P1752 Working Group Meeting
Sponsored by IEEE Engineering in Medicine & Biology (EMB) Standards Committee

Please mark your attendance at:
https://tinyurl.com/yc3oxg6q
(see chat window)

10 March 2021
Teleconference
Attendance

This document shows attendance from previous calls https://tinyurl.com/yc3oxg6q (link in the chat window of join.me). If you attended the call, please verify that your name is listed
- If not, email simona@openmhealth.org

Put your name and affiliation in the chat window for attendance today.
- If your name is not listed, or if you are joining only via phone, please email simona@openmhealth.org with “P1752 WG call” as subject

Attendance is important for determining voting rights, so please remember to “check in”

Voting rights are granted according to the P&P after attending two consecutive calls and by explicit request to the Secretary (Simona)
IEEE Patent Policy
Participants have a duty to inform the IEEE

- Participants shall inform the IEEE (or cause the IEEE to be informed) of the identity of each holder of any potential Essential Patent Claims of which they are personally aware if the claims are owned or controlled by the participant or the entity the participant is from, employed by, or otherwise represents.

- Participants should inform the IEEE (or cause the IEEE to be informed) of the identity of any other holders of potential Essential Patent Claims.

Early identification of holders of potential Essential Patent Claims is encouraged.

Slide #1
Ways to inform IEEE

- Cause an LOA to be submitted to the IEEE-SA (patcom@ieee.org); or
- Provide the chair of this group with the identity of the holder(s) of any and all such claims as soon as possible; or
- Speak up now and respond to this Call for Potentially Essential Patents

If anyone in this meeting is personally aware of the holder of any patent claims that are potentially essential to implementation of the proposed standard(s) under consideration by this group and that are not already the subject of an Accepted Letter of Assurance, please respond at this time by providing relevant information to the WG Chair.
Other guidelines for IEEE WG meetings

• All IEEE-SA standards meetings shall be conducted in compliance with all applicable laws, including antitrust and competition laws.
  • Don’t discuss the interpretation, validity, or essentiality of patents/patent claims.
  • Don’t discuss specific license rates, terms, or conditions.
    • Relative costs of different technical approaches that include relative costs of patent licensing terms may be discussed in standards development meetings.
      • Technical considerations remain the primary focus
  • Don’t discuss or engage in the fixing of product prices, allocation of customers, or division of sales markets.
  • Don’t discuss the status or substance of ongoing or threatened litigation.
  • Don’t be silent if inappropriate topics are discussed … do formally object.

Patent-related information

The patent policy and the procedures used to execute that policy are documented in the:


Material about the patent policy is available at http://standards.ieee.org/about/sasb/patcom/materials.html

If you have questions, contact the IEEE-SA Standards Board Patent Committee Administrator at patcom@ieee.org
IEEE SA Copyright Policy
IEEE SA Copyright Policy (November 2019)

• By participating in this activity, you agree to comply with the IEEE Code of Ethics, all applicable laws, and all IEEE policies and procedures including, but not limited to, the IEEE SA Copyright Policy.

  • Previously Published material (copyright assertion indicated) shall not be presented/submitted to the Working Group nor incorporated into a Working Group draft unless permission is granted.
  • Prior to presentation or submission, you shall notify the Working Group Chair of previously Published material and should assist the Chair in obtaining copyright permission acceptable to IEEE SA.
  • For material that is not previously Published, IEEE is automatically granted a license to use any material that is presented or submitted.
IEEE SA Copyright Policy

- The IEEE SA Copyright Policy is described in the IEEE SA Standards Board Bylaws and IEEE SA Standards Board Operations Manual
  - IEEE SA Copyright Policy, see Clause 7 of the IEEE SA Standards Board Bylaws
    https://standards.ieee.org/about/policies/bylaws/sect6-7.html#7
    https://standards.ieee.org/about/policies/opman/sect6.html

- IEEE SA Copyright Permission
  - https://standards.ieee.org/content/dam/ieee-standards/standards/web/documents/other/permissionltrs.zip

- IEEE SA Copyright FAQs

- IEEE SA Best Practices for IEEE Standards Development

- Distribution of Draft Standards (see 6.1.3 of the SASB Operations Manual)
Determination of Quorum

https://tinyurl.com/yc3oxg6q
Approval of Agenda

1. Attendance
2. Call for Patents
3. Approval of agenda and minutes (if quorum present)
4. Presentation: the IEEE Industry Rapid Activator Program (IRAP) for P1752
5. Other business
Approval of Prior Minutes
(February 2, 2021)
Presentation: IRAP
10 March 2021

