

A panoramic view of the Berlin skyline at sunset, featuring the TV Tower (Fernsehturm) and various city buildings under a clear blue sky.

2024 CDISC + TMF
EUROPE INTERCHANGE

BERLIN

24-25 APRIL: CONFERENCE & EXPO | 22, 23, 26 APRIL: TRAININGS

Digital Health Technologies (DHTs): A Path to Data Standardization

Presented by Christine Connolly, Head of Standards Projects, CDISC



Meet the Speaker

Christine Connolly

Title: Head of Standards Projects

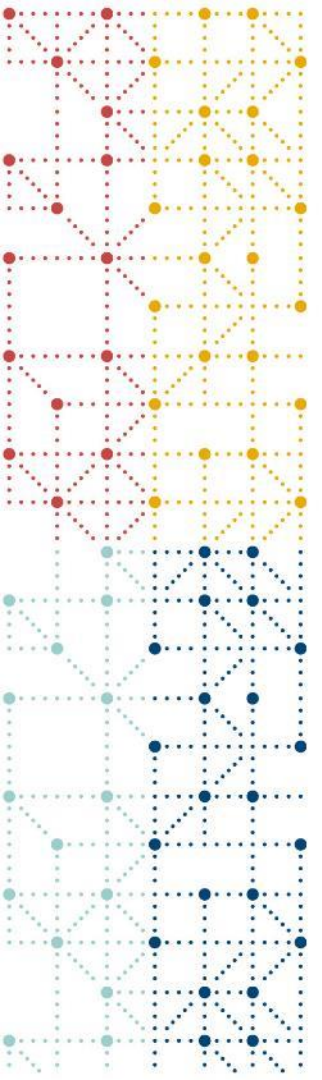
Organization: CDISC

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.



Agenda

1. Digital Health Technologies (DHTs)
2. Standards Through Partnership
3. A Path to Standardization



Digital Health Technologies (DHTs)

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 (DHTs)

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

Sensor-based DHTs

*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>



Advantages of DHTs Clinical Research

Data may better reflect the lived (real world) experience

Understanding of day-to-day variability

Improved recruitment, participant engagement, and retention

Decentralized trials with wider patient access

Continuous or frequent measurements increase statistical power

May reduce burden on participants, sites, and investigators

Reproducible, objective data to complement patient-reported outcomes

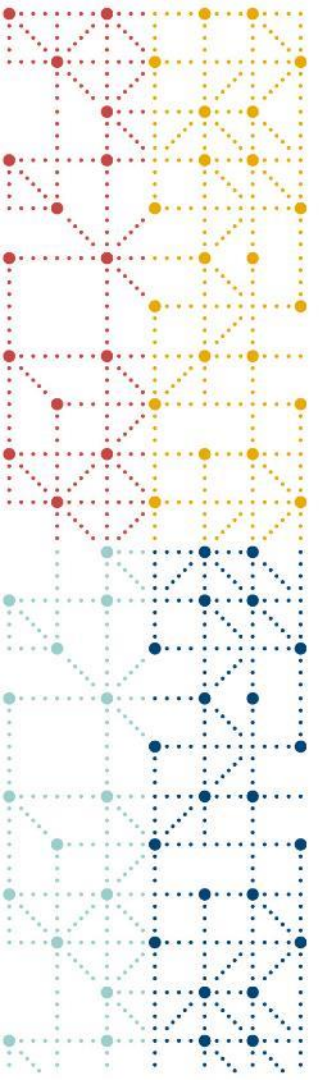


Today

Contexts in which DHTs support clinical research are innovative and evolving.

Although separate components exist, at present there are no connected, end-to-end community resources, from evaluation of DHTs for data collection through subsequent representations of data.

**A volunteer team of diverse stakeholders
is working to address opportunities for
end-to-end resources and data standardization.**



Standards Through Partnership

Standards Through Partnership



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



*Digital Health Measurement
Collaborative Community*

by DiME

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



Create connected standards across the study information lifecycle to enable accessible, interoperable, and reusable data for more meaningful and effective research

Volunteers



Partnership Goals

A **framework** for long-term, ongoing provision of connected, end-to-end community resources to support DHT data collection in clinical research via organizational partnership and volunteer engagement.



