CDISC Technical Webinar Series - Pattern-Based Metadata Repository: A New Approach to Improve the Efficiency and Quality of Data Standards

25 MAY 2017
Agenda

• Pattern-Based Metadata Repository: A New Approach to Improve the Efficiency and Quality of Data Standards
  ▪ Julius Kusserow, Head of Data Standards, PAREXEL
  ▪ Alan Cantrell, Senior Manager, Clinical Database and Statistical Programming, PAREXEL
  ▪ Deb Copeland, Principal Data Standards Analyst, Data Operations Administration, PAREXEL

• Guest Q&A Panelist
  ▪ Sam Hume, Head of Data Exchange Technologies

• CDISC Online Education & Event Updates
  ▪ John Ezzell, Education Manager, CDISC
Question & Answer

• ‘Panelist’: Question
OR
• ‘Presentation’: Question

Examples:

1) What should be supported by ADaM datasets?
2) Is there a limit to the number of variables that can be in ADSL?
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Implementing Pattern Based Data Standards
Applying Theory to a Practical Application

The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research

Julius Kusserow
Alan Cantrell
Deb Copeland

Strength through Collaboration
The Problem we want to Solve

• Many companies have deployed – or are in the process of deploying – a metadata repository (MDR) to manage their data standards.

• In most organisations, data standards are maintained in silos:
  ▪ Data collection /CDASH standards are maintained within Data Management,
  ▪ SDTM is governed by the clinical programmers
  ▪ ADaM is managed by the statistical programmers.

• These different groups collaborate to maintain mapping between the different standards,
  ▪ This remains a challenging process across separate groups with disjointed governance processes.
  ▪ Mapping between the standards remains an “art”, based on manual interpretation and experience from the programmers.
Walking the Line
What is happening today

We work in a linear way...

**BUILD**
We need to build a database before we can enter data

**COLLECT**
Data needs to be entered before we can produce tabulation data (SDTM)

**ANALYZE**
Tabulation data needs to be available before the analysis datasets are created

What would happen if we didn’t need to wait?
How can we change our process to avoid waiting?
Walking the Line
What is needed

We need an end-to-end (E2E) approach to standardize information

When a data collection form is designed we can know how it will impact the tabulation and analysis data

If we know the structure of the data collection forms, and how that is connected to the structure of tabulation and analysis data, we can reduce the waiting time

Clinical Research Concepts and Patterns will help us to realize this
Example: Severity Concept in Adverse events

- Certain aspects of overlap:
  - Data Collection (CDASH):
    » AESEV – raw value
  - Tabulation Data (SDTM):
    » AESEV – raw value
  - Analysis Data (ADaM):
    » AESEV – raw value
    » ASEV, ASEVN – numeric representation
    » ASEV, ASEVN – imputation possible due to numeric representation
- If an element exists in 2 more places, it is (or should be) the same “thing”.

CDASH / Data Collection
AESEV Severity

SDTM / Data Tabulation
AESEV Severity/Intensity

ADaM / Data Analysis
AESEV Severity/Intensity
AESEVN Severity/Intensity (N)
ASEV Analysis Severity/Intensity
ASEVN Analysis Severity/Intensity (N)
SEVGRy Pooled Severity Group y
SEVGRyN Pooled Severity Group y (N)
After identifying the different unique “things” present in the AE module, we created a grouping of them in a “concept” and associate it with a reusable “pattern”
Benefits and Conclusion

INDEPENDENTLY MAINTAINED STANDARDS
MANUAL MAPPING

FLEXIBILITY
STEPPED APPROACH
MAPPING INCONSISTENCIES
WORKLOAD TO GENERATE HIGH QUALITY E2E LINEAGE

CONCEPT LINKED STANDARDS
REUSABLE TEMPLATES

CONSISTENCY
INCREASED QUALITY
INCREASED EFFICIENCY
DEFINITIONS OF PATTERNS
PROCESS CHANGE
MDR TOOL REQUIREMENT
Glossary

• DCI – Data Capture Instrument
• DML – Data Management Lead
• DSA – Data Standards Analyst
• GDO – Global Data Operations
• Item – a discrete point of metadata
• MCC – Metadata Concept Collection
• MDR – Metadata Standards Repository
• SIM – Study Instance Metadata
• Object – a MCC or SIM
MDR and Data Standards
Roles and Process Flow

MDR Standards
- DCI metadata enrichment
- Concept Data Type Mapping
- Data Standards Governance Process
- Review
- Approval

SIM Imported Standards
- Study Specific Modification

eDC
Other DCI (ePRO, LAB, etc.)
Statistical Computing Environment
Other downstream consumers
MetaData Standards Analyst Dashboard

1. Create new Standards
2. Review Approval Requests for Standards and SIMS
3. Create a new Standard

Links to all
- Standards
- SIMs
- Approved SIMs
- Approval Requests.
Populating Metadata content in the MDR

Allows Import of metadata standards from:

- External Source - NCI controlled terminology, CDISC, Metadata spreadsheet template
- Copy from existing standard or SIM – one already in the MDR

- Build metadata content via the user interface
MDR Display of Metadata Standards Content

Metadata Content: Concept Hubs  Spokes: Forms with Value Sets
Reporting variables (SDTM) Analysis Variables (ADaM)
Hub to Spoke (Concept to Variable Representation) Mapping

CDASH

STANDARDS_DEMO v1

Concept Data Type: ordinalCD (code list: Severity/Intensity Scale for Adverse Events)

