Managing ADaM Metadata

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AGENDA

- CDISC metadata components
- Introduction to Toolkit
  - Requirements that led us to develop the toolkit
  - ADaM metadata Ecosystem
- Components of toolkit
  - ADaM metadata database
  - ADaM metadata viewer
  - ADaM metadata spec builder
  - ADaM metadata manager
- Toolkit interaction (how all components work together)
- Conclusion / Summary
- Questions
What’s ADaM Metadata?

Recap

– Metadata is central to the whole process of a CDISC-compliant submission

– It provides a framework for the data;
  • some metadata (e.g. variable type, maximum length etc) is fixed in the standards
  • the metadata can be used as a data specification, e.g. for sharing with suppliers

– and traceability;
  • A key concept in CDISC is a fully-traceable analysis,
    Analytical Results → Analysis Dataset → Collected Data → Source

– at every level of the data;
  • Metadata for datasets, variables, values of variables
  • Additionally, displayed data can optionally have metadata
Introduction to the Toolkit

Requirements

– A central repository to store key ADaM metadata
  • version control
  • Easily updatable

– Easily incorporate to MS tools

– Web based solution

– Consuming of data
Introduction to the Toolkit

Metadata EcoSystem

- Updating
  - ADaM Focus Group Rep
  - ADaM Metadata Manager
    - Validate updates and load changes into repository

- Storing
  - ADaM Metadata Database

- Viewing
  - ADaM Metadata Viewer
    - Provide access to metadata

- Using
  - Internal HARP Spec Creation
  - Copy ADaM Specs into their study's reporting effort
  - Weekly load of latest spec into HARP
  - HARP
    - Load Excel Study Specs into HARP if needed
  - ADaM Metadata Spec Builder
    - Create Specs Outside of HARP

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Components of the Toolkit : Storage

ADaM Metadata Database

- Oracle Database storing a series of tables containing the Metadata.
- Key tables within the AMD include:
  - The Domains table
  - The specifications table

- Version Control
  - controlled terms list that has no version control
  - Specs and Variables tables have Implementation Guide version and date version control
  - “From IG Version” is populated when a spec is entered into the database
  - “To IG Version” (initially missing). When a specification changes as per the IG, the old spec has the “To IG Guide” populated with the old version and a new spec is created for the new IG.

<table>
<thead>
<tr>
<th>DomName</th>
<th>TA</th>
<th>Ind</th>
<th>FromIGVer</th>
<th>ToIGVer</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADSL</td>
<td>CORE</td>
<td>CORE</td>
<td>1.0</td>
<td>2.0</td>
</tr>
<tr>
<td>ADSL</td>
<td>CORE</td>
<td>CORE</td>
<td>2.0</td>
<td></td>
</tr>
</tbody>
</table>
Components of the Toolkit : Storage

Each piece of metadata in the database has “From Date” and “To Date” attributes associated with it.

• This allows updates and new versions to be stored in the same way as the IG version.

The database has been set up so that the specifications are additive. We hold Core, Therapeutic Area (TA), and Indication level specifications.

• Core is the lowest level and all the core variables are available in the TA and Indication level specifications.

• The TA and Indication specific variables and metadata are then added to the core specification.

• This inter-dependence means that any changes made to the core specifications get cascaded down to the TA and Indication levels.
Components of the Toolkit: Storage

ADaM Metadata Database

- There are 2 tables relevant to Controlled Terms within the database.

- The first is The controlled Terms List that stores the domain and type that are associated with the controlled term. This table has no version control.

- The second is the Controlled Term table that stores the code/decode pairs this has internal control only.

- Computational Methods table stores default computational methods. If a default CM is updated then it automatically applies to all new studies, no version control is applied.
Components of the Toolkit: Viewing

