

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

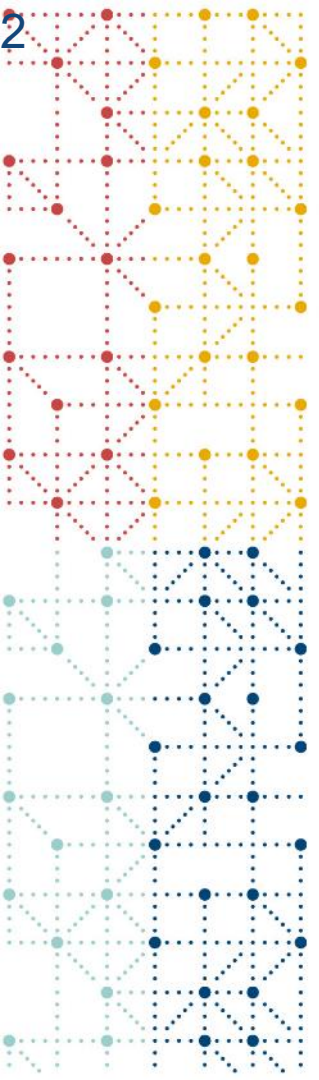
Soumya Rajesh, Standards Engineer, IQVIA

Gary Walker, Education and Standards Development Expert, CDISC

Diane Wold, Sr. Director of Standards Development, CDISC

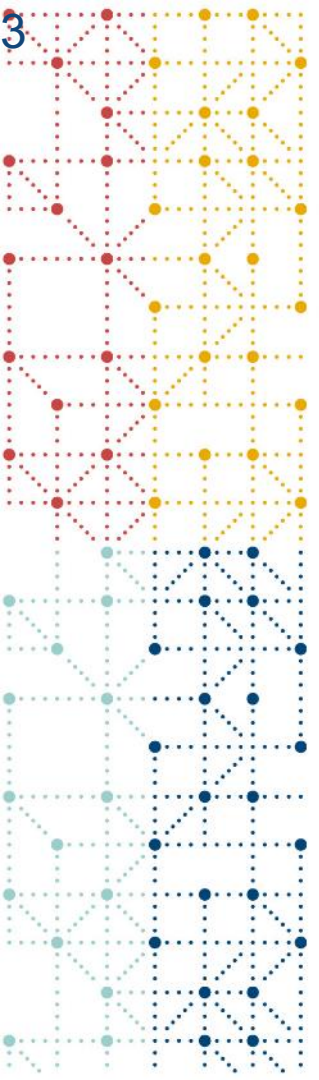


TUE 29 MAR 2022
11:00AM-12:30PM ET



Today's Agenda

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



Housekeeping

Housekeeping



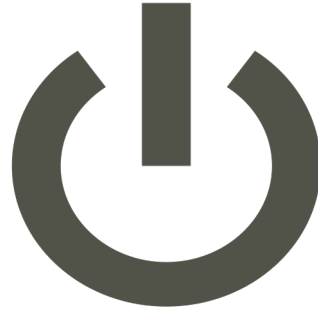
You will remain on **mute**

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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QRS Co-lead
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Senior Project Manager,
Standards Development
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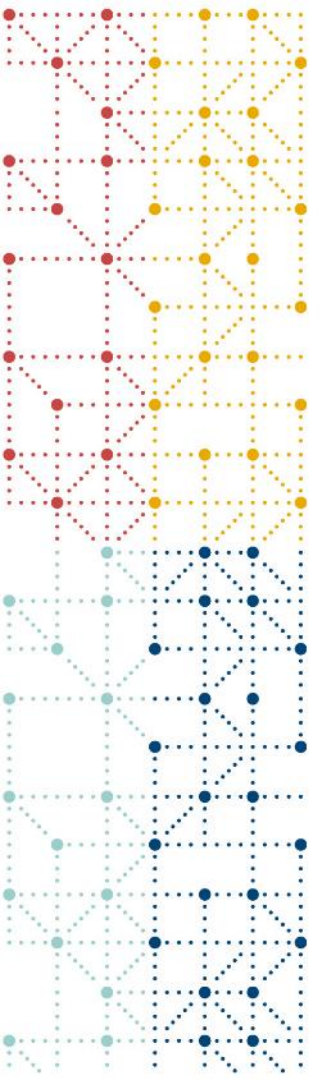
SDTM Office Hours

03.29.2022

The CDISC logo consists of the lowercase letters "cdisc" in a dark blue, sans-serif font. Above the letter "i" are four small, colored dots: red, yellow, green, and light blue, arranged horizontally.