Robust
Community
Engagement



Enhanced
Data
Standardization



Enriched,
Aligned
Resources



End-to-end Resource Alignment

Library of Digital Endpoints

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



Endpoint identifier	Trial identifier	Endpoint positioning	Endpoint description (per trial registration record)	Health concept/s	Technology type	Trial phase	Trial primary purpose	Condition/s	Condition/s category
87	NCT00325728	Primary	Mean Nighttime Total Sleep Time as determined by actigraphy., Week 1	Sleep	Wearable	Phase 2	Treatment	Chronic Insomnia	Sleep/wake
99	NCT01474772	Secondary	Over the Last 7 Days of Each Treatment Period (Week 6 of Each Treatment	Physical activity	Wearable	Phase 3	Treatment	Peripheral Neuropathy	Endocrine or metabolic conditions, Neurological

Glossary

<https://dimesociety.org/glossary/>

Sensor-based digital health technologies (sDHT)

/ˈsɛnsər-beɪst ˈdɪdʒɪtəl hɛlθ tɛk ˈnælədʒɪz/

Connected digital medicine products that process data captured by **mobile** sensors using **algorithms** to generate measures of behavioral and/or physiological function, also referred to as biometric monitoring technologies.

[V3+ Framework](#)

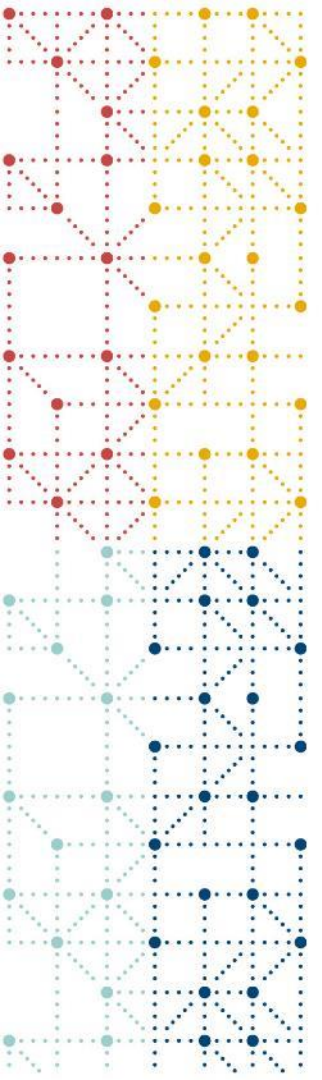


V3+ Framework



<https://dataacc.dimesociety.org/v3/>

Additional resources may also be considered.



A Path to Standardization

Digital Health Technologies Initiative

Three Year



Roadmap

Data Sources

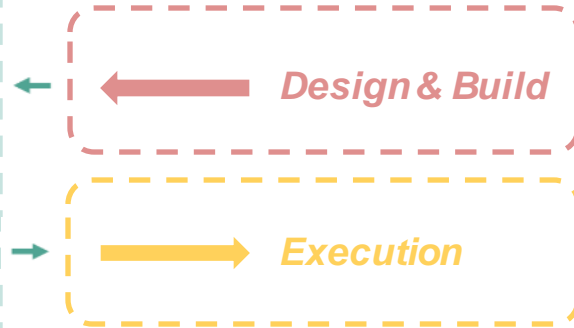


DHT

Integrate Sources

Ensure standard representation for lineage and traceability so data quality meets or exceeds expectations

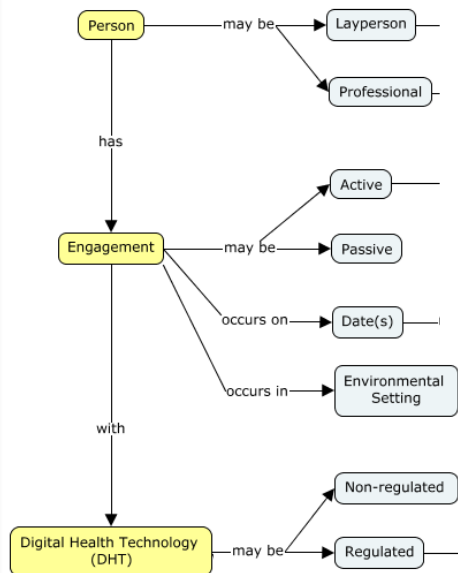
- ✓ Define initial set of usable **Digital Health Technology** endpoints and concepts



