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 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

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

(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

Sleep Schema Subgroup Update (1)

➢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

Sleep Schema Subgroup Update (2)

➢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/

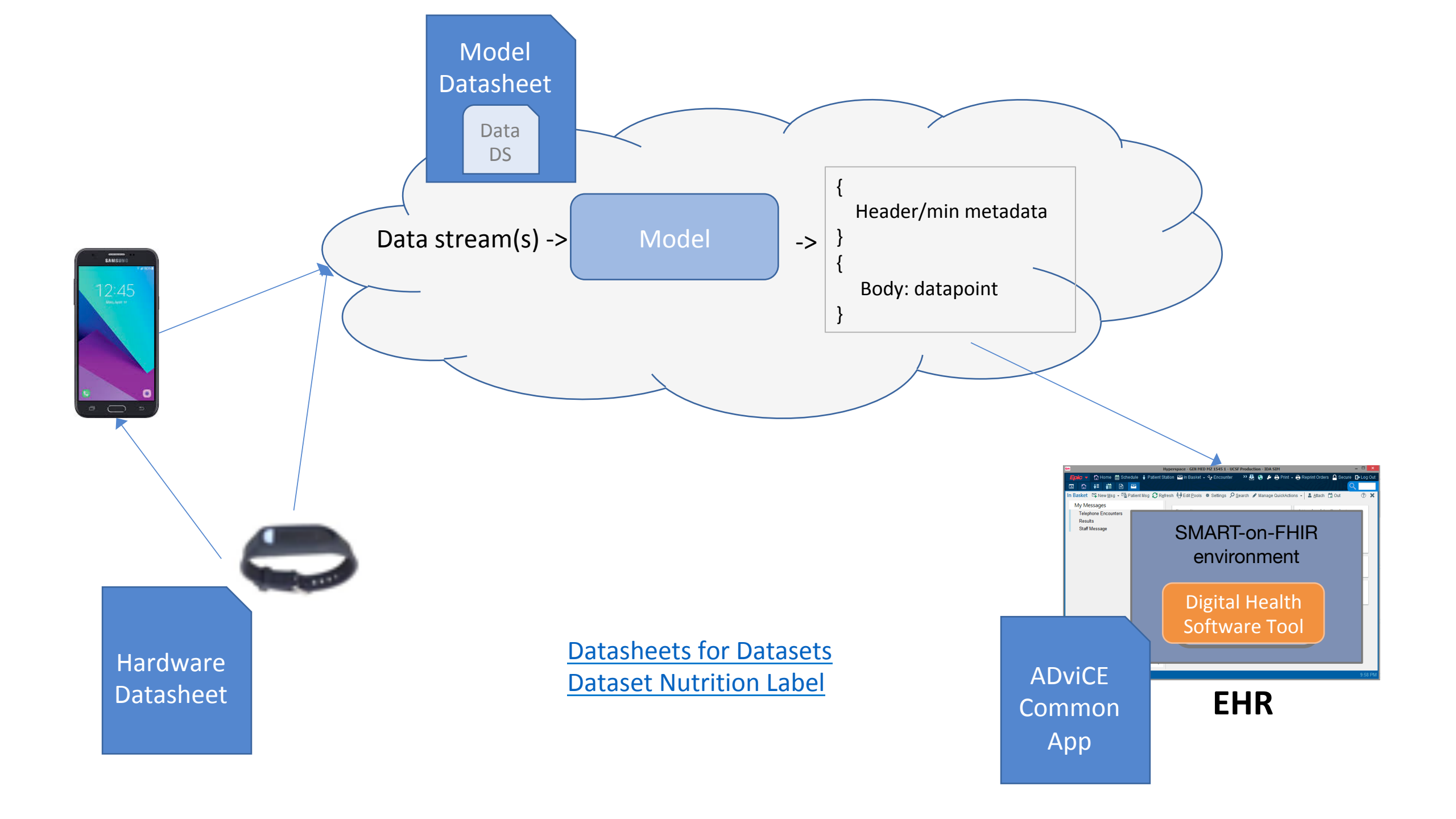