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



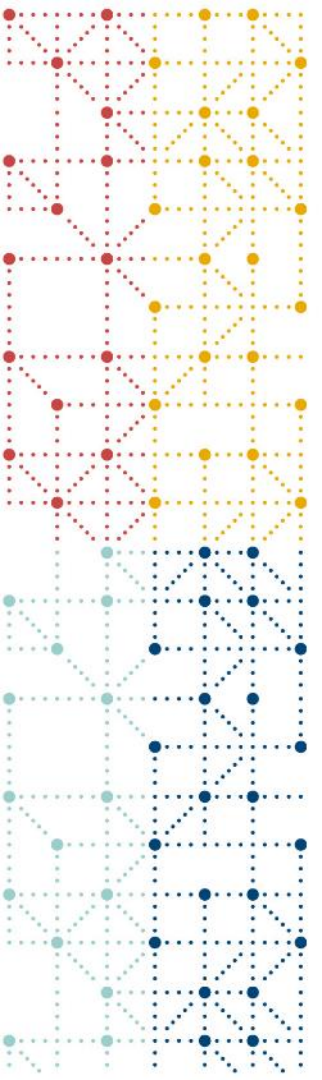
Some Proposed Changes for Next SDTM

- 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

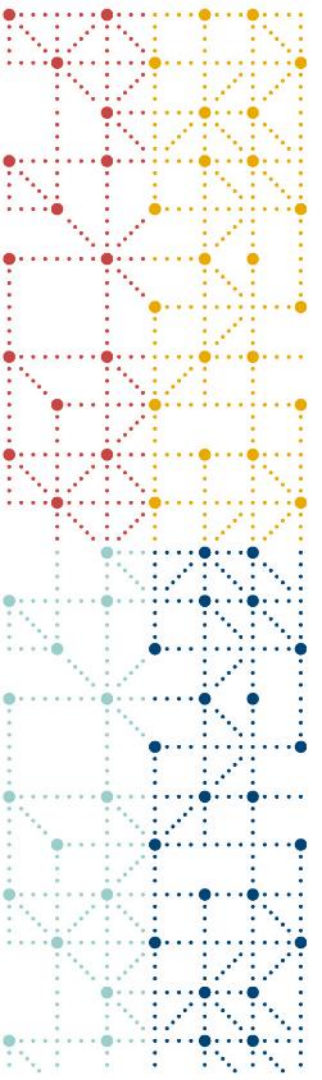
- Structure of Comments domain in SDTM and SDTMIG explained
- DM Race examples revised to make more consistent with CDASH
- REASOC promoted to a standard variable; Exposure examples updated to reflect this
- Changed roles of DOSFRQ and DOSRGM to record qualifier throughout for consistency with SDTM
- 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

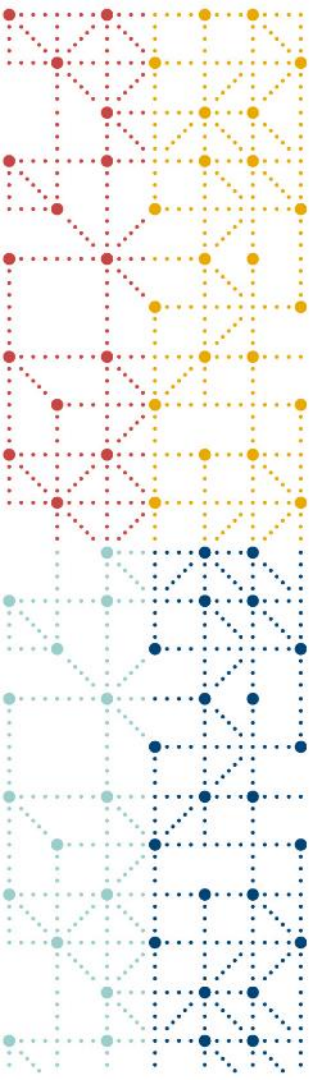
- Adding domains:
 - QX QRS Reference Domain
 - GI Gastrointestinal Domain
- Revising domains:
 - BE, BS, RELSPEC
 - DV
 - MI
- Changing the representation of non-standard variables from the vertical supplemental qualifier form of representation to a horizontal dataset



