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)

- 30 April 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

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

None today

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

Physical Activity & Mobility (PAM) Sub-group

1. PA Schema and sample data
   - Reviewed by group members
   - Walking, swimming, jumping ropes, and running
2. Goal Schema and sample data
   - PA Goal: goal setting with a time frame (Simona)
   - Reviewed by group members

Physical Activity & Mobility Subgroup

Scope: The P1752 Physical Activity & Mobility Schema Subgroup will review and propose Open mHealth schemas related to physical activity and mobility functions. The scope includes but is not restricted to the following: step count, physical activity type and duration, energy expenditure, geotrace, geomobility. The focus of this Subgroup's work is on modeling data pertaining to physical activity and mobility measures, and not on current or future individual devices or apps that measure them.

Physical Activity & Mobility (PAM) Sub-group

1. Next Schema Geotrace/Geomobility

2. Next Meeting: May 16, 2019 (11am to 11:45am Eastern Time)

Update:
Sleep Schema Subgroup

Sleep Schema Subgroup Update (1)

➢Status

Quantitative sleep measure task group:

---Drafting team has addressed review comments for 9 schemas

--ambient_light
--ambient_sound
--apnea_hypopnea_index
--deep_sleep_percentage
--light_sleep_percentage
--sleep_body_movement
--sleep_onset_latency
--arousal_rate
--wake_after_sleep_onset

Sleep Schema Subgroup Update (2)

➢Status (continued)

Qualitative sleep measure task group:

---Drafted the following schemas:

- Pittsburgh Sleep Quality Index (PSQI)
- OSA Stop Bang
- Narcolepsy

---Sent out review request for the drafted schemas to the sleep subgroup

Sleep Schema Subgroup Update (3)

➢Next Steps

Quantitative sleep measure task group:

---Draft team complete addressing the review comments (6 more)

Qualitative sleep measure task group:

---Complete drafting the rest of the schemas for the short listed questionnaires (2 more)

- **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: May 7, 2019 11:30am to 12:30 pm**
- **Join the sleep group: email charlotte.chen@Philips.com or Simona.Carini@UCSF.EDU**

Discussion:
Next steps for schemas

Next steps for the subgroups' work

- Overall approach, JSON Schema schemas and sample data
- Review by WG
  - Of all the subgroups' work
- Validation of schemas and sample data
  - To ensure correct JSON syntax and valid sample data
  - Need volunteers who know JSON Schema
  - Let WG Secretary know: simona@openmhealth.org

Discussion: Metadata: What & Where (continued)

Datapoint: What Do We Need to Know?

Metadata Category	Needs	Property (bold = required)
Datapoint	**Which datapoint is this?**	**datapointID**
	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]

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,** , reference url to e.g., ADviCE Common App
	What OS platform?	**{iOS, Android, WatchOS, Wear OS, ….}** **OS version,** reference URL to Hardware Datasheet
	What firmware/algorithm of the device/ app?	**Firmware name, firmware version**, reference url to Software Datasheet
	Which individual device/app?	ID, ID Type (e.g., UDI)
	Which individual?	**User ID,** confidence, reference to Personal Datasheet

