

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

25 MAY 2017



Strength *through Collaboration*

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?

Content Disclaimer

All content included in this presentation is for educational and informational purposes only. References to any specific commercial product, process, or service, or the use of any corporation name are for the information of our members, and do not constitute endorsement, recommendation, or favoring by CDISC or the CDISC community.

Content Disclaimer

The purpose of CDISC mini-trainings is to provide examples of implementation and should not be considered official recommendations by the standards development teams or CDISC unless otherwise stated in the presentation.

Mini-trainings are not considered to be authorized CDISC courses, are not developed or delivered under COP-005, and should not replace a published IG or UG. Please refer to the latest published standards documents for the most authoritative implementation information.



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

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

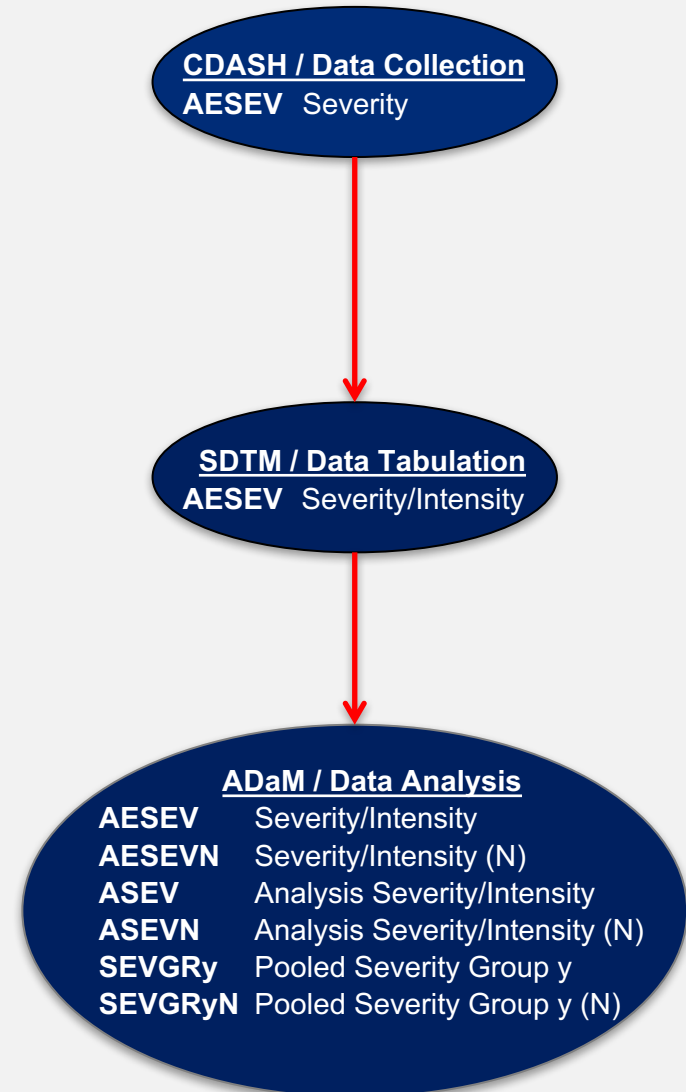


If we know the structure of the data collection forms, and how that is connected to the structure of tabulation and analysis data, we can reduce the waiting time

