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 March 2019
- Teleconference
Attendance

- This document shows attendance from previous calls [https://tinyurl.com/yc3oxg6q](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:

- **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
(February 12 and 26)
Update: Physical Activity and Mobility (PA&M) Schema Subgroup
Physical Activity & Mobility (PAM) Sub-group

1. Developed PA schema
   • PA (type, duration, step count)
2. Thinking of next Schemas
   • PA Goal
   • Energy expenditure
   • Geotrace and Geomobility
   • Sensor Schema
3. Next Meeting: Thursday Mar 14, 2019 (11am to 11:45am Eastern Time)
Update:
Sleep Schema Subgroup
Status

Quantitative sleep measure task group:
---Walked through/Discussed the revised or new schemas with their sample data in the sleep subgroup call
  total_sleep_time schema and sample data
  time_in_bed sample data
  sleep_stages schema and sample data
  sleep_apnea schema and sample data
---Sleep subgroup is reviewing the drafted schemas
---Drafting team has started to review and address the review comments

Qualitative sleep measure task group:
---Drafted the following schemas:
  Stanford Sleepiness Scale
  OSA Stop Bang
Next Steps

Quantitative sleep measure task group:
---Complete reviewing the drafted schemas by the sleep subgroup
---Draft team address the review comments (e.g. modify the schemas, etc.)

Qualitative sleep measure task group:
---Complete drafting the schemas (need more people to sign up)

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:
Beyond Minimum Metadata
Discussion:
Presentation by Andrew Auerbach
(UCSF, ADviCE)
ADviCE
Overview for partners
Digital health software tools show great promise across the learning health system

• Focus areas:
  • Population health
  • Chronic disease management
  • Consumer experience
  • Artificial intelligence
  • Precision medicine
  • Collaborative patient-centered care across institutions
  • Patient-reported outcomes
  • Data from consumer apps and sensors
Potential purchasers remain uncertain how to adopt

45%

Healthcare systems with a “standard process to assess whether to pilot a digital solution”

51%

Healthcare systems with a “standard process to decide whether to take a digital innovation pilot to scale”

AHA & AVIA Digital Innovation Survey (Sep 2017)
Accelerated Digital Clinical Ecosystem (ADviCE)

A collaborative that shares best practices and data for integrating digital health software tools into clinical practice

• **ADviCE’s Vision** is to become world's leading digital health collaborative workspace, linking patients, providers, innovators and health systems to advance health and improve healthcare delivery.

• **ADviCE’s Mission** is to provide information and tools that enable effective and safe use of digital health software tools in clinical practice.
PreCert Focus: Software as a Medical Device (SaMD)
Synergy of FDA and ADviCE: Overview

- Market Authorization (Precertification)
- Market Access (Common Application)
- Market Adoption (Screening and Integration Checklist)
- Market Surveillance (Real-World Performance)

FDA
- Precertification of the quality of vendors and their SaMD

ADviCE
- Sharing best practices, and engaging vendors, patients, and payors
- Access to comparator health systems and partners for deeper understanding of digital health software tools in practice
How might we speed adoption of digital health software

<table>
<thead>
<tr>
<th>Barriers</th>
<th>Potential Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of technical standards</td>
<td>FHIR, Argonaut, Health Services Platform Consortium (HSPC)</td>
</tr>
<tr>
<td>Complex regulatory frameworks</td>
<td>FDA PreCert</td>
</tr>
<tr>
<td>Poor health system readiness</td>
<td>ADviCE</td>
</tr>
<tr>
<td>Vendor uncertainty around health system expectations</td>
<td>ADviCE</td>
</tr>
<tr>
<td>Lack of efficacy data</td>
<td>PreCert + ADviCE (defining real-world outcomes)</td>
</tr>
<tr>
<td>Reimbursement models</td>
<td>Multi-stakeholder</td>
</tr>
<tr>
<td>Swirling and Stuck</td>
<td>Adopted into Care Delivery</td>
</tr>
</tbody>
</table>
Digital Health Common Application

Digital Health Integration Best Practices Framework

Market Surveillance and Real-World Performance
Digital Health Common Application
One application, unlimited possibilities.

Whether you're applying for the first time or you're a transfer student taking the next step in your journey, we're here for you every step of the way. See what's possible by exploring which colleges and universities accept the Common App.
DHCA: A package insert for Digital Health

INVOGANDA® (conagafilin) tablets, for oral use

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use INVOGANDA® safely and effectively. See full prescribing information for INVOGANDA®.