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

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

Software Datasheet

Data Data sheet

Data stream(s) ->

Software/ algorithm/model

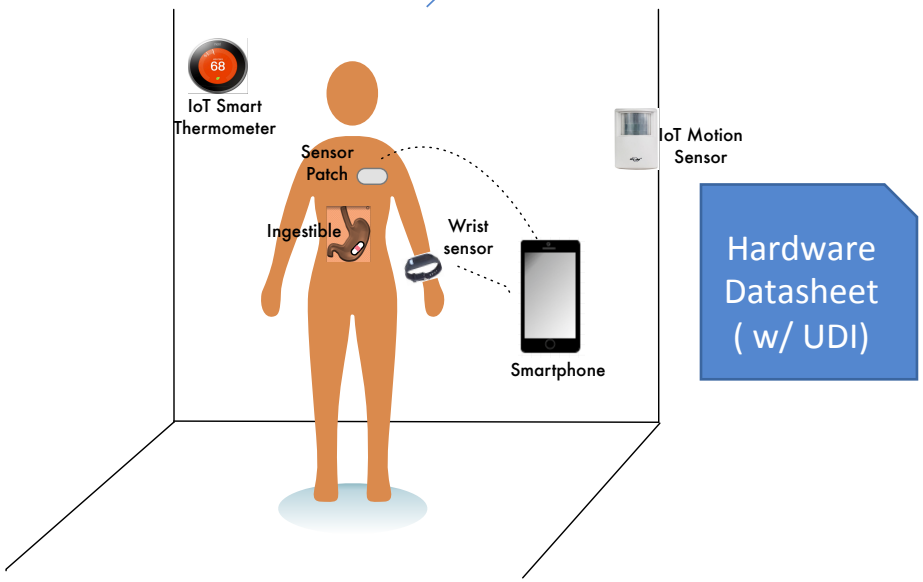
->

{
Header/min metadata
}
{
Body: datapoint
}

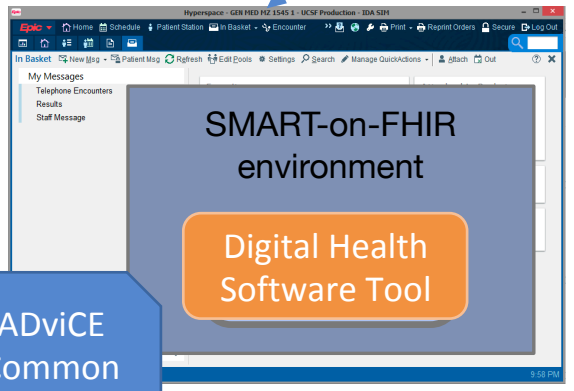
Personal Datasheet

Privacy Policy

Open mHealth data and metadata standards



Hardware Datasheet (w/ UDI)



EHR

ADviCE Common App

Privacy Policy

Next Steps: Metadata

- Minimum metadata properties: how do we finalize?
  - Form subgroup to do initial offline review?
  - Volunteer to help draft proposal for main WG to review?

- Timing: should go to ballot with the sleep schemas

Community Input Process

Open mHealth Community Input/Contributions

- Comments on existing schemas (via OmH website/GitHub)
  - Not actively solicited currently, informal process of response
- Contributing new schemas
  - No current process for new contributions
- Contributing code (e.g.,visualization)

Future Work

Summary of Action Items

Future Meetings

Upcoming Meetings

- Main WG
  - May 21: 8 AM (Pacific)
- Sleep subgroup
  - May 7, 2019 8:30 am to 9:30 am (Pacific)
- PA&M subgroup
  - May 16, 2018 11 to 11:45 am (Eastern)

Adjournment

Hardware Datasheet (static metadata)

- (Static metadata changes on the order of months or less frequently)
- E.g., HL7 FHIR Device Definition and others
- IMDRF/FDA UDI (Unique Device Identification) System draft application guide
  - UDI is required on all regulated medical devices (per Terrie Reed, FDA Senior Advisor for UDI Adoption)
  - The UDI changes for major SaMD revisions that involve complex or significant changes affecting:
    - the original performance and effectiveness
    - the safety or the intended use of the SaMD
  - “These changes may include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.”

Software Datasheet (static metadata)

- Describing validation and verification by the manufacturer and/or independent 3rd party
- Algorithm method and version
  - Input datastreams
  - Input parameters
  - Datasheet for data that the model was trained on (e.g., Datasheets for Datasets, Dataset Nutrition Label)
- Performance
  - E.g., average PPG HR accuracy for person with a specific skin tone
- Open data set available for verification? Where?

Privacy (static and dynamic)

- SaMDs (via ADviCE Common App) and individuals (via Personal Datasheet) have privacy policies (static)
- Algorithms apply privacy policies to output a protection state (dynamic) based on various factors, e.g.,
  - Recipient: e.g., share with my doctors but not my employer, no secondary sharing
  - Purpose: e.g, ok for research, not for marketing, ok for building models
  - Context: e.g., not when I'm at work, or with a certain person, or during a particular time, or when I'm stressed…
  - Derivative products: e.g., ok to share models built with my data
- How data is protected (suppressed/obfuscated/tagged across some administrative boundary) can leak privacy

Other Acquisition Metadata (dynamic)

- Signal quality
- Missingness: tagging gaps in data with reason (e.g., not wearing, system outage, blocked for privacy)
- Etc.
- Ensuring immutability and correctness
  - Data signatures, checksum, etc.
  - Code to enable replay/reproducibility