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

Tuesday, February 27
11 am - 12 pm ET

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V3+ Program Head
Digital Medicine Society (DiMe)
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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.
We launched in May 2019...

Digital Medicine Society Now Accepting Members
New nonprofit aims to advance digital medicine to optimize human health

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

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

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).

**sDHT** = Sensor-based digital health technology
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.
Systematic scoping review

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

Source: Manuscript preprint (currently under peer-review)
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
For sDHTs that are under development (pre-market), begin by developing a proposed intended use statement

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.

**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.

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*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

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.

- **Verification, analytical validation & clinical validation (V3)**: Does the tool measure what it claims to measure? Is the measurement appropriate for the target population?
- **Usability validation (V3+)**: Have human-centered design principles been followed? Is the tool easy, efficient, and satisfying to use?
- **Security**: Does the manufacturer build with safety by design? Is there a Disclosure Policy? Software Bill of Materials?
- **Data rights & governance**: Who has access to the data and when? Is the privacy policy publicly accessible?
- **Economic feasibility**: What's the net benefit versus price? Is cost a one-time or subscription model?

resources to support implementation

- **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**
  Checklist: Essential Usability Validation Questions for sDHT developers

- **Engaging the developer**
  ...and more!

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

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)
Register today for DiMe’s new crash course on Building Fit-for-Purpose Sensor-based Digital Health Technologies.

Special offer: FREE registration for DiMe webinar attendees!
Virtual Journal Club

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)

Ask me anything
Join us for
Physical Activity Industry Day.

Wednesday
April 10
11 am EST

Hosted by
DATAcc
by
Digital Health Measurement Collaborative Community

Network with other professionals in the field & secure your spot today!
THANK YOU

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