Digital Health Technology in Clinical Trials and in Medical Product Development

FDA/FNIH Workshop for Digital Measures: Navigating the Development of a Digitally Derived Endpoint

Jennifer Goldsack
Chief Executive Officer
Digital Medicine Society (DiMe)

DIGITAL MEDICINE SOCIETY

June 24, 2024 | Bethesda, MD

OUR MISSION:

To advance the safe, effective, and equitable use of digital approaches to redefine healthcare and **improve lives**.

OUR VISION:

Better health powered by digital innovation.

DiMe convenes stakeholders to take action to fix the problems in our complex field.

Delivering clinical quality work on a tech timeline

DiMe Approach

Convene & Collaborate

DiMe's superpower is convening stakeholders to drive action – not just admire – the problems in our complex field.

Build & Lead

Harnessing the power of many, we create solutions to reduce the activation energy of digital innovation in healthcare.

Educate & Advise

Combining insights from our diverse community with best practices from our research, DiMe offers an unparalleled perspective on the digitization of healthcare.

About DATAcc

The Digital Health Measurement Collaborative Community (DATAcc) by the Digital Medicine Society (DiMe) is a collaborative community with the FDA's Center for Devices and Radiological Health (CDRH).

DATAcc by DiMe is *the* leading initiative for the industry to engage with and seek information regarding digital health measurement.

Source: About DATAcc

Our mission

To use interdisciplinary expertise, data, and use cases to develop and demonstrate best practices and advance harmonized approaches to speed the use of digital health measurement to improve health outcomes, health economics, and health equity.

Source: About DATAcc

Our vision

To achieve the promise of digital health measurement to improve lives, for everyone. DATAcc advances DiMe's mission to advance the safe, effective, ethical, and equitable use of digital technologies to redefine healthcare and improve lives by redefining health and disease – and the burden of assessing it in the digital era.

Source: About DATAcc

DATAcc project portfolio

- Completed resources
- Living resources
- Active projects
- Upcoming projects

DATAcc by DiMe

Digital Measures Frameworks & Recommendations

Methodological best practices applicable across the board

- The Primer Digital Medicine: Measurement
- Extending the V3 Framework
- EVIDENCE Checklist
- Digital Measures That Matter
- 3Ps of Digital Endpoint Value
- Inclusion in Digital Measurement Product Development
- Inclusion in Digital Measurement Product Deployment
- *The Playbook*: Digital Clinical Measures
- Analytical Validation Library
- Digital Endpoints Library
- Validating Novel Clinical Digital Measures
- Building the Business Case for Digital Endpoints
- Powering Patient Engagement Platforms with Digital Measures

Digital Measures Development

Specific applications by therapeutic area and/or concept

- Digital Measures: Nocturnal Scratch
- Core Measures: Physical Activity
- Core Measures: Sleep
- Core Measures: Alzheimer's & Related Dementias
- Developing a Risk Prediction Engine for Relapse in Opioid Use Disorder
- Digital Safety Measures for Cytokine Release Syndrome
- Advancing the Use of Digital Measures for Mental Health
- HL7 Digital Physical Activity Measure Standards [b]

External Collaborations, Engagements, & Alliances

Strategic partnerships with other consortia and non-profit entities

- CDISC Digital Health Technologies Data Standards
- Partnership with Wound Care Collaborative Community [a]
- Partnership with Physical Activity Alliance [b]

Last updated April 2024

[a, b] Superscript letters indicate linked projects

Active partners in DATAcc

Source: About DATAcc

Level set: It’s not about the technology

What is the problem we are trying to solve for?

Despite hundreds of diseases having no cure, today's clinical trials industry is characterized by...

Protracted timelines

It takes, on average, **10-15 years** to bring a new drug to market.

Recruitment challenges

One in five trials is terminated with no answer about drug efficacy due to failure to recruit

Low rates of technical success

The likelihood of successfully bringing a new molecule to market is **just 5%**.

Patent cliffs

As patents on blockbuster drugs expire, revenue drops dramatically. **New sources of income are needed**.