➢ **Drafted schemas:**

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

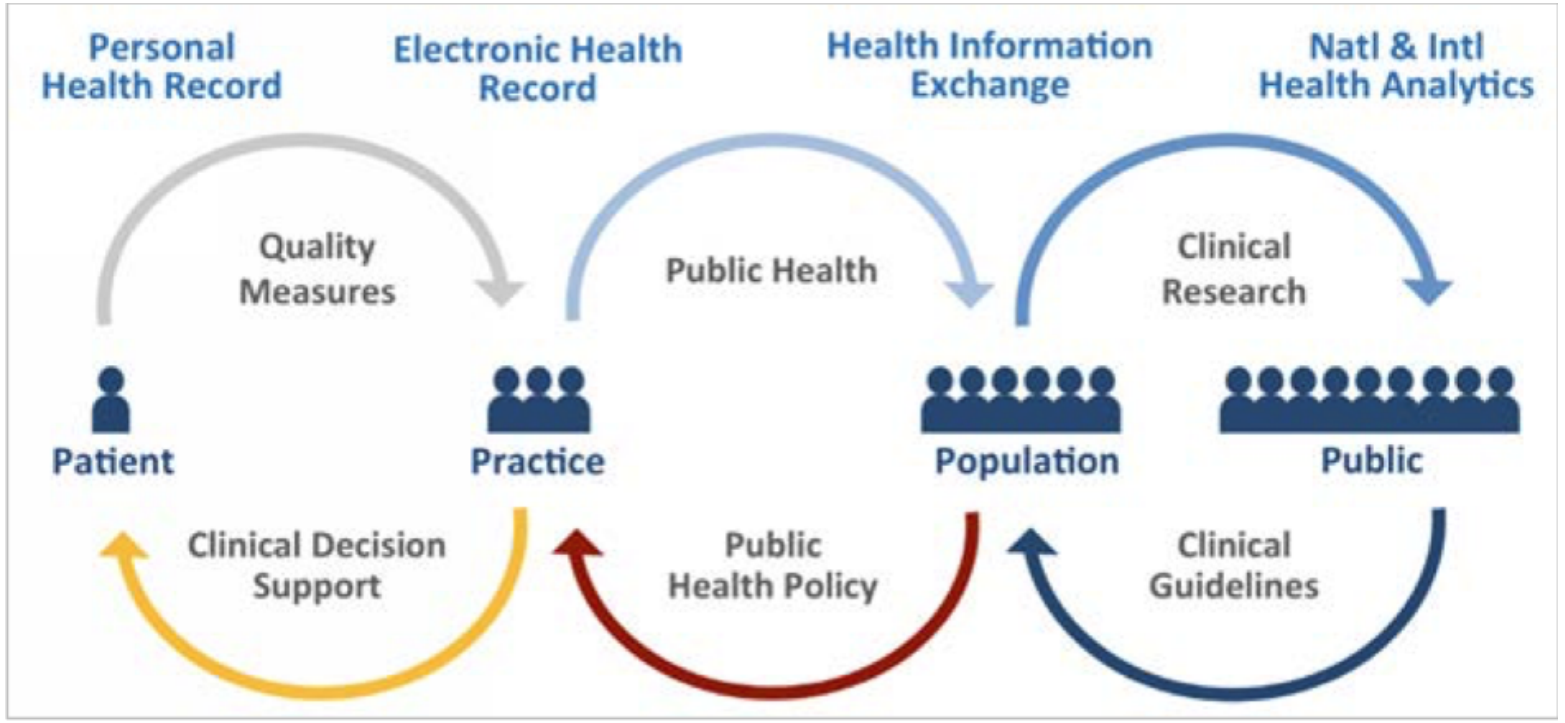

Model Datasheet
Data DS
Data stream(s) ->
Model
->
{
Header/min metadata
}
{
Body: datapoint
}
Hardware Datasheet
Datasheets for Datasets
Dataset Nutrition Label
SMART-on-FHIR environment
Digital Health Software Tool
EHR
ADviCE Common App

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.

