

CDISC Public Webinar – Standards Updates and Additions

Feb 18 2016



Strength through Collaboration

Agenda

- Best Practices for Reviewing Standards Documents
 - Kit Howard, CDISC
- CDISC Membership Updates
 - Ann White, CDISC
- CDISC Online Education & Event Updates
 - John Ezzell, CDISC

Question & Answer

- 'Panelist': Question

OR

- 'Presentation': Question

Examples:

Kit: Where are standards documents in the Wiki?

OR

CDISC: When can we start registering for the European Interchange?

Best Practices for Reviewing Standards Documents

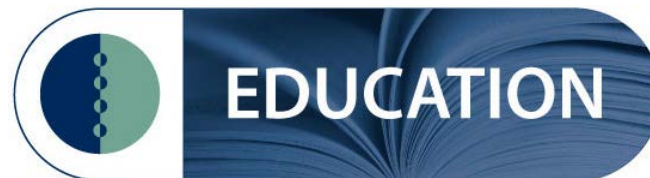
Kit Howard, CDISC



Strength through Collaboration

Best Practices in Constructive Public Review Commenting

Kit Howard
Director of Education
CDISC



Overview

What Does “Reviewing” Mean?

Finding Standards to Review

Who Can Review?

Preparing for the Review

Conducting the Review

How to Submit Comments

What Happens to Comments?

Definition: Standards Review

Process to determine if the standard:

- Accomplishes its stated goals
- Works for most or all of the user community
- Integrates with other standards

Ideally the review is cross-functional

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Where to Find Public Review Documents

CDISC communications

- Newsletters - cdisc.org, Newsletter Signup
- Email blasts
- Twitter - cdisc.org, button upper right
- LinkedIn

CDISC webpage

- Main page News section
- The standard's webpage: column box on right

Where to Find Public Review Documents

The screenshot shows the CDISC website homepage. At the top, there is a navigation bar with links: CONTACT LIST SIGNUP, MAKE A GIFT, CDISC CERTIFICATION, CDISC PORTAL, BECOME A MEMBER, and MEMBER | USER LOGIN. The CDISC logo is on the left, with the tagline "Strength Through Collaboration". A search bar is on the right, and social media icons for Facebook, LinkedIn, Twitter, and YouTube are also on the right. Below the search bar is a main navigation menu with links: ABOUT, STANDARDS, COLLABORATIONS, RESOURCES, NEWS/PUBLICATIONS, EDUCATION, EVENTS, and MEMBERSHIP. The "STANDARDS" and "NEWS/PUBLICATIONS" links are circled in red. Below the navigation menu is a large banner image of a globe with the text "CDISC is the Common Language for Clinical Research". To the right of the banner are two promotional boxes. The first box is titled "CDISC & One Mind Collaborate for PTS and Mental Health Research" and includes a "Learn More" link and an image of a cowboy boot with an arrow pointing up and the text "COWBOY UP". The second box is titled "Members Access eSHARE Today!" and includes a link to "Download CDISC Standards Metadata in Electronic Format" and an image of a globe with people icons. Below the banner is a "What's New" section with a red circle around the text: "New Draft SDTM v1.4 IG v3.2 Conformance Rules V1 Now Available for Public Review - Comments due March 11, 2016". Below this is a "News" section with two articles: "Data Consortium Presses for Global Standards to Spark Collaboration" and "CDISC and One Mind Announce Availability of Research Data Standard for Traumatic Brain Injury".

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CDISC Strength Through Collaboration

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ABOUT **STANDARDS** COLLABORATIONS RESOURCES **NEWS/PUBLICATIONS** EDUCATION EVENTS MEMBERSHIP

CDISC is the Common Language for Clinical Research

CDISC & One Mind Collaborate for PTS and Mental Health Research Learn More

COWBOY UP

Members Access eSHARE Today!

Download CDISC Standards Metadata in Electronic Format

What's New
New Draft SDTM v1.4 IG v3.2 Conformance Rules V1 Now Available for Public Review - Comments due March 11, 2016

Seeking ADaM Instructors in Europe - Apply today!

