V3+: An extension to the V3 framework to ensure user-centricity and scalability of sensor-based digital health technologies

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V3+ Program Head
Digital Medicine Society (DiMe)

DATAcc
Digital Health Measurement Collaborative Community
by DiMe

Tuesday, February 27

11 am - 12 pm ET

Agenda

Introducing V3+	Jessie Bakker | *DiMe*
Panel discussion: *Implementation of V3+ usability validation*	Bryan Cobb | *Genentech* Stéphane Motola | *Sysnav* Oana Paun | *Aardex Group* Benjamin Vandendriessche | *DiMe (moderator)*
Fireside chat: *Regulatory perspectives*	Kim Kontson | *FDA Center for Devices and Radiological Health* Elizabeth Kunkoski | *FDA Center for Drug Evaluation and Research* Jennifer Goldsack | *DiMe (moderator)*

DATACC by DiMe

Our purpose

DiMe is a global non-profit dedicated to advancing the **ethical, effective, equitable, and safe** use of digital medicine to redefine healthcare and improve lives.

Source: Digital Medicine Society

We launched in May 2019...

DATACC by DiME

CISION PR Newswire

Digital Medicine Society Now Accepting Members

New nonprofit aims to advance digital medicine to optimize human health

DiME DIGITAL MEDICINE SOCIETY

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 Log I

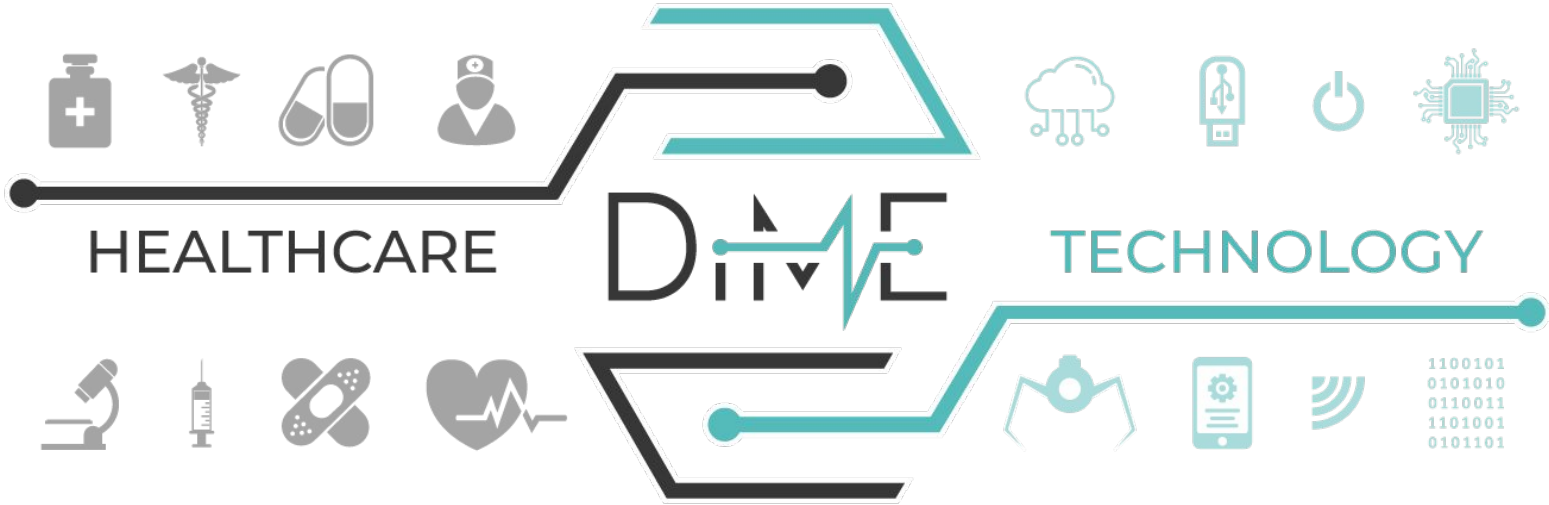
FIRST OPINION

DiMe: Calling all who serve in digital medicine

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

Source: PR Newswire and STAT

… and sit at the intersection of two communities



Source: Digital Medicine Society

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Project Partners

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Stel
sysnav HEALTH CARE
TNO innovation for life

