Upgrade your library from CDASH 1.1 to CDASH 2.0

Sandra Latorre 5th July 2018
Introduction

CDASH v2.0: exploring the updates

Library Upgrade

Conclusion

Q&A
Sponsor CDISC-compliant Library

ROI² return on investment through return on information
Sponsor CDISC-compliant Library

- **Content**: CDASH, SDTM, ADaM...
- **Input**: CDISC/Industry/Sponsor
- **Format**: from simple Excel to complex MDR

**Links**

**Processes**

→ **As many Libraries as sponsors**
Release of new CDASH version

- CDASH Version 1.1 → Version 2.0 25 Sep 2017

- Consequences on your company?
  - Who? ‘Governance board’
  - How? Governance process
  - What? Perform a gap analysis
  - When? Timelines

→ Impact analysis → Decision
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**Gap analysis**

→ Evaluate discrepancies between current library and new CDASH

**Challenge**

**CDASH v 2.0**

→ High level changes
→ Content updates
→ List of differences provided by CDISC: only high level (‘major’)
High Level Changes

Before

CDASH v1.1

CDASH User Guide v 1.1

Now

CDASH Model v1.0

CDASH Implementation Guide (IG) v2.0

NEW

SDTM Model 1.4

SDTM IG 3.2

Controlled Terminology

TAUG releases

Impact on library?
Revision History

**Source: CDASH IG v2.0**

**High level changes**

**Structural changes**
- Organized by class and domain (align with SDTMIG)
- List of attributes removed and attributes added \(\rightarrow\) new Excel structure

**Content changes**
- Updated existing domains (no detail provided)
- Added domains CE, DD, EC, HO, MI, PC, PR, RP, SR
- Updated attributes for every CDASHIG variable
- More flexibility in Question Text and Prompt
- ECPDOSE, ECPDOSU, and ECPOCCUR were deprecated
- Common Identifier Variables were added to each of the Domains

Revision History doesn’t list all the changes
- Go through all documentation
More Flexibility

**Question Text/Prompt: customizable**

<table>
<thead>
<tr>
<th>What [is/was] the outcome (of the event/event topic)?</th>
<th>Outcome</th>
</tr>
</thead>
</table>

- What was the outcome? ✔
- What is the outcome? ✔
- What is the outcome of the migraine? ✔
- What was the outcome of the adverse event? ✔
- Outcome ✔

**Implement this type of change may help reducing waiver requests from CRO**
More Guidance

Model to create new variables

CDASH model v1.0: New document to model variables for any domain you would like

<table>
<thead>
<tr>
<th>Interventions</th>
<th>N/A</th>
<th>36</th>
<th>--</th>
<th>REASOC</th>
<th>Reason for Occur Value</th>
<th>An explanation of why a scheduled intervention did not occur.</th>
</tr>
</thead>
</table>

Detailed instructions on custom variables

Example: If the mapping to SDTM is similar, but not direct “C” can be included before the root variable name to indicate a “collected” version of the variable to which that data will map.

<table>
<thead>
<tr>
<th>Anatomical Location</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>EXLOC</td>
<td>EXCLOC</td>
</tr>
<tr>
<td>Left Arm</td>
<td>Right Arm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EXLOC</th>
<th>EXLAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARM</td>
<td>LEFT</td>
</tr>
</tbody>
</table>

Implementation in library → enhances consistency, traceability
**Alignment with SDTM IG 3.2**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was study treatment administered? (Defaulted)</td>
<td>N</td>
</tr>
<tr>
<td>Study Treatment Category (Defaulted)</td>
<td>MISSED DOSE</td>
</tr>
<tr>
<td>Study Treatment Name (Defaulted)</td>
<td>Sponsor Defined</td>
</tr>
<tr>
<td>Line Number</td>
<td></td>
</tr>
<tr>
<td>What was the intended dose date?</td>
<td><em><strong>/</strong></em>/____</td>
</tr>
<tr>
<td>Reason Treatment Not Administered</td>
<td></td>
</tr>
</tbody>
</table>

**Library upgrade is strongly recommended**
Content changes: What Revision History doesn’t say

Also reworked:
- Best practice
- Conformance rules

No fundamental changes but reorganized and clarified

→ Full evaluation of new CDASH needed
CDASH Attributes

**New Structure**

- Example of deleted attribute: ‘BRIDG’
- Example of new attribute: ‘CDASHIG Variable Label’

**Library implementation**

- Valuable but complex depending on system
Programmatic assessment of changes between CDASH v1.1 and CDASH v2.0

Need to use Excel files but « pending final curation »

<table>
<thead>
<tr>
<th>CDASH Model</th>
<th>1.0</th>
<th>Pending Final Curation</th>
<th>Excel</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDASH IG</td>
<td>2.0</td>
<td>Pending Final Curation</td>
<td>Excel</td>
</tr>
</tbody>
</table>

Need a bit of workaround due to new structure
Impact Analysis: Semantic Linking

Data Collection
SDTM
ADaM
Analysis

In an MDR, an impact analysis functionality can help
Impact Analysis: Points to Consider

- System in use (MDR)
- Impact on partner CROs
- Training needs
- Budget
- Resources
- Timelines
Impact Analysis: Specifics

- **Specificity of this CDASH release: Complex evaluation**

- **Can be evaluated per type of gap instead of a whole**
  (no need to expect a big release of CDASH v2.0-compliant library version)

- **No regulatory requirements, so nothing is critical but all is « nice to have »: implement because you will benefit from it, not because it’s written**
Implementation Decisions

- **Company specific**
- **Effort (see Impact Analysis) vs expected benefits**
  - enhanced traceability,
  - consistency,
  - communication,
  - quality of data,
  - easiness of SDTM programming...
- **Go/No go**
- **Priorities**
Implementation Plan: example

1st step ➔ Full training of librarians on new CDASH

2nd step ➔ Allow customization of question texts

3rd step ➔ Align custom variable names to CDASH variable naming rules

4th step ➔ Align CDASH attribute values
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**CDASH new version**

- It’s here, take advantage of it
- No urgency, no submission requirement
- Enhances traceability with SDTM 3.2
- Involve governance board, apply steps: gap analysis – impact analysis - decision
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