SDTM Office Hours

Dana Booth, Sr. Project Manager, Foundational Standards, QRS Co-lead, CDISC
Christine Connolly, Senior Project Manager, Standards Development, CDISC
Kristin Kelly, Principal Consultant, Consultative Services, Pinnacle 21
Lou Ann Kramer, Sr. Director of Standards Development, CDISC
Soumya Rajesh, Standards Engineer, IQVIA
Gary Walker, Education and Standards Development Expert, CDISC
Diane Wold, Sr. Director of Standards Development, CDISC

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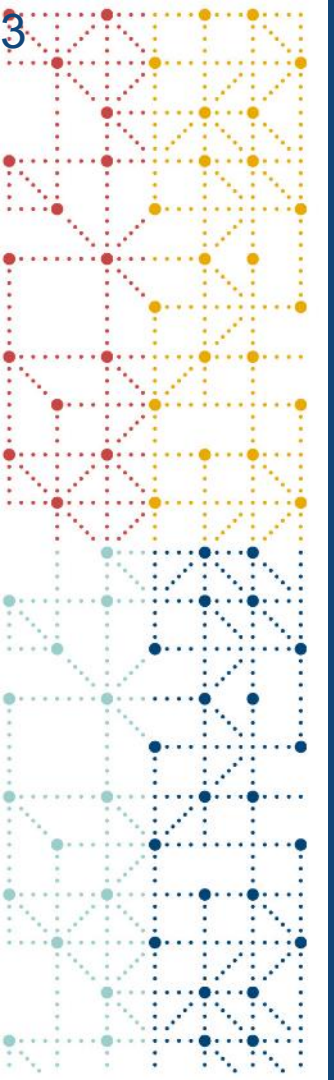
TUE 29 MAR 2022
11:00AM-12:30PM ET

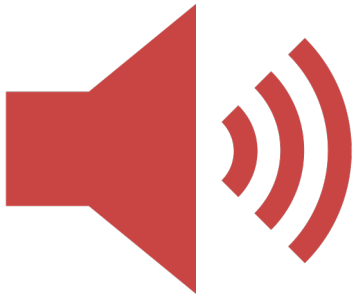
Today's Agenda

1. Housekeeping
2. Speaker Introductions
3. Feature Presentation
4. Upcoming Learning Opportunities & Events



Housekeeping

Housekeeping

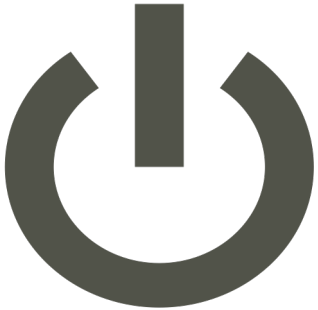


You will remain on **mute**

Housekeeping

Submit questions at any time via the Questions tool on your GTW app

Housekeeping



Audio Issues?

First, close and restart your GoToWebinar App
Second, check your local internet connection strength using the Audio tool

Housekeeping

A recording of this webinar and the slides will be available in the **Members Only** section of CDISC website

Today's Presenters

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Sr. Project Manager, Foundational Standards
QRS Co-lead
CDISC

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Senior Project Manager,
Standards Development
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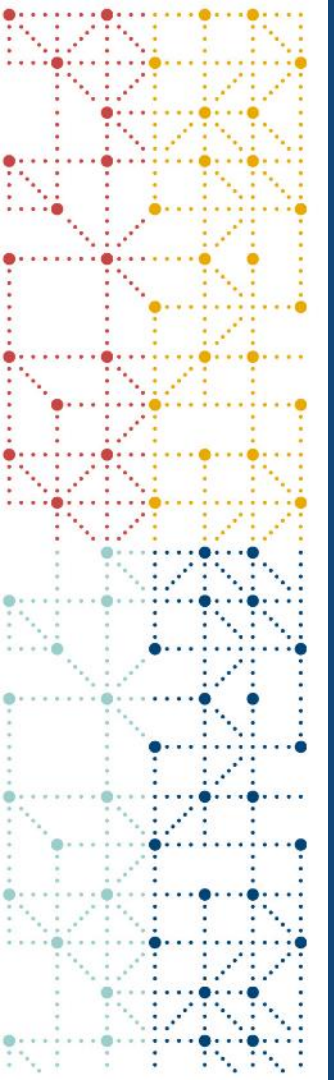
SDTM Office Hours