DATACC
by DiMe

ALZHEIMER'S DISEASE & RELATED DEMENTIAS

Digital Measures Development

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

Project Partners

abbvie
Alzheimer's Drug Discovery Foundation
Biogen
Boston University
Cognito Therapeutics
Eisai
Lilly
LUCA
MERCK
Oregon Health & Science University
Roche

Digital Solutions Collaborators

altoida
Aural Analytics
BioSensics
Cambridge Cognition
Cogniant
Cogstate
Cumulus
ki elements
koneksa
DS MEDIDATA
LINUS HEALTH
SageBionetworks
VIVOSENSE
WINTERLIGHT

Source: ADRD

DATACC by DiMe

NOCTURNAL SCRATCH

Digital Measures Development

Advancing nocturnal scratch as a digital endpoint for atopic dermatitis

Founding Project Partners

abbvie

janssen | Pharmaceutical Companies of Johnson & Johnson

NOVARTIS

Pfizer

ucb

Project Collaborators

Advancing Innovation in Dermatology Accelerator Fund

almirall

gsk GlaxoSmithKline

LEO

Lilly

sanofi

Expert Partners:

National Eczema Association

GLOBAL PARENTS FOR ECZEMA RESEARCH
RESEARCH • SUPPORT • CHANGE

Duke University

Harvard Business School

Boston University

Health Outcomes Insights
Getting targeted answers to patient behaviour and outcomes

NOCTURNAL SCRATCH

Digital Measures Development

LEARN MORE

Patient Research

- Data and evidence from mixed methods research
- Conceptual framework

Measures Terminology & Ontology

- Data and evidence supporting technical definition
- Evidence-based ontology

Deployment to Clinical Trials

- 10 tools supporting successful operational implementation
- Case studies

Payer Acceptance

- Translating patient value to commercial value
- Modeling potential increases in drug utilization
- Key insights & action items

DiME DIGITAL MEDICINE SOCIETY

Predicted Reductions in Trial Duration (mos.) and Enrollment with Digital Endpoints by Phase

	Phase 2 Duration			Phase 3 Duration			Phase 2 Enrollment			Phase 3 Enrollment		
	Predicted	**Absolute decrease**	**Percent decrease**	**Predicted**	**Absolute decrease**	**Percent decrease**	**Predicted**	**Absolute decrease**	**Percent decrease**	**Predicted**	**Absolute decrease**	**Percent decrease**
Diabetes												
Non-digital	13.7			18.2			130.8			312.6		
Digital	10.4	3.3	24.0%	14.2	4.0	22.0%	115.6	15.2	11.6%	276.0	35.6	11.7%
CNS												
Non-digital	17.4			23.9			109.3			277.0		
Digital	13.3	4.2	24.0%	18.7	5.2	22.0%	94.1	15.2	13.9%	244.6	32.4	11.7%
Cardio												
Non-digital	14.8			21.9			93.0			181.2		
Digital	11.2	3.5	24.0%	17.0	4.9	22.0%	77.7	15.2	16.4%	160.0	21.2	11.7%

Predicted values determined at mean values for the continuous variables; based on CT.gov data | Pre-print

Increase in eNPV and ROI per **Phase 2** Investigational Indication for Digital Endpoint Clinical Trials (2023 USD) by Therapeutic Area

Therapeutic Area	Reduction in Trial Duration (mos.)	Reduction in Trial Size	*Mean sponsor implementation cost*		*Median sponsor implementation cost*	
			eNPV delta	ROI	eNPV delta	ROI
Diabetes	3	11.6%	$3.3M	47.7%	$7.0M	350%
CNS	4	13.9%	$2.1M	30.5%	$5.8M	290%
Cardiovascular	4	16.4%	$2.2M	32.4%	$6.0M	300%

Costs and returns discounted to the start of phase 2 testing; ROI = eNPV delta/sponsor implementation cost | Pre-print

Increase in eNPV and ROI per **Phase 3** Investigational Indication for Digital Endpoint Clinical Trials (2023 USD) by Therapeutic Area

Therapeutic Area	Reduction in Trial Duration (mos.)	Reduction in Trial Size	*Mean sponsor implementation cost*		*Median sponsor implementation cost*	
			eNPV delta	ROI	eNPV delta	ROI
Diabetes	4	11.7%	$48.4M	710%	$52.1M	2610%
CNS	5	11.7%	$27.3M	400%	$31.0M	1550%
Cardiovascular	5	11.7%	$33.3M	490%	$36.8M	1840%