IRAP P1752 PILOT PROJECT

MARIA PALOMBINI
DIRECTOR, OPPORTUNITIES AND COMMUNITIES DEVELOPMENT, HEALTHCARE
LIFE SCIENCES PRACTICE LEAD,
IEEE STANDARDS ASSOCIATION
ABOUT THE IEEE

Mission
- The core purpose of IEEE is to foster technological innovation and excellence for the benefit of humanity

Vision
- IEEE will be essential to the global technical community and to technical professionals everywhere, and be universally recognized for the contributions of technology and of technical professionals in improving global conditions
IEEE BY THE NUMBERS

400K MEMBERS

160+ COUNTRIES

46+ TECHNICAL SOCIETIES & COUNCILS

1900+ ANNUAL CONFERENCES

5M+ TECHNICAL DOCUMENTS
ADVANCING TECHNOLOGY FOR HUMANITY

ABOUT IEEE

- Inspiring a global community of innovation
- Where forward-thinking professionals collaborate
- Discover what’s next in tech innovation
- Build technical communities
- Shape and share research
- Create global standards
- Engage in Humanitarian activities
PORTFOLIO OF PROGRAMS & SERVICES

**Industry Connections**
Exploring & incubating new tech & its use

**Standardization**
Creating markets & protecting public safety through standards development

**Membership**
Connecting to experts & resources with advanced participation options

**Conformity Assessment**
Providing confidence & assurance & accelerating market adoption

**Open Source**
Providing a community-powered platform to support open source projects

**Alliance Management**
Providing support to alliances & trade associations

**Registries**
Providing unique identifiers to support global compatibility & interoperability
Addressing global problems through community and consensus.
IEEE SA HEALTHCARE LIFE SCIENCES PRACTICE

To improve the global standard quality of life at every step through affordable healthcare and access to medicines; support innovation to improve overall wellness and improve societal outcomes; and to enable innovation through open and standardized means.

GUIDING OBJECTIVES:
▲ How might we enable greater equity in care globally while lowering the cost and improving the quality at a base level?
▲ How do we enable enhance access to proper nutrition and improve mental wellness at all corners of the world?
▲ How may we best positioned to address the next pandemic? And, further, how may we eradicate global maladies (cancer, obesity,...)

• Pharma/Biotech
• Clinical Health
• Global Wellness
BACKGROUND - IRAP

- A newly formed IEEE SA Industry Connections Program (IC20-024)
  - To help mobilize the industry for engaging with IEEE SA standards
- Aims at accelerating the commercial implementation and/or adoption of recent or soon to be published IEEE standards
- Analogous to successful programs of other SDOs (TM Forum, ETSI, etc.)
- Launches and manages short-term projects to showcase new standards

Program Leadership
- Doug Zuckerman, Chair, d.zuckerman@ieee.org
- Mehmet Ulema, Vice-Chair, mulema@ieee.org
THE PILOT PROJECT
Mobile and wearable devices are increasingly being developed for health care purposes. The IEEE P1752 Standard for Mobile Health Data defines specifications for standardized representations of quantitative sleep and physical activity measures, minimum metadata and subjective reports (surveys). The purpose of this standard is to provide standard semantics to enable meaningful description, exchange, sharing, and use of such mHealth data. Data and associated metadata complying to this standard will be sufficiently clear and complete to support their use for a broad set of consumer health, biomedical research, and clinical care needs. (This standard incorporates open source.)

https://standards.ieee.org/project/1752.html
https://opensource.ieee.org/omh/1752
THE P1752 PILOT

THE PILOT

- Participants will engage in an open and neutral collaborative environment to demonstrate the implementation/use of the P1752 standard providing solutions to critical industry problems.

- The pilot will feature synthetic patient data and focus on the use of consumer (non-FDA approved) or FDA-approved mHealth device generated data complying with the P1752 standard utilized for pharmaceutical sponsored clinical research use case.

- Therapeutic use cases in sleep measure, physical activity and/or blood pressure.

PARTICIPANT QUALIFICATION

- 6 to 8 entities with approximate balance amongst each type (preferred)
  1. Data generators: (wearable technology developer) non/FDA approved mHealth device
  2. Data aggregators: Patient health data aggregator for clinical research
  3. Data consumers: Bio/Pharmaceutical company and/or CRO in clinical research
Use Case: Clinical Trial Using Biomarker Total Sleep Time

Data Collection: same measure may be called differently, or same name may mean different measures (not of interest)

There are three levels of alignment
1) name 2) definition and 3) unit of measure (explicit and consistent, e.g., unit of time duration)

Definition of Total Sleep Time: ANSI/CTA Standard Definitions and Characteristics for Wearable Sleep Monitors (ANSI/CTA/NSF-2052.1)
NSF = National Sleep Foundation
Use Case: Clinical Trial Using Biomarker Total Sleep Time

