DHT – Public Review Webinar

John Owen, CDISC
Diane Wold, CDISC

21st April 2026

Agenda

1. Housekeeping
2. Introduction to the CDISC DHT Project
3. The CDISC DHT Portal
4. Deep Dive into the DHT Content
5. Public Review Instructions
6. Q&A

Housekeeping

- Audience will be on mute during this session.

Shhhh...

- Please submit via Q&A in the Teams App.

Questions?

- First, restart Teams.
- Second, check your local internet connection strength

Audio Issues?

- A recording of this webinar and slides will be available on Public Webinar Archive on CDISC website.

Recording

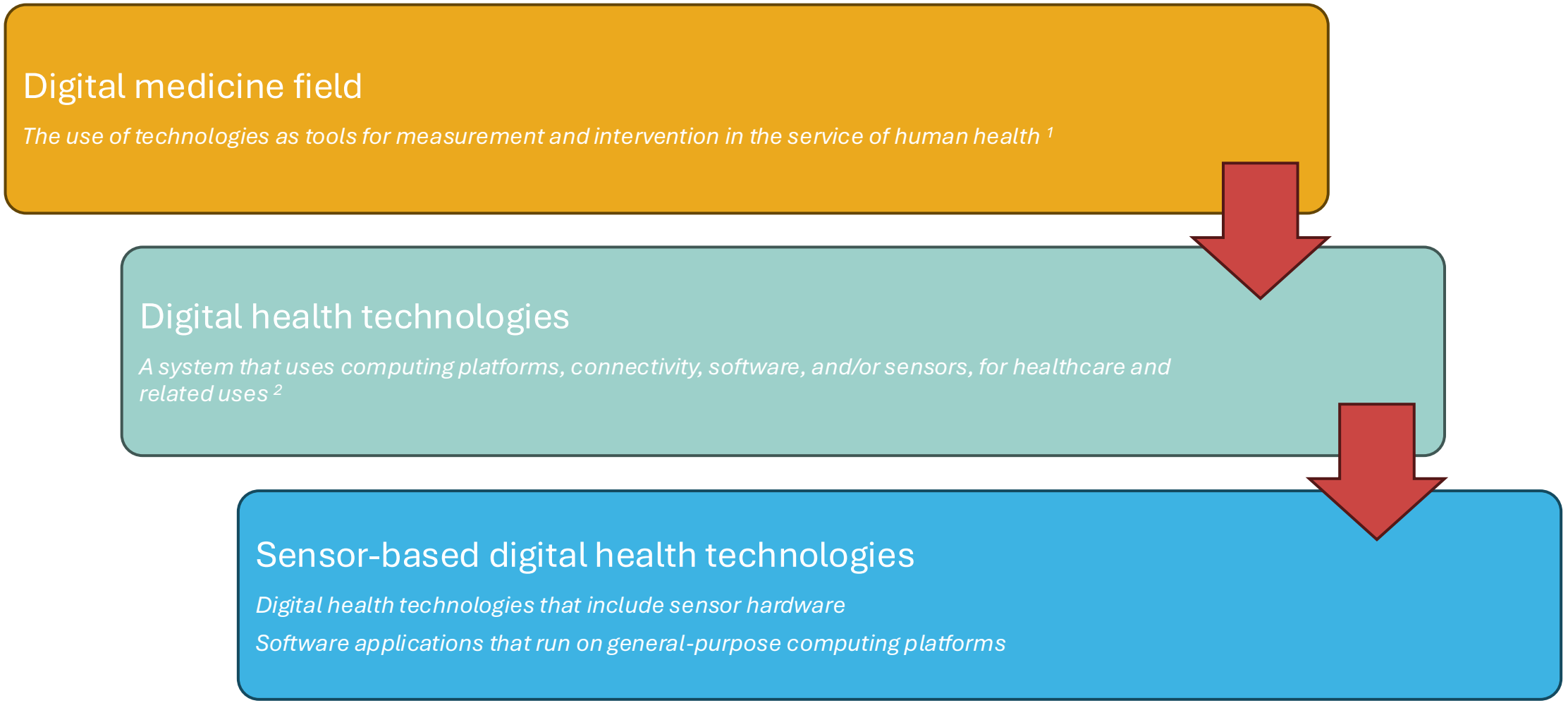
Speakers

John Owen
Senior Director, Standards Operations
CDISC

Diane Wold
Consultant, Data Standards
CDISC

Introduction to the CDISC DHT Project

Digital Medicine



[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

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

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

Volunteers

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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.

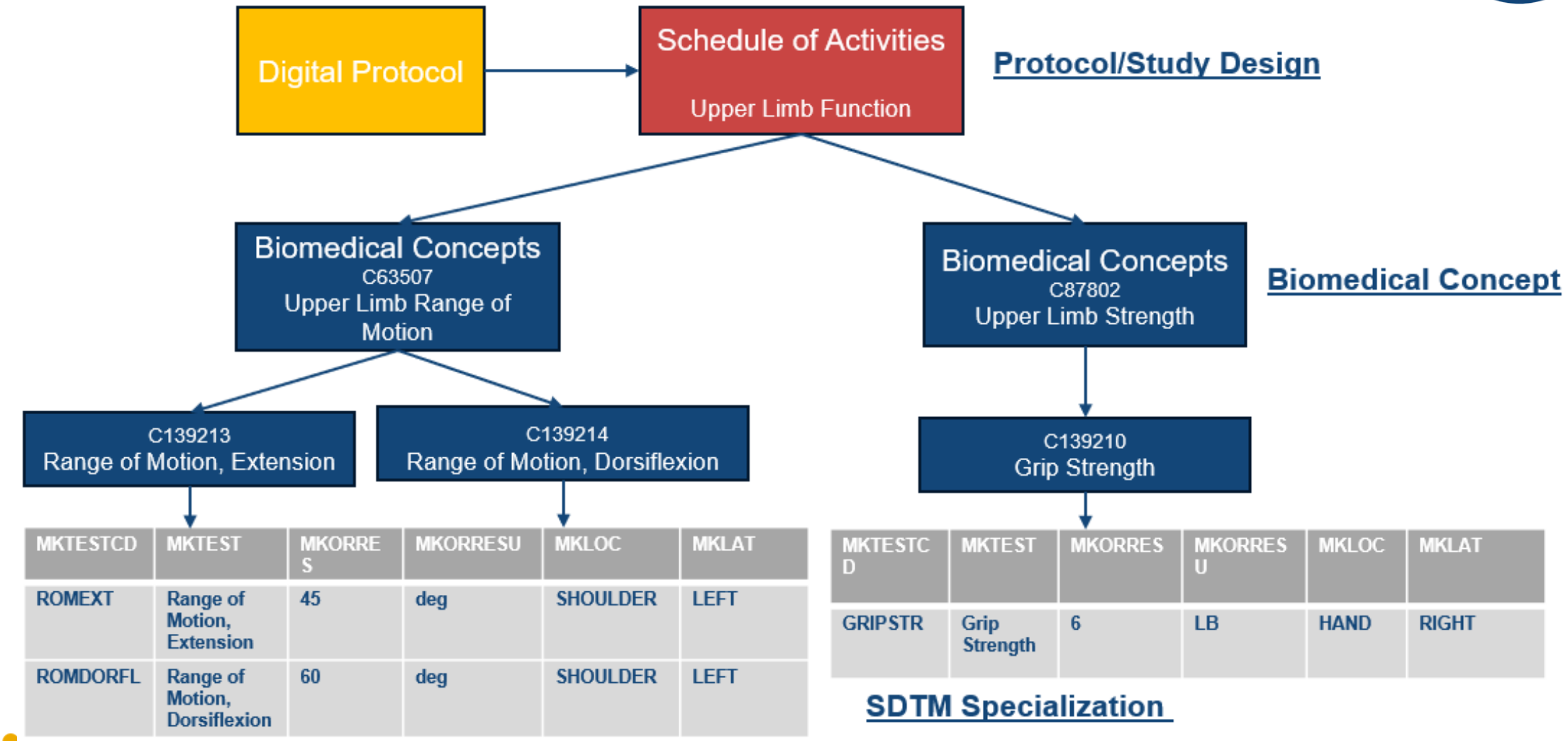
V3+ Framework

Additional resources are considered as we work.