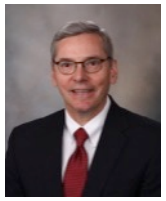
Core team & Partners

Andy Auerbach
UCSF

Julia Adler-Milstein
UCSF

David Bates
Partners Healthcare

Ken Kawamoto
University of Utah

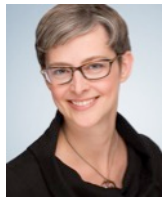


Steve Peters
Mayo Clinic

Cris Ross
Mayo Clinic

Maulin Shah
Providence St. Joseph

David Amor
Pear Therapeutics



Heather Colvin
Johnson & Johnson

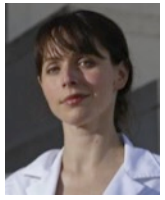
Howard Look
Tidepool

Iyan John
APIAHF

Trent Haywood
BCBS Association

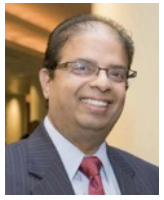
Raman Khanna
UCSF

Aaron Neinstein
UCSF



Marisa Cruz
FDA

Martin Ho
FDA



Bakul Patel
FDA

Mark Savage
UCSF

Ralph Brindis
UCSF

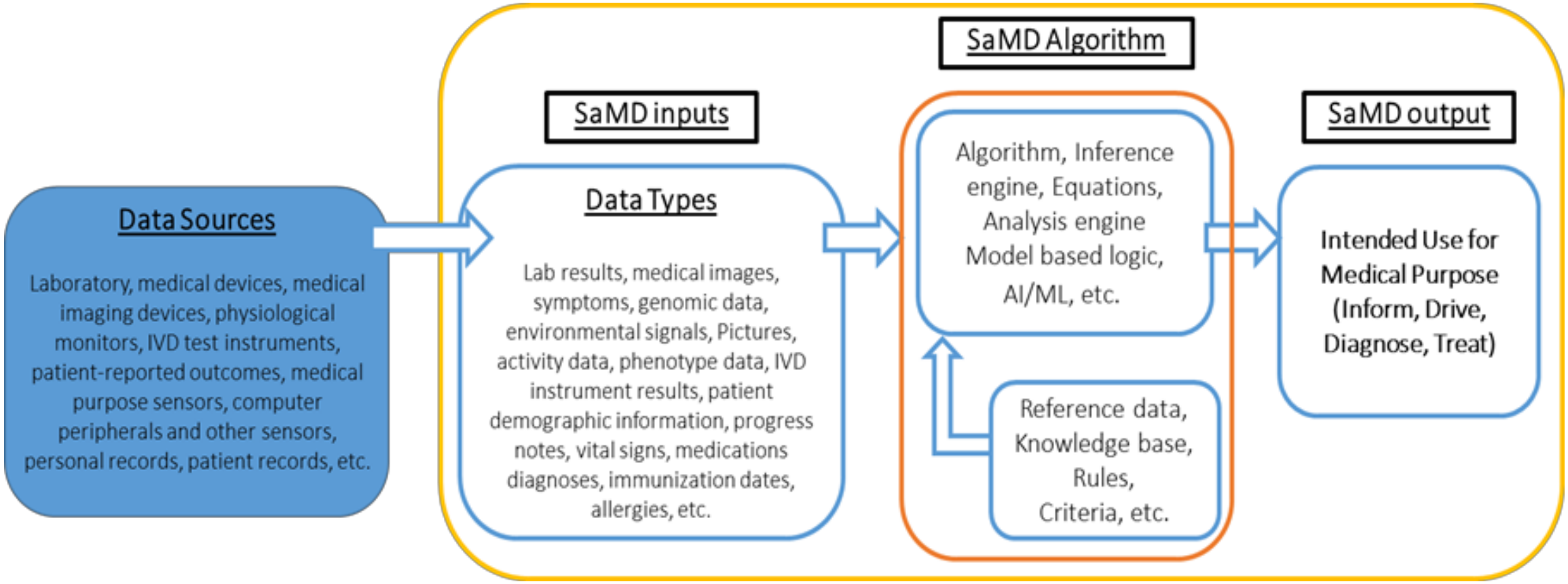
Gautam Shah
UCSF

Steven Chan
UCSF

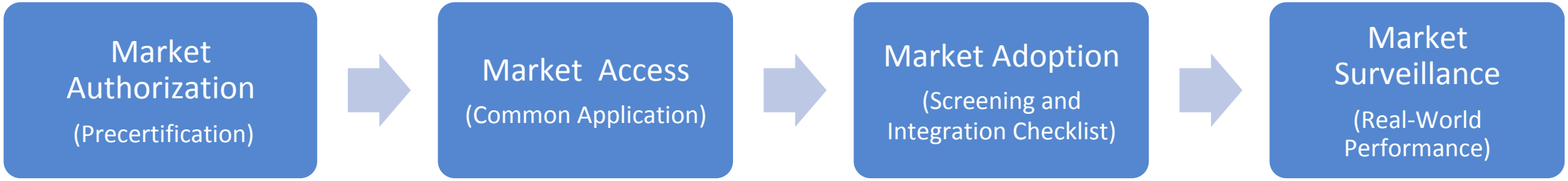
ADVICE Accelerated Digital Clinical Ecosystem

