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**Digital Health Technologies (DHTs):
Data Standardization and Where We Go from Here**

Christine Connolly, Head of Standards Projects, CDISC
Jessie Bakker, Vice President of Digital Measures and Diagnostics, DiMe

Meet the Speakers

Christine Connolly

Title: Head of Standards Projects

Organization: CDISC

Christine Connolly is an advocate for standardization given its potential to expedite improved health outcomes. She has led initiatives, developed, and implemented data standards for almost fifteen years and has twenty-five years of experience working in global clinical trials in both academic and pharmaceutical settings.

Jessie Bakker PhD

Title: Vice President | Digital Measures and Diagnostics

Organization: Digital Medicine Society (DiMe)

Jessie Bakker has extensive experience in the development, validation, and deployment of sensor-based digital health technologies in clinical trials. In her role at DiMe, she leads a portfolio of work focused on digital measures development, alongside evidence-based recommendations for best practices and methodologies.

Agenda

1. About Digital Health Technologies
2. Standards Through Partnership
3. Where we go from here

About Digital Health Technologies

Digital medicine

Digital medicine field

The use of technologies as tools for measurement and intervention in the service of human health [1]

Digital health technologies

A system that uses computing platforms, connectivity, software, and/or sensors, for healthcare and related uses [2]

Sensor-based digital health technologies

Digital health technologies that include sensor hardware

Software applications that run on general-purpose computing platforms

[1] https://dimesociety.org/about-us/defining-digital-medicine/
[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations

Key aspects of sensor-based digital health technologies

Sensor/s + algorithm/s
- Sensor/s that sample a physical construct e.g. acceleration, voltage, light
- Algorithm/s that convert sensor data to clinically-relevant measures

Mobile
- Capture data outside of the clinic/lab setting
- Allows for continuous or frequent data capture

Connected
- Digital method of data transfer
- Wired or wireless

Clinical outcome assessments not captured by sensors

ePRO (Patient-reported outcome)
- An outcome reported by the patient/participant who experienced it
- E.g. an electronic sleep diary or validated sleepiness questionnaire

eObsRO (Observer-reported outcome)
- An outcome reported by an observer when the patient themselves is unable
- E.g. an electronic platform to report an AE experienced by a child

eClinRO (Clinician-reported outcome)
- An outcome that requires clinical knowledge, judgement, or interpretation
- E.g. electronic capture of performance status; interpretation of sensor data

Technology categories

Wearable

Adhesive patch
Wrist-worn tracker

Ingestible

Core body temperature monitor
Imaging capsules

Implantable

Orthopedic force/strain monitors
Cardiac loop recorder

Ambient

Mattress pad sleep monitoring
Smartphone finger-tapping task

Data collection categories

Passive

Continual data collection without user input

Includes tools for which the absence of data is meaningful, such as digital pills for adherence

Active Task-based

Requires user engagement at defined time point

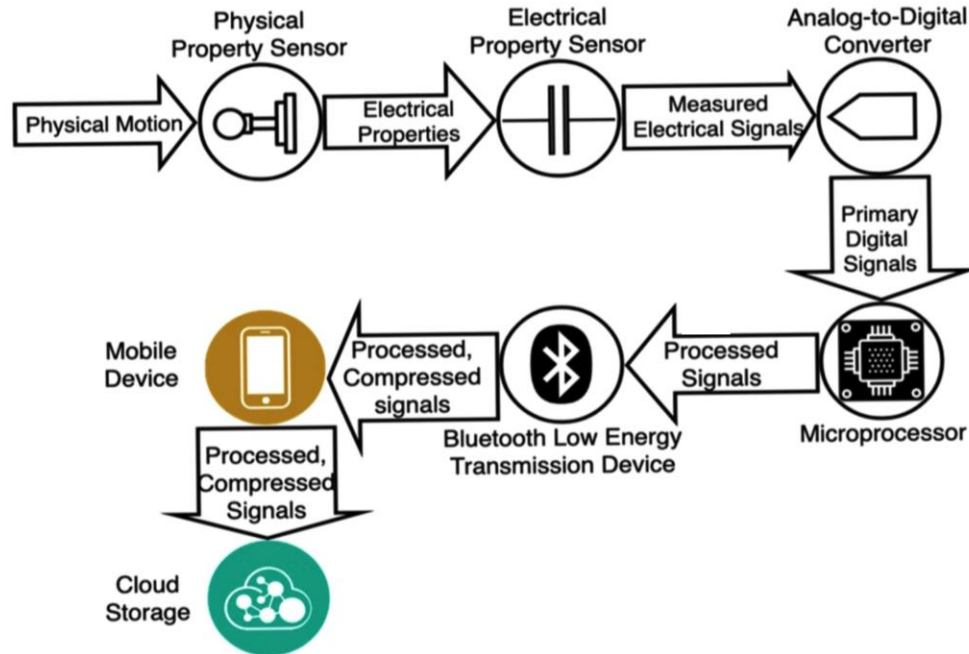*The duration of engagement is not meaningful, such as connected weight scales*

