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)

- 26 March 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.
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:

• IEEE-SA Standards Board Bylaws (http://standards.ieee.org/develop/policies/bylaws/sect6-7.html#6)

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

None today
Update:
Physical Activity and Mobility (PA&M) Schema Subgroup
Physical Activity & Mobility (PAM) Sub-group

1. PA Schema
   • Corrected JSON Schema
2. Sample data for PA schema
   • How many activities?
   • Walking, swimming, jumping ropes, and running
3. Thinking of next Schemas
   • PA Goal (goal setting vs. attainment)
4. Next Meeting: Thursday Mar 28, 2019 (11am to 11:45am Eastern Time)
Update:
Sleep Schema Subgroup
Sleep Schema Subgroup Update (1)

Status

Quantitative sleep measure task group:
---Sleep subgroup has completed the drafted schemas
---Drafting team is reviewing and addressing the review comments

Qualitative sleep measure task group:
---Drafted/Work in progress the following schemas:
  Functional Outcome Sleep Questionnaire (FOSQ) (drafted)
  Karolinska Sleepiness Scale (KSS) (in progress)
Sleep Schema Subgroup Update (2)

Next Steps

Quantitative sleep measure task group:
---Draft team complete addressing the review comments from the sleep subgroup

Qualitative sleep measure task group:
---Complete drafting the rest of the schemas for the short listed questionnaires

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: April 2, 2019 11:30am to 12:30 pm

Join the sleep group: email charlotte.chen@Philips.com or Simona.Carini@UCSF.EDU
Discussion:

Metadata: What & Where
(continued)
Minimum Metadata Categories

- Datapoint ID and Schema ID
- Source Provenance – *from what* did this datapoint come from
- Acquisition Provenance – *how was this datapoint acquired*
- Defer for later
  - Processing provenance – *how was this datapoint computed*
  - Data sharing permissions and record
  - Context (some elements may end up in above categories)
Data stream(s) -> Software/algorithm/model -> { Header/min metadata
  Body: datapoint }

Open mHealth data and metadata standards

Hardware Datasheet (w/ UDI)

Personal Datasheet
Privacy Policy

Software Datasheet
Data Sheet

SMART-on-FHIR environment
Digital Health Software Tool

ADviCE Common App
Privacy Policy

EHR

IoT Smart Thermometer
Sensor Patch
Smartphone

IoT Motion Sensor

Smartphone Wrist sensor
Ingestible Sensor
Patch
## Datapoint: What Do We Need to Know?

<table>
<thead>
<tr>
<th>Metadata Category</th>
<th>Needs</th>
<th>Property (bold = required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Datapoint</td>
<td><strong>Which datapoint is this?</strong></td>
<td>datapointID</td>
</tr>
<tr>
<td></td>
<td>Whose datapoint is this?</td>
<td>userID, confidence</td>
</tr>
<tr>
<td></td>
<td>When was this datapoint created?</td>
<td>creation_date_time</td>
</tr>
<tr>
<td></td>
<td>What does this value represent?</td>
<td>schema ID and schema metadata</td>
</tr>
<tr>
<td></td>
<td>When is the effective time of this data?</td>
<td>[in the datapoint itself]</td>
</tr>
</tbody>
</table>

Should this be in Source metadata?
# Source: What Do We Need to Know?

<table>
<thead>
<tr>
<th>Metadata Category</th>
<th>Needs</th>
<th>Properties (bold = required)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Source (from what did the datapoint come?)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What device/app?</td>
<td>name, manufacturer/publisher, model, reference url to e.g., ADviCE Common App</td>
<td></td>
</tr>
<tr>
<td>What OS platform?</td>
<td>{iOS, Android, WatchOS, Wear OS, ....} OS version, reference URL to Hardware Datasheet</td>
<td></td>
</tr>
<tr>
<td>What firmware/algorithm of the device/app?</td>
<td>Firmware name, firmware version, reference url to Software Datasheet</td>
<td></td>
</tr>
<tr>
<td>Which individual device/app?</td>
<td>ID, ID Type (e.g., UDI)</td>
<td></td>
</tr>
<tr>
<td>Which individual?</td>
<td>User ID, confidence, reference to Personal Datasheet</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:** Device/app refers to hardware devices and software as a medical device (SaMD)
# Digital Health Common App: A package insert for Digital Health

<table>
<thead>
<tr>
<th><strong>INOVOKANA®</strong> (conagafloxin) tablets, for oral use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIGHLIGHTS OF PRESCRIBING INFORMATION</strong></td>
</tr>
<tr>
<td>These highlights do not include all the information needed to use INOVOKANA® safely and effectively. See full prescribing information for INOVOKANA.</td>
</tr>
<tr>
<td>INOVOKANA (conagafloxin) tablets, for oral use</td>
</tr>
<tr>
<td><strong>Initial U.S. Approval: 2013</strong></td>
</tr>
</tbody>
</table>

**WARNING:** LOWER UMBO AMPUTATION  
See full prescribing information for complete boxed warning.

- In patients with type 2 diabetes who have established cardiovascular disease (CVD) or at risk for CVD, INVOKANA has been associated with lower limb amputations, most frequently at the toe and metatarsal, sometimes involving the leg ([5.1]).
- Before initiating, consider factors that may increase the risk of amputation. Monitor patients receiving INOVOKANA for infections or ulcers of the lower limbs, and discontinue if amputation ([5.1]).