**Clinical Research Concepts and Patterns
will help us to realize this**

Example: Severity Concept in Adverse events

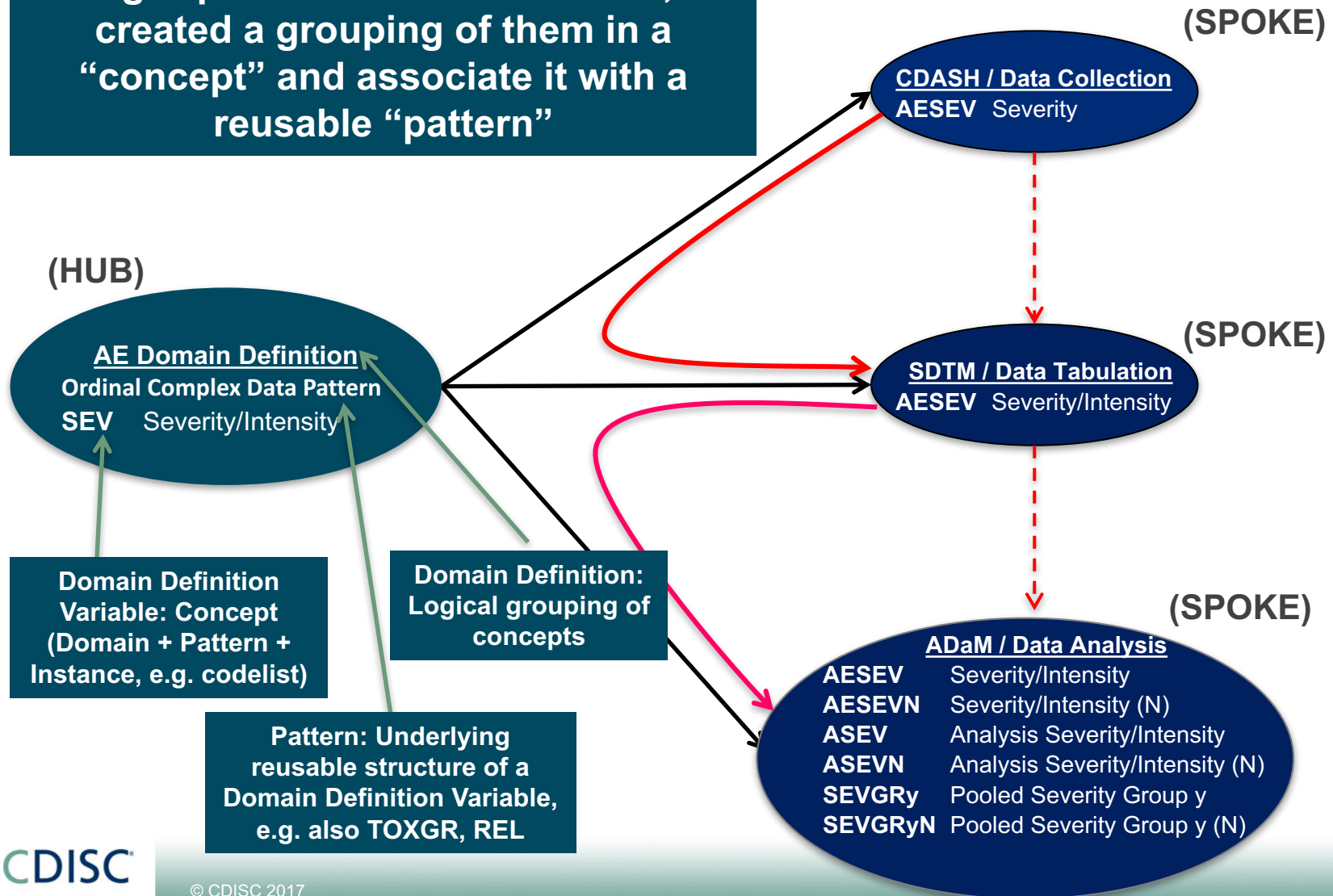
- Certain aspects of overlap:
 - Data Collection (CDASH):
 - »AESEV – raw value
 - Tabulation Data (SDTM):
 - »AESEV – raw value
 - Analysis Data (ADaM):
 - »AESEV – raw value
 - »AESEVN – numeric representation
 - »ASEV, ASEVN – imputation possible due to numeric representation
- If an element exists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



Concepts & Patterns

A Hub and Spoke approach

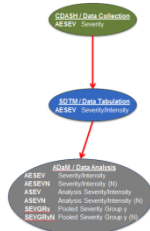
After identifying the different unique “things” present in the AE module, we created a grouping of them in a “concept” and associate it with a reusable “pattern”