V3+ Framework

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

Biomedical Concepts for Upper Limb Function

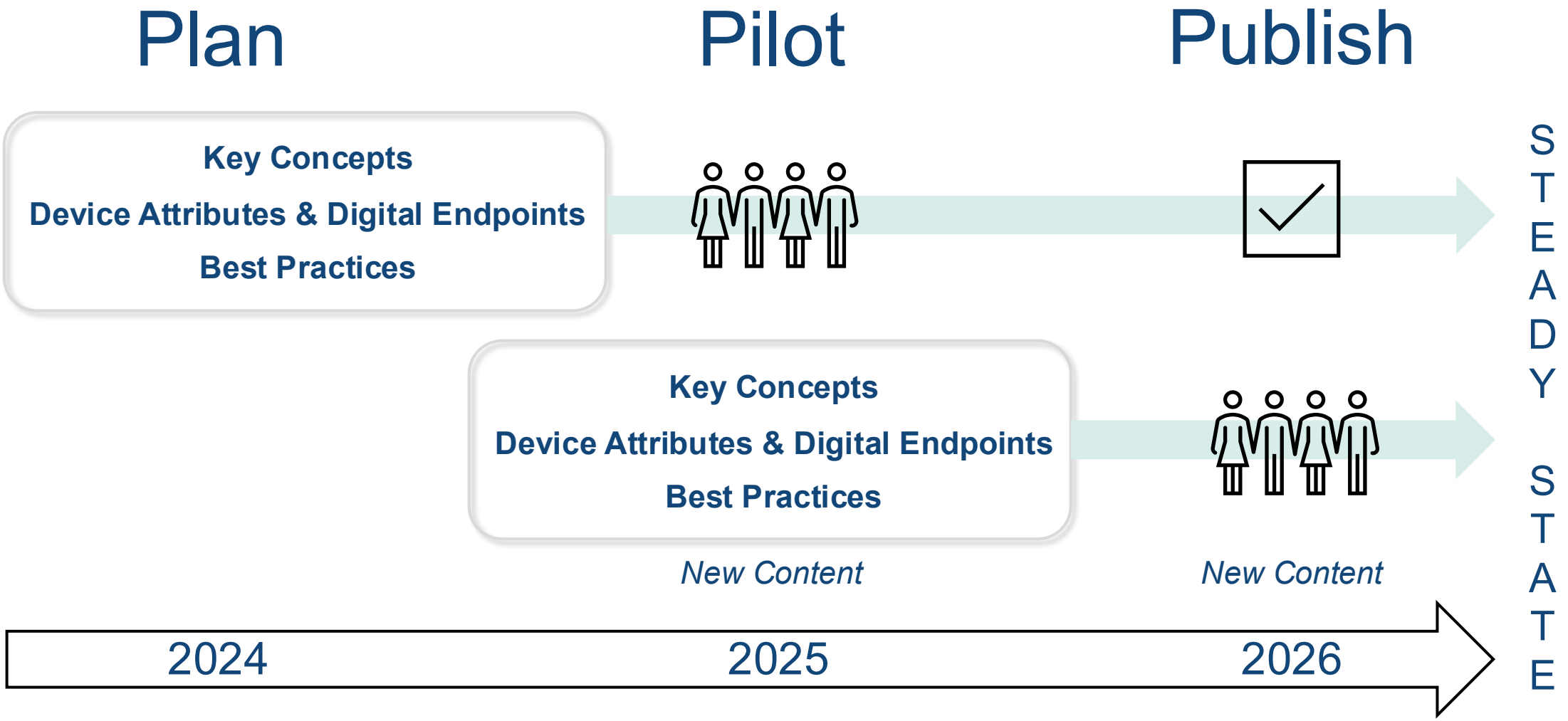


MKTESTCD	MKTEST	MKORRES	MKORRESU	MKLOC	MKLAT
ROMEXT	Range of Motion, Extension	45	deg	SHOULDER	LEFT
ROMDORFL	Range of Motion, Dorsiflexion	60	deg	SHOULDER	LEFT

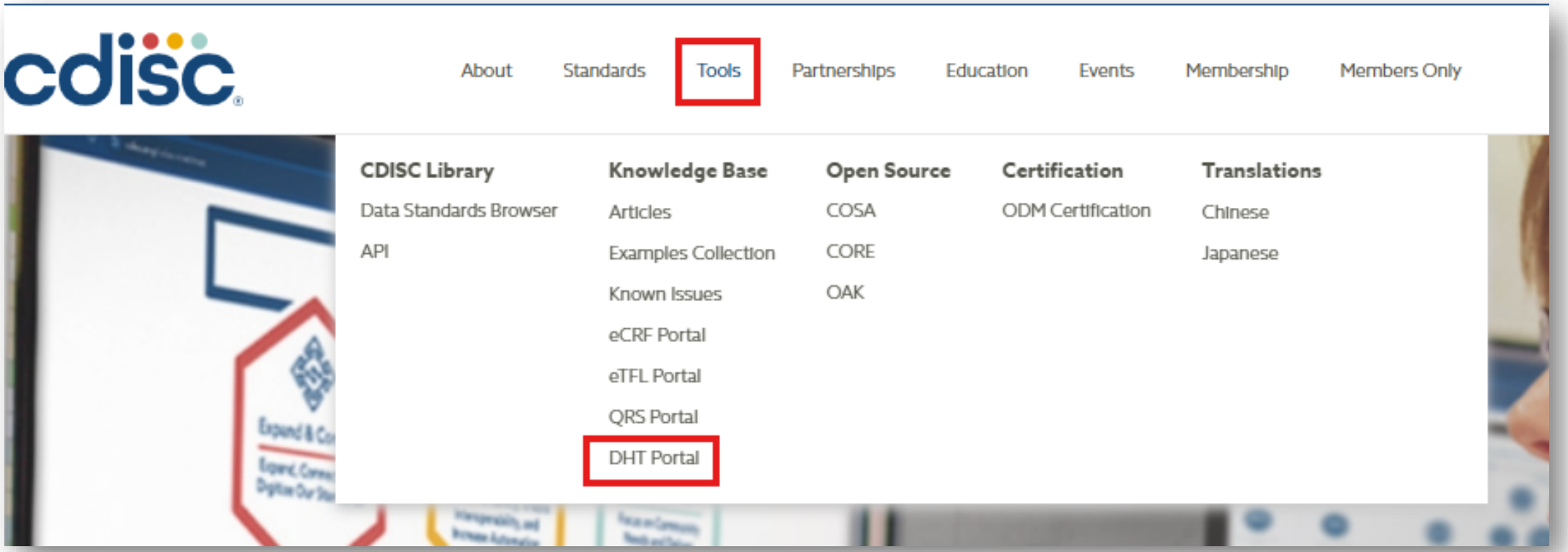
MKTESTCD	MKTEST	MKORRES	MKORRESU	MKLOC	MKLAT
GRIPSTR	Grip Strength	6	LB	HAND	RIGHT

