IEEE SA STANDARDS ASSOCIATION

Mobile Health Applications Standards & Laboratory Services

Industry Connections Activity Initiation Document (ICAID)

Version: 1.0, March 16, 2021

IC21-003-01 Approved by IESS SMDC 22 March 2021

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: Gora Datta, Fellow HL7, IEEE Senior Member, ACM Senior Member
Email Address: goradatta@ieee.org
Employer: CAL2CAL Corp., a Health Information Technology Corporation
Affiliations:

1. IEEE
   a. Advisory Board Chair IEEE SVP: Student Volunteer Program
      i. **part of 2021 IEEE Board of Directors Strategic Initiative**
   b. 1st-elected Chair IEEE Southern California Council
   c. Treasurer IEEE Orange County Section & Past Section Chair, Past Section Vice-Chair
   d. Vice-Chair, IEEE Orange County EMBS Chapter
   e. (founding) Chair IEEE Healthcare: Blockchain and AI Virtual Series 2020-21
   f. Chair IEEE SUSTECH2021 Sustainable Technologies Conference
   g. Vice-Chair IEEE SUSTECH2020
   h. Vice-Chair IEEE SUSTECH 2018

i. Secretary IEEE CoI4x: Communities of Interest
j. IEEE VoLT-2 Graduate

2. HL7
   a. Fellow
   b. International Ambassador
   c. (founding) co-Chair HL7 Mobile Health Work Group
   d. (founding) Member of Education Advisory Committee
   e. Member Devices Work Group
      i. this group works in tandem with IEEE 11073 & ISO/TC215 JWG7 (with IEC/SC 62A WG)
   f. Member Electronic Health Record (EHR) Working Group

3. ISO/TC215
   a. (inaugural) Convenor WG#10 Traditional Medicines
   b. (inaugural) Convenor AHG#4: Standards and Conformance
   c. (inaugural) Convenor TF#3: Outreach and Communications
   d. USA Delegate

4. NSF Digital Health Reviewer

5. Industry Director/PI, Smart Pandemic Management, University of California @ Berkeley

6. P3 Innovation Center, a California Non-Profit Corporation
   a. has an active IEEE Standards Special Reseller License AGREEMENT

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).

Entity-Based.

We expect both entities and individuals to participate in this activity however the voting model will be Entity-Based.

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 proliferation of Digital Health tools, including mobile health apps and wearable sensors, holds great promise for improving human health[1]. The impact of Digital Health on patient care is accelerating with the increasing adoption of mobile health apps and wearable sensors. As per US-FDA: "The broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine."

As of 2019, there are between 400,000 to 500,000[2] health, wellness and fitness apps that run on smartphones, watches, tablets, and other mobile devices, available for download from platform-specific application stores such as the Apple App Store (iOS) and Google Play (Android). This number has rapidly grown from 325,000[3] apps in 2017.

Soon we will have clinicians globally prescribing mobile health apps to patients, similar prescribing medicines or medical devices[4]. In fact, German federal government passed the Digital Healthcare Act (DVG) in Nov 2019[5] and two health apps are already officially available, as of Oct 2020, for prescription[6]. Other countries are also marching down this path.

However, before this becomes as common as prescribing a medicine or a medical device by a provider, the mobile health app needs to be safe/secure/accurate not only for the individual user/patient/family member but also for the clinician/payer/provider/regulatory community. Given the era of cybersecurity and its impact on healthcare[7], it is critical that the healthcare informatics standards community looks into this matter now.

Mobile health apps have access to highly detailed, personally identifiable and clinical information about end-users. Security and privacy are big issues, raising questions about permission control and confidentiality, as well as the integrity of the infrastructure and the individual. There is also a need to clarify how to ensure practicalities of data storage and management, availability and maintenance of the network, as well as compatibility and interoperability. [8]

However, there is no established standardized global mobile health app certification process in existence. It is a possibility that we will see a proliferation of non-standardized, country-specific, siloed certification processes being established over the next few years. We are already seeing efforts[9] in this area.