News
Data Consortium Presses for Global Standards to Spark Collaboration
CDISC and One Mind Announce Availability of Research Data Standard for Traumatic Brain Injury

Where to Find Public Review Documents

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CDISC *Strength Through Collaboration*

Search... [social media icons]

ABOUT **STANDARDS** COLLABORATIONS RESOURCES NEWS/PUBLICATIONS EDUCATION EVENTS MEMBERSHIP

Standards & Implementations

Foundational Standards

PLANNING	DATA COLLECTION	DATA TABULATIONS	ANALYSIS
Protocol Products	CDASH Products Lab	SEND Non-Clinical Products SDTM Clinical Products	ADaM Products

Data Exchange

SDM-XML	ODM-XML	Define-XML DataSet-XML
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Solution Kits

- CFAST Therapeutic Area Products
- Medical Device Products
- Pharmacogenomics/ Genetics
- Other Specialty Areas
- Questionnaires, Ratings and Scales

--Public Review--
SDTM v1.4 IG v3.2 Conformance Rules v1 Comments due March 11, 2016

[Join the Discussion](#)

[Volunteer for CDISC](#)

Introduction to the CDISC Standards
Rebecca Kush, PhD, Founder, President & CEO of CDISC gives a crash course in the CDISC standards and a brief overview of each.

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Who is Allowed to Review?

Anyone

Everyone

You!

Those who know about the area the standard covers

CDISC membership is not required

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Preparing for the Review

Familiarize yourself with related standards

Understand where the standard fits in CDISC

Be aware of the comments due date and plan your internal review accordingly

Identify your internal (cross-functional) review team

- Develop a review process internally
- Orient the team to the standard and the review process
- Develop a checklist of items to consider
- Determine how to consolidate your comments

If there are no comments, submit that

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Understand the Standard

Read the entire document

- Or browse the whole document and read the sections that pertain to your job

Does the document make sense?

Does each part make sense?

Are the clinical and technical concepts clear?

Do you follow the concept maps?

Are there concepts or instruments missing that are usually used?

External Standards

Is the document complete by itself?

Are there references to other documents?
e.g., SDTM, DICOM

Access the other documents and standards
and see if the reference makes sense

Does the document introduce the external
standards adequately?

Clear examples of relevant use cases?

Context and Data Flow

Think inside and outside your own context:
reduce functional boundaries!

Think about the full data flow

- Data capture may look quite different from submission, e.g., Findings About, SUPP--

Clear data flow among the sections

Relevant usage requirements and examples?

Derived Data

Does the document include derived data?

What is the source for the inputs for the calculation?
CRFs? Electronic transfer? Other derivations?

Where is the derivation most appropriately done?

- Site/source data? Data capture environment?
- SDTM environment? Analysis environment?

Does the standard include the derivation algorithm?

- Rules for handling missing source values or other data problems?
- Rules for handling multiple observations per time period
- Provisions for capturing missing or 'not done' observations?

Dataset Structure

Clear dataset structure? Would more guidance help?

Dataset transformation requirements?

Published instruments: accurate representation? Validation status?

Appropriate use of open text fields - analysis or summarization?

Would It Work for You?

Is there enough implementation information to perform a good review?

Try modeling study data using the standard

- Draft CDASH tables and CRFs – can you capture the data you need in a way that can flow into SDTM
- Draft SDTM tables and see if your data will fit
- From those, draft ADaM datasets – can you follow the data flow
- Draft tables, listings and figures layouts with variable annotations
- Check for the relevant controlled terminology
- Check if the results work for the relevant users, e.g., Writers, Clinical Scientists, Statisticians – can you use the resulting TLFs to interpret the data

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Comment Types

- Useful comments address
 - Content
 - Technical accuracy
 - Clinical accuracy
 - Relevance
 - Consistency
 - Implementability
- Useful comments ***do not*** address
 - Layout and formatting
 - Grammar and writing style
 - Terms and acronyms defined in CDISC's glossary or Implementation Guides

How to Submit Comments

Go to the CDISC Public Comment Tracker:

<http://portal.cdisc.org/Pages/Home.aspx>

- a. Login if you are already registered, if not, then register. You can self-register and begin to enter comments immediately. Note: If you see a blank left panel click on “Comments” in the left panel.

The screenshot shows the CDISC Portal Public Comment Tracker interface. At the top, there is a dark blue navigation bar with 'Site Actions' and 'Browse Page'. Below this is the CDISC logo and the text 'PORTAL Public Comment Tracker'. A secondary navigation bar contains links for 'Home Portal', 'CDISC User Networks', 'Public Comment Tracker' (circled in red), and 'Therapeutic Area Repository'. On the left side, there is a sidebar menu with the following items: 'Help', 'Review Documents', 'Comments' (circled in red), 'Assigned To Me', 'By Assigned To', 'By Document Number - Title', 'By Current State', 'By Comment Author', 'By Comment Category', and 'By CDISC Disposition'. At the bottom of the sidebar is a link for 'All Site Content'. A yellow banner with the text 'Please Sign In. If you do not have an account Register here' is positioned above the sidebar menu.