Costs and returns discounted to the start of phase 3 testing; ROI = eNPV delta/sponsor implementation cost | Pre-print

Deploying remote monitoring can **reduce patient burden** and increase enrollment **speed** and **inclusivity** during a clinical trial

Sample Study Schedule of Assessment

Visit	1	2	3	4	5	6	7	8	9	10
Week	-6	0	1	2	3	4	6	8	12	16
Informed consent, Demography, Habits, Medical History	X									
Inclusion/Exclusion Criteria	X	X								
Full Physical, Height & Weight	X									
Prior Medical History	X	X								
Assessment Potential of Adverse Events (AEs)	X	X	X	X	X	X	X	X	X	X
Laboratory assessments	X	X	X	X		X		X	X	X
Drug screen	X									
Urinalysis	X	X				X			X	X
C-reactive protein (CRP)	X	X	X	X		X		X	X	X
12 Lead ECG	X	X	X	X		X		X	X	X
Vital signs	X	X	X	X		X		X	X	X
Randomization		X								
Study medication dispensation		X								
CGM & FBG		X	X	X		X		X	X	
Sleep assessment		X	X	X	X	X	X	X	X	X
Health Assessment Questionnaire Disability Index (HAQ-DI)		X	X	X		X		X	X	X
Questionnaires PROs		X		X		X		X	X	

- On-site
- Virtual Visit (video or audio)
- Connected sensor technology
- Mobile Phlebotomist

In this example, shifting some of the assessments to **remote collection** can **reduce patient burden**:

FROM ***10 site visits***

TO ***4 site visits*** and ***6 at-home visits***

Source: Schedule of Assessments inspired by a COVANCE virtual trials presentation, Playbook team analysis | Access at playbook.dimesociety.org

DATACC by DiME

Building the **Business Case** *for* Digital Endpoints

Establishing the business case for adoption of digital endpoints in clinical trials

Project Partners

abbvie · ActiGraph · Biofourmis · BLUESKEYE AI · Brain & Mind · CHEO · CHUGAI · Roche Group · COPD Foundation · COSINUSS° · Critical Path Institute · Cumulus · EVMS Eastern Virginia Medical School · evinova · Exponent · FDA · Genentech A Member of the Roche Group · Health Advances · IMPERIAL · koneksa · MERCK · Mitsubishi Tanabe Pharma America · Mobilise-D · modality.ai · OmniScience · REGENERON · Roche · Sama · sanofi · seuss · strados · sysnav · TECH DOCTOR · TNO innovation for life · Tufts Center for the Study of Drug Development · UChicago Medicine · VERISIMLife · vivosense · WKB.SMRT

Source: Building the Business Case for Digital Endpoints

Case study: Remote thermal monitoring SmartMats prevent diabetic limb amputations

The Challenge:

Approximately **422 million people** worldwide **have diabetes; 1 in 4 Veterans have diabetes.** Diabetic foot ulcers (DFUs), a disease complication, are responsible for **80 percent of the non-traumatic amputations** at the VA. **In 2018** alone, **the VA treated 75,000 diabetic foot wounds** and spent more than **$3 billion on diabetic foot ulcers**, a precursor to amputations. The most at-risk Veterans face **a 5-year mortality rate of 43%** after developing their first DFU.

The Approach:

The SmartMat solution was implemented at 15 VA Medical Centers. Veternan's utilized a cellular-connected in-home mat which uses machine learning coupled with thermal imaging to **measure the daily temperature of the patient's feet in 20 seconds.**

Clinicians utilized a dashboard for viewing the data which allowed them to take **preventative** action as needed. This solution **brings value** by **detecting diabetic foot ulcers (DFUs) up to five weeks before** they would normally present.