Source: V3+

V3+ project objectives

The original V3 framework has become foundational to the evaluation of sensor-based digital health technologies for technical, scientific, and clinical performance

Our objectives were to build on the success of V3 by adding an evidence-based component addressing **human-centered design**, **human factors**, and **usability**, in order to:

- Optimize development and evaluation processes; *and*
- Advance the use of digital measures for clinical, regulatory, and payer decision-making

Sensor-based digital health technologies

Sensor-based

Sensors that sample a physical construct, such as acceleration, voltage, or light

Algorithm/s convert sensor data to clinically relevant measures

Mobile

Tools that are designed to capture data outside of the clinic or laboratory setting

Allows for continuous or highly-frequent data capture

Connected

Tools that contain a digital method of data transfer from the field to the clinic or laboratory

Data transfer may be wired or wireless

Abbreviated to *sDHTs* | Also referred to as *biometric monitoring technologies*

V3 framework refresher

Technical specification

Verification

Evaluates and demonstrates the performance of a sensor technology within an **sDHT**, 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 **sDHT** to measure, detect, or predict physiological or behavioral metrics

Clinical validation

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

Clinical utility

sDHT = Sensor-based digital health technology

Source: NPJ Digital Medicine

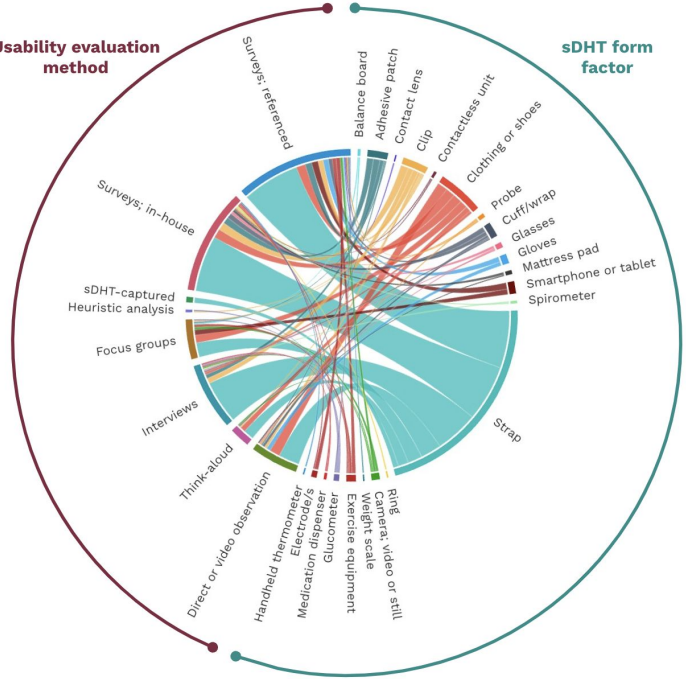
Landscape analysis

The **DATAcc by DiMe Library of Human Factors Resources for sDHTs** compiles and indexes external documents, including regulatory guidance and industry standards, focused on human-centered design, human factors, and usability relevant to sDHTs

