Is Your Clinical Data Standards Library Ready for Change? – Adapting to Therapeutic Area Specific Standards

Lauren Shinaberry
13 October 2014
Is Your Clinical Data Standards Library Ready for Change?

- Introduction
- TAUG Standards
- Managing Content
- Methods for Storing the Metadata
- Conclusions
Introduction

• Brief overview of current, ongoing and planned Therapeutic Area User Guides (TAUGs) from CFAST

• Description of TA standards development and why it matters to your library

• Past-present-future state of storing standard metadata

• Recommendations for best practices
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### Program Overview – September 2014

**Approved Therapeutic Area Standards Projects**

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Project Manager</th>
<th>Proposal Approval Date</th>
<th>Stage 0</th>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3a</th>
<th><em>Stage 3b</em></th>
<th><em>Stage 3c</em></th>
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<tr>
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<td>Dec</td>
<td>Aug</td>
<td>Nov</td>
<td>Feb</td>
<td>May</td>
<td>Q3 14</td>
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<td>Apr 13</td>
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<td>Aug</td>
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<td>Apr</td>
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<td>Q3 14</td>
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<td>Aug 13</td>
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<td>Feb</td>
<td>Mar</td>
<td>Jul</td>
<td>Sept</td>
<td>Q4 14</td>
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<td>Nov</td>
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<td>Q1 15</td>
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</tr>
<tr>
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<td>Q3 15</td>
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</tbody>
</table>

**Key:**
- **Green bar:** Stage completed
- **Light green bar:** Stage ongoing
- **Shaded:** All months reflect when stage is, or is projected to be, completed.

*The Stage 3b concludes at the end of the 30-day review period and Stage 3c concludes when all tasks have been completed and the standard is publicly available.*

**Specific projected publication dates to be added to the notes section at the conclusion of stage 3b.**

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List of planned TA standards and release dates available on website: [http://www.cdisc.org/therapeutic](http://www.cdisc.org/therapeutic)
TAUG Process

• Development requires understanding of the clinical aspects of the data that is unique to the area

• Approach developed by CDISC: good model for development of internal TA standards

• Process: starts with defining scope/clinical concepts (not with SDTM data)
Concept maps
Source: CDISC Diabetes TAUG
Applying TAUGs to your libraries

• Supplement the foundational Standards, do not replace them

• **For the sponsor:**
  how to adapt to the forecasted changes without increasing the administrative burden?
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Managing Content

Modular Libraries

Fully Incorporated Libraries
Fully Incorporated Content

Multiple standalone libraries that incorporate all globally applicable standards with the TA-specific standards.
Modular Content

A single global library that is complemented with discrete TA-specific libraries.
Benefits and drawbacks

Fully incorporated

- Benefits: contains both global standards + TA standards in one single library → simplifies end-user experience; single place to reference for standards needed

- Drawbacks: difficulties for the management of libraries; duplicates global content → high risk of inconsistencies, high effort to make updates in global

Modular

- Benefits: more efficient for librarians to manage updates in one central repository

- Drawbacks: difficulty for end-users to know how to use multiple libraries
Ideal solution?

- For governance and management, would allow the independent libraries proposed in the second approach

- For end users, would present the metadata in a consolidated “single library” view, as it would appear with first approach
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Evolution of metadata storage

Resource Description Framework

Relational Databases

RDB

Spreadsheets

RDF
Methods for Storing the Metadata

Traditional methods

- Excel spreadsheets or other document-based processes
- In a simple file server environment or through a versioned document management system

**Drawbacks:**
- Two-dimensional representation
- Requires extensive manual effort to maintain
- Difficult for end users to understand how to implement
- Little control over the proper use of the content
Methods for Storing the Metadata

<table>
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<tr>
<th>VARIABLES</th>
<th>THERAPEUTIC AREA</th>
</tr>
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<tbody>
<tr>
<td>Name</td>
<td>Description</td>
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<td>COPD</td>
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<td>AESEV</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<tr>
<td>AETOXGR</td>
<td>ONCO</td>
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<tr>
<td>Standard Toxicity Grade</td>
<td>Oncology</td>
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<tr>
<td>...</td>
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</table>

Relational Databases

- Can link specific items in your library to one or more TAs
- Allows more robust querying capability
- Avoids duplication and inconsistencies
- Changes to the concepts may require structural changes
- Relationships between items is hidden in linking of tables
Methods for Storing the Metadata
Concept maps & RDF

Source: CDISC Diabetes TAUG
Learn more about RDF

- There are many good discussions of RDF and CDISC standards on the PhUSE website and wiki
  - Semantic Technology Working Group
  - https://github.com/phuse-org/rdf.cdisc.org
  - And others...

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**rdf.cdisc.org**

FDA/PhUSE Semantic Technology Project

Representing Existing CDISC Standards in RDF

**Introduction**

The FDA/PhUSE Semantic Technology project investigates how formal semantic standards can support the clinical and non-clinical trial data life cycle from protocol to submission. Within this project, several teams work on dedicated tasks to execute this investigation. The first outcome and deliverable of this project is the representation of existing CDISC standards in RDF, including representations of the following CDISC standards:

- CDASH 1.1
- SDTM 1.2 and SDTM Implementation Guide 3.1.2
- SDTM 1.3 and SDTM Implementation Guide 3.1.3
- SEND Implementation Guide 3.0
- ADaM 2.1 and ADaM Implementation Guide 1.0
- Controlled Terminology

Today, CDISC publishes these standards in a paper based format and partly in Excel, which makes it difficult to consistently represent and process this information. The RDF representation addresses both issues by providing at the same time a formal model, a machine readable representation, and an exchange format. Accordingly, we have decided not to reproduce a lot of paper based documentation. This document provides only a few pointers, other than that the RDF models are self-describing and we therefore encourage you to use...
Methods for Storing the Metadata

CDISC-CFAST development of TA standards

• Mirrors the modular approach

• Designed to supplement foundational standards, do not replace them

• Only include implementation specific to the area, do not duplicate standard domains that are not TA-specific
Methods for Storing the Metadata

CDISC SHARE platform

• Organizes metadata in a discrete way rather than duplicating metadata that do not require TA-specific implementations

• Will be offering metadata in RDF format in the near future
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Conclusions

- TA standards should be seen as complementary to the global metadata, not a replacement

- Optimum method for managing the metadata of both global and TA standards would mirror this relationship

- Industry is evolving from two-dimensional spreadsheets to more complex data modeling
  - End-user needs to have easy to use interaction regardless of the storage approach

- The processes for developing TA standards supports the use of these more traditional data modeling
Thank you for your attention.

Join us for a coffee at our stand.
London, United Kingdom, 13 OCT 2014