Benefits and Conclusion

INDEPENDENTLY MAINTAINED STANDARDS

MANUAL MAPPING



FLEXIBILITY

STEPPED APPROACH

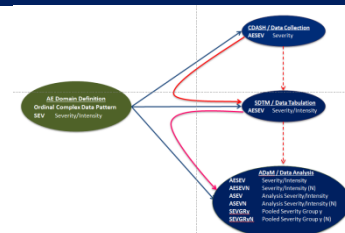
MAPPING INCONSISTENCIES

WORKLOAD TO GENERATE HIGH QUALITY E2E LINEAGE



CONCEPT LINKED STANDARDS

REUSABLE TEMPLATES



CONSISTENCY

INCREASED QUALITY

INCREASED EFFICIENCY

DEFINITIONS OF PATTERNS

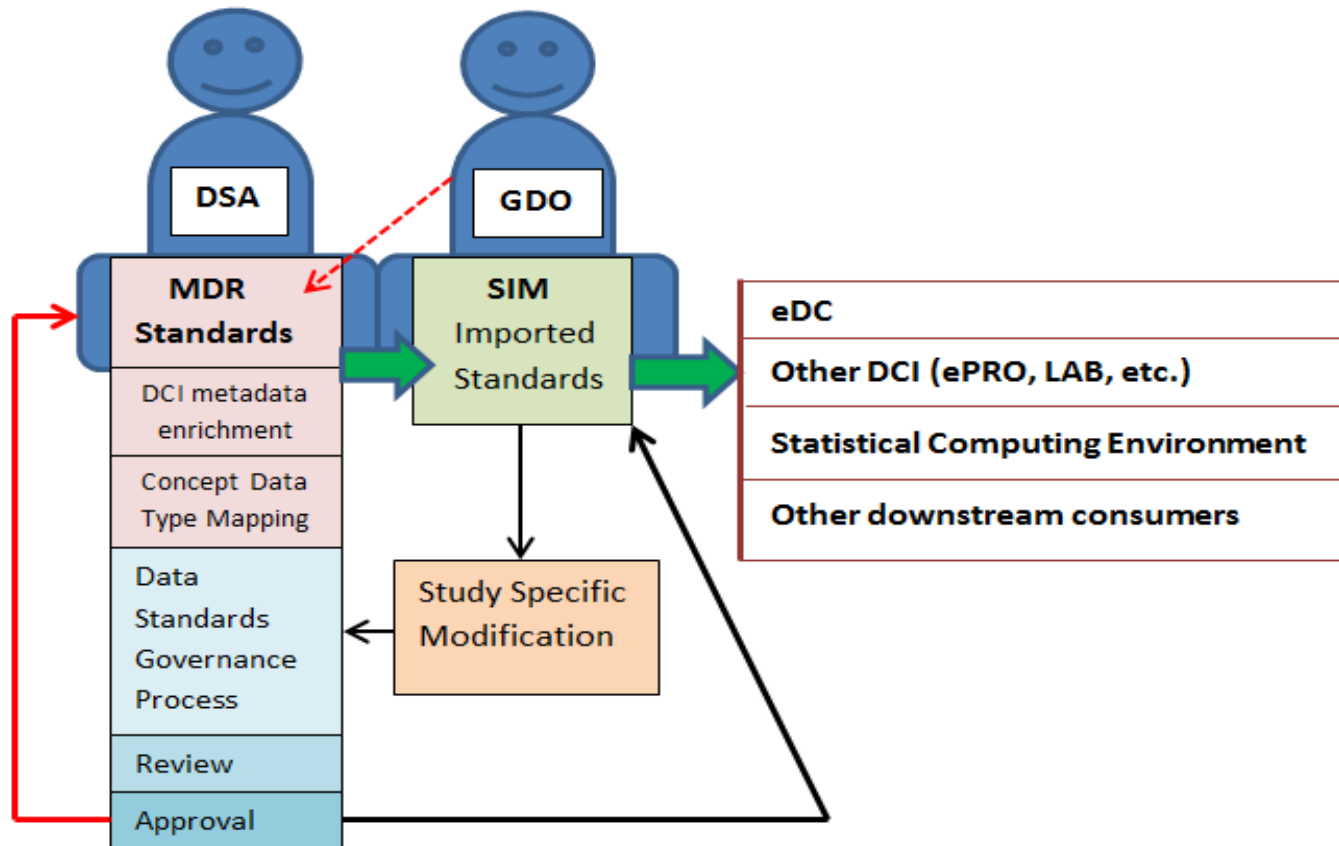
PROCESS CHANGE

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



MetaData Standards Analyst Dashboard

MDR All Activity Reports Issues Search 5113 Sign Out

Welcome back, Logged in as Data Steward in PAREXEL

Metadata Collection

3 Create a new Standard

New Library

NAME	STATUS	SPONSOR	AREA	AUTHOR	UPDATED	ACTIONS
DM_MCC_TEST v1	INCOMPLETE	PAREXEL		Deb.Copeland@parexel.com	02-Oct-2016 09:54am	
CM_MCC_TEST v1	INCOMPLETE	PAREXEL		Deb.Copeland@parexel.com	02-Oct-2016 09:45am	