Source: Library of Human Factors Resources for Digital Health Technologies

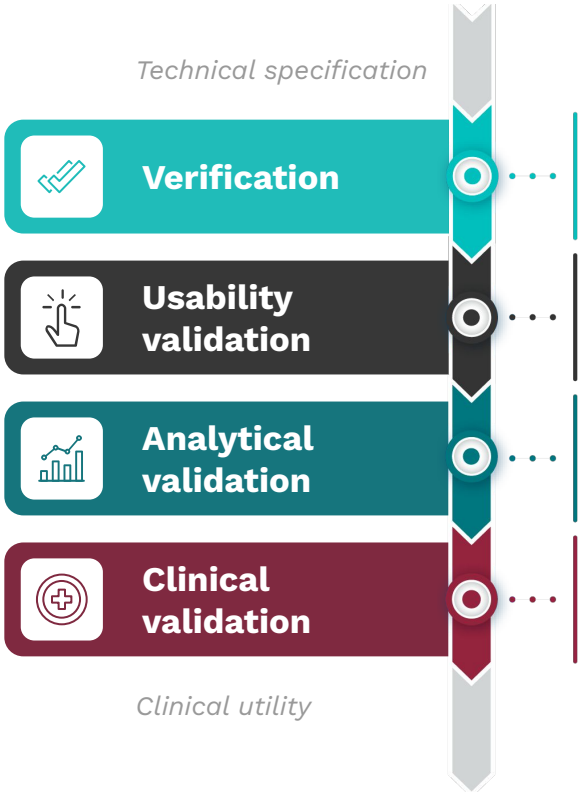
Systematic scoping review

83	Published studies
141	Wearable sDHTs
23	Ambient sDHTs
22	Form factors
20	Health concepts



Source: Manuscript preprint (currently under peer-review)

V3+ evaluation of digital clinical measures



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

Evaluates whether an **sDHT** can be used to achieve specified goals with ease, efficiency, and user-satisfaction

Evaluates the performance of the algorithm, and the ability of this component of the **sDHT** to measure, detect, or predict physiological or behavioral metrics

Evaluates whether an **sDHT** acceptably identifies, measures, or predicts a meaningful clinical, biological, physical, functional state, or experience, in the stated context of use (which includes a specified population)

sDHT = Sensor-based digital health technology

Source: 1. NPJ Digital Medicine 2. V3+ framework

For sDHTs that are under development (pre-market), begin by developing a proposed intended use statement

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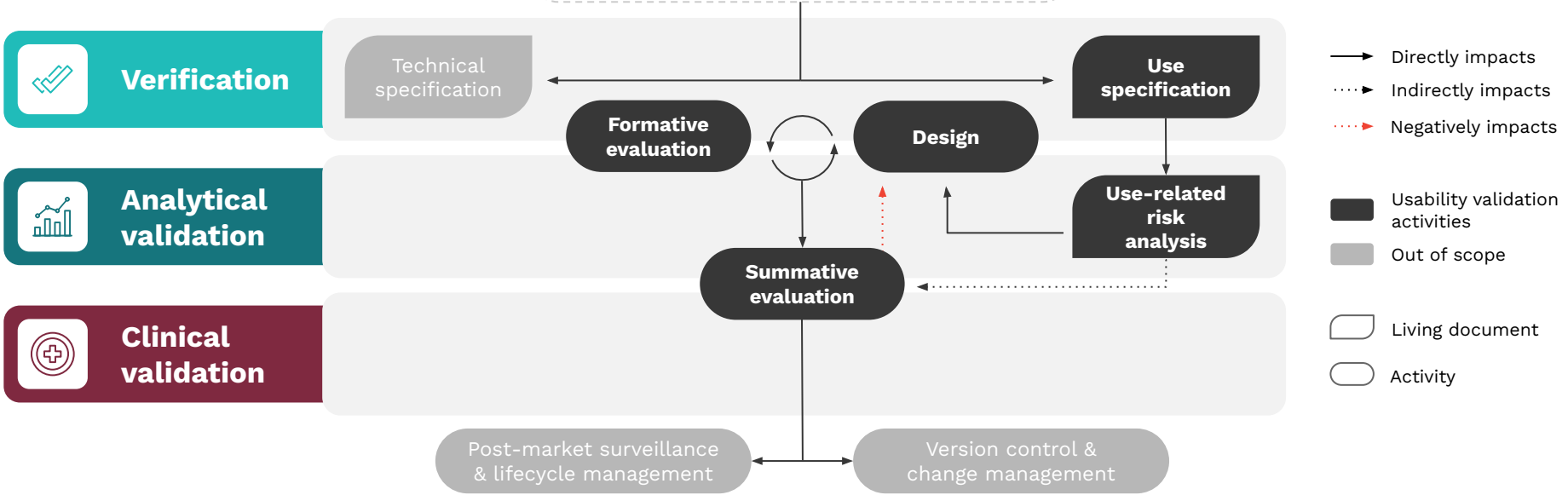
What does the sDHT do?
Who are the intended users?
Where should the sDHT be used?
When should the sDHT be used?
How should the sDHT be used?