03.29.2022

Some Documents Based on SDTM

- SDTMIG v3.4, and SDTM & SDTMIG Conformance Rules v2.0 (based on SDTM v2.0) – all published Nov 29, 2021
- SEND documents:
  - SENDIG-Animal Rule v1.0 (based on SDTM v1.8)
  - SENDIG-DART v1.1 (based on SDTM v1.6)
  - SENDIG v3.1.1 (based on SDTM v1.5)
  - SENDIG v3.1 (based on SDTM v1.2)

- An overview of the most recent documents follows.



SDTM v2.0

Changes from SDTM v1.8 to SDTM v2.0

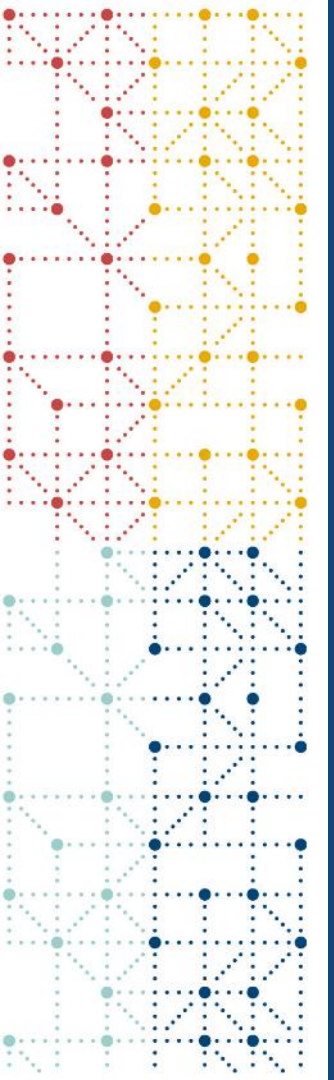
- Sections were reordered and regrouped, which resulted in the renumbering of sections and the elimination of some unnecessary section layers
- Removed and revised outdated text, recognizing that data may be used for regulatory or non-regulatory purposes such as publication, meta-analyses, or warehousing
- Table numbers were removed, as they are redundant with section numbers. All tables now have the same columns, adding Definition and C-code
- New variables to support the Cell Phenotype (CP) domain
- New variables to support the Genomics Findings (GF) domain
- New variables:
  - Interventions – 3
  - Events – 9
  - Findings – 33
  - Timing – 2
  - Subject Elements - 2
- The relationships domain Related Specimens (RELSPEC) was added
- Revisions to SV to meet FDA needs expressed in the sdTCG

Some Proposed Changes for Next SDTM

- More definitions from the SDTM Variable Definitions Team will be incorporated
- --BLFL and TIRL proposed for deprecation
- --MODIFY proposed for deprecation in the Findings class of domains
- --BODSYS is being considered for further restrictions
- --TSTDTL may be made domain-specific, for use only in Microbiology Specimen (MB), Microscopic Findings (MI), and Genomics Findings (GF) domains.
- New clinical and non-clinical variables

A New SDTM Team

- SDTM v2.0 was created largely by Diane Wold, with input from individuals on SDS and SEND, adding new variables and datasets and updating the metadata structure
- We now have an SDTM Team
  - Cross-team of all foundational teams (e.g., SDS, SEND, CDASH, ADaM, MD, etc.)
  - Review proposed new variables prior to GGG variable approval process
  - The SDTM team will develop future SDTM documents



SDTMIG v3.4

Significant Changes

- Specimen-based domains were grouped in Sections 6.3.5.1-6.3.5.7
- Morphology Domain (MO) was decommissioned
- GF (Genomics Findings) and CP (Cell Phenotyping Findings) domains are new
- BE, BS, and RELSPEC were copied into the SDTMIG from SDTMIG-PGx
- SDTMIG-PGx was retired