Besides establishing a certification and associated conformity assessment process for mobile health apps, a need is also envisaged for establishing a global Mobile Health App Registry.

[1] https://www.fda.gov/medical-devices/digital-health

[2] https://research2guidance.com/hipaa-gdpr-and-connected-health-interview-with-jovan-stevovic-ceo-of-chino-io/

[3] https://research2guidance.com/325000-mobile-health-apps-available-in-2017/

[4] https://www.medicaleconomics.com/news/finding-mobile-health-apps-work-doctors-and-patients

[5] https://www.healthcareitnews.com/news/emea/germany-introduces-digital-supply-act-digitalise-healthcare

[6] https://thejournalofmhealth.com/germany-allows-firsts-healthcare-apps-for-prescription/

[7] https://healthinformatics.uic.edu/blog/cybersecurity-how-can-it-be-improved-in-health-care/

[8] https://www.himss.eu/himss-taxonomy-topics/mhealth?page=1

[9] https://www.sspa.juntadeandalucia.es/agenciadecalidadsanitaria/en/safety-and-quality-strategies-in-mobile-health-apps/

The "MOBILE HEALTH APPLICATIONS (MHA): Standards & Laboratory Services" IC will develop the following independent and interrelated activities:

1. **MHA SLS Virtual Series**
    a. Monthly online conferences, workshops, webinars, etc.
    b. Entrepreneurial/Commercialization bootcamps, connectathons, etc.
    c. STEM student outreach and inclusion; Young Professional development;
2. **MHA Standards Collaboration**
    a. IEEE-SA HLS collaboration with HL7, ISO/TC215, IHE and other related entities;
    b. IEEE-SA Mobile Health Standards Development;
    c. Collaboration with IEEE 11073, P2933 and related IEEE standards;
3. **MHA Test & Certification Laboratory Services**
    a. leveraging ICAP framework;
    b. Collaboration with ISO CASCO, as needed;
4. **MHA Global Registry**
    a. leveraging IEEE-SA Registration Authority;
5. **MHA "Sandbox" Laboratory Services**
    a. Standards Research & Development Services;
    b. Software Modeling & Simulation;
    c. Hardware Device Emulation;
    d. Large User-Base R&D Pilot;
    e. Cloud & Edge Deployment;

It is planned that activities #2, #3 & #4 will be developed concurrently as revenue centers.

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.).

The following section summarizes some of the key global players (either other SDOs or Governmental organizations) in the Mobile Health space and the work that they are conducting in the area of Mobile Health Apps.

The author is intimately and actively involved in all of the activities listed below. The impetus for this IC application came from after observing the apparent gap and in consultation with many of these organizations.

HL7:

HL7® Mobile Health Work Group, in June 2018, released a STU (Standards for Trial Use) that provides guidance to mobile health app developers in developing a safe and secure mobile health app:

*HL7 Consumer Mobile Health Application Functional Framework **(HL7 cMHAFF)**, Release 1*

- The primary goals of cMHAFF are to provide a standard against which a mobile app's foundational characteristics -- including but not limited to security, privacy, data access, data export, and transparency/disclosure of conditions -- can be assessed.
- The framework is based on the lifecycle of an app, as experienced by an individual consumer, from first deciding to download an app, to determining what happens with consumer data after the app has been deleted from a smartphone.
- The HL7 confluence project site is: https://confluence.hl7.org/display/MH/cMHAFF+Project
- Additional/current information about cMHAFF is available here: https://cmhaff.healtheservice.com/

HL7 Mobile Health Work Group is now working on publishing STU-2 during 2021.

HL7 cMHAFF is primarily directed at developers and vendors of mobile health apps for consumers, to assist them in building and marketing apps that educate consumers and protect their privacy, security, data access, etc.

The standard will not address the clinical content of such apps (e.g., "Does it give good advice?"), but will provide a framework for security, privacy, and the integration of data generated from apps into Personal Health Record (PHR) and Electronic Health Record (EHR) systems, as well as into other types of data repositories (e.g., personal data stores, population care systems). Health Apps reference applications running typically on smartphones, but also on other consumer devices such as watches, fitness devices and tablets.