The **intended use statement***, which describes the specific clinical circumstance or purpose for which the sDHT is being developed and includes the indications for use, guides subsequent activities

***Note:** The intended use statement is a key component of the labeling of regulated medical devices. An equivalent statement should be developed for non-regulated sDHTs.*



For sDHTs that are commercially available (post-market), begin by developing a proposed context of use statement

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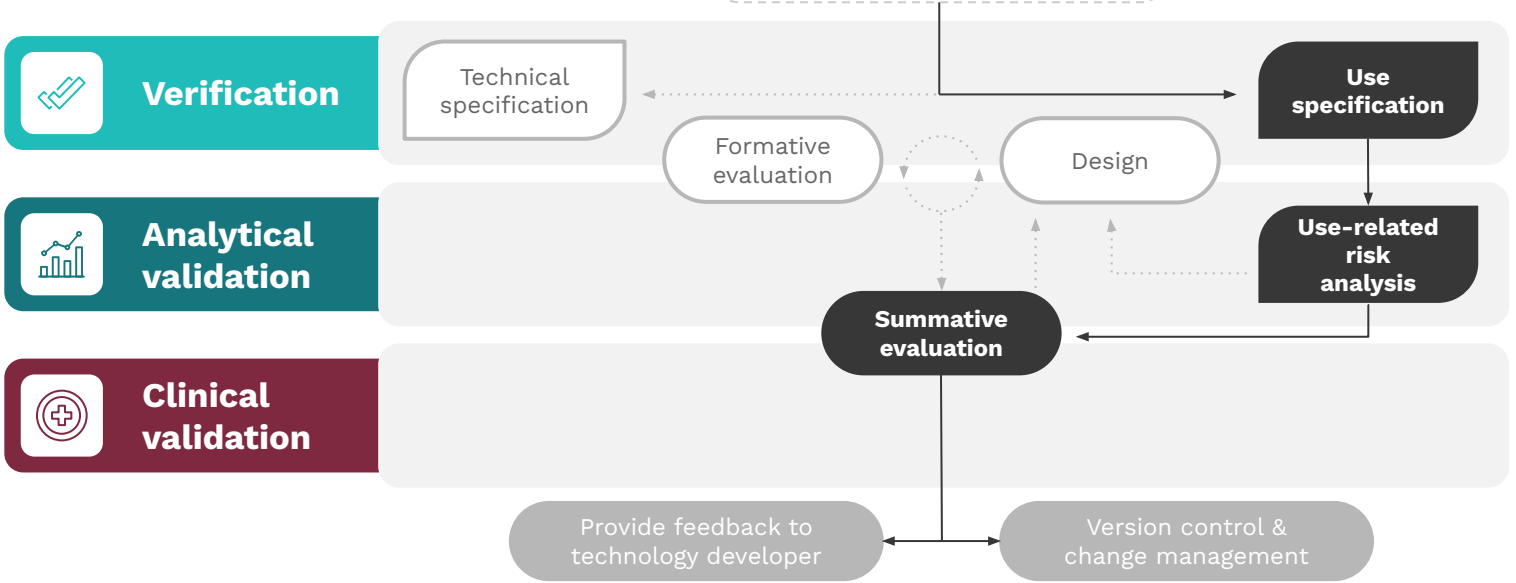
What will the sDHT be used for?
Who are the intended population(s) of interest?
Where will the sDHT be used?
When will the sDHT be used?
How will the sDHT be used?