How to Submit Comments

Enter your comments by clicking on “Comments” in the left window. You can add comments at least two ways:

- a. **Add comments – Method 1** (this method is not available in Datasheet View)
 - i. Click on “+ Add New Item” in the right window, at the bottom of the list of comments. You may need to scroll down to see the “+Add New Item”. Be sure to click on the “Add New Item” part of the string. If you click on the “+”, nothing will happen.

The screenshot shows a software interface with a dark blue header bar containing 'Site Actions', 'Browse', and 'List Tools' (with sub-items 'Items' and 'List'). Below the header is a list of comments. The first comment is partially visible, discussing 'intervention has an interval of time associated with it, and therefore EXENDTC or EXDUR is applicable and should be populated.' The second comment is titled 'EXMETHOD needs a new name' and discusses separating 'method of administration' from 'method of observation'. The third comment is titled 'SDTM IG 001 - EX and EC ExposureDomains v3.1.4 Draft' and discusses terminology. At the bottom of the list, a red circle highlights a yellow button with a plus sign and the text '+ Add new item'. A red arrow points to the plus sign. The page number '1 - 30' is visible in the bottom right corner of the interface.

How to Submit Comments

Add the details about your comment.

- a. **IMPORTANT: Be sure that you select the document being commented on** by using the drop down next to "Document Being Commented On". Otherwise, this field will default to the first document in the list. If you happen to add a comment with the wrong document, you can edit the comment and choose the right document by using the drop down list.

Comments - New Item

Edit

Save Cancel Paste Copy Attach File Spelling

Commit Clipboard Actions Spelling

The content of this item will be sent as an e-mail message to the person or group assigned to the item.

Comment Title *

Document Being Commented On * PGxIG_v1draft - PGxIG_v1draft

Document Section - Archive

Reviewed - No Comments

Comment

Comment Author khoward;

Comment Category Select or Blank

Save Cancel

How to Submit Comments

Add the details about your comment.

- IMPORTANT: Be sure that you select the document being commented on** by using the drop down next to "Document Being Commented On". Otherwise, this field will default to the first document in the list. If you happen to add a comment with the wrong document, you can edit the comment and choose the right document by using the drop down list.

The screenshot shows a 'Comments - New Item' dialog box with a ribbon-style interface. The ribbon includes 'Edit' (Save, Cancel, Paste, Copy, Attach File, Spelling) and 'Commit' (Clipboard, Actions, Spelling). A yellow information bar states: 'The content of this item will be sent as an e-mail message to the person or group assigned to the item.' The form fields are: 'Comment Title *' (empty), 'Document Being Commented On *' (dropdown menu showing 'PGxIG_v1draft - PGxIG_v1draft'), 'Document Section' (empty), 'Reviewed - No Comments' (checkbox), 'Comment' (large text area), 'Comment Author' (text field with 'khoward,'), and 'Comment Category' (dropdown menu showing 'Select or Blank'). At the bottom are 'Save' and 'Cancel' buttons. Red circles highlight the 'Document Being Commented On' dropdown, the 'Comment' text area, and the 'Comment Author' field.

How to Submit Comments

- b. You can also attach a file by clicking on the “Attach File” button, even though it would be more useful to the CDISC teams responding to comments to enter each comment separately.

The screenshot shows a 'Comments - New Item' dialog box. The ribbon at the top contains several buttons: Save, Cancel, Paste, Cut, Copy, Attach File, Spelling, and Commit. The 'Attach File' button is highlighted with a red circle. Below the ribbon is a yellow information bar stating: 'The content of this item will be sent as an email message to the person or group assigned to the item.' The form fields are: 'Comment Title' (empty), 'Document Being Commented On' (SOTM IG 001 - EX and EC ExposureDomains v3.1.4 Draft), 'Document Section' (empty), 'Comment' (a large text area), 'Comment Author' (ievans), and 'Comment Category' (Select or Blank). At the bottom are 'Save' and 'Cancel' buttons.