HL7 cMHAFF provides a framework for assessment of the **common foundations** of mobile health apps:

- Product Information (disclosures/transparency)
- Security (including individual integrity)
- Privacy/consent/authorization
- Risk assessment/analysis
- Data access privileges
- Data exchange/sharing
- Usability & Accessibility

Assessment could include attestation, endorsement, testing, voluntary or regulatory-driven certification.

HL7 cMHAFF focuses specifically on consumer mobile apps that run on devices such as smartphones, tablets, and wearables. It is focused on the general capabilities that can be thought of as "horizontal" features that are applicable to most or all apps, rather than to the specific health, clinical, or medical functionality of an app.

ISO/TC215:

There is also an ongoing effort in ISO/TC215 to develop a technical specification called TS:ISO 82304-2 Quality Criteria for Health and Wellness Apps[10] that is currently (2020-21) underway. The project was

[10] https://www.nen.nl/Standardization/Health-and-wellness-apps.htm

commissioned by the EU Commission as "Health and Wellness Apps – Quality and reliability criteria across the life cycle – Code of Practice".

This specification defines a set of questions and supporting evidence that can be used to make the quality and reliability of the app clear.

The draft Technical Specification is scheduled to be released for review by ISO/TC215 in Q1 2021.

US DHHS:

UMHAI: Unique Mobile Health Application Identifier

The United States Core Data for Interoperability (USCDI)[11] is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. The current version of USCDI is version 1.

A new data element (within the Medical Device and Equipment class) that uniquely identifies a mobile health app instance (UMHAI) was proposed, reviewed and approved, in Nov 2020 by US-DHHS, for public viewing, with an assigned classification level of Comment.[12]

WHO DIGITAL HEALTH[13]

Be He@lthy, Be Mobile (BHBM) aims to maximize access to health information and health services for everyone, everywhere. BHBM initiative was set up by the World Health Organization (WHO) and the International Telecommunication union (ITU). BHBM works with governments to scale up mHealth services for NCDs (non-communicable diseases) and their risk factors. BHBM has 3 core goals in its new strategy.

The first goal is expanding reach to:

- provide technical assistance for the implementation of national mHealth programs in 20 new Member States, in addition to the 12 already being supported
- develop at least 2 new digital health regional knowledge and innovation hubs built on the model from the **European mHealth Hub** (Horizon 2020 project)
- scale a set of integrated digital solutions for specific settings (cities, villages, etc.) to support WHO's Primary Health Care and Universal Health Coverage objectives.

The second goal is to provide a digital solutions bank by:

[11] https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
[12] https://www.healthit.gov/isa/uscdi-data/unique-mobile-health-application-identifier-umhai
[13] https://www.who.int/teams/digital-health-and-innovation/health-technologies

- developing a rapid process that converts guidelines and products from WHO technical units into digital content that can reach and benefit individual end users around the world
- Support the scaling up of potential breakthrough digital solutions and make them available as "digital global goods" Identify digital platforms to support new value propositions for digital health
- Build capacity of member states to adopt, adapt and integrate digital solutions from the Bank.

The third goal is to increase the number of profound partnerships that allow for collaboration around complementary goals, bringing existing technology to scale and co-creating new services that meet the needs of end users.

EU mHealthHUB[14]

The European mHealth Innovation and Knowledge Hub is intended to serve as a mechanism to share success in mHealth across the European region and boost uptake of mHealth solutions amongst national governments.

At a high level, mHealth Hub has a dual focus on knowledge management & innovation, and on practical implementation (supporting EU member states to launch large-scale mHealth interventions).