SDTM Specialization

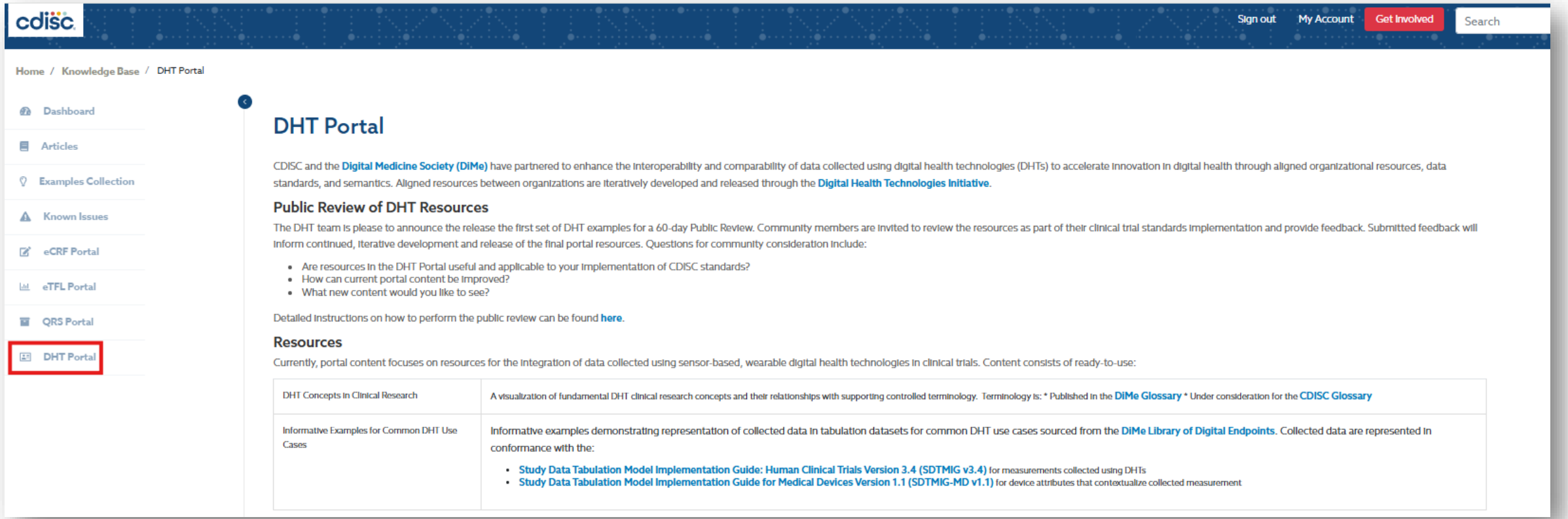
DHT Initiative Initial Planning



The CDISC DHT Portal



http://cdisc.org/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Dashboard
Articles
Examples Collection
Known Issues
eCRF Portal
eTFL Portal
QRS Portal
DHT Portal
DHT Portal
CDISC and the Digital Medicine Society (DiMe) have partnered to enhance the interoperability and comparability of data collected using digital health technologies (DHTs) to accelerate innovation in digital health through aligned organizational resources, data standards, and semantics. Aligned resources between organizations are iteratively developed and released through the Digital Health Technologies Initiative.
Public Review of DHT Resources
The DHT team is please to announce the release the first set of DHT examples for a 60-day Public Review. Community members are invited to review the resources as part of their clinical trial standards implementation and provide feedback. Submitted feedback will inform continued, iterative development and release of the final portal resources. Questions for community consideration include:
Are resources in the DHT Portal useful and applicable to your implementation of CDISC standards?
How can current portal content be improved?
What new content would you like to see?
Detailed instructions on how to perform the public review can be found here.
Resources
Currently, portal content focuses on resources for the integration of data collected using sensor-based, wearable digital health technologies in clinical trials. Content consists of ready-to-use:
DHT Concepts in Clinical Research
A visualization of fundamental DHT clinical research concepts and their relationships with supporting controlled terminology. Terminology is: * Published in the DiMe Glossary * Under consideration for the CDISC Glossary
Informative Examples for Common DHT Use Cases
Informative examples demonstrating representation of collected data in tabulation datasets for common DHT use cases sourced from the DiMe Library of Digital Endpoints. Collected data are represented in conformance with the:
Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.4 (SDTMIG v3.4) for measurements collected using DHTs
Study Data Tabulation Model Implementation Guide for Medical Devices Version 1.1 (SDTMIG-MD v1.1) for device attributes that contextualize collected measurement

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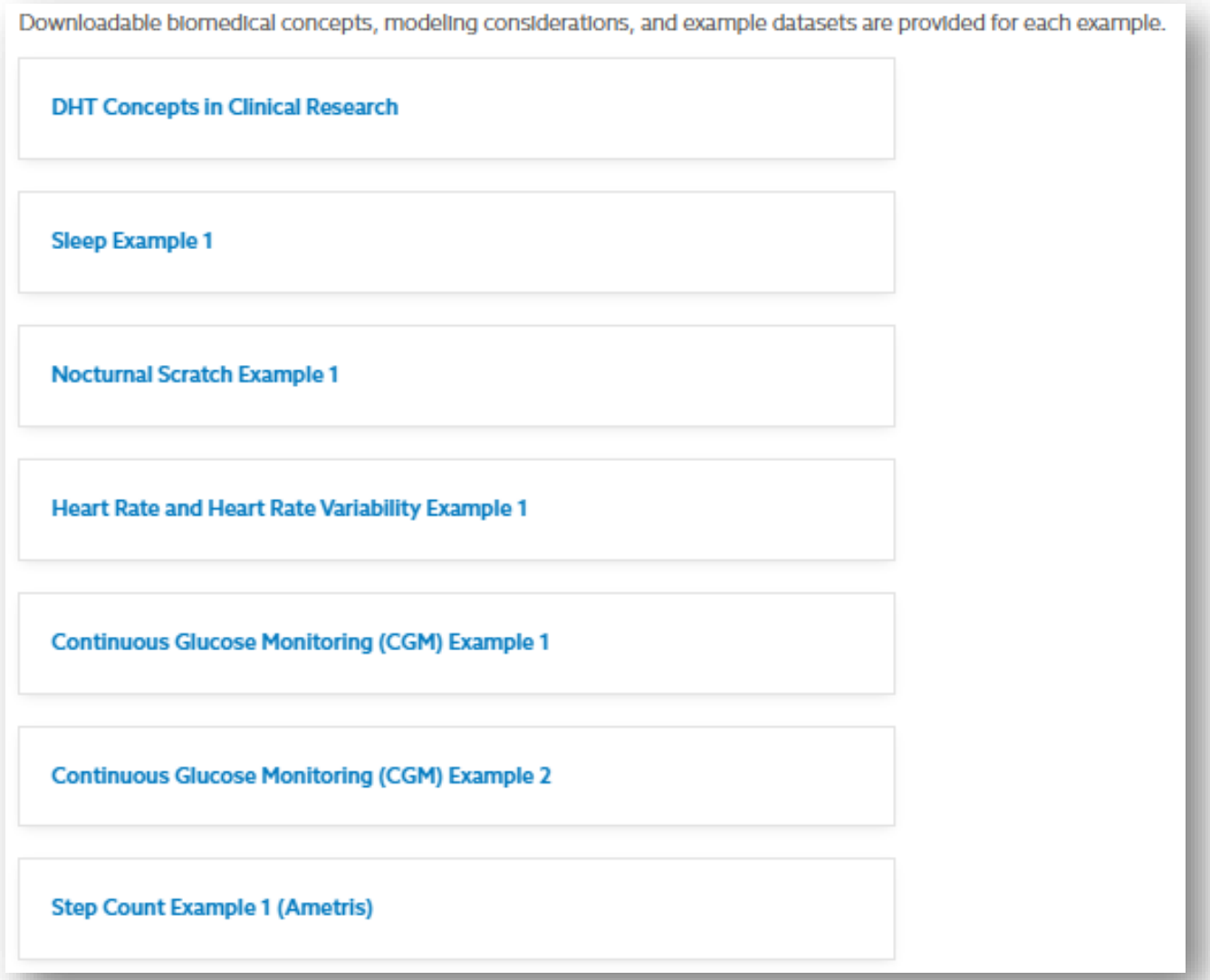
DHT Content


Downloadable biomedical concepts, modeling considerations, and example datasets are provided for each example.
DHT Concepts in Clinical Research
Sleep Example 1
Nocturnal Scratch Example 1
Heart Rate and Heart Rate Variability Example 1
Continuous Glucose Monitoring (CGM) Example 1
Continuous Glucose Monitoring (CGM) Example 2
Step Count Example 1 (Ametris)

Sleep Example 1

Overview | Considerations | SDTM Device Identifiers (DI) | SDTM Related Devices (RELDEV) | SDTM Nervous System Findings (NV) | Download

This example shows findings from an accelerometer device used to support an endpoint of total sleep time. Related endpoint in the DiMe Digital Endpoint Library include endpoints based on total sleep time:

- 87 Mean Nighttime Total Sleep Time as determined by actigraphy., Week 1
- 93 Change from Baseline in Nighttime Total Sleep Time, Weeks 2, 4, 6, and 8 or Final Visit

Relevant endpoints also include those based on closely-related measures of sleep:

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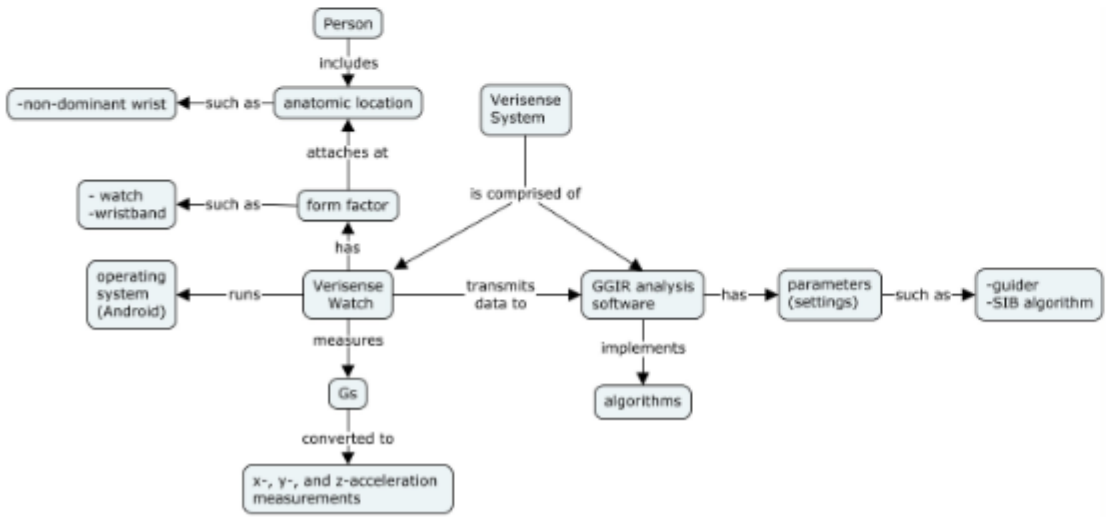
- 15 Change from Baseline in Daytime Total Sleep Time, Weeks 2, 4, 6, and 8 or Final Visit

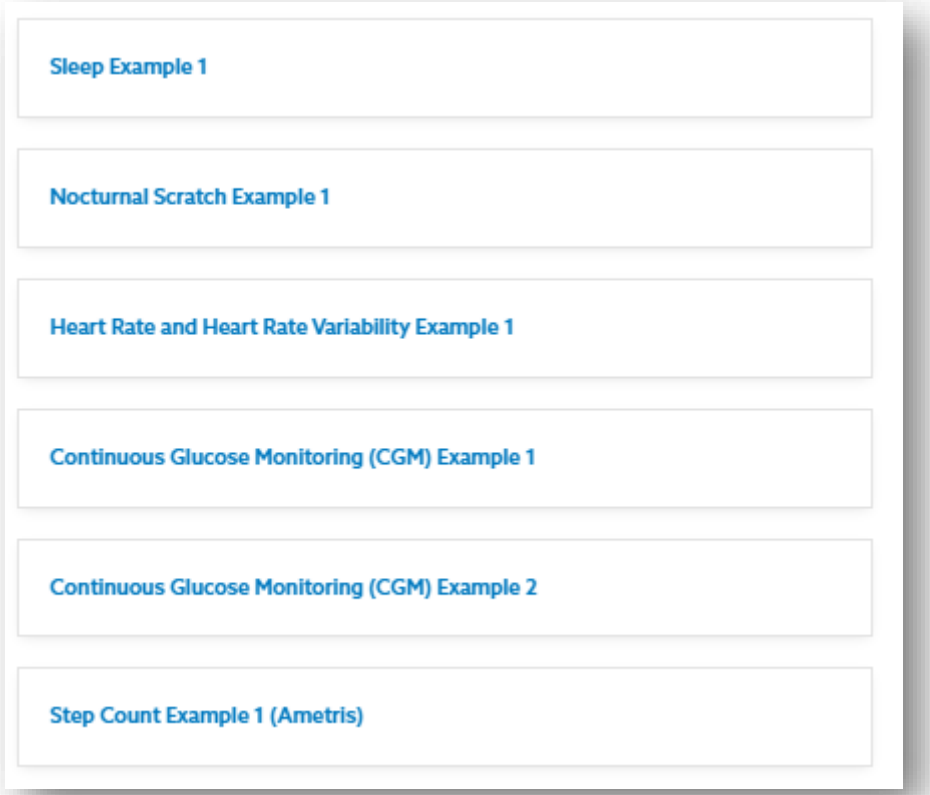
This concept map shows the modelling of the wearable device and the analysis software, which together comprise the Verisense System.



Deep Dive into the DHT Example Content

DHT Examples for Public Review

- 6 examples for Public Review
  - Continuous Glucose Monitor (CGM) Examples
    - 2 examples
  - Step Count Example
  - Sleep Example
  - Nocturnal Scratch Example
  - Heart Rate and Heart Rate Variability



Continuous Glucose Monitor (CGM) Examples

- Data examples for two CGMs
- CGM consists of a sensor and a phone app
- Data represented in the LB domain using existing test GLUCPE, Plasma Equivalent Glucose
- “Considerations” include
  - Granularity for identifying the device (SPDEVID)
  - How to use LBREFID to identify source in device data

Step Count Example

- Example data from one device
- Device consists of sensor and processing system that receives data from the sensor
- Number of steps using existing test MK Domain, STEPSTN, Number of Steps Taken along with evaluation interval “AWAKE WEAR MINUTES IN DAY” and a separate new test for “Awake Wear Minutes”.
- Considerations include
  - Handling device non-wear and other filtering of raw data.
  - Analysis Method (MKANMETH) values
- New NCI Thesaurus terms were requested for biomedical concepts for this kind of device

Sleep Example

- Device data from one device
- Multiple measures of sleep collected, some covered by existing CT, some new
- Considerations include
  - Use or adaptation of existing sleep tests created for sleep studies for sleep monitoring by a wearable device
  - Choice of NV SDTM domain based on domain for current test CT.
  - Handing of device non-wear
  - Variation in how sleep terms are defined, including by different devices.

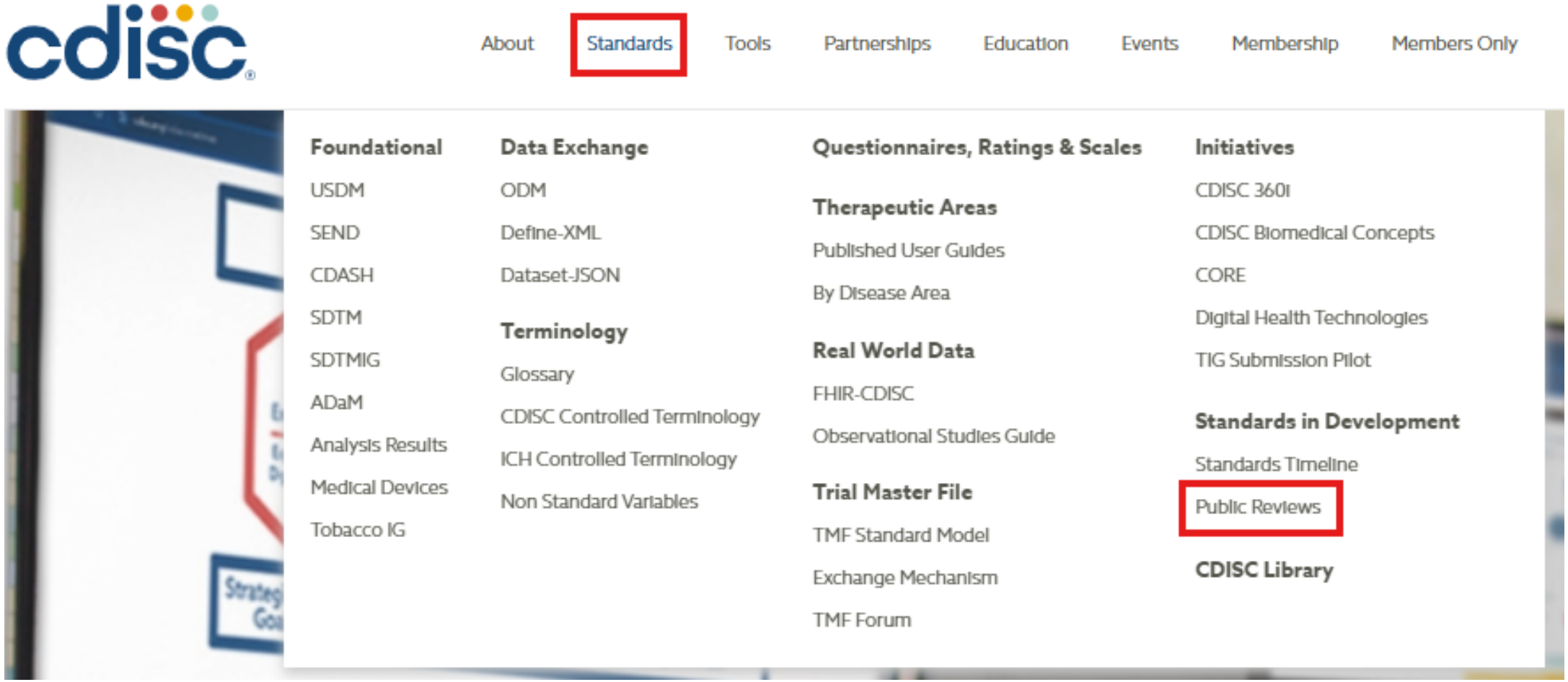
Nocturnal Scratch Example

- Example study used sensors on each wrist along with a unit to process data from the sensors.
- Device data includes both sleep data and scratch data.
- Sleep data represented in SDTM NV domain, scratch data in SDTM MK domain
- Considerations include
  - Variation in how sleep terms are defined, including by different devices.
  - Data missing because device considered an attempt to make a measurement to have failed.