How to Submit Comments

- b. **Add comments – Method 2** (you must use this method if you are in Datasheet View)
 - i. Click on List Tool → Items (under List Tools) → New Item.

The screenshot shows the SharePoint interface. The 'List Tools' menu is circled in red, with a red arrow pointing to it. Below it, the 'Items' and 'List' options are also circled in red. In the ribbon, the 'New Item' button is circled in red with a red arrow pointing to it. Below the ribbon is a table with the following columns: Comment Title, Comment, Document Section, Current State, and Comment Author.

Comment Title	Comment	Document Section	Current State	Comment Author
IR Comment	The link is not for the Guidance itself but leads to a webpage showing where the various types of information are located, including guidances and specifications. The eCTD Guidance is among them, and the actual link is: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072349.pdf	2.2, Page 9, 12th bullet	Select or Blank	cratlife
FDA/CDER	The link leads to "Study Data Standards for Submission to CDER", not "FDA Study Data Specifications". It is important to note that "FDA" would imply specifications applicable to both CDER and CBRL, whereas this page is for CDER. The web page includes a link for "Study Data Specifications [v2.0]", and the actual link for the document is: http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM312964.pdf . Since the document version is likely to further change [currently no longer 1.6 as stated in the Define>XML 2.0.0 Specification Draft], it is better to avoid naming version number.	2.2, Pg 9, 13th bullet	Select or Blank	cratlife
FDA/CDER Comment	"may not" or "should not" instead of "cannot"	3.2, Pg 10, last bullet	Select or Blank	cratlife
FDA/CDER Comment	Purpose of Define>XML is to support meta-data interchange in a machine-readable format. During the webex on Sept 18, it is clear that reviewers feel that there should be an additional purpose in facilitating review of data for human reading	4, Pg 13, Parag 1	Select or Blank	cratlife
FDA/CDER Comment	Text maximum allowed length as 200 characters may be problematic.	4.2.1, Page 18, 1st row	Select or Blank	cratlife

How to Submit Comments

6. **For help on the fields** in the Comment – New Item Form, click on help on the left side of the screen.

The screenshot displays the CDISC Portal interface for the Public Comment Tracker. The top navigation bar includes 'Site Actions', 'Browse', and 'List Tools' (Items, List). The breadcrumb trail shows 'Public Comment Tracker > Comments > All Comments'. The left sidebar contains a 'Help' button (circled in red), 'Review Documents', 'Comments', and various sorting options like 'Assigned To Me', 'By Assigned To', 'By Document Number - Title', 'By Current State', 'By Comment Author', 'By Comment Category', and 'By CDISC Disposition'. The main content area shows a table with columns: Comment Title, Document Being Commented On, Document Section, and Commenter. Below the table is an 'Add new item' button.

Comment Types

- Useful comments address
 - Content
 - Technical accuracy
 - Clinical accuracy
 - Relevance
 - Consistency
 - Implementability
- Useful comments ***do not*** address
 - Layout and formatting
 - Grammar and writing style
 - Terms and acronyms defined in CDISC's glossary or Implementation Guides