SIMs

NAME	STATUS	DRUG	PHASE	AREA	INDICATION	AUTHOR	UPDATED	ACTIONS
218187_22Aug2016 v1	APPROVED	N/A	Phase 3	Infectious Diseases	flu	natraj.patro@parexel.com	10:25am	
PAREXEL_TEST_SIM3 v1	INCOMPLETE	N/A	Phase 2a	Dermatology			20-Sep-2016 11:58am	
20160830_TEST_SIM v1	INCOMPLETE	N/A	Phase 2	Dermatology		natraj.patro@parexel.com	11:58am	
PAREXEL_TEST_SIM_2 v1	INCOMPLETE	N/A	Phase 1	Endocrine and Metabolism Disorders			20-Sep-2016 11:58am	

SIM Catalog

NAME	STATUS	DRUG	PHASE	AREA	INDICATION	AUTHOR	UPDATED	ACTIONS
218187_22Aug2016 v1	APPROVED	N/A	Phase 3	Infectious Diseases	flu	natraj.patro@parexel.com	10:25am	

Approval Requests

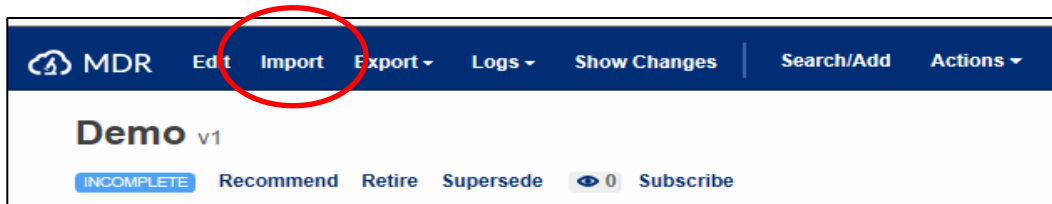
Filter

ID	NAME	STATUS	TA	PRIORITY	CREATED BY	UPDATED	ACTIONS
PAREXEL_TEST_SIM3-1009	Test Approval Request3	Created	Dermatology	Medium	natraj80@gmail.com	16-Sep-2016 10:29am	
PAREXEL_TEST_SIM3-1008	Test Approval Request	Created	Dermatology	Medium	natraj80@gmail.com	16-Sep-	

1 Links to all Standards
SIMs
Approved SIMs
Approval Requests.

2 Data Steward Functions
1. Create new Standards
2. Review Approval Requests for Standards and SIMS

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)

MDR Export Logs Show Changes Actions Show Search 5262 Sign Out

Demo2_MCC v2

STANDARD Back To Qualified Back To Recorded Back To Candidate Retire Supersede Create New Version 0 Subscribe Forms(3) v

Adverse Event

Non-Repeating*

AEYN* N | No
Y | Yes

Did the subject experience any adverse events?

{ NO YES RESPONSE (NY) }

Repeating*

AETERM* text Adverse Event Term

AESPID* text AE Number

AESTDAT* date AESTDAT AESTDTC Start Date

AESTTMHR* 00 | 00
01 | 01
02 | 02
03 | 03
04 | 04
05 | 05
06 | 06
07 | 07 AESTTMHR AESTDTC Start Time (Hours)

Form Properties

Name: Adverse Event

OID: 9e8e8f2d-846d-4940-ad04-4ee3abbff8e2:09178603-dac9-43d6-880f-fceb0da30cbe

Repeating: false

Item Groups:

Items: 55

Required: false

History

Updated At: 04-Oct-2016 07:42am (Deb.Copeland@parexel.com)

Created At: 04-Oct-2016 07:42am (Deb.Copeland@parexel.com)

Sources

CM_MCC_TEST v1

Demo2_MCC v1

Hubs (116) Forms (3) Value Sets (60) Edit check Reporting variable (116) Analysis variable (177)

© 2014-2016 Sycamore Informatics. All rights reserved.
Conditions of Use Privacy Policy Customer Care MDR 2.1.2.5v55