Heart Rate and Heart Rate Variability

- Example from an Apple Watch
- Two different sensors in the Apple Watch are relevant for this data
- Considerations include
  - Data were represented in the SDTM CV domain, since it was not collected with ECG technology or as part of conventional vital signs collection.
  - Heart rate variability is measured in various ways, existing test HRVSDDN was was used for the 24-hour summary in this example
  - Representing the difference between 24-hour summaries of Mean Heart Rate and Mean Resting Heart Rate

Public Review Instructions



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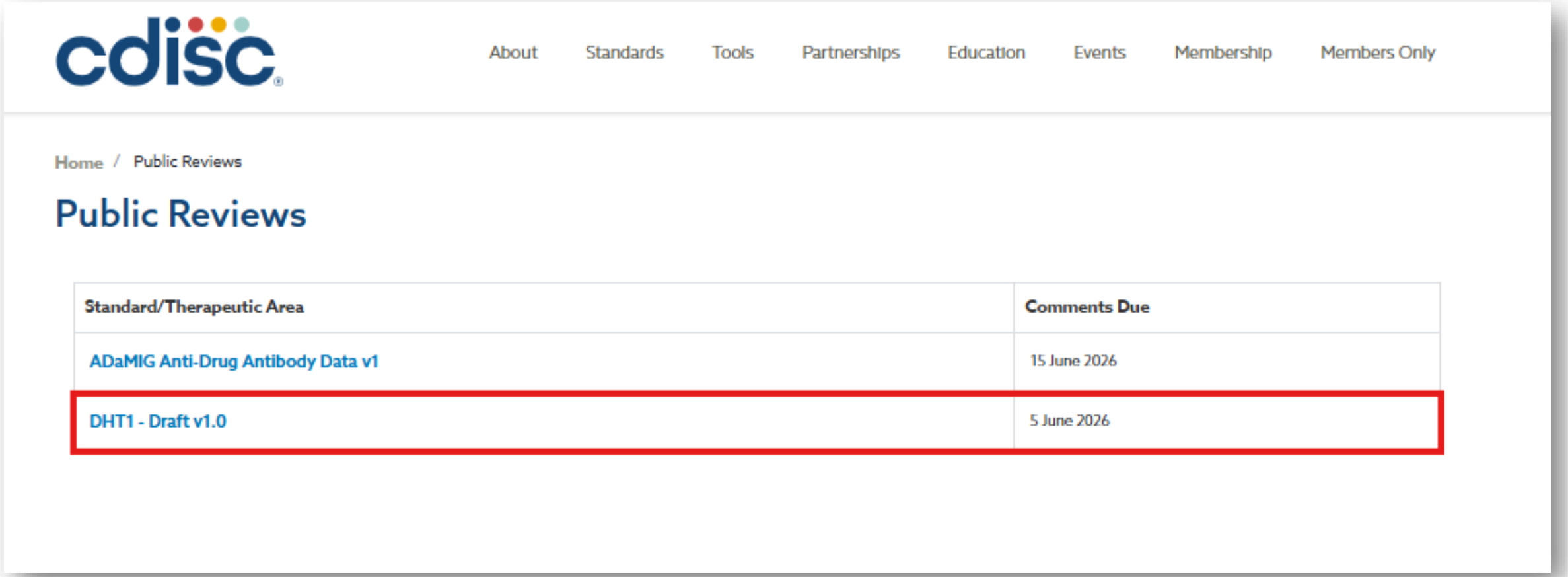
https://www.cdisc.org/



https://www.cdisc.org/public-review

DHT1 - Draft v1.0

Comments Due By
5 June 2026

CDISC is pleased to announce the initial resources for the Digital Health Technologies Portal is entering the Public Review period to solicit your feedback.

Digital Health Technologies (DHTs) are electronic methods, systems, products, or processes that generate, store, display, process, or use data in clinical research or healthcare, enabling rich real-world data collection and supporting preventive, harm-reduction, and therapeutic advancements. To enhance interoperability and accelerate innovation, CDISC and the Digital Medicine Society (DiMe) are partnering with a diverse volunteer team to standardize DHT data through shared semantics and common standards. The DHT team has developed a new portal within the CDISC Knowledgebase, featuring six initial DHT resources now available for community review. These resources represent the first step in expanding shared, standards-based guidance for digital health data.

View the portal: **https://www.cdisc.org/kb/dht**

Instructions for providing comments: **Instructions for Reviewers**

Public Review closes **05 June 2026.**

You will need to log in or register for the CDISC Wiki to provide comments.

- **Register** for the Wiki. If you already have an account on Wiki or JIRA, our issue-tracking system, simply log in to your account; Wiki and JIRA use the same login credentials. CDISC Wiki is a different login from **www.cdisc.org**. Additional instructions can be found in the Instructions for Reviewers link above.

https://www.cdisc.org/public-review/dht1-draft-v1-0

DHT Portal Public Review Instructions

Created by John Owen, last updated on Apr 15, 2026 • 7 minute read

The DHT team is please to announce the release the first set of DHT examples for a 60-day Public Review. Community members are invited to review the resources as part of their clinical trial standards implementation and provide feedback. Submitted feedback will inform continued, iterative development and release of the final portal resources. Questions for community consideration include:

- Are resources in the DHT Portal useful and applicable to your implementation of CDISC standards?
- How can current portal content be improved?
- What new content would you like to see?

Public Review Webinar

We also invite you to register for the DHT Public Review Webinar taking place on Tuesday 21st April 2026 where the DHT team will deep dive into the resources for the Public Review.

The material to be reviewed

The DHT team has created a general diagram showing Key DHT Concepts and draft proposed CDISC Glossary definitions. These can be found in the DHT portal under the *DHT Concepts in Clinical Research* tab. We invite you to review this content and provide your comments using the Jira instructions below.

In addition to the *DHT Concepts in Clinical Research,* there are here are six examples for Public Review:

- Continuous Glucose Monitoring (CGM) Example 1
- Continuous Glucose Monitoring (CGM) Example 2
- Sleep Example 1
- Step Count Example 1 (Ametris)
- Heart Rate and Heart Rate Variability Example 1
- Nocturnal Scratch Example 1

Each of these examples include:

- An overview tab of the use case, with diagrams illustrating the devices used
- Considerations used in deciding how to map source device data to SDTM datasets and CDISC biomedical concepts
- SDTM datasets representing devices and their components and SDTM datasets for findings data from the devices.
- An Excel download file which includes the considerations and SDTM datasets described above as well as spreadsheets representing Biomedical Concepts (standards agnostic concepts) and SDTM specializations (biomedical concepts implemented in SDTM).

How to provide Feedback

Reviewers are requested to provide feedback in JIRA, which uses the same credentials as the CDISC Wiki. You can create an account here Sign Up - Wiki.

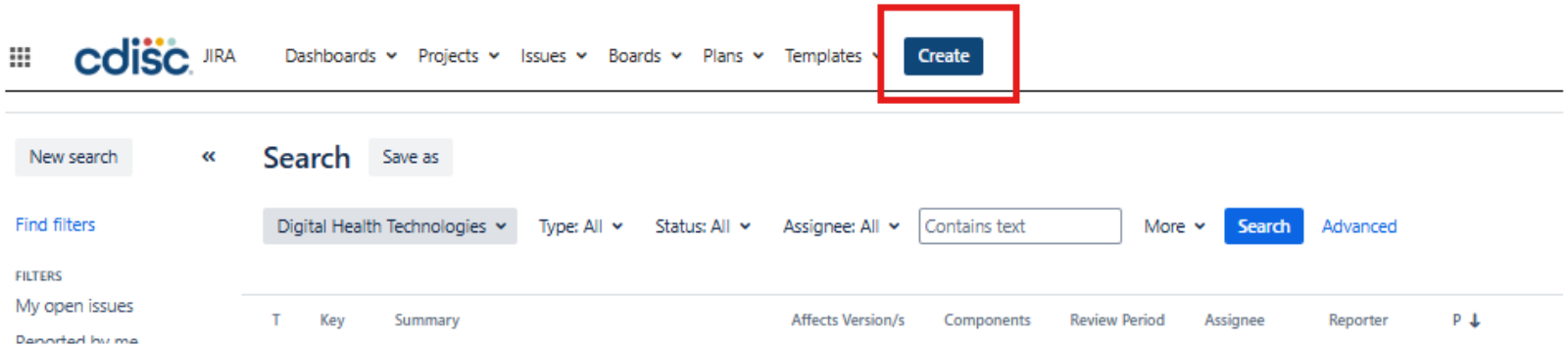
The JIRA project associated with Digital Health Technologies is DHT, located at here.