SDTM and SDTMIG Conformance Rules v2.0

History and Future Plans

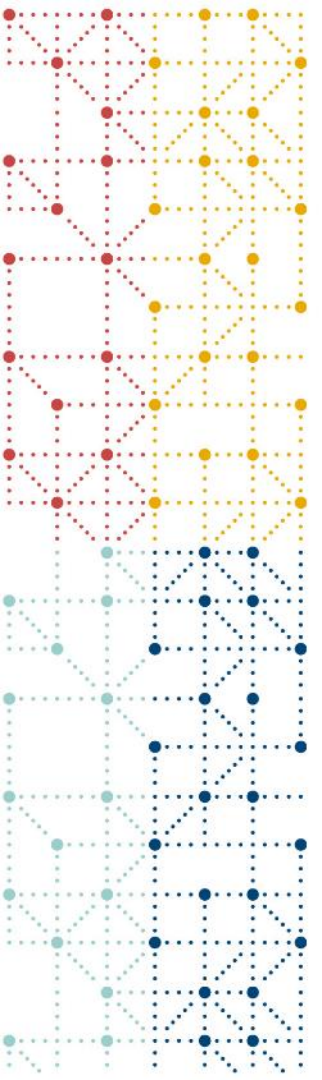
- Initial set of conformance rules were created in 2020 for the SDTMIG v3.2 and v3.3
- SDTM and SDTMIG Conformance Rules v2.0 is a cumulative catalog for SDTMIG v3.2 – v3.4.
- There is a project in development (CORE) to make the rules available electronically.



Thank You!

Dana Booth
dbooth@cdisc.org





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 MULTIPLE 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

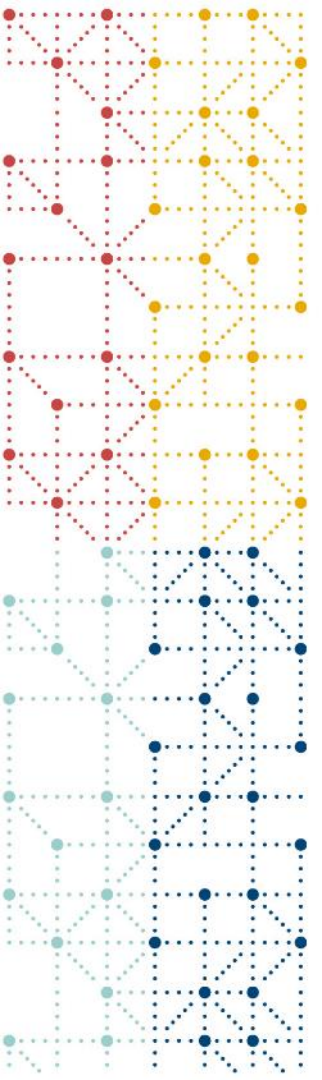
Why can't the Race controlled terminology list be updated to include 'MULTIPLE'?



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

July

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Virtual Training Event

Regional discounts will appear at checkout.

September

US



Virtual Training Event

- Information available at: www.cdisc.org
- Register at: <https://learnstore.cdisc.org/>
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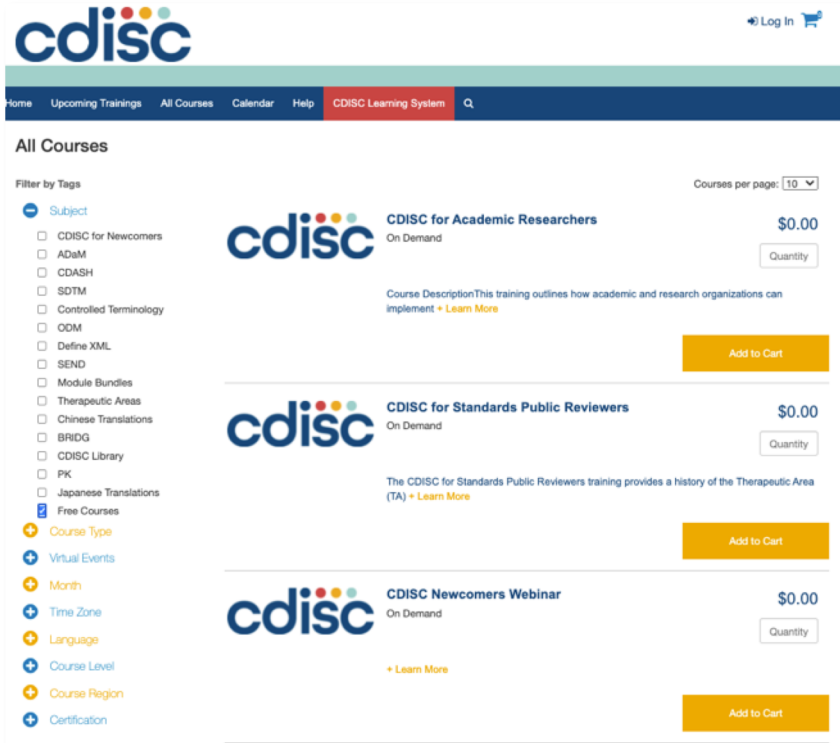