Hub to Spoke (Concept to Variable Representation) Mapping

MDR Edit Import Export Logs Actions Show

STANDARDS_DEMO v1

INCOMPLETE Recommend Retire Supersede 0 Subscribe

Show Mappings

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

Item: STANDARDS_DEMO v1 > Adverse Event > Repeating > AESEV **CDASH**

AESEV* string

Variable: STANDARDS_DEMO v1 > Reporting variable > AE > AESEV **SDTM**

26	AESEV	Severity/Intensity	Char	Perm	The severity or intensity of the event. Examples: MILD, MODERATE, SEVERE.
----	-------	--------------------	------	------	--

Variable: STANDARDS_DEMO v1 > Analysis variable > ADAE > SEVGRYN **ADaM**

61	SEVGRYN	Pooled Severity Group y (N)	Num	Perm	Code SEVGRy to numeric Low intensity should correspond to low value
----	---------	-----------------------------	-----	------	---

Variable: STANDARDS_DEMO v1 > Analysis variable > ADAE > AESEV

56	AESEV	Severity/Intensity	Char	AESEV	Perm	AE.AESEV
----	-------	--------------------	------	-------	------	----------

Variable: STANDARDS_DEMO v1 > Analysis variable > ADAE > AESEVN

57	AESEVN	Severity/Intensity (N)	Num	Numeric AESEV	Perm	Code AESEV to numeric Low intensity should correspond to low value
----	--------	------------------------	-----	---------------	------	--

Hubs (122) Forms (4) Value Sets (60) Method Definitions Edit check Analysis variable (177) Reporting variable (148)

Mapping for variable Analysis variable AE.AESEV

Representations Concept to ADaM Create Mapping

Source: Concept

NAME	VARIABLE	LABEL	TYPE
STANDARDS_DEMO	Adverse Events.SEV		ordinalCD

Destination: ADaM

NAME	VARIABLE	LABEL	TYPE	ORIGIN	ATTRIBUTE
AE	SEVGRYN	Pooled Severity Group y (N)	Num		item.code.value
AE	AESEV	Severity/Intensity	Char		item.displayName
AE	AESEVN	Severity/Intensity (N)	Num		item.code.value

Description:

Old: Adverse Events.SEV

History

Updated At:

31-Oct-2016 03:15pm (deb.copeland@parexel.com)

Created At:

31-Oct-2016 10:30am (deb.copeland@parexel.com)

Sources

DM_MCC_TEST v1

PAREXEL_MCC_AECMVS.xlsx

Actions

Version History

Impact Analysis

© 2014-<%= Date.today.year %> Sycamore Informatics Inc. All rights reserved.
Conditions of Use - Privacy Policy - Customer Care - MDR 2.2.3.0v119

End to End metadata from standards are imported into each study instance metadata Object (SIM)

- MCC Standard

The screenshot shows the 'LIBRARY COMBINED v2' interface. The top navigation bar includes 'MDR', 'Export', 'Logs', 'Show/Compare', 'Actions', and 'Show'. A search bar is on the right. Below the title, there are tabs for 'STANDARD', 'Back To Qualified', 'Back To Recorded', 'Back To Candidate', 'Retire', 'Supersede', 'Create New Version', and 'Subscribe'. A 'Tab Status - Standard' dropdown and 'Forms(3)' are also visible. The main content area has a horizontal list of tabs: 'Hubs (116)', 'Forms (3)', 'Value Sets (60)', 'Method Definitions', 'Edit check', 'Analysis variable (177)', and 'Reporting variable (116)'. Red arrows point from these tabs down to the corresponding tabs in the SIM interface below.

