IEEE STANDARDS ASSOCIATION

IEEE

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)

- 12 February 2019
- 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

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

Slide #2

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.**

For more details, see *IEEE-SA Standards Board Operations Manual*, clause 5.3.10 and *Antitrust and Competition Policy: What You Need to Know* at http://standards.ieee.org/develop/policies/antitrust.pdf

Slide #3

Patent-related information

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

- ***IEEE-SA Standards Board Bylaws*** **(http://standards.ieee.org/develop/policies/bylaws/sect6-7.html#6)**
- ***IEEE-SA Standards Board Operations Manual*** **(http://standards.ieee.org/develop/policies/opman/sect6.html#6.3)**

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

Determination of Quorum

https://tinyurl.com/yc3oxg6q

Approval of Agenda

1. Attendance
2. Call for Patents
3. Approval of agenda and of prior minutes (if quorum present)
4. Updates from subgroups
5. Discussion: upcoming activities
6. Other business

Approval of Prior Minutes

December 5 and January 12

Update:
Physical Activity and Mobility (PA&M) Schema Subgroup

Physical Activity & Mobility (PAM) Sub-group

1. Developed PA schema
   - Used data from other devices to evaluate the current PA schema
   - Definitions
   - Properties for PA Schema
2. PA schema will encapsulates schemas such as Step Count
3. Developing summary/descriptive statistics schema
   - Group discussion (what is important)
   - Reviewed Openmhealth.org schemas
4. Next Meeting: Thursday Feb 14, 2019 (11am to 11:45am Eastern Time)

Update:
Sleep Schema Subgroup

Sleep Schema Subgroup Update (pg.1)

- **Quantitative sleep measure schemas:**

(1) Modified and drafted schemas and sample data presented/discussed during the subgroup meeting:

sleep_onset_latency sample data

ambient_temperature sample data

deep_sleep_pecentage sample data

light_sleep_percentage sample data

wake_after_sleep_onset sample data

ambient_light sample data

sleep_body_movement sample data

ambient_noise schema and sample data

sleep_apnea schema

arousal_rate schema and sample data

snore_count schema and sample data

- **Qualitative sleep measure schemas:**

(1) Reach consensus on using existing OmH framework through survey in the task group

(2) Started signing up to draft the schema for 10 shortlisted Questionnaires

Sleep Schema Subgroup Update (pg.2)

➢Next Step

Quantitative sleep measure task group:

---Complete drafting the schemas and provide sample data

---Prepare and kick off reviewing of the drafted schemas and sample data in sleep group

---Modify the drafted schemas and the sample data based on the review comments

Qualitative sleep measure task group:

---Signing up and start to draft the schemas for the shortlisted surveys

Sleep Schema Subgroup Update (pg.3)

- **Sleep schema subgroup meeting slides/minutes:**

http://sites.ieee.org/sagroups-1752/sleep-subgroup-meeting-materials/

- **Drafted schemas:**

https://ieee-sa.imeetcentral.com/omh/folder/WzIwLDEwMjY4MDc4XQ/

- **Next subgroup meeting: March 5, 2019 11:30am to 12:30 pm**
- **Join the sleep group: email charlotte.chen@Philips.com or Simona.Carini@UCSF.EDU**

Discussion:
From draft standard to ballot

Preparing for the Ballot Process (I)

- Overall standard process: the Standards Development Lifecycle
- Subgroup submits work to WG for comments:
  - Introduction
  - Schemas + sample data
  - Supporting documentation (if applicable)
- WG comments → revisions → WG vote to approve
- Material goes into initial draft standard

Preparing for the Ballot Process (II)

- Use IEEE template to write a stable draft standard
- Draft standard submitted to WG for comments
- Final draft standard approved by WG submitted for mandatory editorial review
- Follow specific timeline for each step

Preparing for the Ballot Process (III)

Just a preview: we will have a detailed presentation later on

- Sponsor Balloting
- Formation of balanced Ballot Group
- IEEE-SA members can sign up to be part of ballot
- Up to 3 IEEE societies invited to participate
- WG members and others can provide feedback and vote on the ballot
- External people can vote if IEEE-SA members or pay a fee

Discussion: Minimum Metadata (continued)

Minimum Metadata Categories

- Datapoint ID and Schema ID
- Source Provenance – *from what* did this datapoint come (Static provenance)
- Acquisition Provenance – *how* was this datapoint *acquired* (Dynamic provenance)
- Defer for later
  - Processing provenance – how was this datapoint computed
  - Data sharing permissions and record
  - Context (some elements may end up in above categories)

Datapoint: What Do We Need to Know?