The Result:

The use of the SmartMat resulted in a **97% early detection rate of DFU, 5 weeks before the onset** of symptoms, with **total elimination of all major amputations. Cost avoidances** were demonstrated with a **52% reduction in hospitalizations** and **40% reduction in ER visits.**

With a **86% patient engagement rate after 12 months**, this innovative care model helps reduce diabetes care disparities related to the geographical location of Veteran patients.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://marketplace.va.gov/innovations/reducing-hospital-admissions-and-amputation-prevention-remote-temperature-monitoring

12 Sponsors have collected digital endpoints

12 Sponsors have collected digital endpoints

Primary, Secondary or Label Claim

Actelion, abbvie, Bellerophon, Cavion, gsk, Pfizer, Novartis, proteus, Regeneron, Sanofi

Exploratory Only

Roche, teva

Sponsors start digital endpoint development early

Digital Endpoints

Phase 0	3%
Phase 1	26%
Phase 2	26%
Phase 3	21%
Phase 4	24%

>47% of examples

Digital endpoints are being used across drug, device, and biologic development

Investigational Product

Drug	47%
Device	32%
Biologic	15%
Other	6%

Pharma trusts digital products, primary/ secondary endpoints

Endpoint Positioning

16	Primary endpoints
4	Secondary endpoints
14	Exploratory
34	**UNIQUE ENDPOINTS**

DiME Digital Medicine Society

Is your company's work missing? Submit it to DiMe: https://bit.ly/DiMe-Endpoints

Source: https://www.dimesociety.org/index.php/knowledge-center/library-of-digital-endpoints

STAT FIRST OPINION

Digital endpoints library can aid clinical trials for new medicines

By JEN GOLDSACK, RACHEL A. CHASSE, *and* WILLIAM A. WOOD / NOVEMBER 6, 2019

Source: https://www.statnews.com/2019/11/06/digital-endpoints-library-clinical-trials-drug-development/

69 Sponsors have collected **440** digital endpoints

Primary, Secondary or Other/Exploratory

Source: Library of Digital Endpoints

Last updated Apr 29, 2024

Of the **69 Sponsors** that have collected digital endpoints...

Sponsors start digital endpoint development early

Digital Endpoints

Phase 0	Phase 1	Phase 2	Phase 3	Phase 4
0%	5%	29%	17%	16%

67% of examples

The remaining 33% of trials in the Library do not have a phase

Digital endpoints are being used for development of many product types

Investigational Product

Drug	**67%**
Device	**25%**
Behavioral	**4%**
Biologic	**3%**
Genetic	**1%**
Combination	**1%**

Industry Sponsors trust digital endpoints

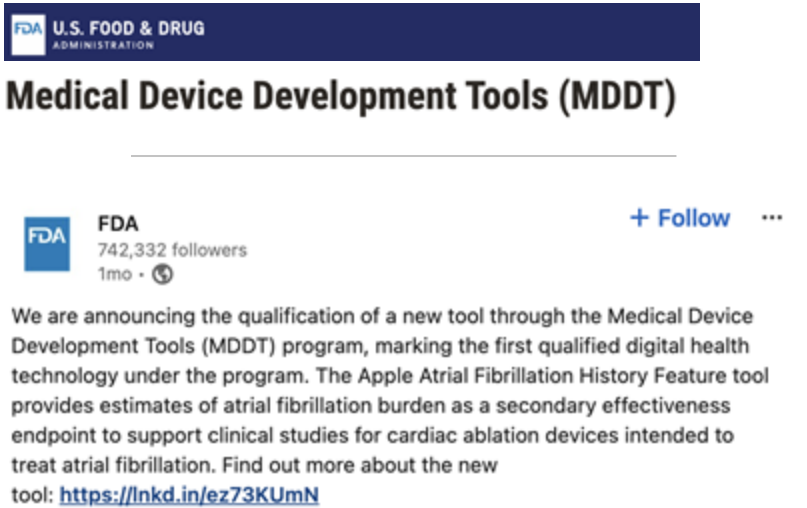
Endpoint Positioning

116	Primary endpoints
258	Secondary endpoints
66	Other / Exploratory
440	**TOTAL ENDPOINTS**

Is your company's work missing?
Submit it to DiMe:
https://bit.ly/DiMe-Endpoints

Source: Library of Digital Endpoints

FDA DHT Guidance and digital endpoint qualification decision



Source: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations and https://www.fda.gov/medical-devices/medical-device-development-tools-mddt

EMA is supporting the advancement of qualified digital endpoints

Source:https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-stride-velocity-95th-centile-secondary-endpoint-duchenne-muscular-dystrophy_en.pdf and https://www.ema.europa.eu/en/documents/other/questions-answers-qualification-digital-technology-based-methodologies-support-approval-medicinal_en.pdf

High value digital solutions for pharma

DIGITAL MEDICINE ACADEMY®

The digital health space is evolving quickly – we are here to help you keep pace.

