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.

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

Presented by Christine Connolly, Head of Standards Projects, CDISC

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

DIGITAL MEDICINE SOCIETY

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

DATACC

Digital Health Measurement Collaborative Community

by DiME

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

cdisc

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 ˈdɪʤətəl hɛlθ tɛk ˈnɑləʤiz/

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

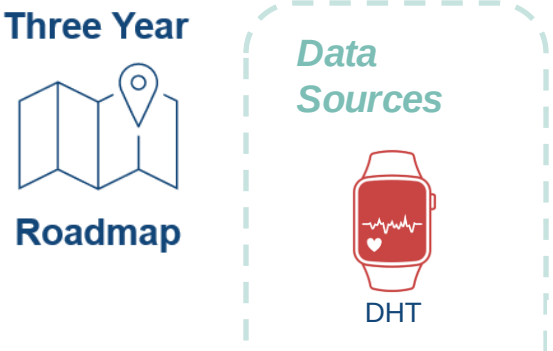
V3+ Framework

https://datacc.dimesociety.org/v3/

Additional resources may also be considered.

A Path to Standardization

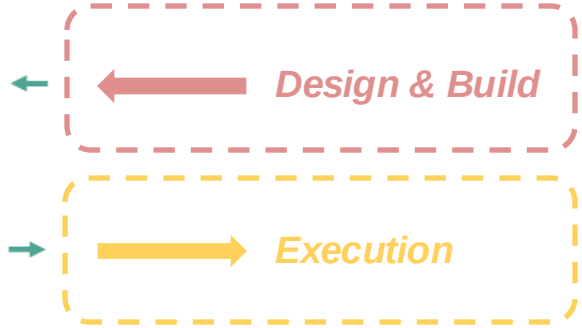
Digital Health Technologies Initiative



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



Digital Health Technologies Initiative

Three Year Roadmap

Plan

- [x] Deliver per initial scope
- [ ] Strategy for release of community resources
- [ ] Prepare pilot resources

Pilot

- [ ] Industry pilot of resources
- [ ] Strategy for iterative publication
- [ ] Begin resource publication

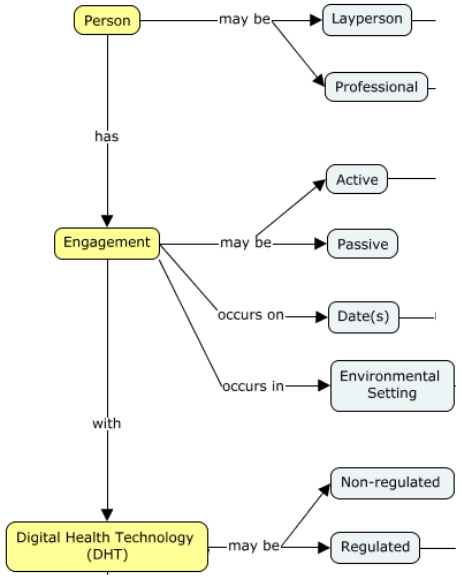
Publish

- [ ] Evaluate lessons learned
- [ ] Refine and implement for steady-state

2024 2025 2026

Initial Scope and Deliverables

Key Concepts



Device Attributes & Digital Endpoints

DiMe Library of Digital Endpoints: 125 CGM

Example 1: Continous 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

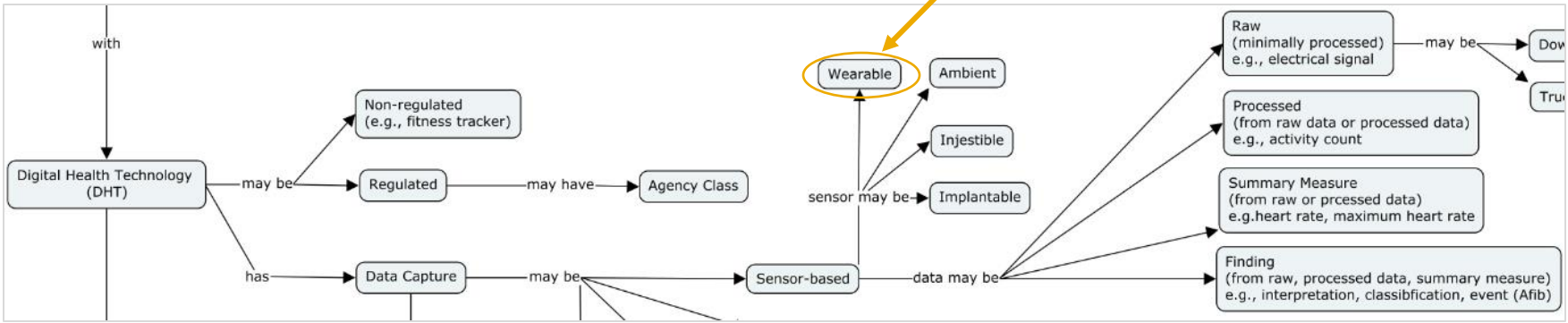
Best Practices

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

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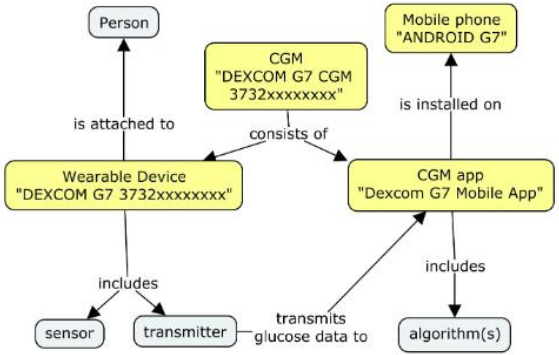


di.xpt

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 3732xxxxxxxx	1	DEVTYPE	Device Type	Sensor/Transmitter
8	ABC	DI	DEXCOM G7 3732xxxxxxxx	1	MANUF	Manufacturer	Dexcom
9	ABC	DI	DEXCOM G7 3732xxxxxxxx	1	SERIAL	Serial Number	3732xxxxxxxx
10	ABC	DI	DEXCOM G7 CGM 3732xxxxxxxx	1	DEVTYPE	Device Type	CGM
11	ABC	DI	DEXCOM G7 CGM 3732xxxxxxxx	1	MANUF	Manufacturer	Dexcom

