



CDISC Standards Update What's New, and What's Next

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Accomplishments Since the May 2018

Foundational Standards

SDTM v1.7

SDTMIG v3.3

SDTMIG-Medical Devices v1.1

ADaM Conformance Rules v2.0

Coming Soon!

ADaMIG v1.2

Define.XML v2.1

Therapeutic Area User Guides

HIV

PTSD

Colorectal Cancer

Huntington's Disease

CDAD

Lung Cancer

Coming Soon!

Traditional Chinese Medicine
Coronary Artery Disease

New Onboarding Process for Volunteers

- Single internal point of contact for onboarding, administrative and record updates, to ensure accurate follow-up of volunteers
- Leveraging of IT tools to facilitate communication and teamwork
- Improved processes and procedures to support volunteer activities

<https://www.cdisc.org/volunteer>



CDISC Staff Support for Foundational Teams



- Project Management Support
 - Scope planning
 - Jira project management
 - Wiki support
 - Navigating the CDISC governance process
- Allows teams to focus on standards development

LOINC – CDISC Mapping



CDISC CT TEAM
HAS COMPLETED
THE LOINC-CDISC
LB MAPPING



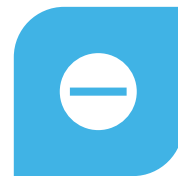
CONTAINS OVER
2,000 LB
MAPPINGS



REVIEW BY THE
REGENSTRIEF
INSTITUTE
COMPLETE



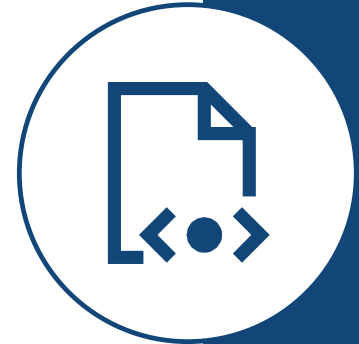
SENT TO THE FDA
LOINC WORKING
GROUP FOR
INTERNAL REVIEW



MAPPING WILL BE
RELEASED FOR
PUBLIC COMMENT

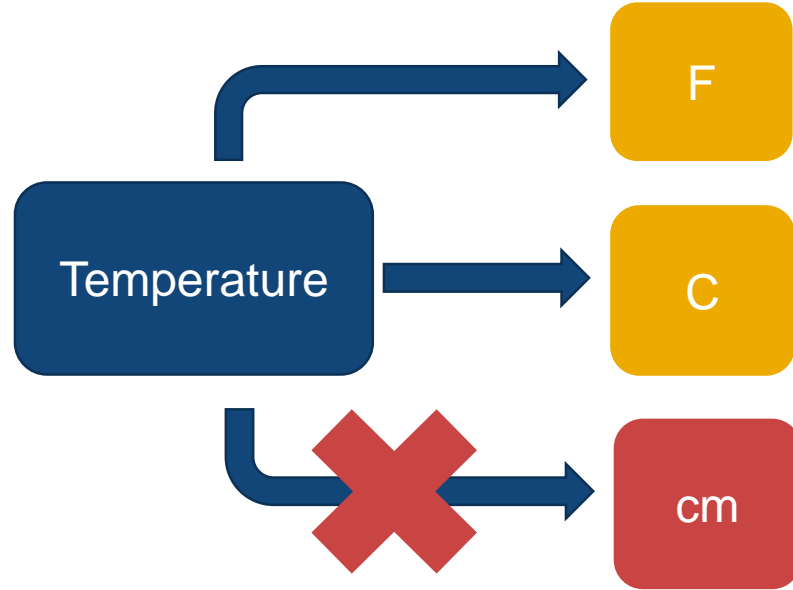
UCUM Codelist Table

- A codelist table that allows users to toggle between UCUM and CDISC Unit codelists
- For each published CDISC submission value across all UNIT-based codelists in SDTM terminology, the mapping provides valid UCUM expressions associated with that unit concept
- Allows for a collected UCUM-compliant unit of measure to be easily matched to the appropriate CDISC submission value associated with that concept