COURSE

Fast Track to Digital Clinical Trials for Pharma

Pharma Edition

Upskill your workforce with education

Corporate licenses are **available today.**

Scan the code and sign up to learn more about course offerings for your organization.

Source: Fast Track to Digital Clinical Trials for Pharma Course

Remote Patient Monitoring CPT code usage

From Definitive Health Commercial Billings Data

It's the **fastest growing area** in healthcare now.

1900% growth in RPM in just 2 years.

65% of practices are actively investing in RPM programs.

Source: https://www.athelas.com/insights/how-to-bill-for-remote-patient-monitoring

A DiMe Project: Driving adoption

The Playbook: Digital Clinical Measures

Introducing the essential guide for successful remote monitoring across *clinical research*, *clinical care*, and *public health*.

ActiGraph · Activ insights · APhA · Big Ideas Lab · BlackThorn · Center for Digital Health · COVANCE by labcorp · DiGITAL HEALTH · DiMe Digital Medicine Society · elektralabs · Lilly · European Medicines Agency · evidation · FDA · Genentech · koneksa · MERCK · MYOKARDIA · Open mHealth · Pfizer · physIQ · sawyy · SageBionetworks · Scripps Research · Takeda · VivoSense

There are currently **13 reimbursable CPT codes** that QHPs can use to bill for services related to clinical digital measures, including:

CPT code 99091:

"**Collection** and **interpretation** of **physiologic data** (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified healthcare professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days."

CPT code 99453:

"**Remote monitoring** of **physiologic parameter**(s) (e.g, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; **set-up** and **patient education** on use of equipment."

CPT code 99454:

"**Device(s) supply** with daily recording(s) or programmed alert(s) transmission, **each 30 days**."

CPT code 98980:

Remote therapeutic monitoring treatment management services, physician or other qualified healthcare professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes.

Note: **CPT code 98981** may be used in addition to 98980 to bill for each additional 20 minutes."

Source: CMS - License for Use of CPT, IMPACT Payment Coding Toolkit

There are currently **13 reimbursable CPT codes** that QHPs can use to bill for services related to clinical digital measures, including:

CPT code 99473

"Self-measured blood pressure using a device validated for clinical accuracy; **patient education** or training and device calibration."

CPT code 99474:

"Separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient."

CPT code 99457:

"Remote physiologic monitoring **treatment management services**, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring **interactive communication** with the patient/caregiver during the month.

Note: **CPT code 99458** may be used in addition to 99457 to bill for each additional 20 minutes

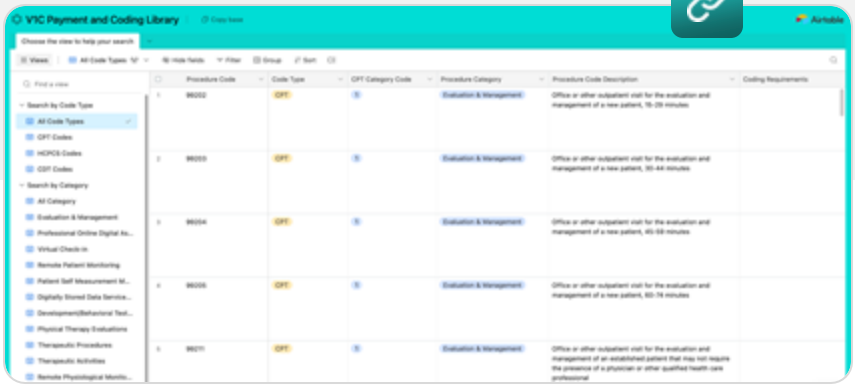
Source: CMS - License for Use of CPT, IMPACT Payment Coding Toolkit

V1C Coalition resource:
V1C Payment & Coding Library

Distills V1C Coalition member experience with coding in 3 sections:

- Codes currently in use in V1C
- Codes that exist but that are restricted in a way that dont allow them to be used in V1C
- Ideas for new codes that could be added to better support V1C coding

