DIGITAL MEDICINE SOCIETY

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The Data Ecosystem Driving Digital Health Measurement at Scale

ActiGraph Digital Data Summit 2024

Feb 28, 2024 | Pensacola Beach, FL

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: https://www.dimesociety.org

We sit at the intersection of two communities

Source: https://www.dimesociety.org

We deliver clinical quality work on a tech timeline

New knowledge & capabilities in the field spark new collaboration opportunities

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.

Actionable, evidence-based resources

Greatest challenges & opportunities to advancing the field

Research

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

Source: https://www.dimesociety.org

The **data ecosystem** driving digital health measurement at scale.

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).

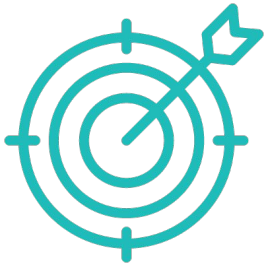
DATAcc by DiMe is *the* leading initiative for the industry to engage with and seek information regarding digital health measurement.

Source: https://datacc.dimesociety.org/about-us/

DATAcc by DiME

DATAcc 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: https://datacc.dimesociety.org/about-us/

Completed resources · Active projects · Living resources · Upcoming projects

DATAcc by DiME

DATAcc Project Portfolio

Digital Measures Frameworks & Recommendations

Methodological best practices applicable across the board

- The Primer Digital Medicine: Measurement
- 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 Endpoints
- Extending the V3 Framework

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
- Core Measures in Serious Mental Illness
- Qualifying Wound Healing Endpoints Generated by Smartphone Images [a]
- 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]

DATAcc work falls into three categories

Source: https://datacc.dimesociety.org/datacc-projects/ Last updated February 2024 [a, b] Superscript letters indicate linked projects

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DATAcc Active Partners

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The Playbook(s)

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*.

Source: https://playbook.dimesociety.org/playbooks/the-playbook/

V3 is a modular evaluation process

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 stated **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://datacc.dimesociety.org/v3/

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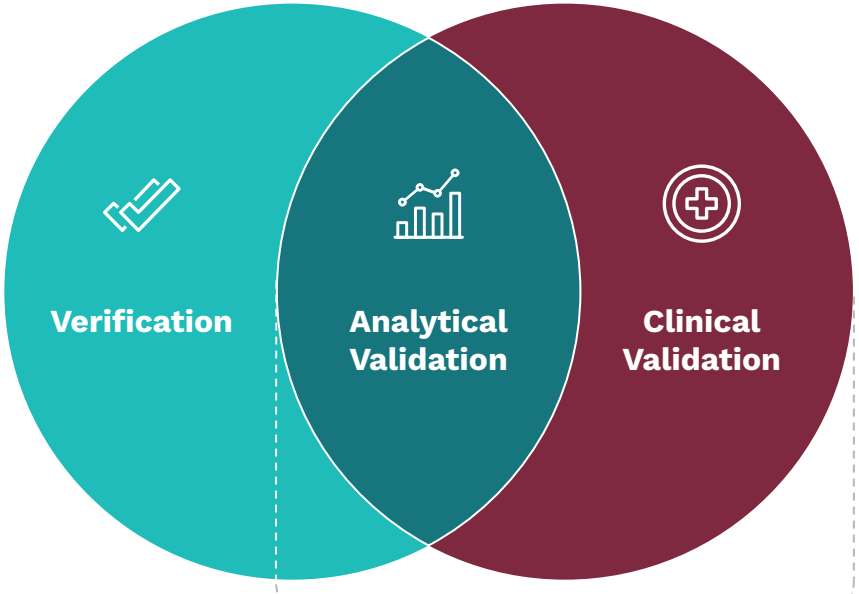
V3 processes require experts across disciplines and domains



Activity performed by:

- (Non-clinical) engineers
- Both engineers and clinically-trained professionals
- Clinically-trained professionals