Significant Changes

- Added many new variables
- Promoted Clinically Significant (--CLSIG) to a standards variable
- Added, removed, or updated various examples throughout
- Updated links
- Updated references to sections that moved and example numbers that changed
- Domain-specific versioning was removed

Other Changes

- Structure of Comments domain in SDTM and SDTMIG explained
- DM Race examples revised to make more consistent with CDASH
- REASOC promoted to a standard variable; Exposure examples updated to reflect this
- Changed roles of DOSFRQ and DOSRGM to record qualifier throughout for consistency with SDTM
- AE variables for Medical Devices were added
- Made some form of update to almost every domain

Planned Changes for SDTMIG v4.0

- Updating metadata tables to reflect structure of SDTM v2.0
- Adding decision trees to help determine which domains to use
- Removing some examples to shrink the size of the IG; these examples will be included on the CDISC website in Examples Collections
- Tightening up conformance (replacing “should” and “could” with more precise language

Planned Changes for SDTMIG v4.0

- Adding domains:
  - QX QRS Reference Domain
  - GI Gastrointestinal Domain

- Revising domains:
  - BE, BS, RELSPEC
  - DV
  - MI

- Changing the representation of non-standard variables from the vertical supplemental qualifier form of representation to a horizontal dataset

SDTM and SDTMIG Conformance Rules v2.0

History and Future Plans

- Initial set of conformance rules were created in 2020 for the SDTMIG v3.2 and v3.3
- SDTM and SDTMIG Conformance Rules v2.0 is a cumulative catalog for SDTMIG v3.2 – v3.4.
- There is a project in development (CORE) to make the rules available electronically.

Thank You!

Dana Booth
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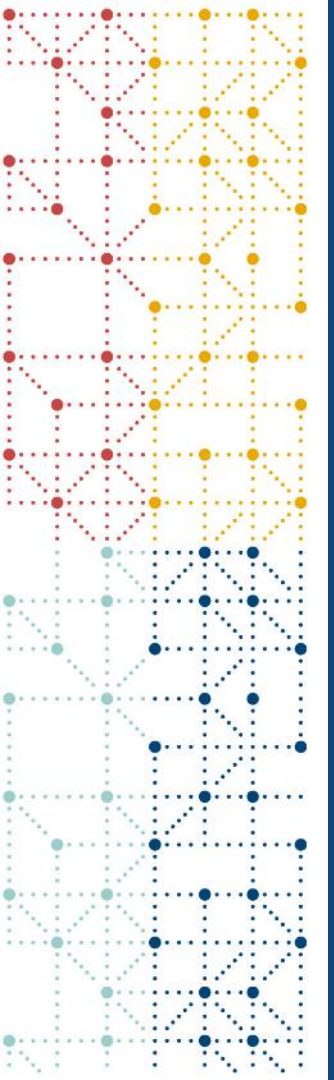

Questions & Answers

Audience Questions

When CDISC or others mention "SDTM" is there a way I can know if they are talking about the base model or SDTMIG?

Audience Questions

How do you capture reactogenicity records in CE & AE for Vaccine studies?

Audience Questions

Should time be included in SV.SVSTDTC/SVENDTC?

Audience Questions

Are pre-specified NSV related to Covid19 kept in main or SUPP domain?

Audience Questions

In SDTM AE domain, in what scenarios do we need to use AETOXGR versus AESEV variable?

Audience Questions

What are some guidelines to map questionnaires to QS vs RS domains?

Audience Questions

What advice do you have for implementing new versions of SDTM (e.g. 3.2 to 3.3 impact assessment, metadata update, remapping, etc.)?

Audience Questions

How do you map Disease Characteristics (Lab related information, Cancer History etc.) collected during Screening for Cancer Studies?

Audience Questions

Request elaboration of requirements of assumption 11 for SV domain (specifically statement starting with "However, if the data")

Audience Questions

How do we bring null ARM/ARMCD values into ADSL?

How do we document any P21 issues?

There is a gap between SDTM IG 3.3 and ADaM?

Audience Questions

Why do some terms in the 'Anatomical Location' codelist contain LEFT/RIGHT? Shouldn't these be mapped to --LAT?