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Comment Review & Management



CDISC Membership Updates

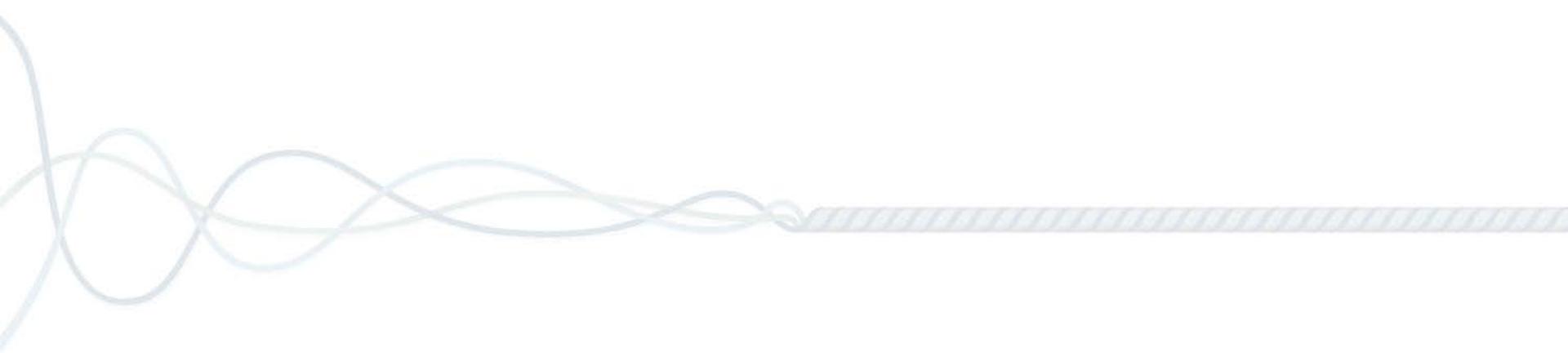
Ann White, CDISC



Strength through Collaboration

CDISC Members Drive Global Standards

Thank you for your support!



CDISC Partner Organizations

- Over 380 members worldwide
- Additional partner organizations



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- Two Levels of Membership – Platinum & Gold
- CDISC Standards
 - Streamline clinical research
 - Improve data quality
 - Increase cost effectiveness of research processes

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CDISC Strength Through Collaboration

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ABOUT STANDARDS COLLABORATIONS RESOURCES NEWS/PUBLICATIONS EDUCATION EVENTS **MEMBERSHIP** MEMBERS ONLY

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CDISC Membership Application
To register for membership, please complete the following information. Please read the details on the membership page BEFORE you apply.

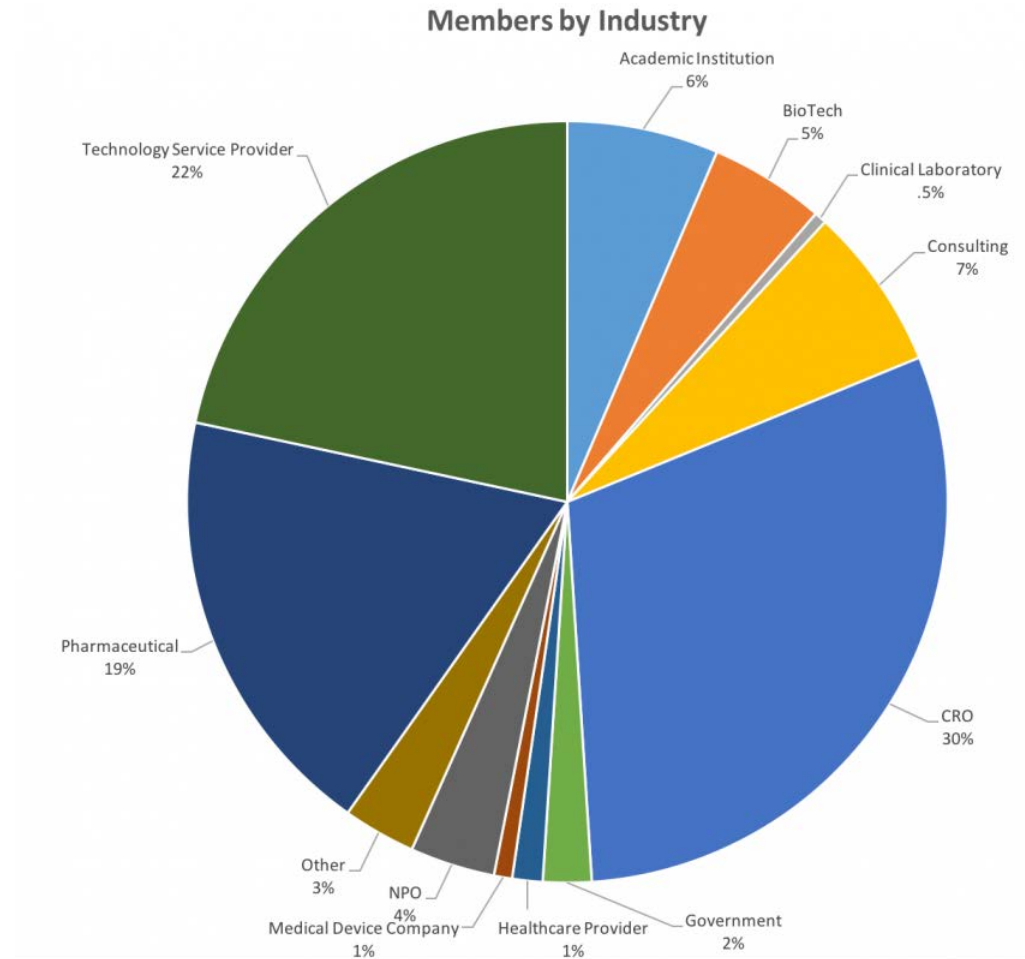
First Name * **Last Name ***

Email *
This will be used as username.