THE MHEALTH HUB AIMS:

- To operationalise an mHealth Innovation Hub for integration into the national health systems in Europe.
- To serve as a focal point for expertise on mHealth in the WHO European Region.
- To assist countries in implementing mHealth strategies.
- To act as facilitator of innovation in mHealth.
- To act as an accelerator for the EU Digital Single Market.
- To produce Knowledge Tools for health systems and services on NCDs.
- To provide a code of ethics for mHealth data.

The push to use Information and Communication Technologies – specifically mobile technology (or mHealth) – to support healthcare has been driven by the need to find cost-effective ways to overcome two major challenges on the horizon for healthcare in Europe: an ageing population suffering from a rise in chronic diseases and an associated rise in cost for provision of healthcare due to these conditions.

The use of mHealth is of interest to parties looking at ways to overcome these challenges because it enables a shift in focus towards early diagnosis and detection of changes in risk of disease, promotion of health and prevention, and self-management of chronic diseases."

For these reasons, the European mHealth Innovation and Knowledge Hub was established to collect and share national experiences on mHealth and to support countries and regions in setting up large-scale mHealth programmes.

[14] https://mhealth-hub.org/

In particular, there are multiple mhealth App assessment frameworks across Europe.[15]

There are also multiple Health App repositories in Europe.[16]

3.3 Previously Published Material

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

List the previously published material, if any.

This is a green-field area and there is minimal previously published material except as outlined below:

1. State of Mobile Health Address @ HL7: by Gora Datta
2. Emerging Mobile Health Standards for ISO/TC215: by Gora Datta
3. Mobile Health Concept Note for IEEE-SA: by Gora Datta

3.4 Potential Markets Served

Indicate the main beneficiaries of this work, and what the potential impact might be.

The Mobile Health Applications Standards & Laboratory Services described in this document will be targeted for the benefit of several categories of market participants, including:

- Standards Development Organizations like IEEE, HL7, ISO, HIMSS, and others;
- Industry Developers of Mobile-enabled Health Informatics Systems and Medical Devices;
- Research & Development Organizations focused on patient mobility technologies and solutions;
- Public Health Agencies responsible for crafting policy and regulations based on Real World Evidence;
- Governmental and multilateral agencies entities forming policies, regulations and laws related Mobile Health Apps adoption, deployment and use
- Physicians and other Practitioners, Health Service Organizations, and Health Laboratories seeking to acquire and integrate standards-base and interoperable Mobile Health Applications into larger health and wellness system;
- Consumers and Patients who purchase and/or use Mobile Health Applications that run on variety of mobile, wearable and/or handheld devices;

The impact of the Standards & Laboratory Services described here will be to establish quality, trust and meaningful use of mobile health applications with the ultimate result of improving the health and well-being of individuals, communities, providers, payors (insurance companies), governments and the global population.

The MHA SLS IC is expected to have participation from the following entities:

[15] https://mhealth-hub.org/assessment-frameworks

[16] https://mhealth-hub.org/health-apps-repositories-in-europe

- IEEE Standards Association (lead entity)
- IEEE OUs
- ISO/TC215
- ISO CASCO
- CEN/TC251
- HL7 International
- ITU-T
- US-FDA (Food & Drug Administration)
- EU-EMA (European Medicines Agency)
- HIMSS
- IHE
- WHO
- US-NIST
- International Medical Device Regulators Forum (IMDRF)
- Multilateral Agencies
    - The World Bank
    - Asian Development Bank
    - African Development Bank
    - ...
- Other competent international authorities/bodies
- Governments (Federal, State, Local)
    - EU mHealth-HUB
- Providers & Provider Groups
- Payors (insurance)
- App Developers
- Patient Advocacy Groups
- Consumers/Patients

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

3.5.1: IEEE Benefits

As stated earlier, there is no established standardized global mobile health app certification process in existence. It is a possibility that we will see a proliferation of non-standardized, country-specific, siloed certification processes being established over the next few years. In fact, we are already seeing efforts in this area.

Besides establishing a certification and associated conformity assessment process for mobile health apps, a need is also envisaged for establishing a global Mobile Health App Registry.