Launched June 2021

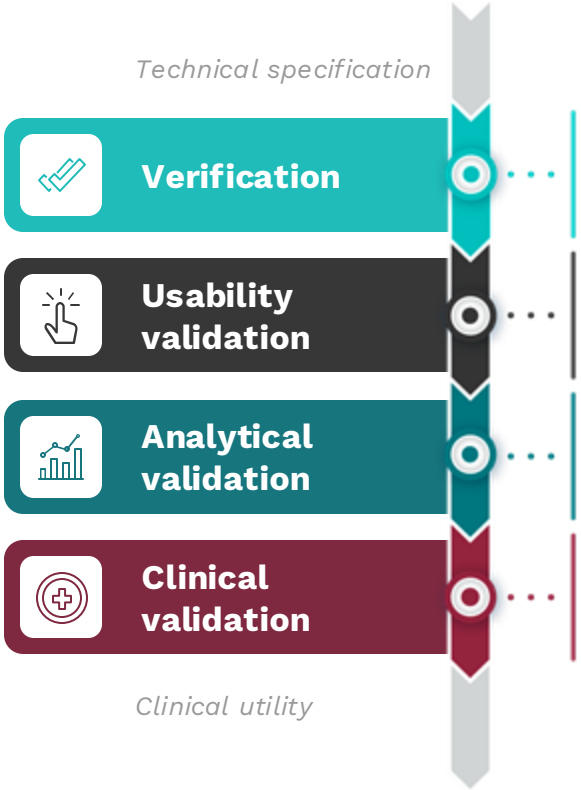


Together, we are making V1C a reality.

Driven by its members, the V1C Coalition convenes leaders across V1C to accelerate toward **truly effective patient care**, where digital interactions are key components of a patient's journey.

Members

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

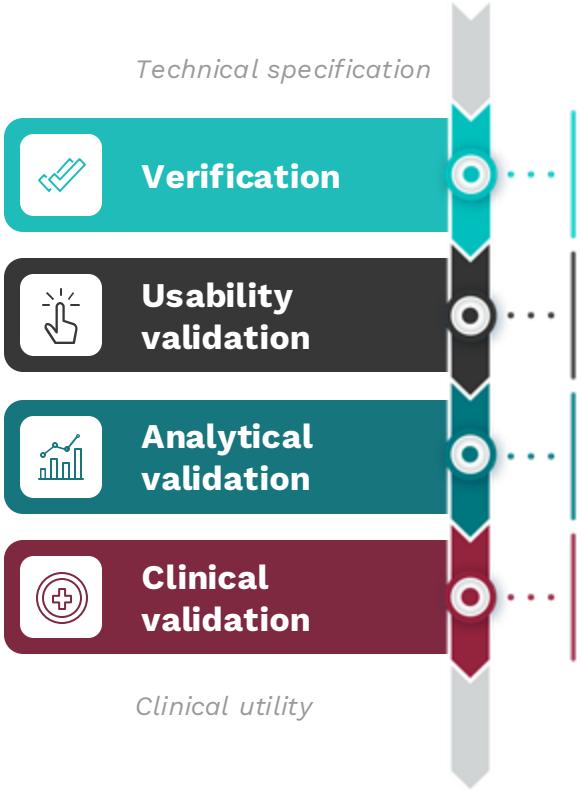
Evaluates the performance of the algorithm, and the ability of this component of the **sDHT** to measure, detect, or predict physiological or behavioral metrics