DHT Portal Public Review Instructions

Instructions on using Jira

Step 1 - Open JIRA | Step 2 - Create Ticket | Step 3 - Review Your Tickets | Step 4 - Making Comments on Issues

- Navigate to the the DHT JIRA Project
- Click the CREATE button to create a new Jira Issue



DHT Portal Public Review Instructions

Step 1 - Open JIRA | Step 2 - Create Ticket | Step 3 - Review Your Tickets | Step 4 - Making Comments on Issues

- In the create issue pop-up box
  - Ensure that the **Project** is set to "Digital Health Technologies (DHT)"
  - **Issue type** will default to "Review Comments" - Please feel free to change the category if appropriate, otherwise it is fine to leave as "Review Comments".
  - In the **Summary** Box please enter a brief description of the comment
  - In the **Components** box please enter the example to which you are commenting
  - Please leave the **Fix Versions** box empty
  - In the **Description** box please copy the following and enter the information and delete as applicable (refer to the example screen shots below)
    - **Section**: OVERVIEW, CONSIDERATIONS, SDTM *specify the domain*, DOWNLOAD
    - **Download Excel file only**: TAB Name = *specify the excel tab name*
    - **Download Excel file only**: BC-ID = XXX VLM_ID = YYY
  - After entering the information above please also provide In the **Description** box a thorough description of your comment.
    - This should be detailed enough for the CDISC DDF team to be able to clearly understand the intent of your comment in order to be able to action the comment.
    - Please also include any suggested changes with a rationale.
    - Please include any links to external material (if appropriate)
  - Please Enter "Public Review" the **Review Period** box
  - Please leave the **Label** box blank.
- Click the CREATE button
  - Note that if you want to create another JIRA issue please check the box near the create button
- Once the JIRA issue is created you will see a confirmation message with a hyperlink to the JIRA issue

Please do not enter more than one issue into a JIRA ticket (unless they are closely related and need to be resolved together). This will ensure that we can link JIRA issues to future product backlog work.

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DHT Portal Public Review Instructions

Resources useful in understanding the material to be reviewed

- **DiMe resources**
  - The DiMe Glossary:Shared definitions are an important foundation for effective communication and collaboration in the digital health field. The DiMe glossary, curated by the Digital Medicine Society (DiMe) catalogs relevant terms, aligned with FDA-NIH's BEST Glossary, that have been collaboratively vetted in an effort to maintain a common, unifying language.
  - The Library of Digital Endpointsby the Digital Health Measurement Collaborative Community (DATAcc) by the Digital Medicine Society (DiMe), is a pioneering library with a comprehensive list of digitally-collected endpoints used in industry-sponsored studies, sourced from credible clinical trial registries and crowdsourced submissions. The library is a living resource that is frequently updated, intended to be both a reference resource and a transparent library the community helps build and maintain. It benchmarks progress in the field and highlights the work we must continue to do to advance the use of digital endpoints to speed medical product development.
  - The Library of Digital Measurement Productsby the Digital Health Measurement Collaborative Community (DATAcc) by the Digital Medicine Society (DiMe), is an interactive, searchable database cataloging sensor-based digital health technologies, high-quality digital clinical measures, and measurement tools. Validated digital health tools, like those in this living library, enable superior monitoring of disease in real-world settings, generating valuable insights into disease progression and treatment responses.

- **SDTM resources**
  - The Study Data Tabulation Model (SDTM) SDTM | CDISC
  - The SDTM Implementation Guide for Human Clinical Trials (SDTMIG) SDTMIG | CDISC
  - The SDTM Implementation Guide for Medical Devices (SDTMIG-MD) Medical Devices | CDISC

- **Biomedical Concept resources**
  - On the CDISC website: CDISC Biomedical Concepts | CDISC
  - This starter package on GitHub: COSMoS/bc_starter_package/README.md at main · cdisc-org/COSMoS · GitHub
  - The BC Curation Principles and Completion Guidelines. The tab labelled "Curation and Mapping Guidelines" describes the columns in the BC and SDTM Dataset Specialization files and provides insights into how the columns should be populated.
  - Each example includes both device BCs and Finding BCs. Device BCs all have the same structure, which maps directly the SDTM DI dataset structure. The Findings BCs have been mapped to particular SDTM findings domains. After reviewing the SDTM content, you can then trace back to the associated BCs which are standards agnostic. The link between the SDTM Dataset Specializations and BCs is the 'bc_id'. This is a unique NCIt code or in rare cases, a placeholder
  - SDTM Dataset Specializations are 'value level instances' of a parent SDTM dataset. For Findings classification, the specialization is centered around the –TESTCD. The identifier for an SDTM Dataset Specialization is the vlm_group_id.
  - CDISC Biomedical Concepts provide the standards agnostic, semantic definition and are based on NCI Thesaurus. Keep in mind that there can be multiple SDTM Dataset Specializations associated with a single BC (refer to BC Principles and Guidelines).

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JIRA view

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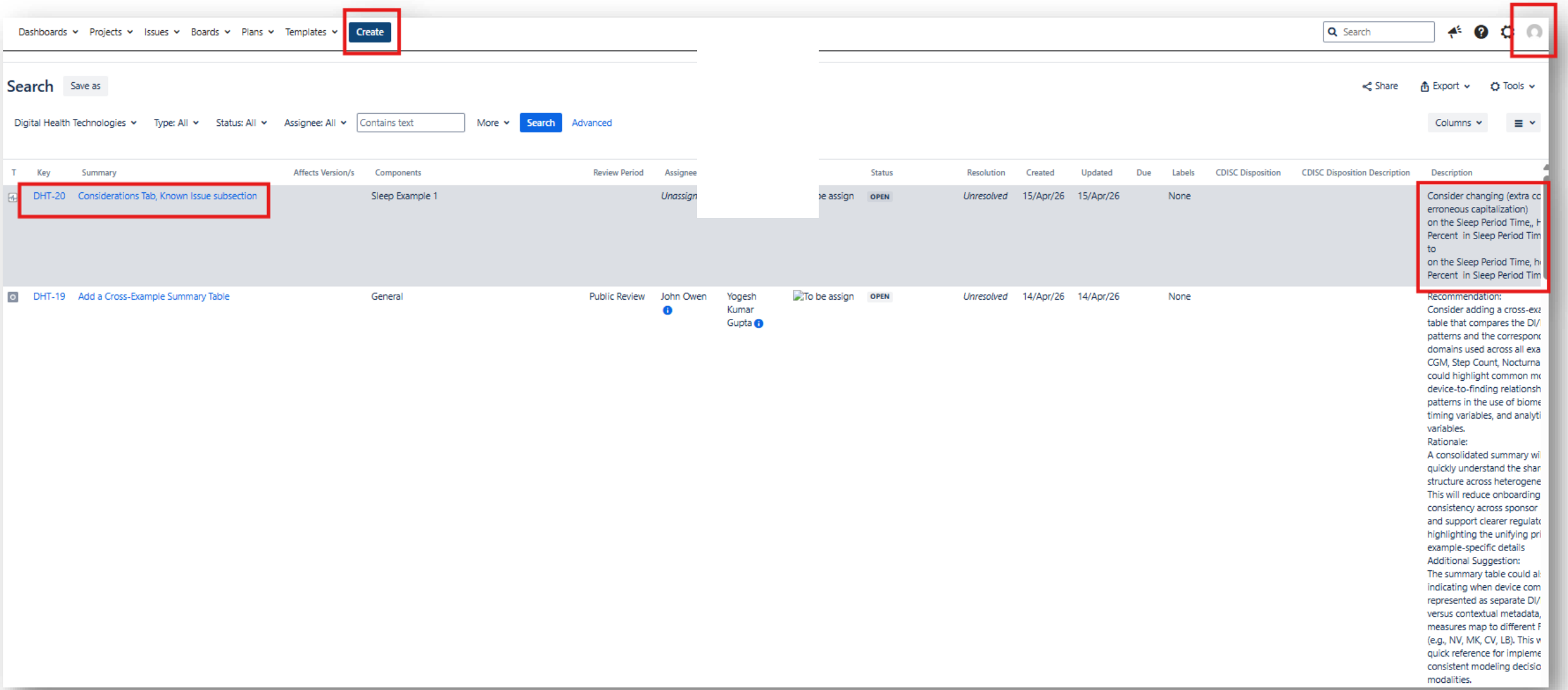