Extending the V3 Framework

DATAcc by DiME

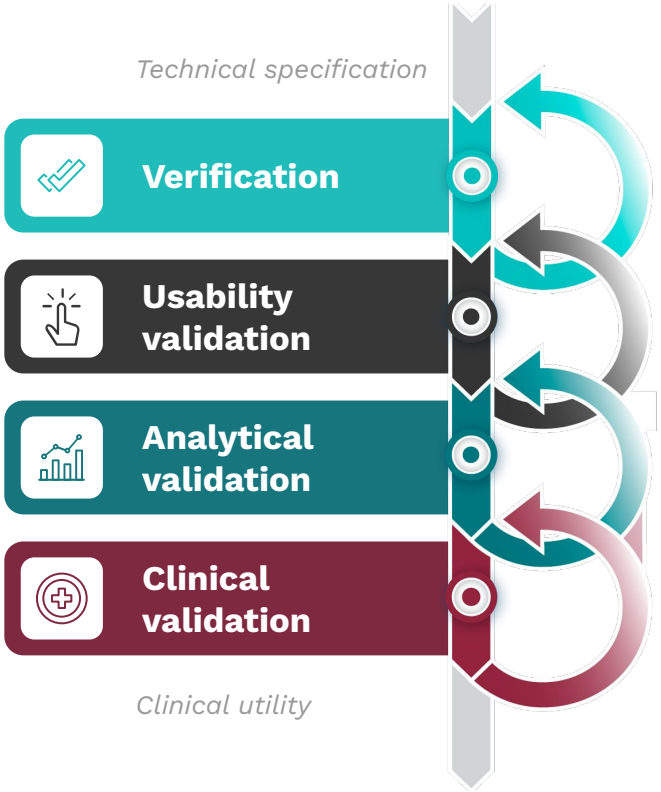
An extension to the V3 framework to ensure **user-centricity** and **scalability** of sensor-based digital health technologies

Project Partners

AARDEX GROUP
ActiGraph
ATCORE A CARDIEX COMPANY
Exponent
Genentech A Member of the Roche Group
Janssen Pharmaceutical Companies of Johnson & Johnson
pkg by Global Kinetics
Sage Therapeutics
Stel
REGENERON
sysnav HEALTH CARE
TNO innovation for life

Source: https://dimesociety.org/access-resources/extending-v3

V3+ extended framework



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

Evaluates whether a **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 a **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: http://dimesociety.org/access-resources/extending-v3 & V3+ manuscript preprint

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Analytical Validation Library Snapshot

Analytical validation evaluates the performance of algorithms to convert sensor data into digital clinical measures in a way that is fit-for-purpose for clinical decision-making and reliable across the entire population of interest.

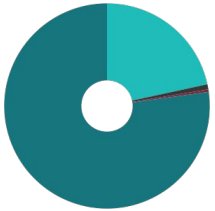
#1 Sensor: Accelerometer

#1 Form Factor: Strap/brace

Top 5 Health Outcomes

- **35** Gait
- **26** Heart rate/rhythm
- **24** Blood pressure/arterial stiffness
- **24** Sleep staging
- **18** Mobility

Technology Types

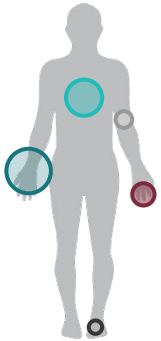


- **78%** Wearable
- **22%** Ambient
- **<1%** Ingestible
- **<1%** Implantable

Top 5 Therapeutic Areas

- **46%** Healthy/non-specific (96)
- **9%** General/other (19)
- **8%** Cardiovascular (17)
- **8%** Neurology (16)
- **6%** Gastrointestinal (12)