Digital Endpoints

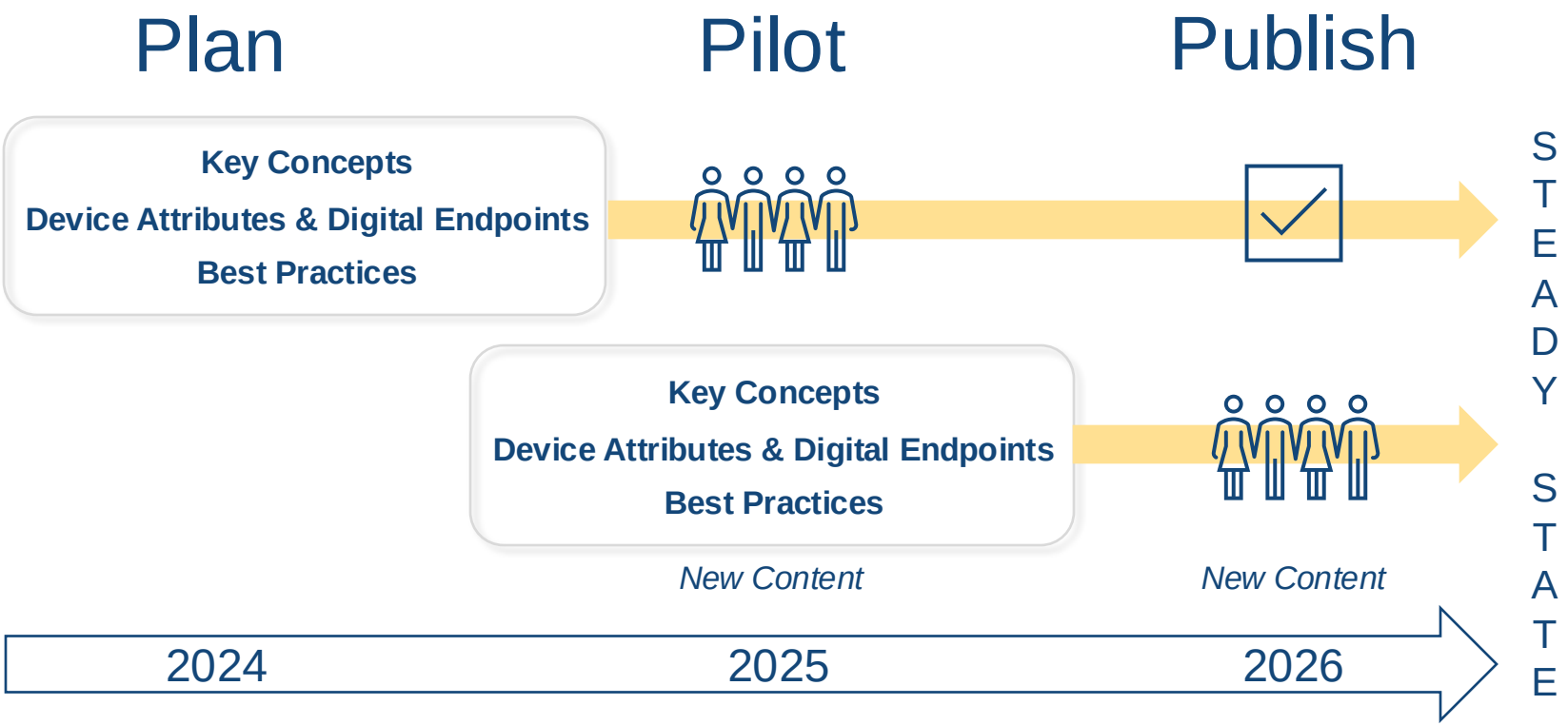
Draft Example 1: Continuous Glucose Monitoring

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	LBDTC
1	ABC	ABC-001	DEXCOM G7 CGM 3732xxxxxxxx	1	3732xxxxxxxx-1684	EGV	Estimated Glucose Value	82	mg/dL	INTERSTITIAL FLUID	BIOSENSOR	ALGORITHM	2023-06-15T08:00:56
2	ABC	ABC-001	DEXCOM G7 CGM 3732xxxxxxxx	2	3732xxxxxxxx-1984	EGV	Estimated Glucose Value	89	mg/dL	INTERSTITIAL FLUID	BIOSENSOR	ALGORITHM	2023-06-15T08:05:56
3	ABC	ABC-001	DEXCOM G7 CGM 3732xxxxxxxx	3	3732xxxxxxxx-1684	EGV	Estimated Glucose Value	94	mg/dL	INTERSTITIAL FLUID	BIOSENSOR	ALGORITHM	2023-06-15T08:10:57

Framework


Plan
Pilot
Publish
Key Concepts
Device Attributes & Digital Endpoints
Best Practices
Key Concepts
Device Attributes & Digital Endpoints
Best Practices
New Content
New Content
STEADY STATE
2024
2025
2026

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!