The **context of use statement*** fully and clearly describes the way the sDHT is to be used and the purpose of the use

***Note:** The context of use should be compared against the original intended use of the sDHT; this gap analysis will guide subsequent activities.*



V3+ modular evaluation of digital measures

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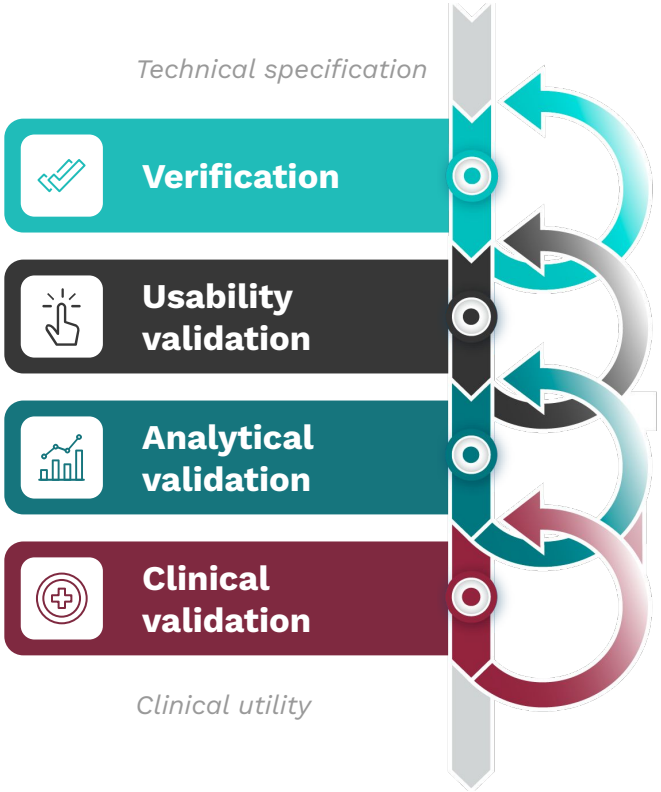

Changes to hardware/firmware?	• *Reverification, or* • *Documentation of back-compatibility*
Changes to use specification?	• *Repeat usability validation, or* • *Documentation of generalizability*
Changes to software that change algorithm?	• *Repeat analytical validation, or* • *Documentation of back-compatibility*
Expansion to a new patient population?	• *Repeat clinical validation if usability and analytical validation in new population is documented, or* • *Repeat usability and/or analytical validation in addition to clinical validation*

Source: 1. NPJ Digital Medicine 2. V3+ framework

V3+ is the first step of a comprehensive evaluation framework for fit-for-purpose connected sensors

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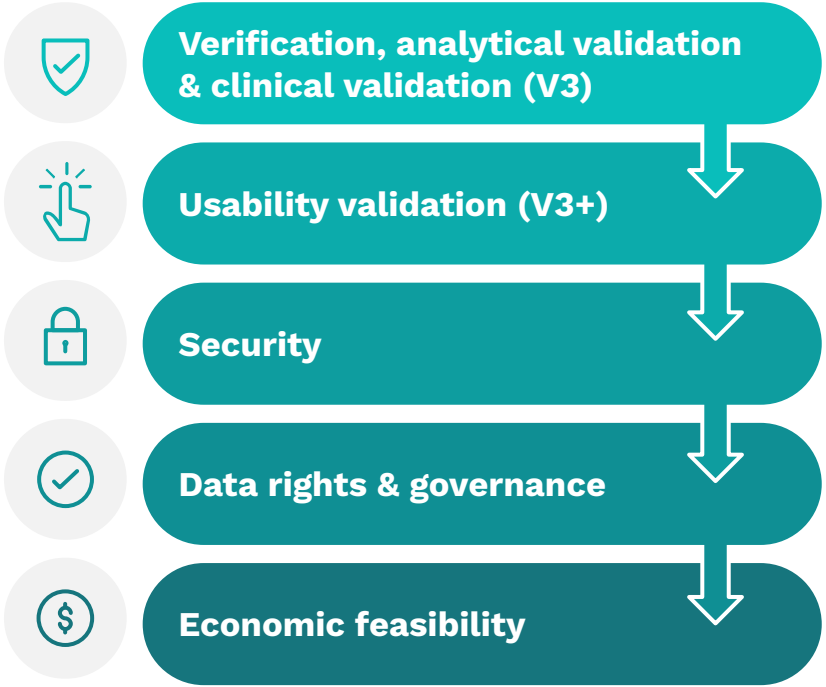