ADaM Metadata Viewer

<table>
<thead>
<tr>
<th>Domain Name</th>
<th>Label</th>
<th>Repeating</th>
<th>Class</th>
<th>Source</th>
<th>Data Structure</th>
<th>Key Variables</th>
<th>Description</th>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADAE</td>
<td>Adverse Events Analysis</td>
<td>Y</td>
<td>ADE</td>
<td>AE</td>
<td>One record per subject per each adverse event recorded in SDTM AE domain</td>
<td>STUDYID, USUBBD, ATBD, AEDECOD</td>
<td>Contains the adverse event analysis</td>
<td></td>
</tr>
<tr>
<td>ADCM</td>
<td>Concomitant Medications</td>
<td>Y</td>
<td>OTHER</td>
<td>CM</td>
<td>One record per subject per medication/ingredient</td>
<td>USUBBD, ADECOD, CMSTDC, CMENDTC</td>
<td>Contains Concomitant Medications</td>
<td>The GSK drug version should be same as the one used for SDTM.</td>
</tr>
<tr>
<td>ADCOMP</td>
<td>Compliance Analysis</td>
<td>Y</td>
<td>BDS</td>
<td>DA</td>
<td>One record per subject per visit per dasgit per parametor</td>
<td>STUDYID, USUBBD, APERIOD, AVISIT, DACAT, DASCAT, PARAMIN</td>
<td>Contains the compliance analysis</td>
<td></td>
</tr>
<tr>
<td>ADDS</td>
<td>Disposition Analysis</td>
<td>Y</td>
<td>BDS</td>
<td>DS</td>
<td>One record per subject per downtime per parameter per result</td>
<td>STUDYID, USUBBD, ADT, ATM, PARCH, PARAMCD, AVALORD</td>
<td>Contains Disposition analysis</td>
<td></td>
</tr>
<tr>
<td>ADDV</td>
<td>Deviation and Pop Exclusion</td>
<td>Y</td>
<td>OOS</td>
<td>DV, POPEX</td>
<td>One record per study, per subject, per term, per start time, per reporting timepoint</td>
<td>STUDYID, USUBBD, ATERM, ASIDT, ARETPT</td>
<td>Contains protocol deviation and analysis/ population exclusion details</td>
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<tr>
<td>ADEG</td>
<td>ECG Analysis</td>
<td>Y</td>
<td>BDS</td>
<td>ECG, ADSL</td>
<td>One record per subject per parameter per analysis visit per timepoint</td>
<td>STUDYID, USUBBD, PARAM, AVISIT, ADT, ASIM, ARETPT</td>
<td>Contains ECG analysis</td>
<td></td>
</tr>
</tbody>
</table>

Filters:
- Domain Name: ALL
- Class: ALL

Tools:
- Reset All Filters
- Export to Excel
# Components of the Toolkit: Viewing

## ADaM Metadata Viewer

### Filters:
- **Domain Name:** ADPFT
- **Therapeutic Area:** RESPIRATORY
- **Indication:** RESPIRATORY: CORE
- **Variable Name:** ALL

### Tools:
- Reset All Filters
- Export to Excel

### Table of Variables

<table>
<thead>
<tr>
<th>Domain Name</th>
<th>Therapeutic Area</th>
<th>Indication</th>
<th>Variable Name</th>
<th>Label</th>
<th>Type</th>
<th>Max Length</th>
<th>Significant Digits</th>
<th>Variable Order</th>
<th>Value Level Metadata</th>
<th>Controlled Term or Formats</th>
<th>Computational Method</th>
<th>Mandatory</th>
<th>Sort Order</th>
<th>Definition / Comments</th>
<th>Additional Information</th>
<th>Required</th>
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<td>Race</td>
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<td>Analysis Country</td>
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<td></td>
<td></td>
<td>Perm</td>
</tr>
</tbody>
</table>
Components of the Toolkit: Using ADaM Metadata Spec Builder

Instructions:
To begin, click on the button to open the ADaM Spec Builder.
Next, click on "Add Standard Specific Domain" screen.
Finally, to add custom domains and/or add more ADaM spec builder windows.

Select ADaM IG Version:
Select Therapeutic Area:
Select Indication:
Select GSK Version Date:
Components of the Toolkit : Updating

ADaM Metadata Manager

Instructions:
To start, click the "Start: Load Domain" button.
Choose the dataset to be modified from the list or choose the domain to modify.

Select Domain to Modify

Select Domain: ADLB
Select Therapeutic Area: CORE
Select Indication: CORE

Admin Only:

Prepare Server
Components of the Toolkit: Updating
ADaM Metadata Manager

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Indication</th>
<th>Variable Name</th>
<th>ADaM IG From Version</th>
<th>ADaM IG To Version</th>
<th>Variable Order</th>
<th>Mandatory</th>
<th>Significant Digits</th>
<th>Sort Order</th>
<th>Required</th>
<th>Controlled Term or Formats</th>
<th>Value Level Metadata</th>
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<tbody>
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<td>CONSUMER HEALTHCARE: CORE</td>
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<td>Perm</td>
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</tr>
</tbody>
</table>
Toolkit interaction (how all components work together)

Updating
- ADaM Focus Group Rep
- ADaM Metadata Manager

Storing
- ADaM Metadata Database

Viewing
- ADaM Metadata Viewer

Using
- Internal HARP Spec Creation
  - Copy ADaM Specs into their study’s reporting effort
- Weekly load of latest spec into HARP
- Load Excel Study Specs into HARP if needed
- Create Specs Outside of HARP

ADaM Metadata Spec Builder

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Summary

– The ADaM Metadata Toolkit is the current method that enables the management, storage and viewing of the metadata that has thus far been developed. The toolkit is user friendly enabling the metadata to be viewed by version and/or date and allows updates to the metadata by administrators.

– Uploading of updated metadata is loaded into the database via a SAS® script. The creation of a define.xml from AMSB is also via a SAS script. These SAS scripts complete the requirements of the toolkit.

– The toolkit provides a complete system to manage GSK’s ADaM Metadata and the initial user feedback (for the pilot) has been very positive on every aspect.
Thank-you