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

V3+ is a modular evaluation process



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*

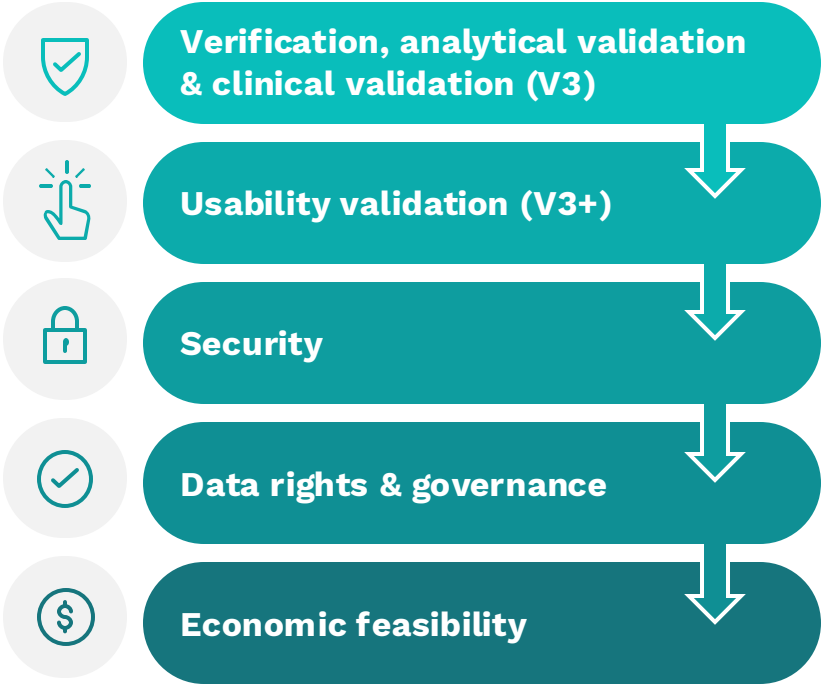
Expansion to a new patient population?

- *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

DATACC by DiME



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

DIVERSITY, EQUITY, & INCLUSION in Digitized Clinical Trials

Design a person-centered strategy with digital tools to increase diversity, equity, and inclusion in clinical trials

1 Assess

Assess opportunities for utilizing digital tools to be more diverse, equitable, and inclusive with your clinical trial design

2 Identify

Identify which digital tools are best suited to each step of your design process

3 Implement

Implement the person-centered principles as you put together a diversity plan

SENSOR DATA INTEGRATIONS

DIGITAL MEDICINE SOCIETY

TOOLKITS

Data Architecture

- Reference data architectures
- Sensor data flow design tool

Data Standards

- Interactive landscape of standards
- Standards in development

Implementation

- ‘ART’ criteria
- Considerations & best practices
- ‘ART’ criteria prioritization tool
- Case examples

Organizational Readiness

- Capabilities maturity model
- Capabilities maturity calculator

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

3Ps of Digital Endpoint Value Project Toolkit

All Stakeholders

Using evidence from digital endpoints to demonstrate the value of a new drug: Considerations and recommendations

Opportunities and challenges to using digital clinical measures to inform reimbursement decisions in drug development

Key terms glossary

Quick start guide to drug reimbursement – U.S.

Quick start guide to drug reimbursement – Europe

Pharma Toolkit

Recommendations for pharma

Decision tool: Integrating digital endpoint evidence into integrated evidence plans

Recommendations for pharma at-a-glance

Payer Toolkit

Recommendations for payers

Recommendations for payers at-a-glance

3P

The 3Ps of Digital Endpoint Value

PATIENTS · PHARMA · PAYERS

Available at: https://www.dimesociety.org/tours-of-duty/3ps-of-digital-endpoint-value/

Ensure you identify measures that matter

Digital Biomarkers

Digit Biomark 2020;4:69-77

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Viewpoint **Review Article**

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

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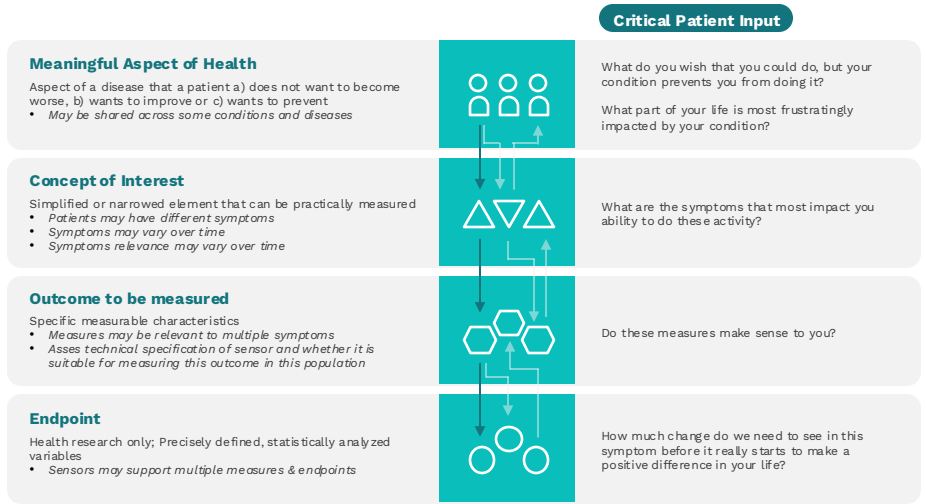
Digital Measures That Matter to Patients: A Framework to guide the Selection and Development of Digital Measures of Health
Digit Biomark 2020;4;69-77 = DOI:10.1159/00509725