Top 5 Wear Locations

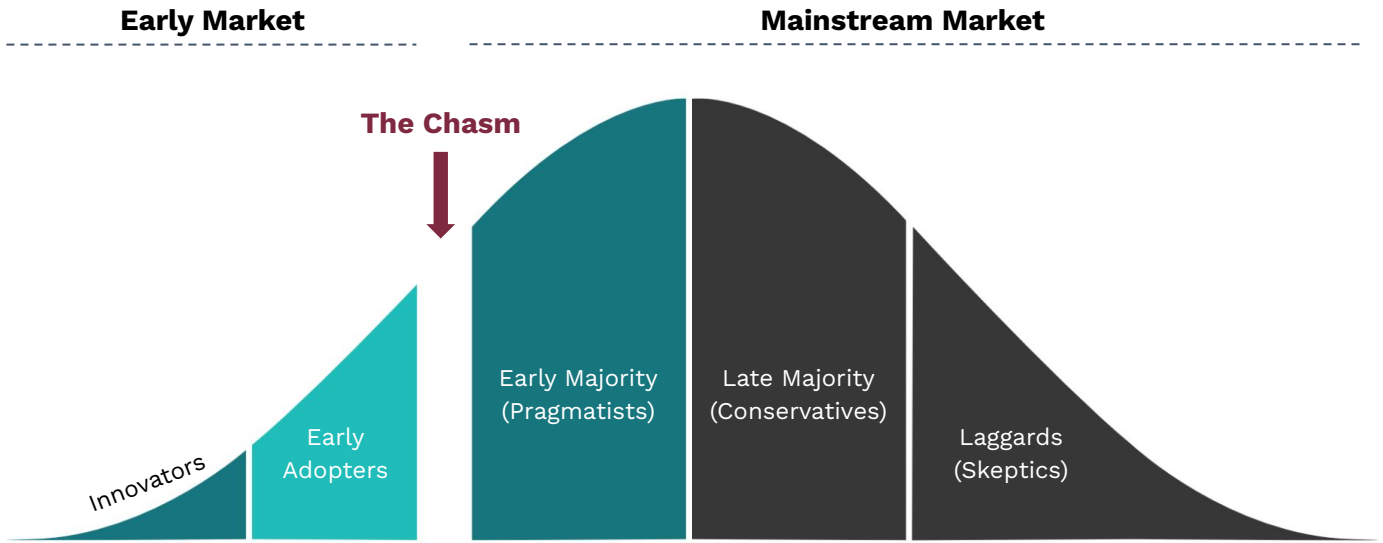


- **48** Wrist/s
- **39** Chest, torso, trunk
- **24** Finger/s
- **18** Arm/s
- **15** Foot/feet

Source: https://datacc.dimesociety.org/analytical-validation-library/

The data ecosystem driving digital health measurement **at scale**.

DiMe and Partners are leading the charge to scale and accelerate the use of digital measures



Source: adapted from https://thinkinsights.net/strategy/crossing-the-chasm/

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65 Sponsors have collected 422 digital endpoints

Primary, Secondary or Other/Exploratory

Abbott, abbvie, ABIDE THERAPEUTICS, ACTELION, addex Therapeutics, ALKAHEST, Allurion, AstraZeneca, BAYER, Bellerophon THERAPEUTICS, BIOAGE, biodelivery SCIENCES, Boehringer Ingelheim, CEREGATE, CIONIC, Clexio Biosciences, CuraSen, Daiichi-Sankyo, dexcom, Diurnal, EIP PHARMA, Eisai, Lilly, Forest Laboratories, Inc., Genentech, GILEAD Creating Possible, gsk, idorsia, INmuneBio INNATE IMMUNITY, Insulet, janssen Johnson & Johnson, Jazz Pharmaceuticals, KHONDRION, KYOWA KIRIN, MARREK, MEDICIS, Medtronic, MERCK, Neurolixis, NOEMA PHARMA, NOVARTIS, novo nordisk, CONEU Therapeutics, Pfizer, PHARMACOSMOS, PRAXIS, REGENERON, Sage Therapeutics, SANOFI, SAREPTA THERAPEUTICS, SIGNOS, SoniVie, Takeda, TANDEM DIABETES CARE, teva, ucb, ultragenyx pharmaceutical, VANDA PHARMACEUTICALS INC., VERTEX, VIATRIS, Vitro BIOPHARMA, ZOLL, zucara

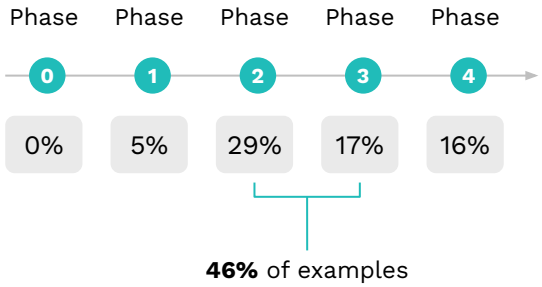
Source: https://dimesociety.org/get-involved/library-of-digital-endpoints/