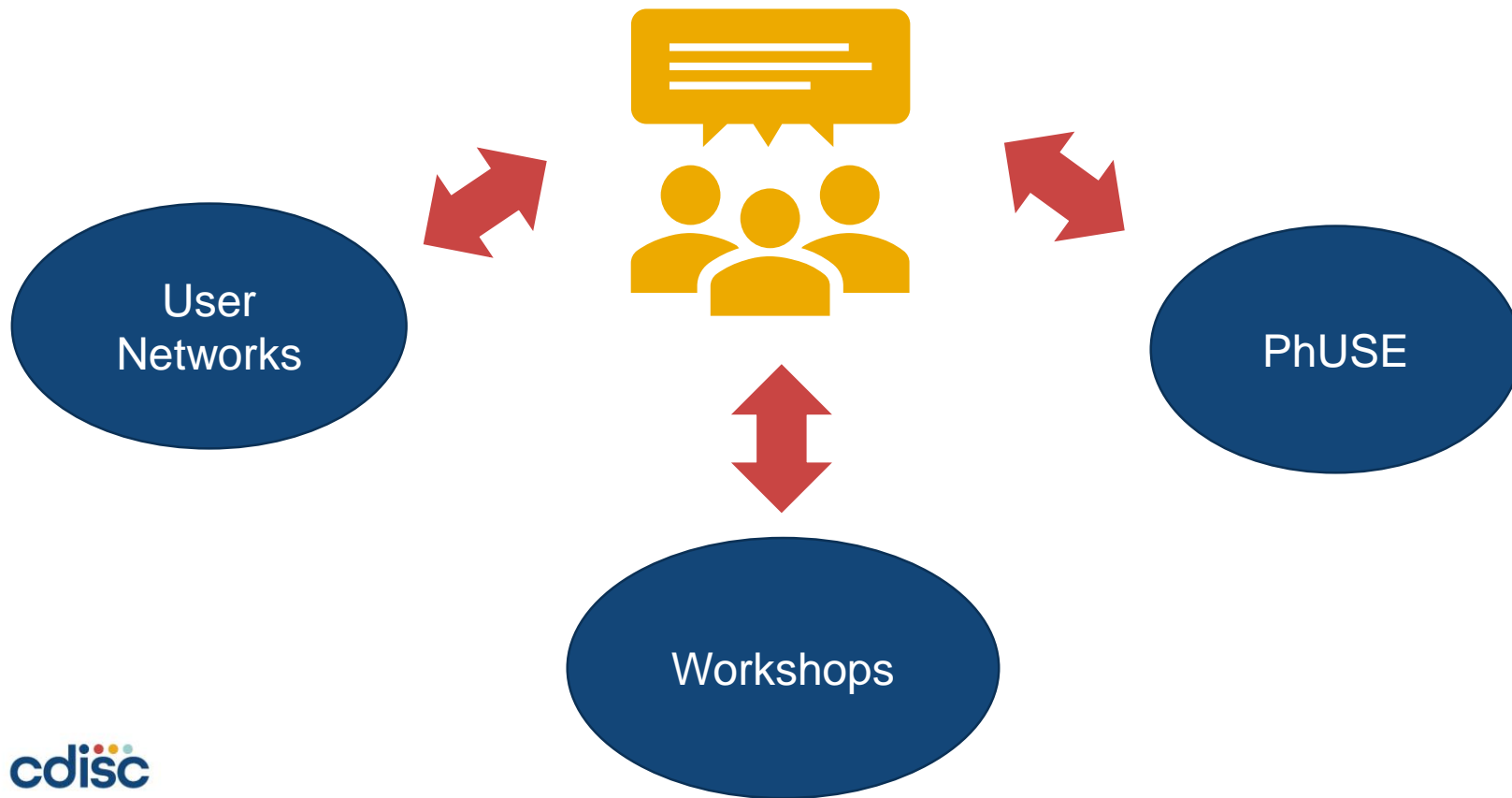


Codetable Mapping Files

- Built to show explicit relationships between terms in different codelists
- DS, CV, EG, TU/TR/RS (Oncology) Race/Ethnicity, SC, TS, VS

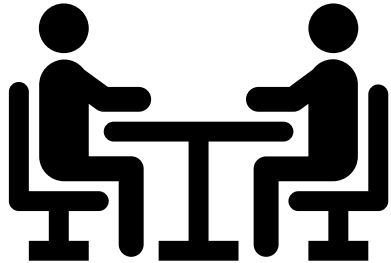


Increased Interaction With Our User Community





PhUSE/CDISC Collaboration to Create an Implementation Primer



How to get started with
CDISC

Linking of standards

Traceability

Compliance

What Are We Working on Now?