JIRA Example

In the **Description** box please copy the following and enter the information and delete as applicable (refer to the example screen shots below)

- **Section**: OVERVIEW, CONSIDERATIONS, SDTM *specify the domain*, DOWNLOAD
- **Download Excel file only**: TAB Name = *specify the excel tab name*
- **Download Excel file only**: BC-ID = XXX VLM_ID = YYY

Sleep Example 1

Overview | Considerations | SDTM Device Identifiers (DI) | SDTM Related Devices (RELDEV) | SDTM Nervous System Findings (NV) | Download

This example shows findings from an accelerometer device used to support an endpoint of total sleep time. Related endpoint in the DiMe Digital Endpoint Library include endpoints based on total sleep time:

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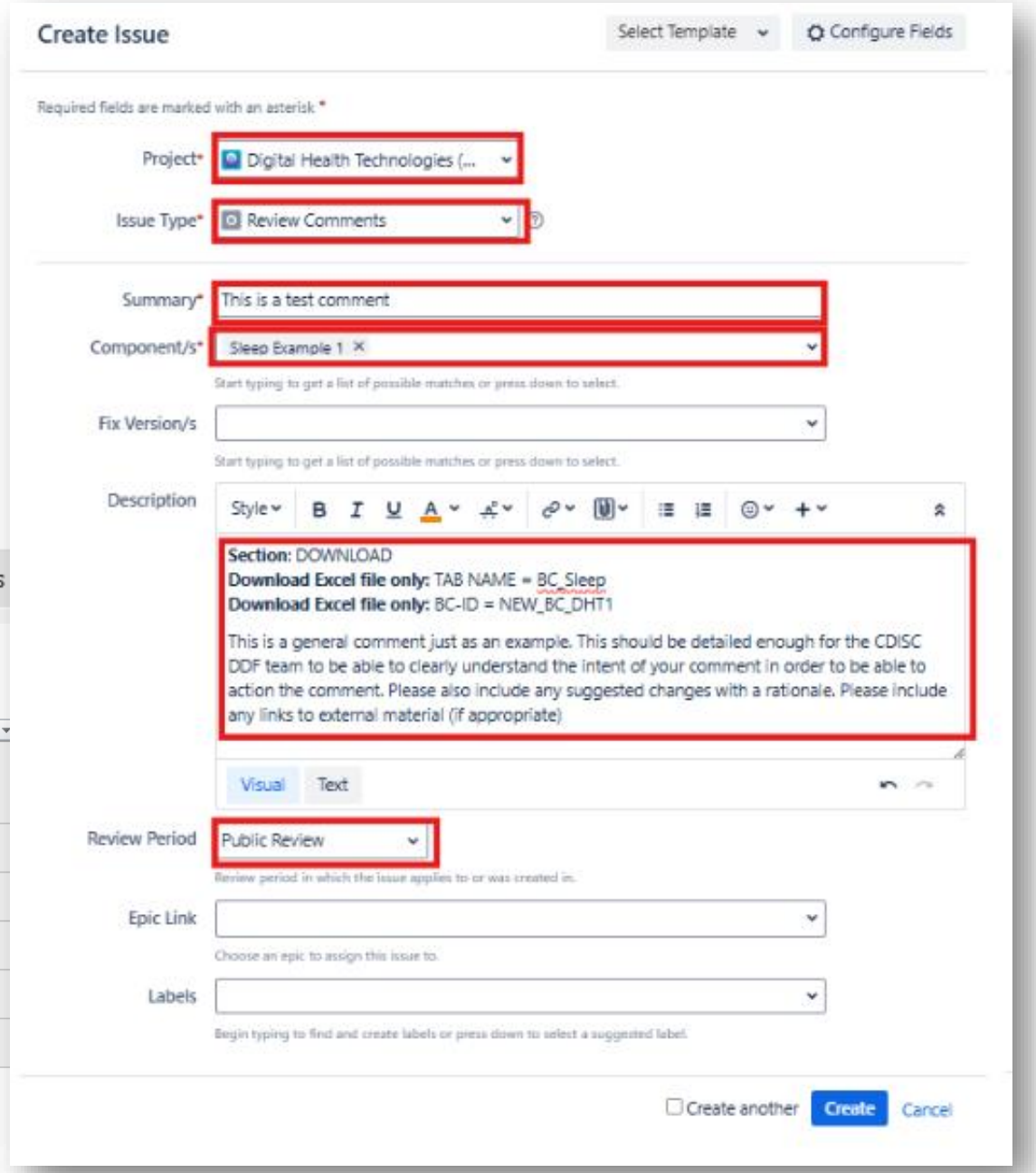
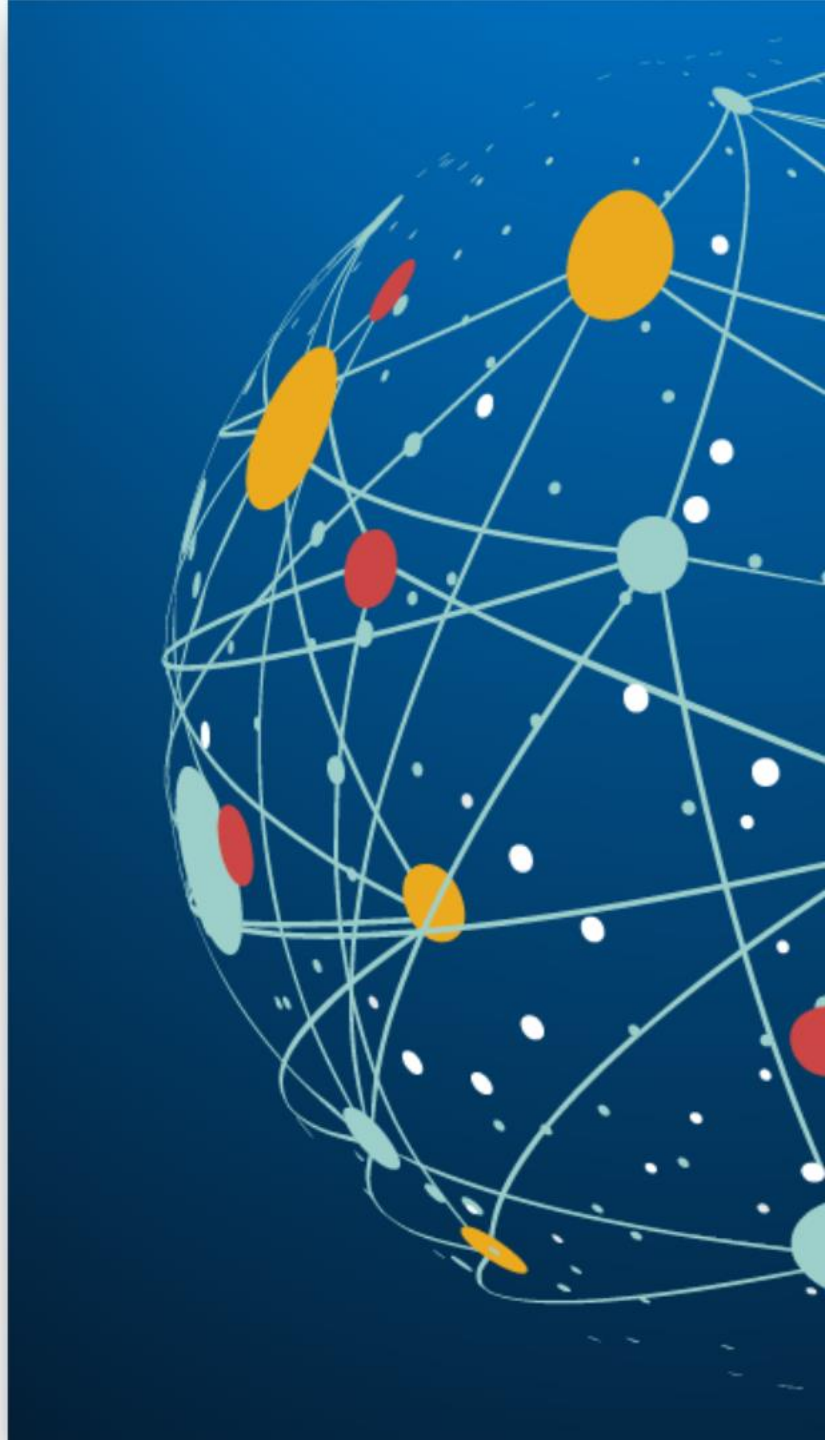
Read Me | Considerations | BC_DI | BC_Sleep | SDTM_DI | SDTM_Sleep | Device Identifiers