- ✓ Define an exchange mechanism to represent lineage, traceability, and quality of the data for real world data
- ✓ Continuously deliver proof of concepts demonstrating integration use cases

Initial Scope and Deliverables

Key Concepts



Device Attributes & Digital Endpoints

DiMe Library of Digital Endpoints: 125 CGM



Example 1: Continuous Glucose Monitoring

This example shows findings from assessments of estimates of blood glucose from a continuous glucose monitor (CGM) with the purpose of supporting DiMe Endpoint 125, "CGM % Time 70-180 mg/dl," in a clinical trial. The device data needed for the trial is specified in the study protocol.

The following dataset is an example of data output by the CGM. The data in the columns "Insulin Value (u)" and "Carb Value (grams)" are for data input by the user; they are not used in this example.

> [dexcom g7.xpt](#)

Relevant glucose data from the device output file have been mapped to the following LB domain dataset.

> [lb.xpt](#)

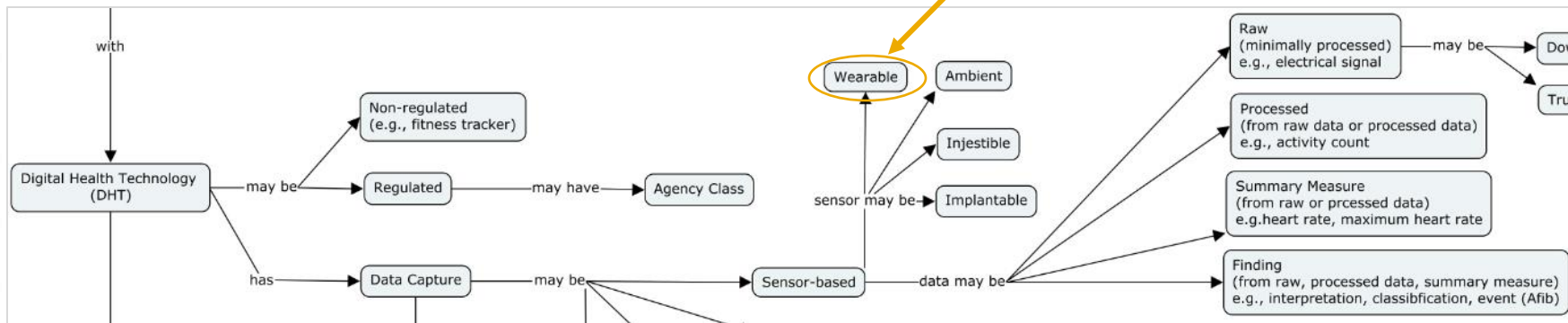
Best Practices

Key Concepts

DiMe Library of Digital Endpoints

Endpoint identifier	Trial identifier	Endpoint positioning	Endpoint description (per trial registration record)	Health concept/s	Technology type	Trial phase	Trial primary purpose	Condition/s
125	NCT03668808	Secondary	CGM % Time 70-180 mg/dl, % time 70-180 mg/dl by CGM, In flight period of time and for 72 hours at each	Blood/skin/other biomarkers	Wearable	Phase 4	Treatment	Diabetes Mellitus Type 1

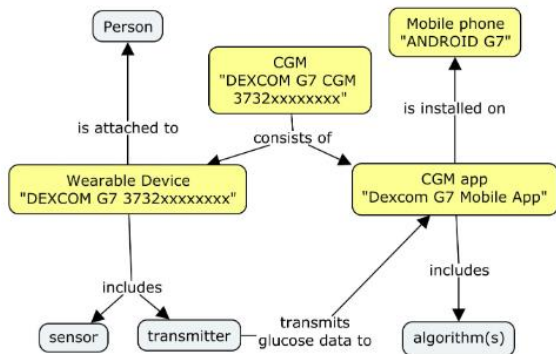
Draft Concept Map



Device Attributes

Draft Example 1: Continuous Glucose Monitoring

This example shows findings from assessments of estimates of blood glucose from a continuous glucose monitor (CGM) with the purpose of supporting DiMe Endpoint 125, "CGM % Time 70-180 mg/dl," in a clinical trial. The device data needed for the trial is specified in the study protocol.