Standards in Development

Foundational Standards

CDASHIG v2.1

SENDIG – Animal Rule

SENDIG v3.1.1(PC/PP)

Conformance Rules

SDTM v2.0

ADaM OCCDS v1.1

ADaM Data Structures for Integration

Therapeutic Area User Guides

Type 1 Diabetes

Crohn's Disease

Acute Kidney Injury

Psoriasis

Heart Failure

TCM Acupuncture

<https://www.cdisc.org/standards/in-development>



Publication of Errors and Known Issues

Errors

- Small errors such as typos that do not affect conformance
- Errors that affect conformance

Known Issues

- Inconsistencies within a CDISC standard
- Inconsistencies between standards
- Inconsistencies between a CDISC standard and regulatory agency advice
- Gaps in standards

Publication of Errors and Known Issues

Provide possible solutions

Vetted and approved by the CDISC Global Governance Group

Will be made available in real-time to the user community

Occurrence of one of a group of Events or Interventions

Affected Standard	SDTMIG v3.3 and earlier
Data to be represented	A finding of the form "Did an <event or intervention in this group> occur?"
Reason for uncertainty	<p>Occurrence questions at the level of a domain (e.g., "Did the subject take any concomitant medications?" or "Did the subject have any adverse events?") can be represented in CDASH, but are not included in SDTM datasets.</p> <p>Occurrence questions at the level of a specific event or intervention are represented in an events or interventions domain in a record with the specific event or intervention in the topic variable --PRESP = "Y" and the response to the question ("Y" or "N") in --OCCUR.</p> <p>No guidance is given about questions at an intermediate level, although such questions are common. For example, "Has the subject taken any opiate-containing medications?" or "Has the subject had any respiratory infections?"</p>
Possible solution for affected version(s)	<p>The Therapeutic Area User Guide for Asthma represented questions about groups of medications in a CM record with both CMTRT and CMSCAT equal to the name of the group (e.g., "SHORT-ACTING BETA-AGONISTS" or "SYSTEMIC CORTICOSTEROIDS") and CMPRESP = "Y". The fact that the value in CMTRT is equal to the value in CMSCAT indicates that the question is about a group of concomitant medications.</p> <p>This convention, of populating both the topic variable and either --CAT or --SCAT with the name of the group, can be used as a solution with current versions of the SDTMIG. Whether --CAT or --SCAT is used depends on whether --CAT is available or is being used for another purpose. The use of this convention should be explained in the Clinical Study Data Reviewers Guide (cSDRG).</p>
Efforts to resolve issue	<p>This convention is being considered for inclusion in a future version of the SDTMIG. It has been logged as a JIRA issue: https://jira.cdisc.org/browse/SDS-26</p>

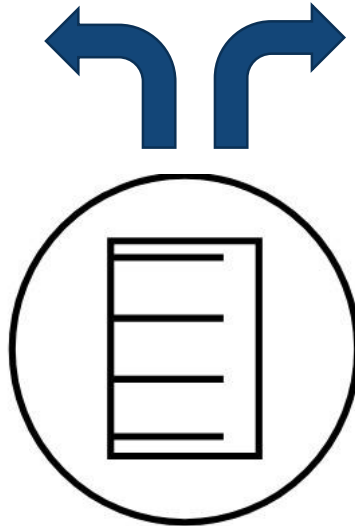
Curated Non-Standard Variable Registry

Enables consistency
in the absence
of a standard variable

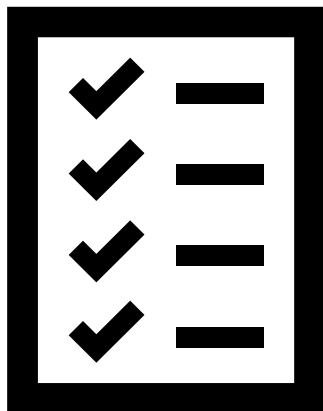
Will contain all non-
standard variables used in
CDISC Implementation
and User Guides

Vetted by the CDISC
Global Governance
Group

Will be made available in
real-time to the
user community



Consideration Documents for Regulatory Requirements



Race and ethnicity

QRS logically
skipped items

Representation of SI and
conventional units

Update of Metadata Submission Guidelines Package

Current package enables users to become familiar with the SDTM submission components

Contains annotated CRF, submission datasets, define.xml file, define.xml stylesheet, and Reviewers' Guide

Cross team collaboration

Goal is to publish update as soon as possible



SDTM Reorganization

Update outdated language

Move domain-specific variables

Make metadata consistent and separated

- Definitions will be added, and definition-like material will be removed from description column

Will be published in November 2020 as SDTM v2.0

Conformance Rules

- CDISC authors rules that determine conformance with the standard by version of standard
- Regulatory agencies have their own rules specific to their needs, these may or may not be the same as CDISC authored conformance rules
- Historical development of rules
 - Standards were written before the rules which led to ambiguity
 - The guides were specific to a team and standard