Audience Questions

How are we supposed to populate EX and DM.ARM/ACTARM variables during double-blinded, placebo-controlled studies?

Audience Questions

For questionnaire data, if raw data doesn't have decode values, is it ok to decode ourselves in QSORRES? Eg., Mc_QOL data.

Audience Questions

We are beginning to use actigraphy data from a wearable device. Is there any guidance on what domain it would go to?

Audience Questions

What is the plan to update domains to meet sdTCG requirements?

1. Include SUBJID in all domains
2. Update SV to occurrence

Audience Questions

Can a decision tree be provided to help guide which domains lab data should go (i.e. LB, MI, MB, BS, CP, IS, MS)?

Audience Questions

If using a domain which is part of a newer SDTMIG version or a TAUG or other IG which is not included in the version you are submitting (it would be considered a custom domain under the version you're working in), is it recommended to change the domain code to use the XYZ naming convention or use the future-version domain code and just document it accordingly in SDSP/cSDRG?

Audience Questions

When multiple values are selected for a non-result variable and 'MULTIPLE' is mapped to the variable, how should the numbering work in the QNAMs in the SUPP domain?

Option 1: QNAM# mapped in sequential order according to how many values are selected: QNAM1, QNAM2, etc.

Option 2: QNAM# mapped according to a pre-determined number according to the CRF text placement: QNAM2, QNAM5

For example, 'Face' and 'Leg' are selected out of the following list: Neck; Face; Arm; Leg. Should the QNAMs be --LOC1 and --LOC2 or --LOC2 and --LOC4?

(Note, the RACE example in the SDTMIG uses option 1, but other examples use option 2)

Audience Questions

Please provide some guidance on how to map REPEAT visits to SV domain, should they be considered as UNSCHEDULED visits?

Audience Questions

What LBTESTCD to use when I have 'Not Done' for a lab? I used to use LBALL, but Pinnacle complains that LBALL is not found in LBTESTCD extensible codelist

Audience Questions

Can I still use MUTIPLE as RACE? If not, how can I map 'more than one race' to DM?

Audience Questions

How to populate TULOBXFL and TRLOBXFL when there are multiple lesions at screening visit? If I code Y to all lesions, Pinnacle complains multiple records for the same test

Audience Questions

Can only be decoded for QRS with a user guide?

Audience Questions

How do I code 'SCREEN FAILURE' from DM to ADSL? 'SCREEN FAILURE' is no longer populated in ARM, but in ARMNRS. If I leave ARM as null for the screen failures, Pinnacle complains ARM value is null in ADSL

Audience Questions

Is there ever a chance that "subject" will be changed to "participant" in order to have a more respectful term for people who are a part of studies?

Audience Questions

What should the value of QORIG be for supplemental coding variables? They are not collected on the CRF, and if it is 'Assigned' then we need to provide an 'evaluator', but there doesn't seem to be a proper 'evaluator' in the controlled terminology list

Audience Questions

How should country-specific inclusion/exclusion criteria be documented in the IE and TI domains? With IETESTCD having a limit of 8 characters, it is hard to document all global and country-specific criteria changes.

Audience Questions

Why can't the Race controlled terminology list be updated to include 'MULTIPLE'?

Audience Questions

How would you map drug screening when it is collected if all were negative and if not check which test are positive in LB

Upcoming Learning Opportunities

April - May

2022

Europe Interchange Trainings

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Virtual Training Event

Regional discounts will appear at checkout.