Active Session-based

Requires user engagement at defined timepoints

The duration of engagement is meaningful, such as connected exercise equipment

Complexities of data processing

Advantages of digital health technologies for capturing clinical research data

Real-world data may better reflect the lived experience

Understand day-to-day variability

Improved recruitment, participant engagement, and retention

Decentralized trials with wider patient access

Continuous or frequent measurements increase statistical power

Reproducible, objective data to complement patient-reported outcomes

May reduce burden on participants, sites, and investigators

Standards Through Partnership

Standards Through Partnership

To advance the ethical, effective, equitable, and safe use of digital medicine to redefine healthcare and improve lives

A collaborative community hosted by DiMe with the FDA's Center for Devices and Radiological Health

To advance data standards and transform incompatible formats, inconsistent methodologies, and diverse perspectives to amplify data's impact for research and global health.

Volunteers

Partnership Goals

Robust Community Engagement

Enhanced standardization of digital health technologies data to improve health outcomes

Enriched and aligned resources to support the stakeholder community

Where we go from here

We Facilitate Innovation

Digital health technologies (DHTs) are innovative tools to support improved health outcomes

So, the question becomes:

• How can we best support?

And the answers reflect:

• Observations and opportunities

Digital Health Technologies (DHTs)

Key Concepts

DHT concepts are defined at a high-level with varying definitions across different sources

Opportunity

Observation

Development of new and adoption of existing terminology for DHT concepts

Digital Health Technologies (DHTs)

Device Attributes

For data generated to be meaningful, data describing devices are needed

Observation

Opportunity

Enhanced standards to represent attributes of DHTs used for data collection

Digital Health Technologies (DHTs)

Endpoints

Data generated may be novel and are reported with varying structures, terminologies, and formats

Opportunity

Observation

Development of new and adoption of existing standards for measures which comprise endpoints

Digital Health Technologies (DHTs)

Best Practice

Best practices for use of CDISC
standards with DHTs does not exist

Opportunity

Observation

Development of new and adoption
of existing best practices for
effective use of standards

Approach

Partner

- Expert organizations
- Expert volunteers

Standardize

Concepts, device attributes, endpoints, and best practices

Resources

Robust & aligned

Scope

June - October

Develop

Start in November

Deliver

2024 staged releases

Digital Health Technologies (DHT) Team

Purpose:

- To explore and enhance standardization of digital health technologies data

Goals:

- Increase our collective knowledge of digital health technologies and related data;
- In collaboration with a diverse group of stakeholders;
- To determine how CDISC standards can further support use of DHTs; and to
- Develop and publish new supporting standards

Acknowledgements

We would like to thank the CDISC Digital Technologies (DHT) team for making this work possible.
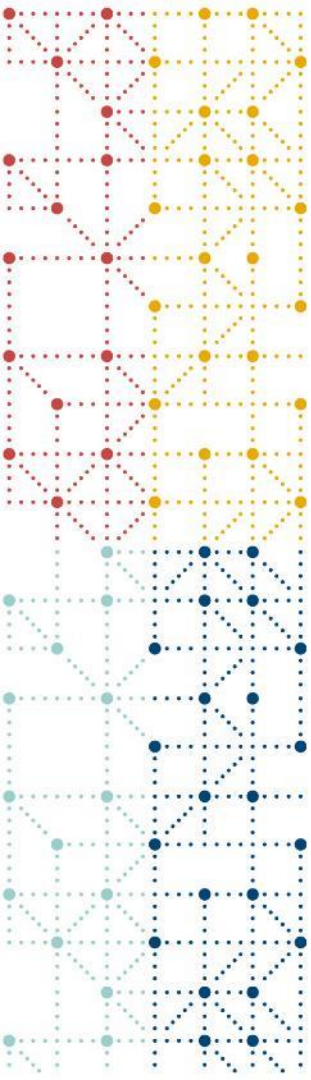
Please join us

Become a Digital Health Technologies (DHT) Team volunteer

- www.cdisc.org/volunteer
  - Click link to Become a Volunteer
  - Current commitment is generally a one-hour weekly meeting with preparation as needed
  - It is never too late to volunteer

- Review draft standards as they are released

We hope to see you as we continue to move forward!

Thank You!

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