IEEE Conformity Assessment Program (ICAP) develops and implements programs that couple standards development activities with conformity assessment activities to help accelerate market adoption while reducing implementation costs.

Conformity assessment involves a set of processes that show your product, service or system meets the requirements of a standard. When applied to products, it involves testing to an established performance standard, as well as inspection, quality management, surveillance, accreditation and declaration of conformity. Undergoing the conformity assessment process has a number of benefits:

- It provides **consumers** and other stakeholders with added confidence, security and integrity.
- It gives your **company** a competitive edge.
- It helps **regulators** ensure that health, safety or environmental conditions are met.

This provides an unique and timely commercial opportunity for IEEE at large and IEEE-SA in particular to play a leadership and guiding role in this emerging area of Mobile Health Apps Standards & Laboratory Services.

3.5.2 Benefit to Society

Health information is a fundamental category of information for maintaining personal, public and global health, as well as for informing research and development efforts and public policy. Electronic health information comes in many forms, whether human-generated or generated by electronic or other devices. – This activity will coordinate the efforts of actors in industry, academia, government and the general population to develop interoperable standards, testing, and certification procedures to accelerate and optimize the use of mobile health information applications in support of global health and wellness. It is envisaged that there may be commercial opportunity for IEEE to leverage the de-identified meta-data (e.g., annual/quarterly market research report without compromising the privacy and security of the individual health record).

In addition, the United Nations Sustainable Development Goals (UN SDGs, also known as the Global Goals) are 17 goals with 169 targets that all UN Member States have agreed to work towards achieving by the year 2030. They set out a vision for a world free from poverty, hunger and disease.

Health has a central place in SDG 3 “Ensure healthy lives and promote well-being for all at all ages”; in short this is also referred as “Good Health and Well Being”.[17]

Ensuring healthy lives and promoting well-being at all ages is essential to sustainable development. Currently, the world is facing a global health crisis unlike any other — COVID-19 is spreading human suffering, destabilizing the global economy and upending the lives of billions of people around the globe.

During this pandemic era, Mobile Health and its applications have very rapidly emerged as a key tool to mitigate its impact.

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(s): 03/2023

[17] https://www.un.org/sustainabledevelopment/health/

#	ACTIVITIES	START DATE	END DATE	COMMENTS
1	**MHA SLS CREATION & VIRTUAL SERIES (VS)**	JULY 2021	DEC 2021	Virtual-Series will be on-going and will generate revenue from 2022
2	**MHA Standards "SDO" Collaboration Platform**	OCT 2021	DEC 2023	Interim delivery: DEC 2022
3	**MHA Test & Certification Laboratory (TCL) and TCL Authorization Program**	OCT 2021	SEP 2024	Interim delivery: June 2023
4	**MHA Global Registry**	JULY 2021	DEC 2022	Interim delivery: June 2022
5	**MHA Sandbox Laboratory Services (SLS) and SLS Authorization Program**	JAN 2022	DEC 2024	Interim delivery: June 2023
6	**MHA Collaboration Platform Launch and Large User-Base Pilot Program**	JAN 2022	DEC 2024	Interim delivery: June 2023

Section#5 (see below) details the deliverables of each of the above activities.

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.

Specify the deliverables for this IC activity, please be specific.

The MOBILE HEALTH APPLICATIONS: Standards & Laboratory Services (MHA-SLS) Industry Connection activity will create the following deliverables:

1. **MHA Industry Connection Virtual Series**
    a. Monthly virtual conferences, webinars, workshops & tutorials;
    b. Live industry panelists, moderators, audiences;
    c. Virtual series recorded and placed in publicly accessible repositories (YouTube, IEEE.tv, etc.)
    d. MHA developer bootcamps, technology bake-offs & connectathons, entrepreneurship & commercialization accelerators;
    e. STEM student outreach and inclusion; Young Professional development;