Future of Conformance Rules



RULES ARE NOW REQUIRED
AT THE TIME OF PUBLICATION
OF ANY STANDARD



WORKING ON ESTABLISHING
CROSS-TEAM RULES
DEVELOPMENT METHODS



SUPPORTED BY CDISC
LIBRARY



CDISC Knowledge Base Project

cdisc

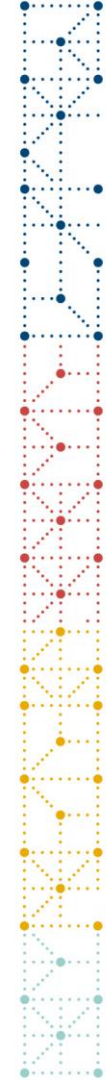


CDISC Knowledge Base – What is it?

An open, assessible and user-friendly interface on the CDISC Website to host useful information for CDISC implementers:

- Searchable, central access to new and existing website content
 - E.g., CDISC webinar archive, regulatory documents, PhUSE deliverables
- Coordinated with redeveloped standards website pages
 - FAQs, errors, known issues, education for each CDISC standard
- New technical articles written by CDISC staff and teams
- Community-generated content, curated by CDISC
- Community questions, with curated CDISC team answers

CDISC Knowledge Base



cdisc New to CDISC Standards Education Resources Events Membership

Home / Knowledge Base / Knowledge Base Articles

Knowledge Base Articles

Search Filter by Standard Proficiency Audience

Concept maps for adverse events with increasing levels of detail

15 May 2019 **cdisc**

A query about adverse events is, at heart, an observation. Data on the adverse event may also include location and pattern. This concept map includes those details, as well as terminology that would...

[Read more](#)

Standard(s)	Proficiency
SDTM	Intermediate

Translating CDASH "PRIOR" and "ONGO" to SDTM relative timing variables

15 May 2019 **cdisc**

If data is collected in a log form, and if you know the range of dates or visits for collection of log data then The date or visit at which the log is initiated can be used to populate STTPT...

[Read more](#)

Standard(s)	Proficiency
CDASH, SDTM	Intermediate

When Did That Happen? A Brief Guide to Representing Timing in SDTM

13 May 2019 **cdisc**

In ordinary conversation, depending on what "that" is, the question, "When did that happen?" could be answered in many ways. The fact that there are so many ways to say when something happened helps...

[Read more](#)

Standard(s)	Proficiency
SDTM	Novice

Pre-specified Events and Pre-specified Findings

13 May 2019 **cdisc**

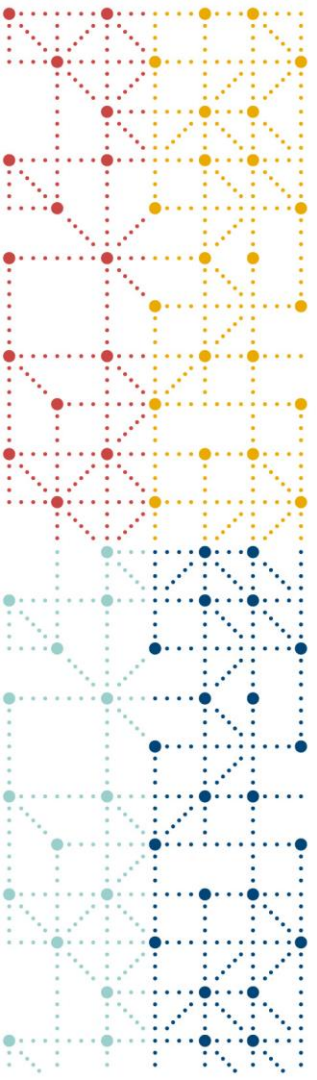
Pre-specified Events Collection of adverse event, clinical events, and medical history events can follow two approaches: Were there any events? If yes, what were the events?...

[Read more](#)

Standard(s)	Proficiency
CDASH, SDTM	Expert

Knowledge Base – Content Build Plan

Initial Release – US Interchange	Mid Term	Long term
Technical Articles (n=9)	Local Translations	Community generated content
Link to existing Team generated FAQs (CT & QRS today).	Community Questions - to be answered by Teams – under development	Continuous load of content as available and approved.
Link to Errors	CDISC teams FAQs – under development	
Link to Non-Standard Variables in CDISC Library	Link to CDISC Primer - under development	
Link to known issues		
Webinar Archive tagged & Linked		
Link to PhUSE Deliverables and WGs		
Link to most used Regulatory Guidance		



Thank you!

cdisc