Last updated Jan 25, 2024

65 Sponsors have collected 422 digital endpoints

Sponsors start digital endpoint development early

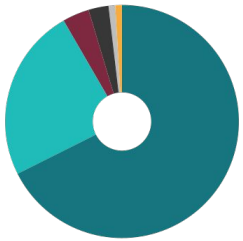
Digital Endpoints



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	68%
Device	24%
Behavioral	4%
Biologic	3%
Genetic	1%
Combination	1%

Industry Sponsors trust digital endpoints

Endpoint Positioning

114	Primary endpoints
250	Secondary endpoints
58	Other / Exploratory
422	**TOTAL ENDPOINTS**

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

Source: https://dimesociety.org/get-involved/library-of-digital-endpoints/

Last updated Jan 25, 2024

New Final Guidance: DHTs in Clinical Trials

In Dec 2023, FDA published final guidance to address themes including the use of DHT-based measurements as endpoints in clinical trials.

In this guidance, FDA clarifies that DHTs used in clinical research do not need to be medical devices, but should be verified and validated for their context of use.

Source: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations

The Rapid Evolution of Digital Endpoints: Are We Headed in the Right Direction?

The number of unique digital endpoints being used in industry-sponsored trials of new medical products is skyrocketing, but is more always better?

Jennifer Goldsack

Jan 26 · 6 min read

Source: https://medium.com/digital-medicine-society-dime/the-rapid-evolution-of-digital-endpoints-are-we-headed-in-the-right-direction-c25bbcb32eee

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… and none of this matters if you didn't pick a measure that matters

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

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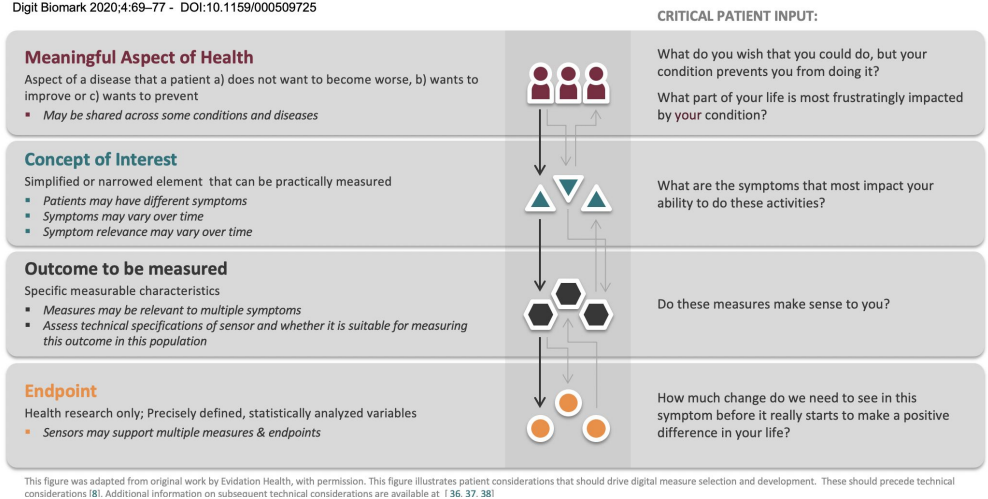
[a]Digital Medicine Society, Boston, MA, USA; [b]Elektra Labs, Boston, MA, USA; [c]Evidation Health, Inc., San Mateo, CA, USA

Keywords
Digital medicine · Patient engagement · Digital measures

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:10.1159/000509725



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

DIGITAL MEDICINE SOCIETY

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

almirall

gsk GlaxoSmithKline

LEO

Lilly

sanofi

Expert Partners:

National Eczema Association

GLOBAL PARENTS FOR ECZEMA RESEARCH
RESEARCH • SUPPORT • CHANGE

Duke University

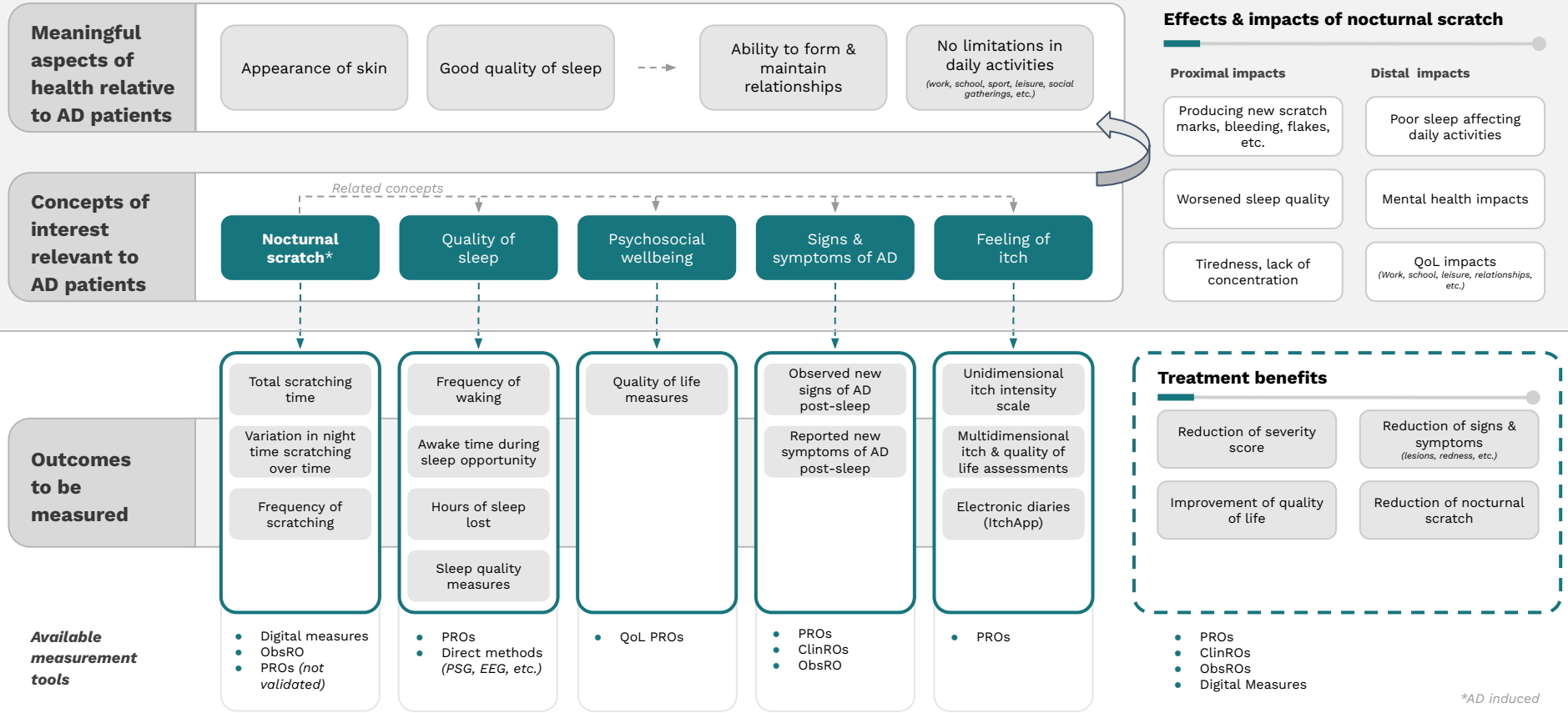
Harvard Business School

Boston University

Health Outcomes Insights
Getting targeted answers to patient behaviour and outcomes

Source: https://www.dimesociety.org/tours-of-duty/digital-measures-nocturnal-scratch/

Conceptual Model for **Nocturnal Scratch** in AD



DIGITAL MEDICINE SOCIETY

CORE MEASURES *of* PHYSICAL ACTIVITY

Digital Measures Development

Project Partners

ALEXION
ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY
COPD FOUNDATION
DEFENSE INNOVATION UNIT
Duke | BIG IDEAS LAB
MERCK
THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH
Nestlé
Open mHealth
savvy COOPERATIVE

