CDISC Public Webinar – Standards Updates and Additions

22 May 2014
Agenda

• How to Review and Comment On CDISC Standards
  ▪ Kit Howard, CDISC

• CDISC Education and Events Updates
  ▪ Saad Yousef, CDISC

*Time permitting
Question & Answer

• ‘Presenter’: Question

Or

• ‘Presentation’: Question

Examples:

Sandra: What does ADaM stand for?

Or

SDTM: What does SDTM stand for?
How to Review CDISC Documents
Overview

What does reviewing a document mean?

Why should you review CDISC’s documents?

What kinds of documents does CDISC send out?

What kinds of comments does CDISC want?

What should you know beforehand?

How can you make your review meaningful and useful for CDISC and you?

How and where can you find CDISC documents for review?

How do you use the CDISC Public Comments tool?

What does CDISC do with your feedback?
Definition: Standards Review

• A process by which we determine if the standard
  ▪ Correctly and usefully accomplishes its stated goals
  ▪ Works for most or all of the user community
  ▪ Integrates appropriately with other CDISC standards and external standards, when applicable

• Ideally the review is cross-functional,
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Why Review?

- CDISC’s standards are designed to maximize data reusability, e.g.,
  - Within and among companies
  - Between companies and regulators
  - Between companies and academia, healthcare systems and non-profits
- CDISC’s standards will be required for regulatory submissions so reviewing is in your best interests
- Much non-submission research will need to access submission data
- Providing your feedback increases the chances that the standards will be as widely usable as possible
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Documents to be Reviewed

• All standards and standards-related documents
  ▪ Controlled Terminology
  ▪ Foundational standards models
  ▪ Implementation Guides
  ▪ User Guides
  ▪ New domains
  ▪ Therapy Area User Guides (TAUGs)
  ▪ Data transport standards
  ▪ Healthcare Link models
  ▪ Metadata definitions (e.g., define-xml)
  ▪ Updates
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Comment Types

• Comments address
  ▪ Content
  ▪ Technical accuracy
  ▪ Clinical accuracy
  ▪ Relevance
  ▪ Consistency
  ▪ Implementability

• 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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Who is Allowed to Review?

- Anyone
- Everyone
- You!
- If you have knowledge of a domain or part of the implementation process, we want your feedback
- You do NOT have to be a member to review a standard!
Preparation

- Familiarize yourself with related standards
- Understand where the standard fits with respect to other CDISC standards
- Be aware of the comments due data and plan your internal review accordingly
- Develop a review process internally
- Identify your internal review team and orient them to the standard and the review process
- Develop a checklist of items to consider (or use the one provided here)
- Determine how to consolidate your comments
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Making Your Reviews Useful

• Read the entire document
• Think inside and outside your own context
• Think about the full data flow
  ▪ Data capture may look quite different from submission, e.g., Findings About, SUPP—
• Does the standard make sense? Is it unambiguous?
• Does each part make sense? Is there enough information to understand how to implement it?
• Is the document complete by itself? If not, does it reference all the other relevant documents? If appropriate, does it provide examples of how to use the standard or domain with others?
Making Your Comments Useful

• Does the document reference any other applicable widely used standards, e.g., DICOM
• Is there an introduction to the standard that provides an overview, where appropriate?
• Do the examples (when used) clearly demonstrate relevant use cases?
• For derived data, where should they appear?
• Would they need to be calculated by the site?
• What would need to be included in data capture to provide the source data for the calculation?
Making Your Review Useful

• Is the derivation more appropriately done in the analysis environment? Data capture environment? SDTM environment?

• Does the standard define how to do the derivation? And what to do if there are missing source values or other data problems?

• Does the standard define what to do if there are multiple observations per time period, if not covered by the relevant Implementation Guide?

• Are provisions made for capturing missing observations or ones that were not done, depending upon whether they should be represented?
Making Your Review Useful

• Is the dataset structure clear, e.g., normalized vs. denormalized? Is it clear how to convert from one to the other?

• For published instruments, does the standard accurately reflect the published version? CDASH, SDTM and ADaM? And CT?

• Is open text used for any variables that may be needed for analysis or summarization?
Making Your Review Useful

• Are there any potential confidentiality or privacy issues with the data capture?
• Are all appropriate literature and other references included and, where appropriate, incorporated?
• When analysis datasets or methodologies are defined, is it clear where the data would come from? If from other standards (e.g., SDTM) are they in the right format?
Therapy Area Standards

• Are the clinical concepts clear?
• Are all relevant concepts present?
• Do you follow the concept maps?
• Can you understand how they flow among the sections and the requirements for their use?
• Does the standard give you what you need to interpret the domains?
• Are there instruments missing that are typically used?
Would It Work for You?