UCSF Center for Digital Health Innovation | MAYO CLINIC | PARTNERS HEALTHCARE | Providence St. Joseph Health | HEALTH UNIVERSITY OF UTAH + APIAHF ASIAN & PACIFIC ISLANDER AMERICAN HEALTH FORUM + BlueCross BlueShield + J&J | PEAR THERAPEUTICS

PreCert Focus: Software as a Medical Device (SaMD)



Synergy of FDA and ADviCE: Overview



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

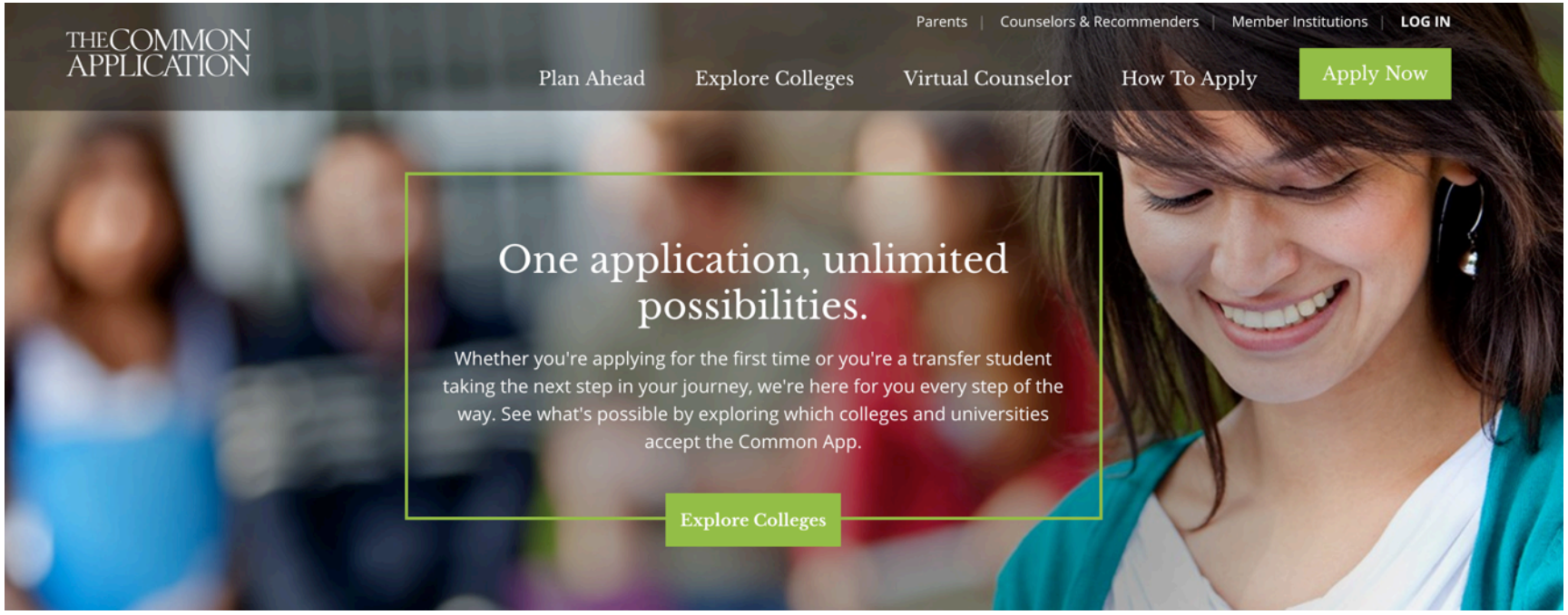
Barriers	Potential Solutions
Lack of technical standards	FHIR, Argonaut, Health Services Platform Consortium (HSPC)
Complex regulatory frameworks	FDA PreCert
Poor health system readiness	ADviCE
Vendor uncertainty around health system expectations	ADviCE
Lack of efficacy data	PreCert + ADviCE (defining real-world outcomes)
Reimbursement models	Multi-stakeholder
Swirling and Stuck	**Adopted into Care Delivery**