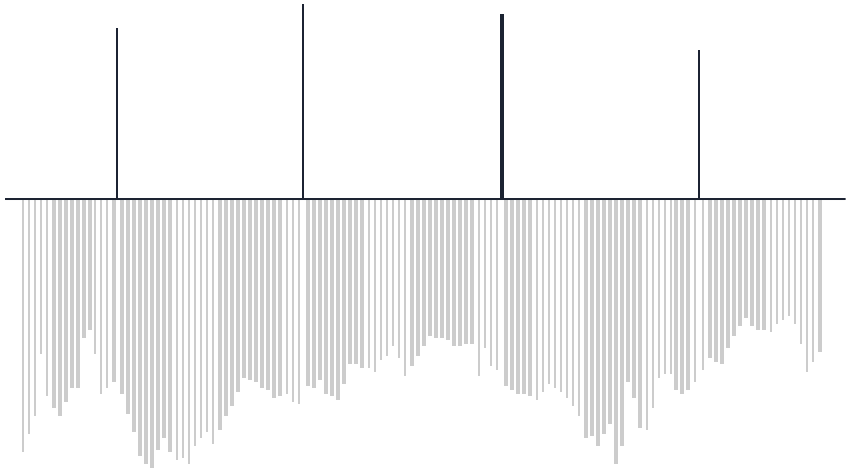


This figure was adapted from original work by Evidation Health, with permission. This figure illustrates patient considerations that should drive digital measure selection and development, these should precede technical considerations [8]. Additional information on subsequent technical considerations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

Source: https://datacc.dimesociety.org/digital-measures-that-matter/

Remote monitoring using connected sensors offers *a more holistic view* of a person's lived experience

Visible Data Points
(episodic)



Data collected from **traditional** visits to hospitals, clinics, and sites

Invisible Data Points
(continuous)

Data collected **remotely** from everyday life

Source: "Visible vs. Invisible Data" chart designed by Evidation Health, re-worked by Elektra Labs, Playbook team analysis | playbook.dimesociety.org

Validating Novel Digital Clinical Measures

Addressing the remaining methodological gap in the science underpinning the development and evaluation of digital clinical measures by defining:

1. How to select the optimal reference measure(s) for novel digital clinical measures and endpoints
2. Performance requirements against these existing measures

Source: https://datacc.dimesociety.org/validating-novel-digital-clinical-measures/

DATACC by DiME

DE-RISKING CYTOKINE RELEASE SYNDROME

Digital Measures Development

Leveraging digital innovations to support the development of a risk prediction tool for CRS

Project Partners

ACCC · ActiGraph · Analog Devices · Atrium Health Levine Cancer Institute · ASH Research Collaborative · Best Buy Health · Biofourmis · blue spark · Bristol Myers Squibb · canopy · doccla · FDA · FNIH · Friends of Cancer Research · Genentech · IEEE · Johnson & Johnson Innovative Medicine · Leukemia & Lymphoma Society · Mika · Orion Pharma · Pfizer · Takeda · verily

Partners also include the National Cancer Institute

Source: CRS

DATACC by DiMe

Developing a Risk Prediction Engine *for* Relapse in Opioid Use Disorder

Project Collaborators

Triangle CERSI

DATACC Digital Health Measurement Collaborative Community by DiMe

Duke | BIG IDEAS LAB

FDA U.S. FOOD & DRUG ADMINISTRATION

OCS Office of Regulatory Science and Innovation (ORSI)

Center for Devices and Radiological Health (CDRH)

Advancing the use of **sensor-based digital health technologies** (sDHTs) for the early detection and monitoring of mental health symptoms

Advancing the Use of Digital Measures *for* Mental Health

DATAcc by DiMe

UCLA Depression Grand Challenge

Funded by Wellcome

Thank you

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