    EXPECTED TIMEFRAME: July 2021 - ongoing rolling basis

2. **MHA Standards "SDO" Collaboration Platform:**
    a. Develop an SDO Collaboration Platform using Open Source Software tailored for the specific use of MHA standards development and consensus building by industry practitioners, academic researchers and government agencies;
    b. Platform will focus on developing "Computable/Executable Standards" and "Semantic Model Standards" over and above traditional "narrative" or "structured" document-based standards;
    c. Platform will be targeted for MHA collaboration between IEEE-SA, ISO, HL7 and IHE, as well as other relevant stakeholders such as JIC, WHO, ITU, etc.;
    d. Initial use-case will be focused on proposing IEEE-SA Mobile Health standards in conjunction with IEEE 11073, P2933, ISO/TC215, and others;

    EXPECTED TIMEFRAME: 18-24 months from start;

3. **MHA Test & Certification Laboratory (TCL) and TCL Authorization Program:**
    a. Establish a fee-based model for Test & Certification Laboratories for MHA Conformity Assessment;
    b. The **Model TCL** will be established at the P3 Innovation Center in Irvine, Calif. and will serve as the primary body for authorizing licensed **3rd-party TCLs** through the **TCL Authorization Program**;
    c. The TCL Program will use the ICAP framework;
    d. The TCL Program will align with the ISO CASCO framework;

    EXPECTED TIMEFRAME: 18-36 months from start;

4. **MHA Global Registry:**
    a. Establish a fee-for-registration MHA Global Registry;
    b. Registry will use the IEEE-SA Registration Authority;

    EXPECTED TIMEFRAME: 12-18 months from start;

5. **MHA Sandbox Laboratory Services (SLS) and SLS Authorization Program:**
    a. Establish a series of fee-based Sandbox Laboratory Services, over and above test & certification -- in particular, research & development services that are preliminary to test

& certification services and part of the data science and discovery phases of standards R&D;

b. SLS will include **Software Modeling & Simulation Services**, i.e. cloud-based services in support of developing object-oriented and semantic-based models of standards that may be used for standards experimentation, analysis and use-case/scenario discovery;
c. SLS will include **Mobile Device Emulation and Hardware Application Services**, i.e. device-specific hardware-oriented services that follow software-oriented services and precede final test & conformity services;
d. The **Model SLS** will be established at the P3 Innovation Center in Irvine, Calif. and will serve as the primary body for authorizing licensed **3rd-party SLSs** through the **SLS Authorization Program**;

EXPECTED TIMEFRAME: 18-36 months from start;

6. **MHA Collaboration Platform Launch and Large User-Base Pilot Program:**
   a. Launch of the Open Source Collaboration Platform and finalized fee-based TCL and SLS services at the P3 Innovation Center;
   b. Rollout of a Large User-Base Deployment Pilot that includes the participation of hundreds of standards development practitioners;

EXPECTED TIMEFRAME: 18-36 months from start;

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? **Yes**

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.

Specify funding requirements and sources, if any.

The following is a 5 year funding requirement projection. It is expected that the MHA SLS IC will be self-sustaining from year 3 onwards.

Year 1: $500,000

- IEEE: $300,000 [for external contracted service]
    - this maybe a matching fund initiative between IEEE.org, IEEE-USA, IEEE-Foundation & IEEE-SA [fund disbursement will be 10%, 20%, 30% and 40% spread across each quarter as a risk-mitigation strategy)
    - There is a very good chance that the external grant funding amount may exceed the proposed target (of $200,000) by Q3-Q4 of the first year. If so then the amount requested from IEEE in (remaining) Year-1 and Year-2 will be reduced accordingly.
- External Grant funding [Government, Private]: $200,000
- MHA IC Membership: $0 - $25,000

Year 2: $500,000

- IEEE: $200,000 [for external contracted service]
    - this may not be required if External Grant Funding exceeds the projected target
- External Grant funding [Government, Private]: $300,000
- MHA IC Membership: $100,000

Year 3: $750,000 [self-sustaining]

- External Grant funding [Government, Private]: $500,000
- MHA IC Membership: $200,000
- MHA SLS Revenue: $50,000

Year 4: $900,000 [self-sustaining]

- External Grant funding [Government, Private]: $500,000
- MHA IC Membership: $300,000
- MHA SLS Revenue: $100,000

Year 5: $1,500,000 [self-sustaining]

- External Grant funding [Government, Private]: $1,000,000
- MHA IC Membership: $300,000
- MHA SLS Revenue: $200,000

For Year 1 and Year 2, a total amount of $500,000 is ear-marked for creating and operationalizing MHA SLS.

