

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

Public launch event

July 18, 2021 | 10.30am - noon ET



**Micky Tripathi**  
National Coordinator for  
Health Information  
Technology, HHS  
Keynote

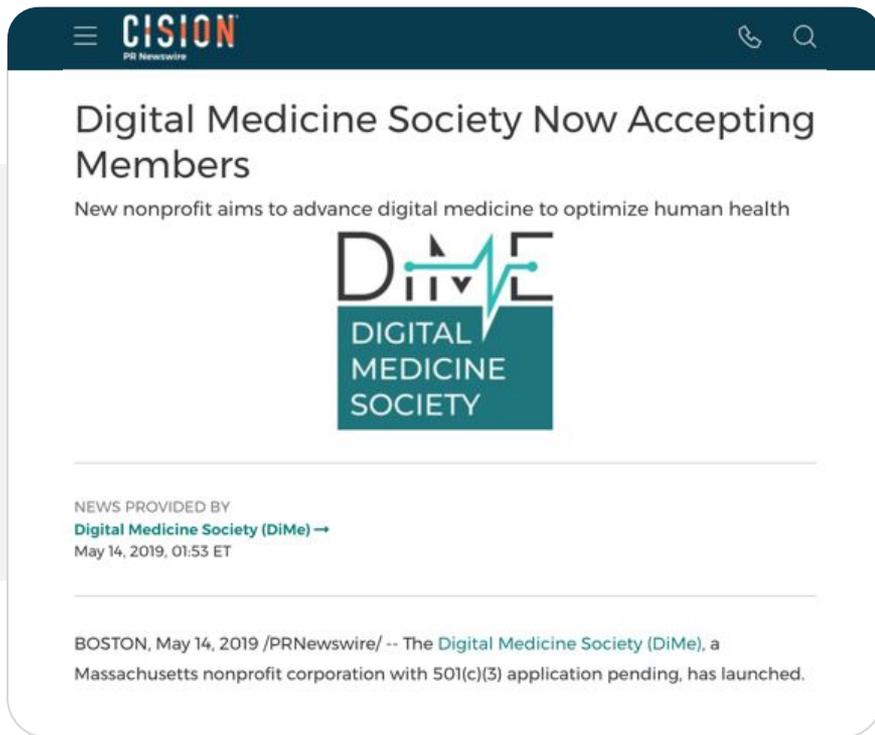


**Jennifer Goldsack**  
Chief Executive Officer,  
Digital Medicine  
Society, DiMe  
Moderator

## 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

# We launched in May 2019...



**CISION**  
PR Newswire

## Digital Medicine Society Now Accepting Members

New nonprofit aims to advance digital medicine to optimize human health



NEWS PROVIDED BY  
**Digital Medicine Society (DiMe)** →  
May 14, 2019, 01:53 ET

BOSTON, May 14, 2019 /PRNewswire/ -- The **Digital Medicine Society (DiMe)**, a Massachusetts nonprofit corporation with 501(c)(3) application pending, has launched.