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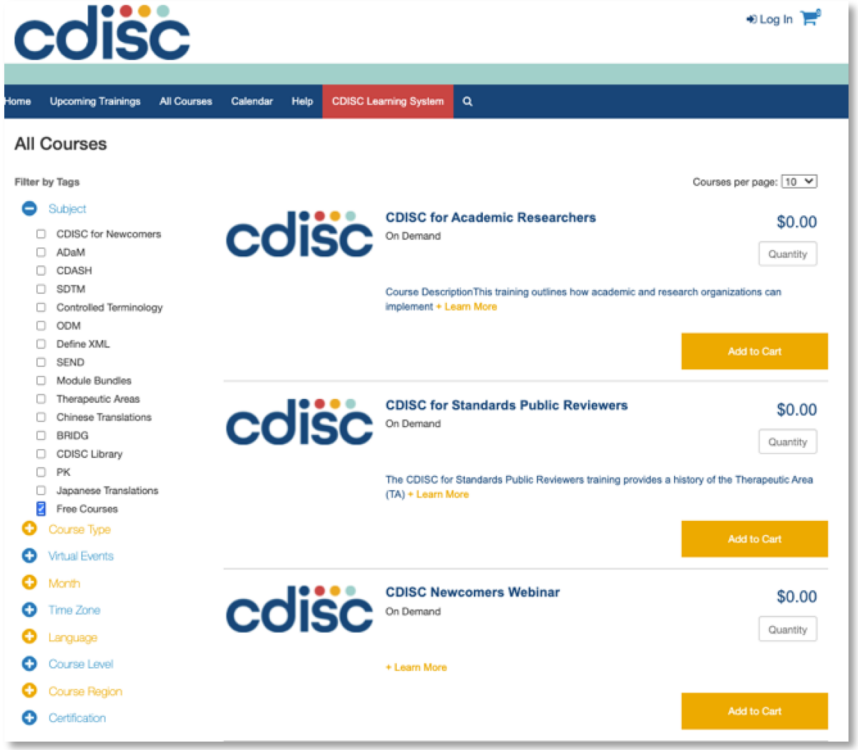

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2022 EUROPE INTERCHANGE
CDISC VIRTUAL CONFERENCE
27-28 APRIL


2022 JAPAN INTERCHANGE
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13-14 JUNE

COSA OpenStudyBuilder Workshop

Friday, April 29th

Register for FREE!

Register on the Europe Interchange registration page – no requirement to register for the main conference.

The OpenStudyBuilder is an open-source project for clinical study specification. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets, analysis, reporting, submission to health authorities and public disclosure of study information.

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2022 CHINA INTERCHANGE

29 - 30 JULY | BEIJING

2022 US INTERCHANGE

26-27 OCTOBER | AUSTIN, TX

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Upcoming Webinars

Date	Webinars
31 March	CDISC Open Source Alliance (COSA) Spotlight
5 April	Controlled Terminology Updates for Q1 – P49 Publication / P50 Public Review
19 April	QRS Office Hours
21 April	SDTM Genomics Findings Office Hours (registration coming soon!)
28 June	Controlled Terminology Updates for Q2 – P50 Publication / P51 Public Review

Ideas or suggestions for webinar topics?
Any topics you would love to see us cover?

Let us know via our topic suggestion form:
https://www.cdisc.org/form/webinartopicreq

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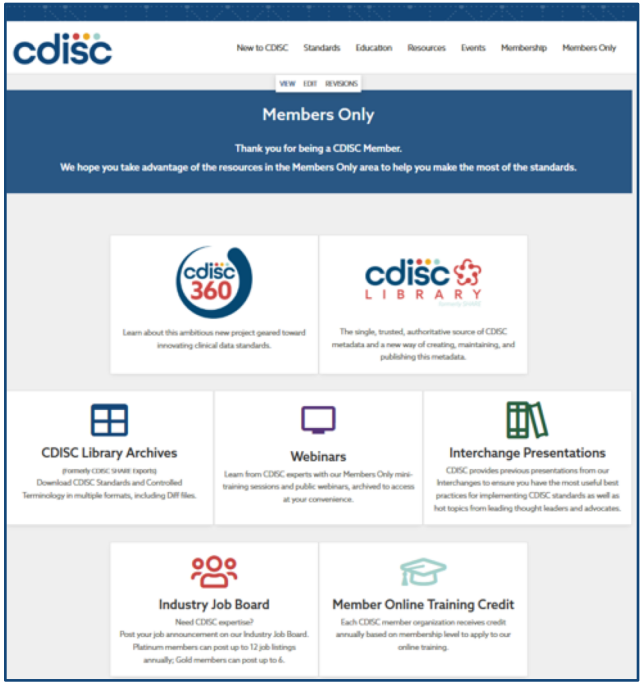

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