Sensor data integrations to power better decisions, faster, across healthcare & research

Public launch event

July 18, 2021 | 10.30am - noon ET
Our purpose

DiMe is a global non-profit dedicated to advancing the **safe**, **effective**, **equitable**, and **ethical** use of digital products to optimize human health.

Source: https://www.dimesociety.org/index.php/about-us-main
Introducing the Digital Medicine Society (DiMe)

We launched in May 2019...

Introducing the Digital Medicine Society (DiMe)

... and sit at the intersection of two communities

Source: https://www.dimesociety.org/index.php/about-us-main
Introducing the Digital Medicine Society (DiMe)

We deliver clinical quality work on a tech timeline

**Communication & education**
Resources & publications generated by DiMe & thought leaders in the field are exchanged between various stakeholders & across the many disciplines in the field.

**Community**
DiMe members, partners, & experts from across tech & healthcare unite to collaborate & identify ways to overcome barriers to success.

**Research**
Experts from across all disciplines address shared challenges through deep inquiry & data generation, creating actionable, evidence-based resources.

**New knowledge & capabilities in the field spark new collaboration opportunities**

**Greatest challenges & opportunities to advancing the field**

Source: https://www.dimesociety.org/index.php/knowledge-center/dime-generated-content
Housekeeping

• This session will be recorded
  • Slides and recording will be available on DiMe’s webinar page after the session

• Participating in the discussion
  • ‘Raise your hand’ in the Reactions and the moderator will unmute you, or
  • Type your question in the chat box
  • The chat is not saved and shared to promote open discussions... grab the links as we go!
Driving better decisions, faster, through the successful use of sensor generated data at scale in patient care and clinical research.
Sensor data integrations to power better decisions, faster, across healthcare & research

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Micky Tripathi
National Coordinator for Health Information Technology, HHS
Keynote

Jennifer Goldsack
Chief Executive Officer, Digital Medicine Society, DiMe
Moderator
V3 framework

**Design Specifications & Modular Prototyping**

- **Verification**
  - Evaluates and demonstrates the performance of a sensor technology within a BioMeT, and the sample-level data it generates, against a pre-specified set of criteria.

- **Analytical validation**
  - Evaluates the performance of algorithm, and the ability of this component of the BioMeT to measure, detect, or predict physiological or behavioral metrics.

- **Clinical validation**
  - Evaluates whether a BioMeT acceptably identifies, measure, or predicts a meaningful clinical, biological, physical, functional state, or experience, in the states context of use (which includes a specified population).

**Clinical Utility**

*BioMeT* - Biometric Monitoring Technology

Source: [https://www.nature.com/articles/s41746-020-0260-4](https://www.nature.com/articles/s41746-020-0260-4)
Measures that matter framework

Digital Biomarkers

Digit Biomark 2020;4:69-77

DOI: 10.1159/000509725
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Published by S. Karger AG, Basel
www.karger.com/dib

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Digital Measures That Matter to Patients: A Framework to guide the Selection and Development of Digital Measures of Health

Digit Biomark 2020;4:69-77 = DOI:10.1159/00509725

Viewpoint Review Article

Digital Measures That Matter to Patients: A Framework to Guide the Selection and Development of Digital Measures of Health

Christine Manta a,b Bray Patrick – Lake a,c Jenifer C, Goldsack a

a Digital Medicine Society, Boston, MA, USA; b Elektra Labs, Boston, MA, USA; c Evidation Health, Inc., San Mateo, CA, USA

Meaningful Aspect of Health
- Aspect of a disease that a patient a) does not want to become worse, b) wants to improve or c) wants to prevent
  - May be shared across some conditions and diseases

Concept of Interest
- Simplified or narrowed element that can be practically measured
  - Patients may have different symptoms
  - Symptoms may vary over time
  - Symptoms relevance may vary over time

Outcome to be measured
- Specific measurable characteristics
  - Measures may be relevant to multiple symptoms
  - Assess technical specification of sensor and whether it is suitable for measuring this outcome in this population

Endpoint
- Health research only; Precisely defined, statistically analyzed variables
  - Sensors may support multiple measures & endpoints

Critical Patient Input
- What do you wish that you could do, but your condition prevents you from doing it?
- What part of your life is most frustratingly impacted by your condition?
- What are the symptoms that most impact your ability to do these activity?
- Do these measures make sense to you?
- How much change do we need to see in this symptom before it really starts to make a positive difference in your life?