STAT Topics Opinion Podcast Video Newsletters Events Q Log I

FIRST OPINION

## DiMe: Calling all who serve in digital medicine

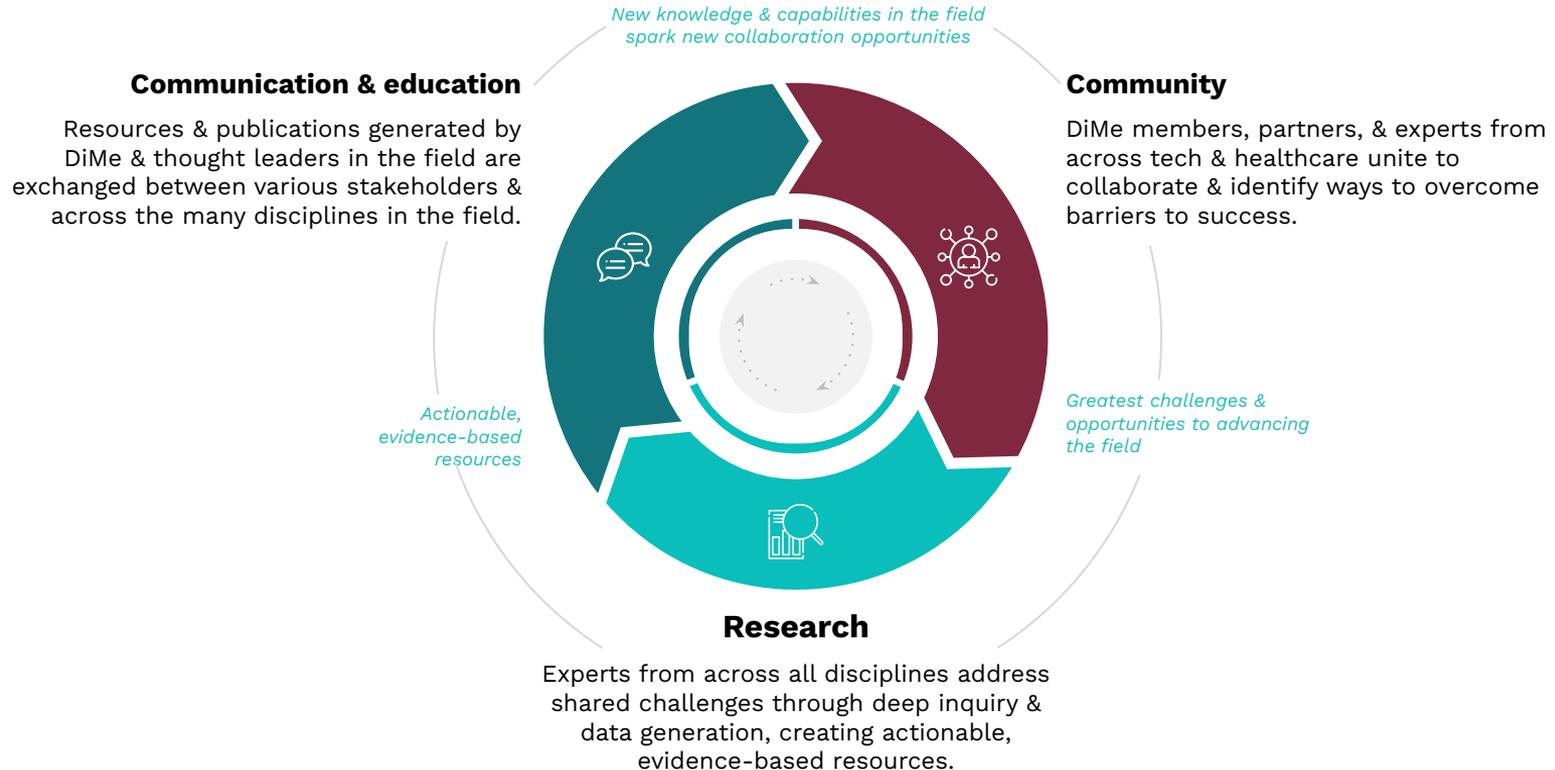
By JEN GOLDSACK, BEAU WOODS, and ERIC PERAKSLIS / JUNE 5, 2019



# ... and sit at the intersection of two communities



# We deliver clinical quality work on a tech timeline



# 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!



## SENSOR DATA INTEGRATIONS

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

### Project Partners



evidation



HumanFirst



MEDABLE



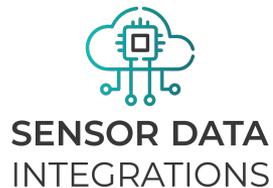
Open mHealth



VA



U.S. Department  
of Veterans Affairs



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

Public launch event

July 18, 2021 | 10.30am - noon ET



**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

# Measures that matter framework

## Digital Biomarkers

Digit Biomark 2020;4:69-77

DOI: 10.1159/000509725  
Received: May 9, 2020  
Accepted: June 25, 2020  
Published online: September 15, 2020

© 2020 The Author(s)  
Published by S. Karger AG,  
Basel  
www.karger.com/dib

This article is licensed under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License (CC BY-NC-ND) (<http://www.karger.com/Services/openAccessLicenses>). Usage and distribution for commercial purposes as well as any distribution of modified material requires written permission.