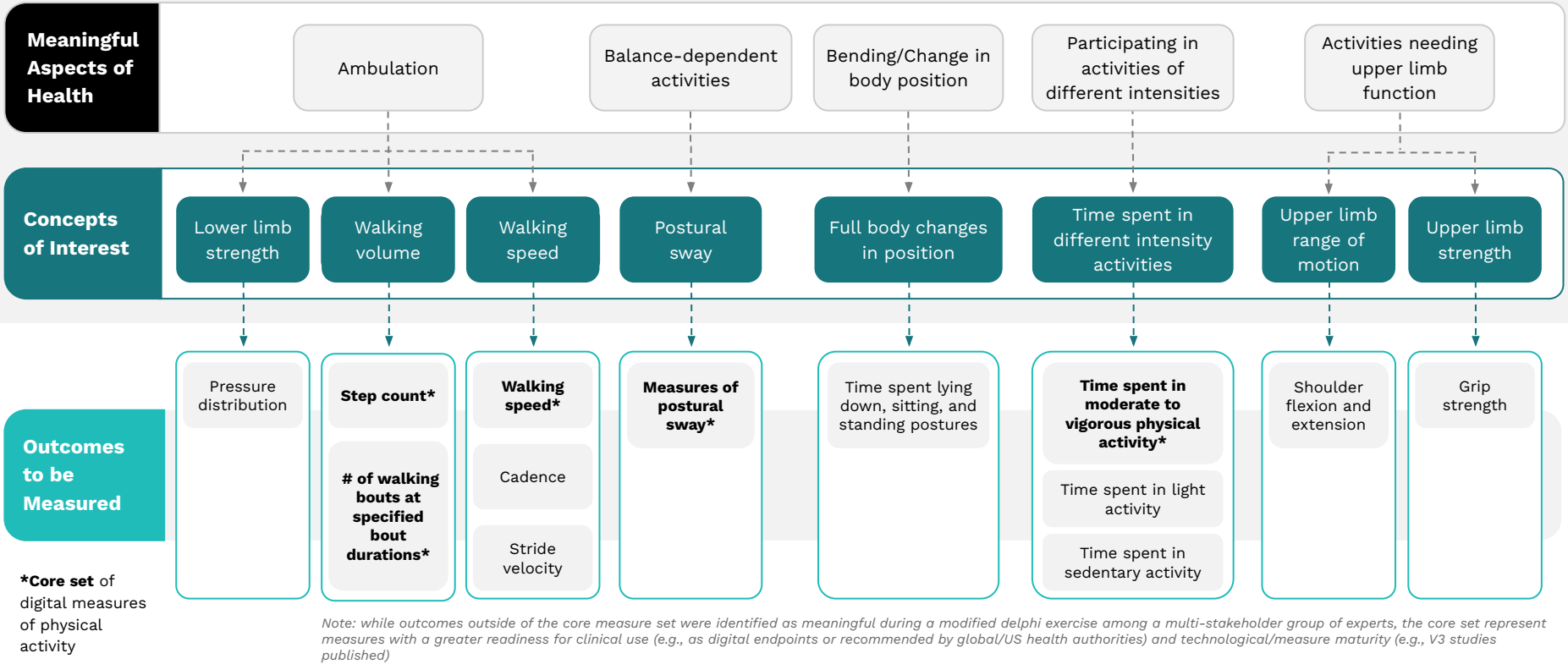
Digital Solutions Collaborators

Activinsights
ANALOG DEVICES AHEAD OF WHAT'S POSSIBLE™
empatica
evidation
fitbit
HumanFirst
IQVIA
koneksa
Medable
parexel
verily
VivoSense

Source: https://www.dimesociety.org/access-resources/digital-measures-physical-activity/

CORE MEASURES *of* PHYSICAL ACTIVITY
Digital Measures Development

Conceptual Model for Physical Activity



***Core set** of digital measures of physical activity

Note: while outcomes outside of the core measure set were identified as meaningful during a modified delphi exercise among a multi-stakeholder group of experts, the core set represent measures with a greater readiness for clinical use (e.g., as digital endpoints or recommended by global/US health authorities) and technological/measure maturity (e.g., V3 studies published)

Source: https://www.dimesociety.org/access-resources/digital-measures-physical-activity/

LIBRARY *of* **DIGITAL MEASUREMENT PRODUCTS**

Snapshot of

CORE MEASURES *of* PHYSICAL ACTIVITY

DATACC by DiME

96 Identified technologies

165 Pieces of evidence...
so far. It's still growing!

Technology types

90% wearables

10% ambient or non-wearable

Using V3

Verification: **2** technologies

Analytical validation: **108** technologies

Clinical validation: **68** technologies

Top 3 Therapeutic areas

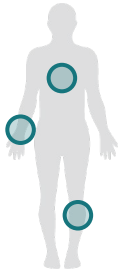
(Excluding general/healthy populations)