• Find an appropriate study and try modeling the 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 you can get your data into them
  ▪ From those, draft ADaM or analysis datasets – can you follow the data flow
  ▪ Draft tables, listings and figures layouts with variable annotations
  ▪ Check the relevant controlled terminology
  ▪ Check if the results work for the relevant use, e.g., Writers, Clinical Scientists, Statisticians – can you use the resulting TLFs to interpret the data
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Providing Comments

• CDISC communications
  ▪ Newsletters
  ▪ Email blasts
  ▪ Twitter
  ▪ LinkedIn
• Usually on the standard’s CDISC webpage
• In the Public Comment section of the CDISC portal
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Using the Comments Tool

Demo
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Comment Review

• Gather the comments
• Development Team reviews all
• Eliminate duplicates
• Send editorial comments to document editor
• Triage the remainder into those that can be answered by the team alone
• Team addresses these
• Collaborate with other individuals/teams to address the remainder
• Add responses to all comments in the portal
• Publish responses
Thank You!
Questions?
CDISC Education & Events Announcements

Saad Yousef, CDISC, Manager of Education and Membership Services
## Upcoming Public Course Events

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<th>Dates</th>
<th>Courses Offered</th>
<th>Registration Deadline</th>
<th>Discounts?</th>
<th>Host</th>
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<tr>
<td>South San Francisco, CA</td>
<td>10-13 June</td>
<td>SDTM, CDASH, ADaM</td>
<td>27 May</td>
<td>12 April; expired</td>
<td>Genentech</td>
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<td>London (Reading, Berkshire), UK</td>
<td>1-4 July</td>
<td>SDTM, CDASH, ADaM</td>
<td>17 June</td>
<td>25 April; expired</td>
<td>Quintiles</td>
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<tr>
<td>Durham, NC</td>
<td>22-25 July</td>
<td>SDTM, CDASH, ADaM</td>
<td>22 June</td>
<td>22 May (TODAY!!)</td>
<td>Duke Clinical Research Institute</td>
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<tr>
<td>Seattle, WA</td>
<td>26-29 Aug</td>
<td>SDTM, CDASH, ADaM</td>
<td>25 July</td>
<td>3 March; expired</td>
<td>Axio</td>
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<tr>
<td>Brussels, Belgium</td>
<td>8-11 Sep</td>
<td>SDTM, CDASH, ADaM</td>
<td>8 Aug</td>
<td>3 March; expired</td>
<td>Business &amp; Decision Life Sciences</td>
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Upcoming Interchange Events

• CDISC Asia-Pacific Interchange in Tokyo, Japan (28 Jul-1 Aug)
  ▪ PMDA, FDA, and CDISC Board Members expected to speak at event. Registration to open soon!
  ▪ **Education Courses Offered (28-30 July):** SDTM, Define-XML, Controlled Terminology, CDASH, ADaM
  ▪ **Main Conference:** 31 July-1 August

• CDISC International Interchange in Bethesda, MD (10-14 Nov)
  ▪ Registration to open soon. Additional event details found [here](#).

*All interchange information can be found at [www.cdisc.org/interchange](http://www.cdisc.org/interchange)*
CDISC In-House Education

• Below courses readily available for ‘in-house’ training:
  - ADaM
  - BRIDG Deep Dive
  - CDASH
  - SDTM
  - SDTM for Medical Devices
  - SEND
  - Others pending availability

• For more information visit our [website](http://www.cdisc.org/private-courses) or submit request [here](http://www.cdisc.org/private-courses).
Online Training

• SDTM online training course now available on CDISC Training Campus.
• CDASH and BRIDG Deep Dive coming soon.
• Account registration
  ▪ Link: http://CDISC.trainingcampus.net
Next Public Webinar

• **Agenda:**
  - Overview: Scope and Registration for CDISC Online Courses

• **Date:** 5 June 2014, 11:00-12:30 PM EST

• **Speakers:**
  - Kit Howard, CDISC
  - Shannon Labout, CDISC
  - Saad Yousef, CDISC

• Register [here](#).
Next Member’s Only Webinar

- **Topic**: TBD
- **Date/Time**: 17 July 2014, 11:00-12:30 PM EST
- **Speaker**: TBD

- Register [here](#).

*Webinar details also at [www.cdisc.org/webinars](http://www.cdisc.org/webinars)*
Any more questions?

Thank you for attending this webinar.

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