### Viewpoint Review Article

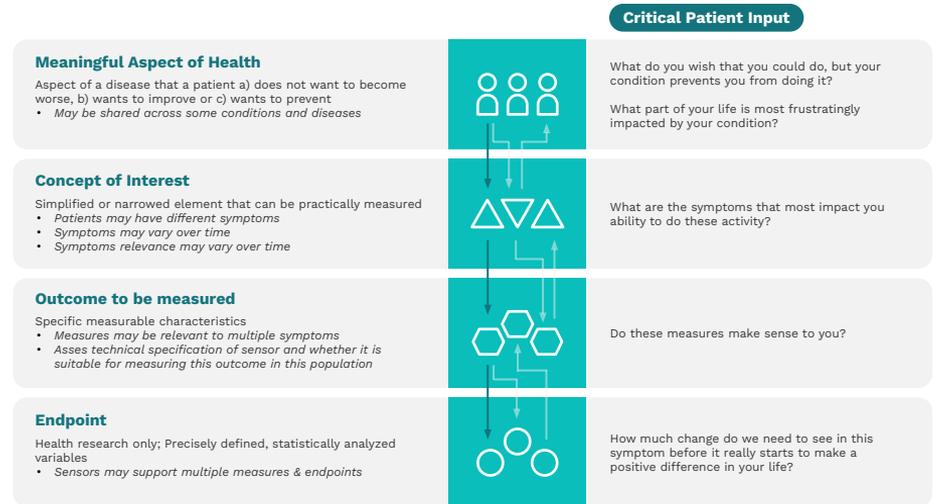
## Digital Measures That Matter to Patients: A Framework to Guide the Selection and Development of Digital Measures of Health

Christine Manta <sup>a,b</sup> Bray Patrick – Lake <sup>a,c</sup> Jenifer C, Goldsack <sup>a</sup>

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

### 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



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 ]

# EVIDENCE Checklist

*Evaluating Connected Sensor  
Technologies Checklist*

a DiMe Tour of Duty

## Digital Biomarkers

### NODE – Review Article

Digit Biomark 2021;5:127–147  
DOI: 10.1159/000515835

Received: January 25, 2021  
Accepted: March 10, 2021  
Published online: May 18, 2021

## EVIDENCE Publication Checklist for Studies Evaluating Connected Sensor Technologies: Explanation and Elaboration

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

<sup>a</sup>Digital Medicine Society, Boston, MA, USA; <sup>b</sup>Elektra Labs, Boston, MA, USA; <sup>c</sup>Pfizer Inc., Cambridge, MA, USA;  
<sup>d</sup>Philips, Monroeville, PA, USA; <sup>e</sup>Tibi Health Inc., San Francisco, CA, USA; <sup>f</sup>Koneksa Health Inc., New York, NY, USA;  
<sup>g</sup>Geisinger Health System, Danville, PA, USA; <sup>h</sup>Eli Lilly and Company, Indianapolis, IN, USA; <sup>i</sup>Independent Consultant,  
Mumbai, India; <sup>j</sup>Byteflies, Antwerp, Belgium; <sup>k</sup>Department of Electrical, Computer and Systems Engineering, Case  
Western Reserve University, Cleveland, OH, USA; <sup>l</sup>Nymbly.work, Seattle, WA, USA

# *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

## Project partners



evidation



## NOCTURNAL SCRATCH



*Digital Measures Development*

*Advancing nocturnal scratch  
as a digital endpoint for atopic dermatitis*

### Founding Partners

abbvie

janssen  | PHARMACEUTICAL COMPANIES OF  
Johnson & Johnson

 NOVARTIS

 Pfizer



### Collaborating Partners

 Advancing Innovation in  
Dermatology  
Accelerator Fund

 almirall

 gsk  
GlaxoSmithKline



*Lilly*

sanofi



## ALZHEIMER'S DISEASE & RELATED DEMENTIAS



### *Digital Measures Development*

*Identifying Patient Specified Digital Measures in Alzheimer's Disease and Related Dementias*