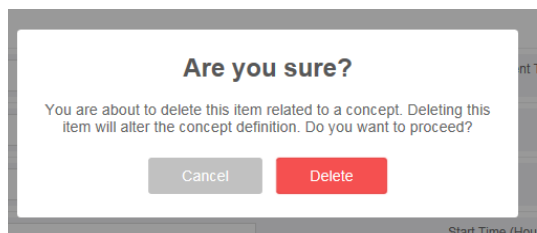
- SIM

The screenshot shows the 'SIM_COMBINED_new' interface. The top navigation bar includes 'MDR', 'Edit', 'Import', 'Export', 'Logs', 'Show/Compare', 'Search/Add', 'Actions', and 'Show'. A search bar is on the right, along with a notification bell showing '8171' and a user icon. Below the title, there are tabs for 'INCOMPLETE', 'Recommend', 'Retire', 'Supersede', and 'Unsubscribe'. A 'Tab Status - Incomplete' dropdown and 'Forms(3)' are also visible. The main content area has a horizontal list of tabs: 'Hubs (116)', 'Forms (3)', 'Value Sets (60)', 'Method Definitions', 'Edit check', 'Analysis variable (177)', and 'Reporting variable (116)'. Red arrows point from these tabs down to the corresponding tabs in the SIM interface below.

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

AESDISAB	N No NA Not Applicable U Unknown Y Yes	(No Yes Response)	Did the Adverse Event result in Persistent or Significant Disability or Incapacity?
AESDTH	N No Y Yes	(No Yes Response (NY))	Did the adverse event result in death?
AESDTH	N No NA Not Applicable U Unknown Y Yes	(No Yes Response)	Did the adverse event result in death?
AESHOSP	N No	(No Yes Response)	Did the adverse event result in initial or

Comparison to Source

MDR								
Comparison Report								
Standard: SIM_COMBINED_new v1 Compared to: Source Source Standard(s): LIBRARY COMBINED v2								
CHANGE	LEVEL	FORM	IDENTIFIER	ATTRIBUTE CHANGED	OLD VALUE	NEW VALUE	UPDATED BY	DATE/TIME OF CHANGE
Delete	Item	Adverse Event	AESPID (LIBRARY COMBINED v2)				deb.copeland@parexel.com	14-Mar-2017 06:40am
Update	Item	Adverse Event	AESDTH (LIBRARY COMBINED v2)	Value Set	No Yes Response	No Yes Response (NY)	deb.copeland@parexel.com	14-Mar-2017 06:42am
Update	Item	Adverse Event	AESDTH (LIBRARY COMBINED v2)	required	true	false	deb.copeland@parexel.com	14-Mar-2017 06:42am

Comparison to Standard

MDR

Edit

Import

Export

Logs

Search

6182

SIM_COMBINED_new

v1

Standard for SIM_COMBINED_new

INCOMPLETE

LIBRARY COMBINED

v1

LIBRARY COMBINED

RETIRED

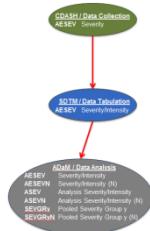
Compared with

	Y Yes			
<div><div></div><div>A</div></div> <div>AESDTH</div>	<div>N No</div> <div>Y Yes</div>	<div>(No Yes Response (NY))</div>	<div>Did the adverse event result in death?</div>	<div>Concept -> Form:</div> <div>Adverse Events.SDTH</div>
<div><div></div><div>B</div></div> <div>AESDTH</div>	<div>N No</div> <div>NA Not Applicable</div> <div>U Unknown</div> <div>Y Yes</div>	<div>(No Yes Response)</div>	<div>Did the adverse event result in death?</div>	<div>Concept -> Form:</div> <div>Adverse Events.SDTH</div>
<div>AESHOSP</div>	<div>N No</div>	<div>(No Yes Response)</div>	<div>Did the adverse event result in initial or</div>	<div>Concept -> Form:</div>