This figure was adapted from original work by Evidation Health, with permission. This figure illustrates patient considerations that should drive digital measure selection and development, these should precede technical considerations [8]. Additional information on subsequent technical considerations are available at [36, 37, 38].

Source: https://www.karger.com/Article/Pdf/509725
EVIDENCE Publication Checklist for Studies 
Evaluating Connected Sensor Technologies:
Explanation and Elaboration

Christine Manta^a,^b Nikhil Mahadevan^c,h Jessie Bakker^a,d Simal Ozen Irmak^e Elena Izmailova^f Siyeon Park^9 Jiat-Ling Poon^b Santosh Shevade^1 Sarah Valentine^h Benjamin Vandendriessche^j,k Courtney Webster^l Jennifer C. Goldsack^3

^aDigital Medicine Society, Boston, MA, USA; ^bElekta Labs, Boston, MA, USA; ^cPfizer Inc., Cambridge, MA, USA; ^dPhilips, Monroeville, PA, USA; ^eTibi Health Inc., San Francisco, CA, USA; ^fKoneka Health Inc., New York, NY, USA; ^gGeisinger Health System, Danville, PA, USA; ^hEli Lilly and Company, Indianapolis, IN, USA; ^iIndependent Consultant, Mumbai, India; ^jBtwillies, Antwerp, Belgium; ^kDepartment of Electrical, Computer and Systems Engineering, Case Western Reserve University, Cleveland, OH, USA; ^lNimbly.work, Seattle, WA, USA

Source: https://www.dimesociety.org/tours-of-duty/evidence/
The Playbook: Digital Clinical Measures

Terminology supporting the essential guide for successful remote monitoring across clinical research, clinical care, and public health.
The 3Ps of Digital Endpoint Value

PATIENTS • PHARMA • PAYERS

Reimbursement for New Medical Products
Developed using Digital Drug Development Tools

Source: www.dimesociety.org/tours-of-duty/digital-measures-adrd/
NOCTURNAL SCRATCH
Digital Measures Development
Advancing nocturnal scratch as a digital endpoint for atopic dermatitis

Founding Partners:
- AbbVie
- Janssen
- Novartis
- Pfizer
- UCB

Collaborating Partners:
- Almirall
- GSK
- GlaxoSmithKline
- LEO
- Lilly
- Sanofi

Source: www.dimesociety.org/tours-of-duty/digital-measures-adrd/
ALZHEIMER’S DISEASE & RELATED DEMENTIAS

Digital Measures Development
Identifying Patient Specified Digital Measures in Alzheimer’s Disease and Related Dementias

Source: www.dimesociety.org/tours-of-duty/digital-measures-adrd/
Project Partners

Driving better decisions, faster, through the successful use of sensor generated data at scale in patient care and clinical research.

Source: https://www.dimesociety.org/tours-of-duty/sensor-data-integrations/
Three key stakeholders

Data Producer
Individuals & organizations generating sensor data for use in clinical decision-making in health care & research

Data Processor
Individuals & organizations that collect, store, adapt, retrieve, consult, transmit, manage, restrict, or destruct sensor data

Data Consumer
Individuals & organizations that rely on sensor data to drive their objectives and decision-making

Source: https://www.dimesociety.org/tours-of-duty/sensor-data-integrations/access-resources/
## Sensor data integrations toolkit contents

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[Source: https://www.dimesociety.org/tours-of-duty/sensor-data-integrations/resource-catalog/]
Enter coupon code **SDI2021** to receive one year of free individual membership at DiMe

THANK YOU

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