### Partners

abbvie



Alzheimer's  
Drug Discovery  
Foundation



### Digital Solutions Collaborators

altoida

Aural Analytics



Cogstate



MEDIDATA



SageBionetworks





## SENSOR DATA INTEGRATIONS

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

### Project Partners



evidation



HumanFirst



MEDABLE



Open mHealth

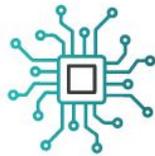


VA

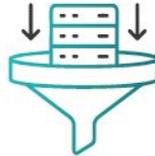


U.S. Department  
of Veterans Affairs

# Three key stakeholders



*Flows of  
sample-level data*



*Access to  
processed datasets*



## Data Producer

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

## Data Processor

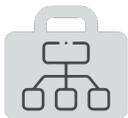
Individuals & organizations that collect, store, adapt, retrieve, consult, transmit, manage, restrict, or destruct sensor data

## Data Consumer

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

# Sensor data integrations toolkit contents

## Sensor Data Architecture Toolkit



- Logical data architecture
- Reference data architectures
- Sensor data flow design tool

## Sensor Data Standards Toolkit



- Interactive landscape of standards
- Standards in development

## Organizational Readiness Toolkit



- Capabilities maturity model
- Capabilities maturity calculator

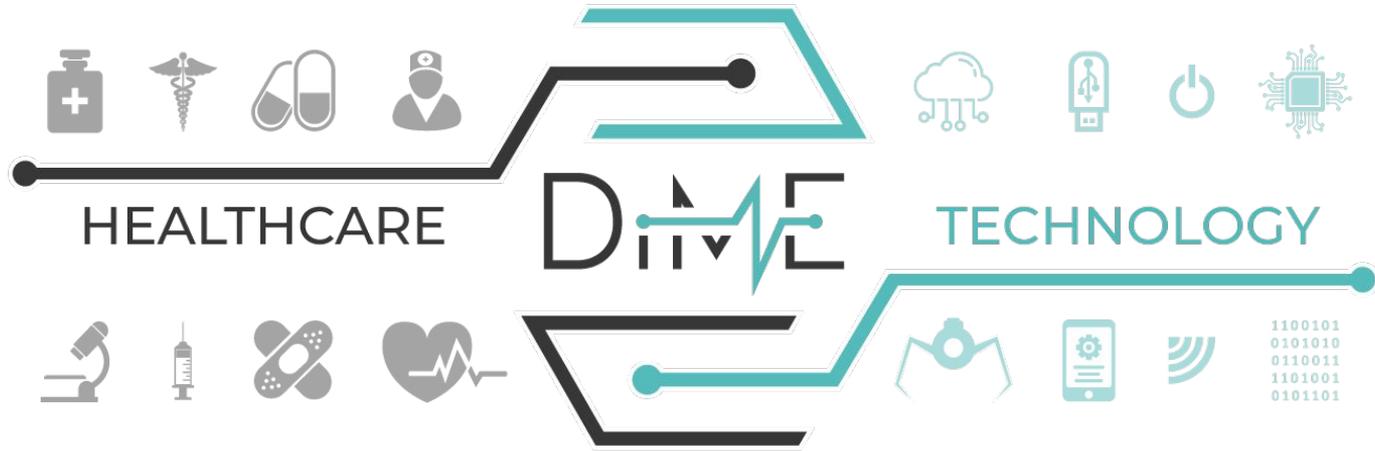
## Implementation Toolkit



- 'ART' criteria
- Considerations & best practices
- 'ART' criteria prioritization tool



Glossary



Enter coupon code **SDI2021** to receive one year of free individual membership at DiMe

<http://bit.ly/Join-DiMe>



THANK YOU



@\_DiMeSociety



[linkedin.com/company/dime-society](https://www.linkedin.com/company/dime-society)