WEBINARS



WORKSHOPS

Free CDISC Courses



The screenshot shows the CDISC Learning System website. The top navigation bar includes links for Home, Upcoming Trainings, All Courses, Calendar, Help, and CDISC Learning System. The main content area is titled "All Courses" and features a "Filter by Tags" sidebar on the left. The sidebar lists various filters such as Subject, Course Type, Virtual Events, Month, Time Zone, Language, Course Level, Course Region, and Certification. The main content area displays three course cards, each with the CDISC logo, course title, price (\$0.00), and an "Add to Cart" button. The courses are: "CDISC for Academic Researchers", "CDISC for Standards Public Reviewers", and "CDISC Newcomers Webinar".

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All Courses

Filter by Tags Courses per page: 10

- Subject
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 - CDASH
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 - Controlled Terminology
 - ODM
 - Define XML
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Course Description This training outlines how academic and research organizations can implement + Learn More
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**2022 EUROPE INTERCHANGE
CDISC VIRTUAL CONFERENCE**

27-28 APRIL



**2022 JAPAN INTERCHANGE
CDISC VIRTUAL CONFERENCE**

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.



2022 CHINA INTERCHANGE

29 - 30 JULY | BEIJING



WITH STANDARDS – UNLOCK THE POWER OF DATA



2022 US INTERCHANGE

26-27 OCTOBER | AUSTIN, TX



WITH STANDARDS – UNLOCK THE POWER OF DATA

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>

Why Become a Member?

- To ensure the CDISC standards remain open and free
- To support CDISC in the development and maintenance of global standards
- To work with the CDISC community and be a voice in the development of clinical research standards
- To impact the development of regulatory requirements for submissions
- To access members only resources and benefits
- To gain visibility in the marketplace

The screenshot displays the CDISC website's 'Members Only' section. At the top, the CDISC logo is on the left, and navigation links for 'New to CDISC', 'Standards', 'Education', 'Resources', 'Events', 'Membership', and 'Members Only' are on the right. Below the navigation is a 'VIEW EDIT REVISIONS' button. The main heading is 'Members Only' with a sub-heading 'Thank you for being a CDISC Member.' and a message: 'We hope you take advantage of the resources in the Members Only area to help you make the most of the standards.'

The content is organized into several tiles:

- cdisc 360**: Learn about this ambitious new project geared toward reworking clinical data standards.
- cdisc LIBRARY**: The single, trusted, authoritative source of CDISC metadata and a new way of creating, maintaining, and publishing this metadata.
- CDISC Library Archives**: formerly CDISC Grant Reports. Download CDISC Standards and Controlled Terminology in multiple formats, including DDF files.
- Webinars**: Learn from CDISC experts with our Members Only mini-training sessions and public webinars, archived to access at your convenience.
- Interchange Presentations**: CDISC provides previous presentations from our Interchanges to ensure you have the most useful best practices for implementing CDISC standards as well as hot topics from leading thought leaders and advocates.
- Industry Job Board**: Need CDISC expertise? Post your job announcement on our Industry Job Board. Platinum members can post up to 12 job listings annually. Gold members can post up to 6.
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Thank you!



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events@cdisc.org



Contact Education inbox:
training@cdisc.org



Contact Bernard directly:
bklinke@cdisc.org