**RECENT MAJOR CHANGES**

**Boxed Warning**

**Warnings and Precautions (5.1)**

**INDICATIONS AND USAGE**

INOVOKANA is a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus ([1]).

**Limitations of Use**

- Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis ([1]).

**DOSE AND ADMINISTRATION**

- The recommended starting dose is 100 mg once daily taken before the first meal of the day ([3.1]).
- Dose can be increased to 300 mg once daily in patients tolerating INOVOKANA 100 mg once daily who have an eGFR of 60 mL/min/1.73 m² or greater and require additional glycemic control ([3.1]).
- Assess renal function prior to initiation and periodically thereafter ([3.2]).

**CONTRAINDICATIONS**

- Hypersensitivity to any component.
- Severe renal impairment (eGFR <30 mL/min/1.73 m²) or dialysis-dependent renal impairment.
- History of urosepsis or other severe infections.
- Fracture risk is increased with INOVOKANA treatment ([5.6]).

**WARNINGS**

**LOW BLOOD PRESSURE**

- In patients with type 2 diabetes who have established cardiovascular disease (CVD) or at risk for CVD, INVOKANA has been associated with hypotension, which may be severe and may occur when INOVOKANA is administered at the start of treatment or after dose increases ([5.2]).
- Monitor blood pressure and heart rate ([5.2]).

**LIVER FUNCTION**

- Monitor liver function before starting and periodically throughout treatment ([5.3]).

**HYPOTENSION**

- In patients with type 2 diabetes who have established cardiovascular disease (CVD) or at risk for CVD, INVOKANA has been associated with hypotension, which may be severe and may occur when INOVOKANA is administered at the start of treatment or after dose increases ([5.2]).

**ACUTE KIDNEY INJURY**

- Acute kidney injury and impairment in renal function. Consider temporarily discontinuing in settings of reduced renal function or fluid losses. If acute kidney injury occurs, discontinue and promptly treat. Monitor renal function during therapy ([5.6]).

**HYPOKALEMIA**

- Hypokalemia: Monitor potassium levels in patients with impaired renal function and in patients predisposed to hyperkalemia ([5.6]).

**Renal Impairment**

- Evaluate patients with low and symptomatic urinary tract infections and treat promptly, if indicated ([5.6]).

**Gastrointestinal**

- Consider a lower level of insulin or the insulin analogue to reduce the risk of hypoglycemia when used in combination with INVOKANA ([5.7]).

**DRUG INTERACTIONS**

- Must not be used with insulin or the insulin analogue to reduce the risk of hypoglycemia when used in combination with INVOKANA ([5.7]).

**ADVERSE REACTIONS**

- Most common adverse reactions associated with INVOKANA (5% or greater incidence) are genital mycotic infections, urinary tract infections, and increased urination ([6.1]).

**To report SUSPECTED ADVERSE REACTIONS, contact Janssen Pharmaceuticals, Inc. at 1-800-285-7735 or FDA at 1-888-FDA-1088 or www.fda.gov/medwatch.**

**DRUG INTERACTIONS**

- UGT inhibitors (e.g., rifampin): Concomitant exposure is reduced. Consider...
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
  - 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
## Acquisition: What Do We Need to Know?

<table>
<thead>
<tr>
<th>Metadata Category</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Acquisition</strong></td>
<td><em>(how was the datapoint acquired?)</em></td>
<td><em>source_creation_datetime</em>&lt;br&gt;date-time schema represents a point in time (ISO8601). Timezone is UTC unless otherwise specified</td>
</tr>
<tr>
<td></td>
<td>When was this datapoint created at the source?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Was the datapoint sensed or self-reported?</td>
<td><em>modality</em></td>
</tr>
<tr>
<td></td>
<td>How often was data sampled and was the sampling regular?</td>
<td><em>sampling rate and regular or not (Boolean)</em></td>
</tr>
<tr>
<td></td>
<td><em>Type of filtering, if used</em></td>
<td><em>e.g., values averaged</em></td>
</tr>
</tbody>
</table>
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
Data stream(s) -> Software/algorithm/model -> 

{ 
  Header/min metadata 
} 

{ 
  Body: datapoint 
} 

Where is dynamic acquisition metadata stored?

Open mHealth data and metadata standards

SMART-on-FHIR environment

Digital Health Software Tool

EHR

ADviCE Common App

Privacy Policy

Hardware Datasheet (w/ UDI)

Software Datasheet

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Ingestible Sensor

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SMART-on-FHIR environment

Digital Health Software Tool

EHR
Next Steps: Metadata

• Comments on metadata what & where: send to ida@openmhealth.org

• Minimum metadata properties: how do we finalize?
Future Work
Summary of Action Items
Future Meetings
Upcoming Meetings

• Main WG
  • April 16: 8 AM (Pacific)

• Sleep subgroup
  • April 2, 2019 8:30 am to 9:30 am (Pacific)

• PA&M subgroup
  • March 28, 2018 11 to 11:45 am (Eastern)
Adjournment