**INVOGANDA® (conagafilin) tablets, for oral use**

**Software version**

**Target users**

**Desired implementation approach**

**Data on effectiveness or safety (if any)**

Where data go. Who owns data. Is the tool actually used anywhere?
Digital Health Common Application

• A trusted resource for patients and those prescribing and integrating DHST into practice

  • Vendors/developers enter data themselves (Market Entry)
  • Vendors enter at time they contact potential ‘customers’
  • Current customers enter information on DHST or SaMD currently in use or under consideration.

• A marketplace of users and vendors relying on validated information to make choices about how to work together
Digital Health Integration Best Practices Framework
ADviCE Implementation Best Practices Framework

• Consensus based best practices domains
  • Pre-implementation governance:
    • Does your site have a process for assessing for conflicts of interest?
    • Does your site require an executive sponsor before considering for implementation?

• Data privacy and informatics
  • Does your site require service level agreements prior to use?
  • Does your site require a training plan prior to implementation?
  • Does your privacy process assess for subsidiary data vendors?
Market Surveillance and Real-World Performance
Real-World Data: ADviCE

<table>
<thead>
<tr>
<th>Real World Performance Analytics (RWPA)</th>
<th>User Experience Analytics (UXA)</th>
<th>Real World Health Analytics (RWHA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Performance Analytics (PPA)</td>
<td>User Experience Analytics (UXA)</td>
<td>Real World Health Analytics (RWHA)</td>
</tr>
<tr>
<td>Cybersecurity</td>
<td>Human Factors, Usability Engineering, and Universal Design</td>
<td>Health Benefits</td>
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<tr>
<td>Product Performance</td>
<td>User Satisfaction</td>
<td>Clinical Safety</td>
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<tr>
<td>Interoperability</td>
<td>User Feedback Channels</td>
<td>Real World Usage</td>
</tr>
<tr>
<td>Issue Resolution</td>
<td>User Engagement and Workflow</td>
<td></td>
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ADviCE Real World Performance Data

• Technical goals
  • What are the technical requirements for ‘instrumenting’ selected DHST?
  • FHIR APIs to key data sources – National/Payor, Local, Vendor

• Evaluation goals
  • What sort of evaluation is appropriate for the ‘risk’ of the DHST?
  • Which data sources would be needed to gain a picture of real-world performance?
  • How would data be shared/governed?
ADviCE’s value proposition

• By providing a curated environment of vendors, health systems, and users, ADviCE will provide
  • Provide trustworthy information on digital tools and solutions
    • Which align with consumer and prescriber priorities
    • Which align with potential customers and regulators
  • Increase visibility of digital health’s impact on health
  • Guide developers, investors, and innovators towards effective integration approaches
    • Provide information on how to speed adoption
  • Guide all stakeholders towards effective solutions, regardless of whether they are ‘regulated’
<table>
<thead>
<tr>
<th></th>
<th>Curated warehouse of DHST</th>
<th>Regulatory awareness</th>
<th>Tools to make purchasing and use decisions</th>
<th>Engagement with DHST purchasers (or prescribers)</th>
<th>Engagement with patients</th>
<th>Emphasis on evaluation and post-market surveillance</th>
</tr>
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<tbody>
<tr>
<td>Avia</td>
<td>No</td>
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<td>EU only</td>
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<td>Through ratings</td>
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<td>Yes</td>
<td>TBD</td>
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<tr>
<td>ADviCE</td>
<td>Yes</td>
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</table>
ADviCE 2019

• Take working DHCA prototype and expand its use to include DHST being integrated/used at partner sites

• Finalize the Integration Checklist’s use in context of DHST and marketplace

• Evaluation data
  • Prioritization - Which areas of the data model are most important to which stakeholders (and under which conditions)?
  • Instrumentation – Using DHCA pilot groups as a guide to understanding the technical approaches
  • Evaluation plans - Using DHCA pilot groups as a guide to understanding data requirements, potential registry designs
ADviCE 2019

• Fundraising to support 2019 goals, particularly the work of populating and validating the DHCA environment and instrumentation approach

• Grants to support collaborative meetings and consensus-format projects (prioritization)

• Coordinating with FDA around PreCert launch in 12/2019
  • Expanding beyond initial PreCert partners
  • Support for Collaborative Communities
Future Work
Summary of Action Items
Future Meetings
Upcoming Meetings

• Main WG
  • March 26: 8 AM (Pacific)

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

• PA&M subgroup
  • March 14, 2019 11 to 11:45 am (Eastern)
Adjournment