Digital Health Common Application

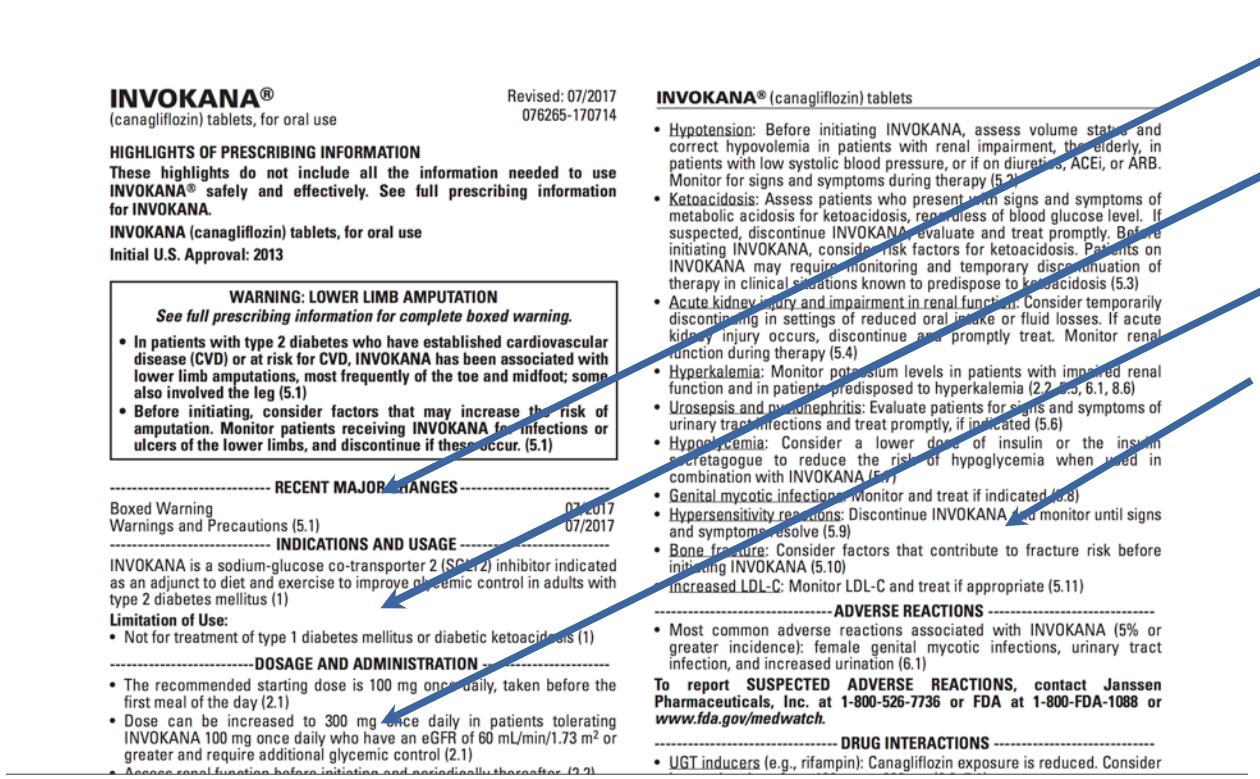
Digital Health Integration Best Practices Framework

Market Surveillance and Real-World Performance

Digital Health Common Application


THE COMMON APPLICATION
Parents | Counselors & Recommenders | Member Institutions | LOG IN
Plan Ahead
Explore Colleges
Virtual Counselor
How To Apply
Apply Now
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.
Explore Colleges