	Year 1	Year 2	Year 3	Year 4	Year 5
IEEE	$300,000	$200,000	-	-	-
External	$200,000	$300,000	$500,000	$500,000	$1,000,000
MHA IC Membership	$ 25,000	$100,000	$200,000	$300,000	$300,000
MHA SLS Revenue	-	-	$50,000	$100,000	$200,000

Total	$525000	$600,00	$750,000	$900,00	$1,500,000

7. Management and Procedures

7.1 Activity Oversight Committee

Indicate whether an IEEE committee of some form (e.g., a Standards committee) has agreed to oversee this activity and its procedures.

Has an IEEE committee agreed to oversee this activity? No

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

IEEE 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.).

Activity management will be provided by an executive committee, not to exceed 12-15 members and daily operational activities executed by external specialized contract service.

The executive committee includes a chair, vice-chair(s), focus/activity group chairs and at-large committee members. Each focus/activity group will have a chair.

7.3 Procedures

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.

Specify the policies and procedures document to be used. Attach a copy of chosen policies and procedures.

This activity will use the policies and procedures in the Industry Connections modified baseline document.

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.

Specify types of entities or groups of individuals.

It is recommended that a "consortium" of following entities be established, under the leadership of IEEE-SA to create MHA SLS to address issues related to mobile health standards, conformity assessment framework, mobile health apps certification guidance and mobile health app registry:

- ISO/TC215
- EU Mobile Health HUB
- CEN/TC251
- HL7 International Mobile Health Work Group
- ITU-T Digital Health
- US-FDA (Food & Drug Administration) Digital Health Center of Excellence
- EU-EMA (European Medicines Agency)
- HIMSS
- IHE International
- WHO Digital Health
- US-NIST Health-IT
- International Medical Device Regulators Forum (IMDRF)
- Multilateral Agencies
    - The World Bank
    - Asian Development Bank
    - African Development Bank
    - Inter-American Development Bank
    - ...
- Other competent international authorities/bodies

Not having a collaborative approach amongst various global stakeholders runs the risk of seeing a "proliferation of non-standardized, country-specific, siloed certification processes being established over the next few years" in the mobile health app space.

Another aspect that was briefly mentioned earlier and is critical for mobile health app usage, by both patients and healthcare providers, is the impact of cyber security on these apps[18].

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.

Number of entities or number of individuals. - at least 50 entities

MHS SLS IC is envisioned to engage hundred+ collaborators, including participants from industry (both large vendors and small app developers from across the globe), national and international governments, multilateral organizations, academic institutes, non-governmental organizations, health industry stakeholders, patient advocacy groups and even general public.

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
CAL2CAL	Gora Datta	
P3 Innovation Center	Brian Hagerty	
Draeger Medical Systems	Ken Fuchs	
Breakthrough Solutions Foundry	Todd Cooper	
Children's Hospital of Philadelphia	Igor Yuabov	
MedCrypt	Axel Wirth	
Palm Associates	Paul Petronelli	
Westat	Nathan Botts	

[18] https://www.nccoe.nist.gov/news/security-recommendations-mobile-health-apps

Mayo Clinic	Matthew Graham	
St. John's Health	Sandip Ray	
North Carolina A & T State University	Christopher Doss	
Universitair Medisch Centrum Groningen	Frank Ploeg	
Samsung Medical Center	Byoung-Kee Yi	
Philips	Timon Grob	
FDA	Kosta Makrodimitris	

Use the following table for an individual-based activity:

Individual		**Employer**	**Affiliation**
Name			