1. **Neurological**
2. **Musculoskeletal system or connective tissue**
3. **Cardio/Cerebrovascular**

Top 3 Technology form factors

1. **Strap or brace**
2. **Watch or wristband**
3. **Smartphone or tablet**

Top 3 Locations for wearables



- Chest/torso/waist/trunk
- Wrist
- Legs

Source: https://www.dimesociety.org/access-resources/digital-measures-physical-activity/

Last updated Feb 9, 2024

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

OHSU Oregon Health & Science University

Roche

Digital Solutions Collaborators

altoida

Aural Analytics

BioSensics™

Cambridge Cognition

Cogniant

Cogstate

Cumulus

ki elements

koneksa

MEDIDATA

LINUS HEALTH

SageBionetworks

VivoSense

WINTERLIGHT

Source: https://datacc.dimesociety.org/digital-measures-adrd/

LIBRARY *of* DIGITAL MEASUREMENT PRODUCTS

Snapshot of

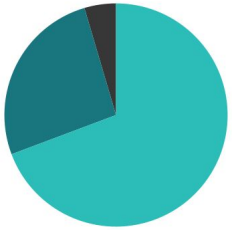
ALZHEIMER'S DISEASE & RELATED DEMENTIAS

DATACC by DiME

99 Identified technologies

153 Pieces of evidence...
so far. It's still growing!

Technology types



69% ambient or non-wearable

26% wearables

5% both

Using V3+

Verification: **2** technologies

Usability validation: **13** technologies

Analytical validation: **60** technologies

Clinical validation: **112** technologies

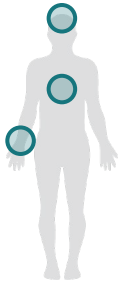
Top 3 Health concept areas

- **Neurocognitive**
- **Physical activity**
- **Sleep**

Top 3 Technology form factors

- **Smartphone/tablet**
- **Strap/brace**
- **Contactless**

Top 3 Locations for wearables



- Head/scalp
- Chest/torso/waist/trunk
- Wrist

DATACC by DiME

CORE MEASURES *of* SLEEP

Digital Measures Development

Sleep disturbance greatly impacts quality of life and it's often the first indicator of a larger issue. Let's measure it the right way.

Project Partners

- Bayer
- Boston University
- Defense Innovation Unit
- Duke
- GSK
- Jazz Pharmaceuticals
- Lilly
- National Sleep Foundation
- NextSense — Revolutionizing Brain Health
- Sage Therapeutics
- Takeda
- T.C. Demiroğlu Bilim University
- UZ Leuven
- VA | U.S. Department of Veterans Affairs

Digital Solutions Collaborators

- Activinsights
- BeaconBiosignals
- Biostrap
- Byteflies
- dreem
- Google
- ŌURA
- Primasun
- sleep number
- Softmatter
- TNO innovation for life
- VivoSense

Source: https://datacc.dimesociety.org/core-measures-sleep/

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 · Atrium Health Levine Cancer Institute · ASH Research Collaborative · Best Buy Health · blue spark · Bristol Myers Squibb · doccla · FDA · FNIH Foundation for the National Institutes of Health · Friends of Cancer Research · Genentech A Member of the Roche Group · IEEE Advancing Technology for Humanity · Johnson & Johnson Innovative Medicine · Leukemia & Lymphoma Society · Orion Pharma · Pfizer · Takeda · verily a precision health company

Partners also include the National Cancer Institute

Source: https://datacc.dimesociety.org/advancing-digital-capabilities-to-enable-digital-risk-prediction-for-cytokine-release-syndrome-crs/

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

DIGITAL MEDICINE SOCIETY

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

Join us in our next project as we convene leaders from across the field to **develop the business case** to support the development, adoption, and scale of digital endpoints!

Share your interest in joining us:
Building the Business Case for Digital Endpoints

Source: https://pages.insightly.services/digital_endpoints

THANK YOU

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DIGITAL MEDICINE SOCIETY

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