DHCA: A package insert for Digital Health



INVOKANA®
(canagliflozin) tablets, for oral use

Revised: 07/2017
076265-170714

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

INVOKANA (canagliflozin) tablets, for oral use

Initial U.S. Approval: 2013

WARNING: LOWER LIMB 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 of the toe and midfoot; some also involved the leg (5.1)**
- **Before initiating, consider factors that may increase the risk of amputation. Monitor patients receiving INVOKANA for infections or ulcers of the lower limbs, and discontinue if these occur. (5.1)**

RECENT MAJOR CHANGES

Boxed Warning 07/2017
Warnings and Precautions (5.1) 07/2017

INDICATIONS AND USAGE

INVOKANA 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)

Limitation of Use:

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

DOSAGE AND ADMINISTRATION

- The recommended starting dose is 100 mg once daily, taken before the first meal of the day (2.1)
- Dose can be increased to 300 mg once daily in patients tolerating INVOKANA 100 mg once daily who have an eGFR of 60 mL/min/1.73 m² or greater and require additional glycemic control (2.1)

INVOKANA® (canagliflozin) tablets

- Hypotension: Before initiating INVOKANA, assess volume status and correct hypovolemia in patients with renal impairment, the elderly, in patients with low systolic blood pressure, or if on diuretics, ACEi, or ARB. Monitor for signs and symptoms during therapy (5.2)
- Ketoacidosis: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue INVOKANA, evaluate and treat promptly. Before initiating INVOKANA, consider risk factors for ketoacidosis. Patients on INVOKANA may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis (5.3)
- Acute kidney injury and impairment in renal function: Consider temporarily discontinuing in settings of reduced oral intake or fluid losses. If acute kidney injury occurs, discontinue and promptly treat. Monitor renal function during therapy (5.4)
- Hyperkalemia: Monitor potassium levels in patients with impaired renal function and in patients predisposed to hyperkalemia (2.2, 2.3, 6.1, 8.6)
- Urosepsis and pyelonephritis: Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated (5.6)
- Hypoglycemia: Consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia when used in combination with INVOKANA (5.7)
- Genital mycotic infections: Monitor and treat if indicated (5.8)
- Hypersensitivity reactions: Discontinue INVOKANA and monitor until signs and symptoms resolve (5.9)
- Bone fracture: Consider factors that contribute to fracture risk before initiating INVOKANA (5.10)
- Increased LDL-C: Monitor LDL-C and treat if appropriate (5.11)

ADVERSE REACTIONS

- Most common adverse reactions associated with INVOKANA (5% or greater incidence): female genital mycotic infections, urinary tract infection, and increased urination (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Janssen Pharmaceuticals, Inc. at 1-800-526-7736 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

DRUG INTERACTIONS

- UGT inducers (e.g., rifampin): Canagliflozin exposure is reduced. Consider

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?

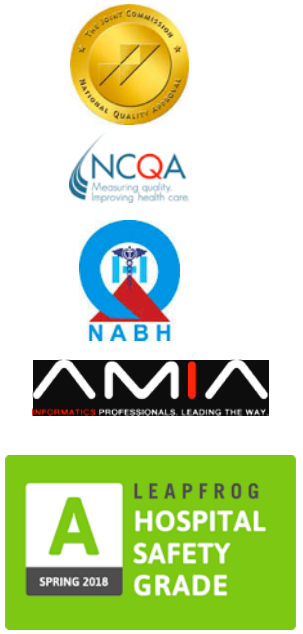
Digital Health Common Application

- 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

Real World Performance Analytics (RWPA)		
Product Performance Analytics (PPA)	**User Experience Analytics (UXA)**	**Real World Health Analytics (RWHA)**
Cybersecurity	Human Factors, Usability Engineering, and Universal Design	Health Benefits
Product Performance	User Satisfaction	Clinical Safety
Interoperability	User Feedback Channels	Real World Usage
Issue Resolution	User Engagement and Workflow	

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'

	Curated warehouse of DHST	Regulatory awareness	Tools to make purchasing and use decisions	Engagement with DHST purchasers (or prescribers)	Engagement with patients	Emphasis on evaluation and post-market surveillance
Avia	No	No	Yes	Yes	No	No
Valify	No	No	Yes	Yes	No	No
ORCHA	Yes	EU only	Use only	Through ratings	No	No
EXCERTIA	TBD	No	No	Yes	TBD	No
ADviCE	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**

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