Metadata Category	Needs	Property (bold = required)
Datapoint	**Which datapoint is this?**	**datapointID**
	Whose datapoint is this?	**userID**
	When was this datapoint created?	**creation_date_time**
	What does this value represent?	**schema ID and schema metadata**
	When is the effective time of this data?	[in the datapoint itself]

Schema: What Do We Need to Know?

Metadata Category	Need	Property (bold = required)
Schema	Which schema does this datapoint follow?	**schema namespace and name**
	What is this schema about?	annotation to controlled term
	Which version of the schema?	**schema version**
	Where can I find this schema ?	url **Omit this?**
	What *can* be said with this schema?	[properties in the schema itself]
	What *must* be said?	[*required* properties in the schema itself]
	In what units?	[in the schema itself]
	How is effective time handled?	[in the schema itself]

Source: What Do We Need to Know?

Metadata Category	Needs	Properties (bold = required)
Source (*from what* did the datapoint come?)		
	What device/app?	**name, manufacturer/publisher, model**
	What OS platform?	**{iOS, Android, WatchOS, Wear OS, ….}** **OS version**
	What firmware/algorithm of the device/app?	**Firmware name, firmware version**, reference url to “Package Insert”
	Which individual device/app?	ID, ID Type (e.g., UDI)

Notes: Device/app refers to hardware devices and software as a medical device (SaMD) or software in a medical device (SiMD).

Acquisition: What Do We Need to Know?

Metadata Category	Needs	Properties (bold = required)
Acquisition (*how* was the datapoint acquired?)		
	When was this datapoint created at the source?	**source_creation_datetime** date-time schema represents a point in time (ISO8601). Timezone is UTC unless otherwise specified
	Was the datapoint sensed or self-reported?	modality
	How often was data sampled and was the sampling regular?	sampling rate and regular or not (Boolean)
	Type of filtering, if used	e.g., values averaged

NEW

Belongs in the Datapoint

- What is the placement of the datapoint source ?
  - in relation to the body
    - **{body location} and {laterality} and {laterality dominance}**
    - Body locations include finger, wrist, chest, head, ears, feet, waist, neck, stomach, eye/ gaze, hip, ankle
  - not in relation to the body (e.g., for IoT)
    - Top NW corner of the living room
- What is the geolocation of the datapoint source?
  - geoposition, named location, etc.
  - Geolocation can also be captured separately using the geolocation schema

Offloading Metadata to the “Package Insert”

- ADviCE Project of the FDA funded UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (CERSI)

Mission: provide information and tools that enable and evaluate effective and safe use of digital health software tools throughout clinical practice and the healthcare ecosystem.

Presentation to P1752 WG on March 12, 2019 8 AM Pacific

“Package Insert” Contents

- Source
  - Firmware/algorithm (e.g., dates of versions, validation details)
  - Type of source sensor(s) (if any) e.g., PPG
  - What is the sensor hardware platform? Eg What chip is in the device?
  - *Performance characteristics*
- Acquisition
  - Source data modification
    - Assumptions about immutability of data? Any experience with this?
  - Measure of missing samples and reason [Acquisition]
    - If sampling is regular and periodic, then missing samples are known to be missing
    - Reason for missingness can be very complex
- Verification/validation: TBD
- Privacy, consent status: static, dynamic privacy/consent needs a run-time infrastructure

Future Work

Next Steps: Metadata

- Minimum metadata properties: Stable? Additional comments?
- “Package Insert”
  - refine our suggestions
  - meet with ADviCE, consensus building with other stakeholders (e.g., CMIOs)
- We are still conducting one-on-one conversations with WG members to more deeply understand your use cases

Do you have hands-on experience with using mHealth data?
Do you have hands-on experience handling metadata to summarize/visualize it?

Contact us! We are scheduling 30 minute calls until end of February

- ida@openmhealth.org or simona@openmhealth.org

Summary of Action Items

Future Meetings

Upcoming Meetings

- Main WG
  - February 26: 8 AM (Pacific) – schemas for generic surveys
  - March 12: 8 AM (Pacific) – ADviCE presentation
- Sleep subgroup
  - March 5, 2019 8:30am to 9:30 am (Pacific)
- PA&M subgroup
  - February 14, 2018 11 to 11:45 am (Eastern)

Adjournment