Does the tool measure what it claims to measure?
Is the measurement appropriate for the target population?

Have human-centered design principles been followed?
Is the tool easy, efficient, and satisfying to use?

Does the manufacturer build with safety by design?
Is there a Disclosure Policy? Software Bill of Materials?

Who has access to the data and when?
Is the privacy policy publicly accessible?

What's the net benefit versus price?
Is cost a one-time or subscription model?

Source: 1. NPJ Digital Medicine, 2. NPJ Digital Medicine 3. V3+ framework

V3+ resources to support implementation

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Use specification

Quickstart Guide: V3+ Use Specification

Human-centered design

At-a-Glance: Incorporating human-centered design into sDHT development

Use-related risk analysis

Quickstart Guide: V3+ Use-related risk analysis

Usability study metrics

At-a-Glance: Selecting metrics for evaluating usability validation

Case studies

AARDEX GROUP

ActiGraph

Cleveland Clinic Children's

TNO innovation for life

INTELLIGENT FUTURES RESEARCH LAB

...and more!

Engaging the developer

Checklist: Essential Usability Validation Questions for sDHT developers

Source: V3+ resources, V3+ case studies

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Panel discussion

Bryan Cobb
Pr. Medical Science Director
Genentech

Stéphane Motola
Strategic Partnership Project Manager
SYSNAV

Oana Paun
QA Manager
Aardex Group

Benjamin Vandendriessche
VP, Science
DiMe (moderator)

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Regulatory fireside chat

Kim Kontson
Biomedical Engineer
Center for Devices and Radiological Health, U.S. FDA

Elizabeth Kunkoski
Health Science Policy Analyst
Center for Drug Evaluation and Research, U.S. FDA

Jennifer Goldsack
CEO
DiMe (moderator)

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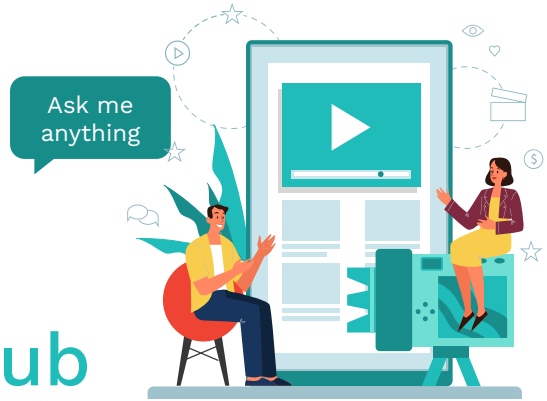

Defining the Dimensions of Diversity to Promote Inclusion in the Digital Era of Healthcare

March 27, 2023 | 11 am ET

Anindita (Annie) Saha
Associate Director for Strategic Initiatives
Digital Health Center of Excellence, FDA

Amy Sheon
Digital Health Equity Consultant and President
Public Health Innovators

Michael Crawford
Assistant Vice President for Strategy and Innovation, Office of Health Affairs
Howard University

Yashoda Sharma
Program Director
Digital Medicine Society (DiMe)

Jennifer Goldsack
CEO
Digital Medicine Society (DiMe)

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Wednesday
April 10
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