Display Name *

CDISC Membership Benefits

- Access to our Members Only Area
 - Download eSHARE Content
- Significant Discounts on Training (private, public, online)
- Opportunities to Participate in Programs and Serve on Councils



Questions

Contact us at membership@cdisc.org

CDISC Online Education & Event Updates

John Ezzell, CDISC



Strength through Collaboration

CDISC Online Training

- SDTM, CDASH, BRIDG, ADaM, PGx and Therapeutic Area modules are currently available on CDISC Training Campus (<http://CDISC.trainingcampus.net>)
- Bundle packages available for SDTM, CDASH, and BRIDG modules
- *All members should contact training@cdisc.org to retrieve company-specific discount code.*



CDISC Online Training Production Update

- Just Released
 - Pharmacogenomics, Module 1
- In Final Stages of Production:
 - Pharmacokinetics, Module 1
 - TA COPD

Online Courses in Development
TA Alzheimer's
TA Diabetes
TA QT Studies
TA Breast Cancer
TA Dyslipidemia
TA COPD
TA TBI
TA Rheumatoid Arthritis
TA Virology V2
ADaM Modules 3-8

UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered	Register by:	Early registration discount:	Host
Audubon, PA	2-11 Mar	Courses corresponding to standards listed in Data Standards Catalog. See web .	2 Mar	Expired	
Emeryville, CA	11-15 Apr	Courses corresponding to standards listed in Data Standards Catalog. See web .	11 Apr	Expired	
North Chicago, IL	23-27 May	SDTM, CDASH, ADaM Primer, ADaM T&A	23 Apr	23 Feb	
Toronto, ON	24-27 May	SDTM, CDASH, ADaM Primer, ADaM T&A	23 Apr	23 Feb	

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered	Register by:	Early registration discount:	Host
Paris, France	8-11 Mar	<u>SDTM, ADaM Primer, ADaM T&A Define-XML</u>	8 Mar	Expired	
Europe Interchange in Vienna, Austria	25-29 Apr	See <u>web</u> .	8 Apr	19 Feb	 
Frankfurt, Germany	13-17 Jun	<u>SDTM, ADaM Primer, ADaM T&A, Define-XML</u>	13 May	14 Mar	
Brussels, Belgium	5-9 Sep	<u>SDTM, CDASH, ADaM Primer, ADaM T&A</u>	5 Aug	6 Jun	
Copenhagen, Denmark	Oct 2016	SDTM, SEND, ADaM Primer, ADAM T&A, Defne-XML	1 Sep	3 Jul	

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Register by:	Early Registration Discounts	Host
Tokyo, Japan	23-29 Mar	<u>SDTM</u> , <u>CDASH</u> , <u>ADaM</u> , <u>ODM</u> , <u>Define-XML</u>	9 Mar	21 Feb	 
Ho Chi Minh City, Vietnam	29-31 Mar	<u>SDTM</u> , <u>CDASH</u>	29 Feb	Expired	
Tokyo, Japan	30 May – 3 Jun	See <u>web</u> .	13 May	26 Feb	

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

2016 Members-Only Mini-Trainings

2016 Scheduled Members Only Webinars		
Presenter	Topic	Webinar Date
Phil Pochon, Covance	LOINC Standards	Feb 25, 2016
Kit Howard, CDISC	Overview of Medical Device Domains	Mar 3, 2016
Lauren Shinaberry, AbbVie	Reference Time Points	April 7, 2016
Melanie Paules, GSK; Barrie Nelson, Diane Wold, CDISC	SDTM Trial Disease Assessment Domain	May 5, 2016
Fred Wood, Accenture	TBD	Jun 2, 2016

Webinar details and registration at www.cdisc.org/webinars

Standard currently out for review

- SDTM v1.4 IG v3.2
Conformance Rules v1
 - Visit <http://cdisc.org/sdtm> for more information
 - Comments due March 11, 2016

Click [here](#) to submit your comments.

Any more questions?

Thank you for attending this webinar.

**CDISC's vision is to:
Inform Patient Care & Safety Through Higher Quality Medical Research**



Strength *through collaboration.*

CDISC Members Drive Global Standards

Thank you for your support!



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