Items: STANDARDS_DEMO v1 - Adverse Event - Reporting - AE

SDTM

Variable: STANDARDS_DEMO v1 - Reporting variable - AE - AESEV

<table>
<thead>
<tr>
<th>Value</th>
<th>Description</th>
<th>Severity/Intensity</th>
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<tbody>
<tr>
<td>25</td>
<td>AESEV</td>
<td>Severity/Intensity</td>
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ADaM

Variable: STANDARDS_DEMO v1 - Analysis variable - AAD - SEVORYN

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<tr>
<td>61</td>
<td>SEVORYN</td>
<td>Pooled Severity Group y (N)</td>
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Variable: STANDARDS_DEMO v1 - Analysis variable - AAD - AESEV

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Variable: STANDARDS_DEMO v1 - Analysis variable - AAD - AESEV

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<tr>
<td>57</td>
<td>AESEV</td>
<td>Severity/Intensity (N)</td>
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</table>
End to End metadata from standards are imported into each study instance metadata Object (SIM)

- MCC Standard

- SIM
MDR facilitated SIM Review
All SIMS undergo Data Standards review and approval process

MDR alerts when required standards are being altered

MDR Standards Comparison tools

Show changes

Comparison to Source

Comparison to Standard
Benefits and Conclusion

**INDEPENDENTLY MAINTAINED STANDARDS**

MANUAL MAPPING

- FLEXIBILITY
- STEPPED APPROACH
- MAPPING INCONSISTENCIES
- WORKLOAD TO GENERATE HIGH QUALITY E2E LINEAGE

**CONCEPT LINKED STANDARDS**

REUSABLE TEMPLATES

- CONSISTENCY
- INCREASED QUALITY
- INCREASED EFFICIENCY

- DEFINITIONS OF PATTERNS
- PROCESS CHANGE
- MDR TOOL REQUIREMENT
THANK YOU

Questions?

Julius Kusserow
Alan Cantrell
Deb Copeland
CDISC Online Education & Event Updates

John Ezzell, CDISC
Standard currently out for review

• Duchenne Muscular Dystrophy v1.0
  ▪ Comments Due by: 6 Jul 2017
# Upcoming Webinars

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<tr>
<th>Topics</th>
<th>Presenters</th>
<th>Webinar Date</th>
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<tr>
<td>Colorectal Cancer TA User Guide Public Review</td>
<td>Colorectal Therapeutic User Guide Development Team</td>
<td>30 MAY 2017, 11:00 AM EST</td>
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<tr>
<td>Duchenne Muscular Dystrophy TA Public Review</td>
<td>Duchenne Muscular Dystrophy Therapeutic Area User Guide Development Team</td>
<td>1 JUN 2017, 11:00 AM EST</td>
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<tr>
<td>Governance for Data Capture Standards Members Only Mini-Training</td>
<td>Gary Walker, Associate Director, Quintiles</td>
<td>15 JUN 2017, 11:00 AM EST</td>
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<td>Michael Ward, Data Standards Consultant, Eli Lilly</td>
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<td>Melissa Binz, Study Data Management, Pfizer</td>
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<td></td>
<td>Judy Tran, Medidata Solutions</td>
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Webinar details and registration at [www.cdisc.org/webinars](http://www.cdisc.org/webinars)
Online Training

• Course content developed the same way teams develop standard content
  ▪ In collaboration with standards experts
  ▪ Creating opportunities for “real-world” applications of standards

Visit cdisc.trainingcampus.net for more information!
CDISC Online Training Production Update

• Just Released
  • Mini-Training: Null Flavors
  • ADaM Module 6

Online Courses in Development

<table>
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<tr>
<td>TA Rheumatoid Arthritis</td>
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<td>TA Malaria</td>
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<tr>
<td>CT Module 1</td>
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<tr>
<td>(Japanese Language Version)</td>
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<td>CT Module 2</td>
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<tr>
<td>Define XML Module 2</td>
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<tr>
<td>ADaM Modules 7-9</td>
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Drag and Drop Exercise: Required, Conditionally Required and Permissible ADSL Variables

Instructions: Drag the Required, Conditionally Required and Permissible variables into the correct barrels. When you are complete, click the “Submit” button to check your answers.

Drag and Drop Exercise: Required, Conditionally Required and Permissible ADSL Variables

Required or Conditionally Required variables

Permissible variables

Submit

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## UPCOMING NORTH AMERICA PUBLIC COURSES

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered:</th>
<th>Discount period ends:</th>
<th>Late fees kick(ed) in:</th>
<th>Host</th>
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<td>Toronto, ON</td>
<td>5-9 Jun 2017</td>
<td>SDTM, CDASH</td>
<td>6 Mar 2017</td>
<td>5 May 2017</td>
<td>McDougall Scientific</td>
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<td>Austin, TX</td>
<td>13-17 Nov 2017</td>
<td>CDISC Standards from the Start, CDASH, SDTM, SEND, ADaM, Define-XML</td>
<td>31 Aug 2017</td>
<td>3 Nov 2017</td>
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## UPCOMING EUROPE PUBLIC COURSES

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# UPCOMING ASIA PUBLIC COURSES

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<td>Tokyo, Japan</td>
<td>5-9 Jun 2017</td>
<td>SDTM, CDASH, ADaM Primer, ADaM T&amp;A, Define-XML, ODM</td>
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<td>Beijing, China</td>
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Any more questions?

Thank you for attending this webinar.

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

Thank you for your support!

Learn CDISC from CDISC!