Data Collection from P1752-compliant solutions

- Total sleep time
- Total sleep time
- Total sleep time
- Total sleep time

Total sleep time
The total amount of time spent asleep, calculated as the sum of all asleep time within a sleep period

Data Aggregation
No mapping necessary: semantics are clear, metadata is complete

Data Analysis and Visualization
Analysis on, and visualization of, data of known format: clear semantics and complete metadata

Definition of Total Sleep Time: ANSI/CTA Standard Definitions and Characteristics for Wearable Sleep Monitors (ANSI/CTA/NSF-2052.1) NSF = National Sleep Foundation
PILOT GOALS

- Real-world data coming from multiple devices in a standardized 1752 format eases aggregation and analytics
- Reduction of data friction
- Provides commercial health wearable developers/manufacturers a platform and opportunity to provide data for clinical research applications
- Provides consumers of health data access to “cleaner,” “more understandable data” from these wearables enabling greater access to more patients for study
- Create a public use synthetic data set for researchers
- Technical goal: data collected from various devices (same measure) and 1752 compliant (i.e., compliant with 1752 schemas: metadata + data) can be pooled for analysis
- Demonstrate comparative impact before and after use of the application of the standard across all three sectors (generator, aggregator, consumer)
- Early participation with potential FDA recognition of data format for regulatory submission
PARTICIPATION REQUIREMENTS

• No cost to the entity to participate in the pilot
• Confirm participation by 2 April 2021
• Agree and sign IEEE SA Pilot NDA
• Commit to participate in actual project estimated at 6 months
• All project meetings will be conducted in a virtual environment (frequency to be established with pilot participants)
• Collaboratively build consensus on development of project timeline benchmarks
• Documentation collected for the purpose of this pilot will be stored in the official IEEE Virtual Repository Space (ie iMeet central)
• Final outcomes to be written into an official report to be published in a medical/clinical trade publication and/or IEEE related publication. All participants will review and approve the final document before publishing.
• Participate in at least one virtual demo (Q4 2021) and one or more in-person demo at large industry conference in 2022
VALUE PROPOSITION FOR PROJECT PARTICIPANTS

- Enables quicker promotion and deployment of participant’s solution based on upcoming standards, i.e., shortens time to market.
- Pools together stakeholders towards a common goal.
- Offers fresh perspectives into participant’s project through feedback from stakeholder colleagues.
- Provides opportunity for hands-on work with others from industry.
- Provides framework to foster innovative industry solutions.
- Provides participant’s organization with market exposure through IEEE and other industry channels (e.g., IEEE events, conferences, and other relevant IEEE industry events).
- Leverages open-source solutions when appropriate.
- Helps participant’s save resources - IEEE SA manages the pilot through structured programs adhered to by all participants.
INDIVIDUAL PROJECT STRUCTURE

Each project is responsible for:
- Developing its project plan (budget, schedule, tasks, resources)
  - Forming its project team
  - Defining its project scope, goals, and deliverables
- Obtaining the approval of its project plan (from IRAP Committee)
- Executing the approved plan
- Communicating with the IRAP Committee,
  - Providing a regular status report
THANK YOU

GET INVOLVED:
Connect with me to be a part of this program.

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APPENDIX

OTHER PROGRAMS AND OPPORTUNITIES WITH THE IEEE SA HEALTHCARE LIFE SCIENCE PRACTICE
INDUSTRY CONNECTIONS – HEALTH LIFE SCI PROGRAMS

- Tech & Data Harmonization for Decentralized Clinical Trials
- Digital Inclusion, Identity Trust and Agency (DIITA)
- Connectivity Harmonization of the Digital Citizen (WAMIII)
- IoT Ecosystem Security
- Neuro Tech for Brain-Machine Interfacing
- MyData Health
- Global Initiative to Standardize Fairness in the Trade of Data
- Global Initiative on Blockchain-based Omnidirectional Pandemic Surveillance
- AI Systems for Governance for Cities
- Transforming the Telehealth Paradigm
- Responsible Innovation of AI in Life Sciences

https://standards.ieee.org/industry-connections/activities.html
LET’S TALK

IEEE SA GLOBAL WAMIII VIRTUAL TALK SERIES
Putting a global multi-disciplinary community to share ideas and challenges for enabling trust in and validation of connected wireless medical devices.

standards.ieee.org/events/wamiii/virtual-talk-series-2020.html

RE-THINK HEALTH PODCAST SERIES
Exploring new tools, technologies and applications to re-think the approach to better health for all.

standards.ieee.org/practices/healthcare-life-sciences/rethink-health.html
Summary of Action Items
Future Meetings
Upcoming Meetings

• Main WG meeting
  • TBD, after ballot recirculation ends
Adjournment