di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABC	DI	ANDROID G7	1	DEVTYPE	Device Type	Mobile phone
2	ABC	DI	ANDROID G7	1	MANUF	Manufacturer	Samsung
3	ABC	DI	ANDROID G7	1	VERSION	Version Identifier	7
4	ABC	DI	Dexcom G7 Mobile App	1	DEVTYPE	Device Type	Mobile phone app
5	ABC	DI	Dexcom G7 Mobile App	1	MANUF	Manufacturer	Dexcom
6	ABC	DI	Dexcom G7 Mobile App	1	VERSION	Version Identifier	7
7	ABC	DI	DEXCOM G7 3732xxxxxxx	1	DEVTYPE	Device Type	Sensor/Transmitter
8	ABC	DI	DEXCOM G7 3732xxxxxxx	1	MANUF	Manufacturer	Dexcom
9	ABC	DI	DEXCOM G7 3732xxxxxxx	1	SERIAL	Serial Number	3732xxxxxxx
10	ABC	DI	DEXCOM G7 CGM 3732xxxxxxx	1	DEVTYPE	Device Type	CGM
11	ABC	DI	DEXCOM G7 CGM 3732xxxxxxx	1	MANUF	Manufacturer	Dexcom

Digital Endpoints

Draft Example 1: Continuous Glucose Monitoring

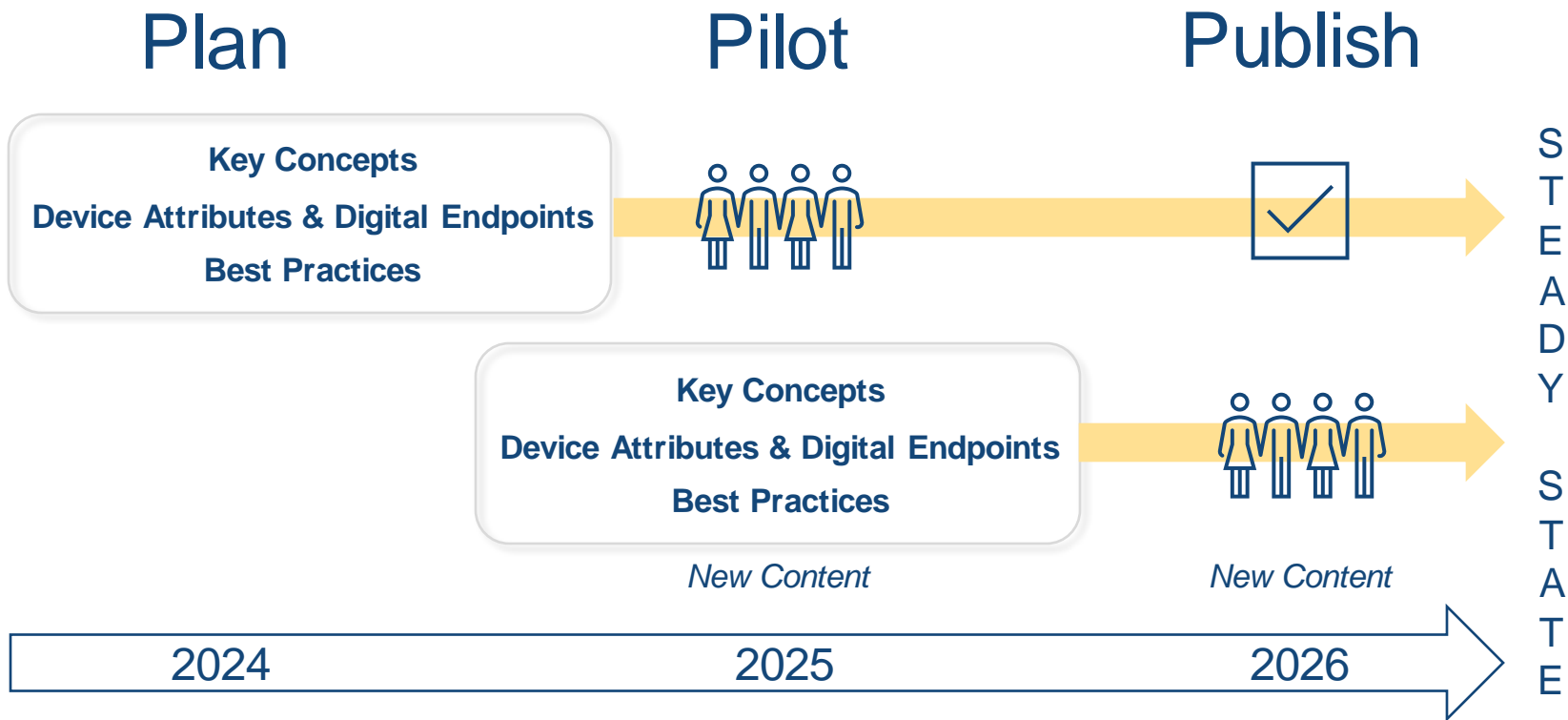
This example shows findings from assessments of estimates of blood glucose from a continuous glucose monitor (CGM) with the purpose of supporting DiMe Endpoint 125, "CGM % Time 70-180 mg/dl," in a clinical trial. The device data needed for the trial is specified in the study protocol.



