an IEEE Standards Committee or Standards Development Working Group has agreed to oversee this activity and its procedures.

Has an IEEE Standards Committee or Standards Development Working Group agreed to oversee this activity?: No

If yes, indicate the IEEE committee's name and its chair's contact information.

IEEE Committee Name: Committee Name
Chair's Name: Full Name
Chair's Email Address: who@where

Additional IEEE committee information, if any. Please indicate if you are including a letter of support from the IEEE Committee that will oversee this activity.

IEEE collects personal data on this form, which is made publicly available, to allow communication by materially interested parties and with Activity Oversight Committee and Activity officers who are responsible for IEEE work items.

7.2 Activity Management

If no Activity Oversight Committee has been identified in 7.1 above, indicate how this activity will manage itself on a day-to-day basis (e.g., executive committee, officers, etc).

The Activity will be chaired by Moira Schieke and managed as defined in the Industry C Activity Abridged Policies and Procedures.

7.3 Procedures

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Indicate what documented procedures will be used to guide the operations of this activity; either (a) modified baseline *Industry Connections Activity Policies and Procedures,* (b) Standards Committee policies and procedures accepted by the IEEE SA Standards

Board, or (c) Working Group policies and procedures accepted by the Working Group's Standards Committee. If option (a) is chosen, then ICCom review and approval of the P&P is required. If option (b) or (c) is chosen, then ICCom approval of the use of the P&P is required.

This activity will follow the Industry Connections Activity Abridged Policies and Procedures.

8. Participants

8.1 Stakeholder Communities
Indicate the stakeholder communities (the types of companies or other entities, or the different groups of individuals) that are expected to be interested in this IC activity, and will be invited to participate.

Healthcare industry including machine vendors, pharmaceutical companies, and electronic health record companies

8.2 Expected Number of Participants
Indicate the approximate number of entities (if entity-based) or individuals (if individual-based) expected to be actively involved in this activity.

Digital Medicine iCIAD group will seek > 100 participants/year representing a fair distribution of stakeholders via whitepaper working groups, roundtable and meeting discussions, and social media participation..

8.3 Initial Participants
Provide a number of the entities or individuals that will be participating from the outset. It is recommended there be at least three initial participants for an entity-based activity, or five initial participants (each with a different affiliation) for an individual-based activity.

Use the following table for an entity-based activity:

Entity	Primary Contact	Additional Representatives
Entity Name	Contact Name	Name

Use the following table for an individual-based activity:

Individual		Employer	Affiliation
Moira Schieke	Chair	Cubismi, Inc	Cubismi
Scott Whitmire			Mayo Clinic

Victoria Hailey		Vicky Hailey Group	Vicky Hailey Group
Jim St. Clair			Lumedic
Paul Knowles		Humman Colossus Foundation	Trust Over IP Foundation

8.4 Activity Supporter/Partner

Indicate whether an IEEE committee (including IEEE Societies and Technical Councils) has agreed to participate or support this activity. Support may include, but is not limited to, financial support, marketing support and other ways to help the Activity complete its deliverables.

Has an IEEE Committee agreed to support this activity?: Yes

If yes, indicate the IEEE committee's name and its chair's contact information.

IEEE Committee Name: Engineering in Medicine and Biology Society (EMBS) Standards Committee
Chair's Name: Carole Carey
Chair's Email Address: c.carey@ieee.org

Please indicate if you are including a letter of support from the IEEE Committee.

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