short_name	bc_id	ncit_code	parent_bc_id	bc_categories	synonym	result_scales
Actigraphy Sensor	C218443	C218443	C50166	Therapeutic or Research Equipment;Device;Medical Device;Monitoring	Actigraphy Sensor Device	
Instrumentation	C16742	C16742	C19238	Diagnostic, Therapeutic or Research Equipment		
Sensor Signal Processor	C218444	C218444		Manufactured Object;Diagnostic, Therapeutic or Research	Sensor Signal Processing	
Actimetry Signal Processor	C218446	C218446	C218444	Manufactured Object;Diagnostic, Therapeutic or Research	Actimetry Signal	Quantitative
Actimetry Signal Processor	C218446	C218446	C218444	Manufactured Object;Diagnostic, Therapeutic or Research	Actimetry Signal	
Actimetry Signal Processor	C218446	C218446	C218444	Manufactured Object;Diagnostic, Therapeutic or Research	Actimetry Signal	



Reminder deadline for comments

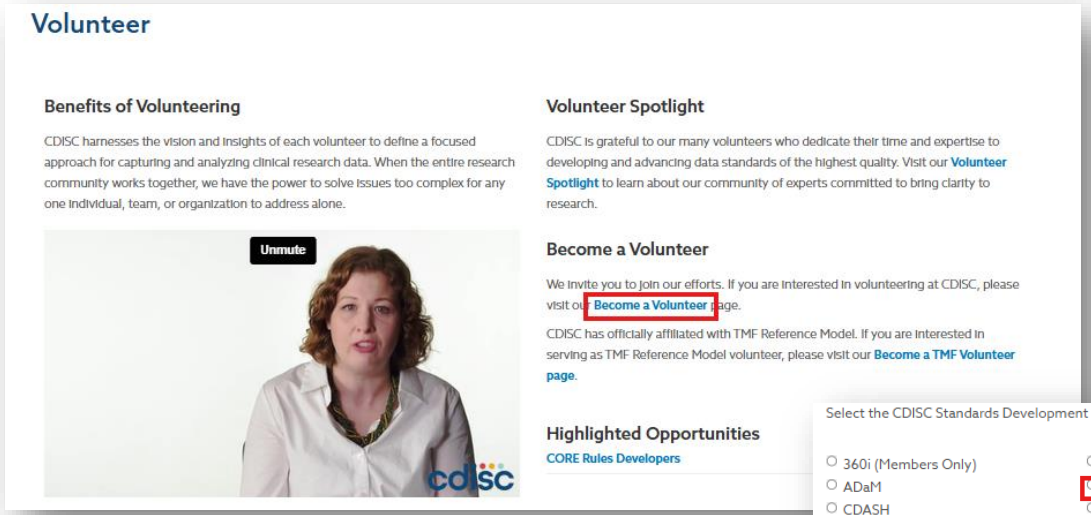
5th June 2026

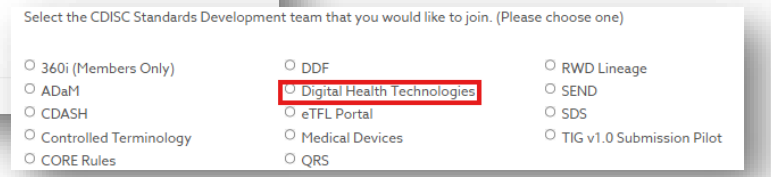


DHT Team

Want to join the CDISC DHT Team

- Provide examples to be developed for the next DHT Portal release
- Input into modelling of examples
- Network with other DHT experts





https://www.cdisc.org/volunteer

Q&A

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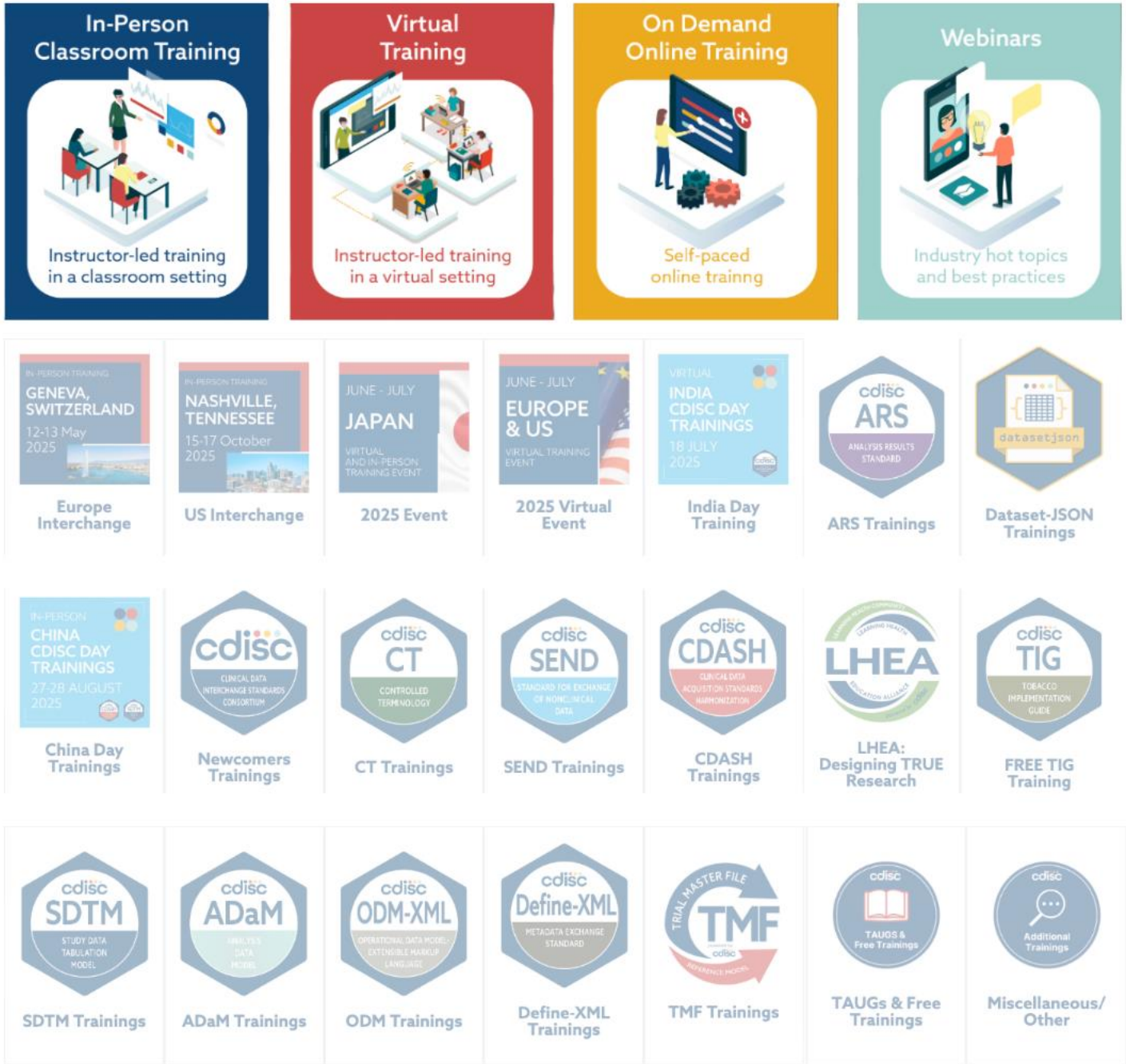

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Clear Data. Clear Impact.

Standards Transform Clinical Research
Membership Join Our Global Community
Education Learn CDISC From CDISC

Thank you!