lb.xpt

Row	STUDYID	USUBJID	SPDEVID	LBSEQ	LBREFID	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSPEC	LBMETHOD	LBANMETH	LBDC
1	ABC	ABC-001	DEXCOM G7 CGM 3732xxxxxxx	1	3732xxxxxxx- 1684	EGV	Estimated Glucose Value	82	mg/dL	INTERSTITIAL FLUID	BIOSENSOR	ALGORITHM	2023-06- 15T08:00:56
2	ABC	ABC-001	DEXCOM G7 CGM 3732xxxxxxx	2	3732xxxxxxx- 1984	EGV	Estimated Glucose Value	89	mg/dL	INTERSTITIAL FLUID	BIOSENSOR	ALGORITHM	2023-06- 15T08:05:56
3	ABC	ABC-001	DEXCOM G7 CGM 3732xxxxxxx	3	3732xxxxxxx- 1684	EGV	Estimated Glucose Value	94	mg/dL	INTERSTITIAL FLUID	BIOSENSOR	ALGORITHM	2023-06- 15T08:10:57

Framework



A Path to Community Benefit



Resource development helps to address current community needs and supports adoption of DHTs.



Piloting supports real-time content release and is comparable to an extended Public Review where content is used with real-time feedback



A steady-state framework empowers the community to develop content in real-time per innovation and evolving needs.

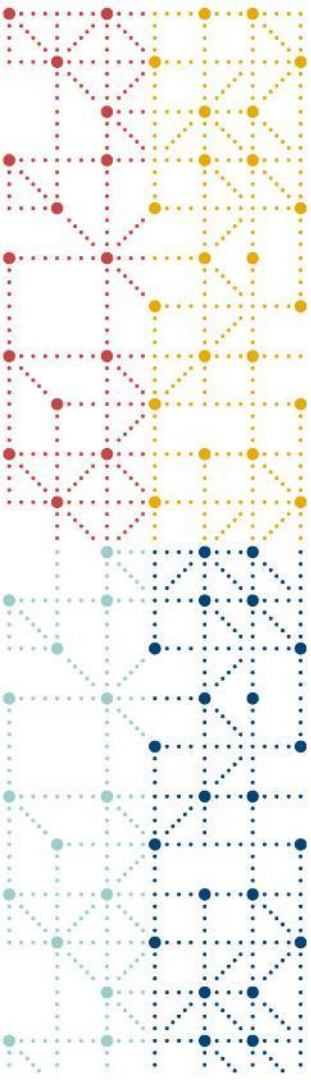
Please join us!

Become a volunteer

www.cdisc.org/volunteer

<https://dimesociety.org/get-involved/>





Thank You!

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