Benefits and Conclusion

INDEPENDENTLY MAINTAINED STANDARDS

MANUAL MAPPING



FLEXIBILITY

STEPPED APPROACH

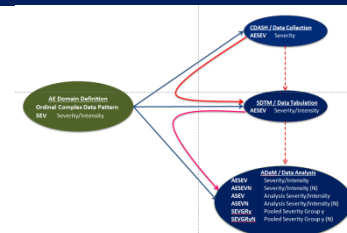
MAPPING INCONSISTENCIES

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

Q&A



CDISC Online Education & Event Updates

John Ezzell, CDISC



Strength *through Collaboration*

Standard currently out for review

- Duchenne Muscular Dystrophy v1.0
 - Comments Due by: 6 Jul 2017

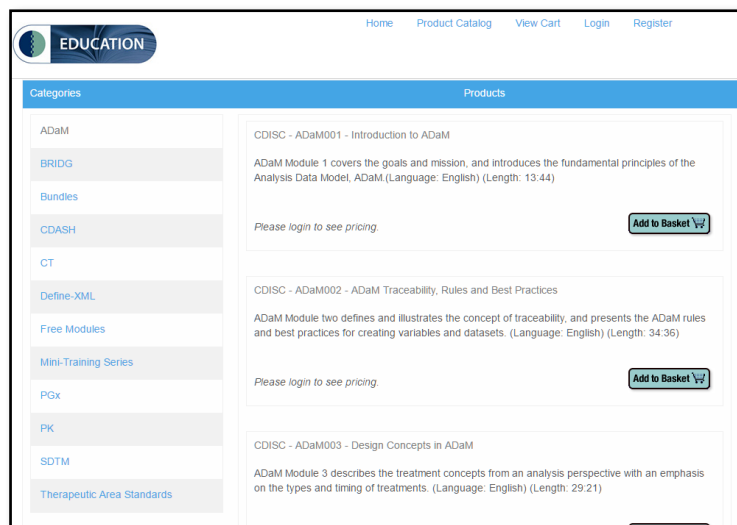
Upcoming Webinars

Topics	Presenters	Webinar Date
Colorectal Cancer TA User Guide Public Review	Colorectal Therapeutic User Guide Development Team	30 MAY 2017, 11:00 AM EST
Duchenne Muscular Dystrophy TA Public Review	Duchenne Muscular Dystrophy Therapeutic Area User Guide Development Team	1 JUN 2017, 11:00 AM EST
Governance for Data Capture Standards Members Only Mini-Training	Gary Walker, Associate Director, Quintiles Michael Ward, Data Standards Consultant, Eli Lilly Melissa Binz, Study Data Management, Pfizer Judy Tran, Medidata Solutions	15 JUN 2017, 11:00 AM EST

Webinar details and registration at 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
TA Rheumatoid Arthritis
TA Malaria
CT Module 1 (Japanese Language Version)
CT Module 2
Define XML Module 2
ADaM Modules 7-9

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.

Variables available for drag:

- SITEGRY: pooled group of sites used for analysis
- USUBJID: unique subject identifier
- AGEGRY: pooled age group
- REGIONY: pooled groups of sites into geographic regions
- AGE and AGEU
- SITEID: unique site identifier
- RACE
- SUBJID: subject identifier used within study
- RACEGRY: pooled race group
- STUDYID: study identifier

Target barrels:

- Required or Conditionally Required variables
- Permissible variables

CDISC © CDISC 2016 Submit

UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends:	Late fees kick(ed) in:	Host
Toronto, ON	5-9 Jun 2017	SDTM, CDASH	6 Mar 2017	5 May 2017	 McDOUGALL SCIENTIFIC INSIGHTS YOU CAN TRUST
Whippany, NJ	17-21 Jul 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	18 Apr 2017	18 Jun 2017	 BAYER Bayer HealthCare
Seattle, WA	25-29 Sep 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	26 Jun 2017	26 Aug 2017	 Axio PARTNERS IN RESEARCH
Austin, TX	13-17 Nov 2017	CDISC Standards from the Start, CDASH, SDTM, SEND, ADaM, Define-XML more...	31 Aug 2017	3 Nov 2017	 CDISC

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends:	Late fees kick(ed) in:	Host
Frankfurt, Germany	19-23 Jun 2017	SDTM, CDASH, Define-XML, ADaM Primer, ADaM T&A	20 Mar 2017	20 May 2017	
Leiden, Netherlands	11-15 Sep 2017	SDTM, CDASH, Define-XML, ADaM Primer, ADaM T&A	12 Jun 2017	13 Aug 2017	
Copenhagen, Denmark	2-10 Nov 2017	SEND, SDTM, ADaM Primer, ADaM T&A, Define-XML	2 Aug 2017	3 Oct 2017	

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Discount period ends:	Late fees kick(ed) in:	Host
Tokyo, Japan	5-9 Jun 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML, ODM	14 Jun	5 May	
Beijing, China	18-20 Sep	SDTM, CDASH, ADaM Primer, ADaM T&A, ODM, Define-XML	TBD	TBD	TBD

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

Any more questions?

Thank you for attending this webinar.

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



Strength *through collaboration.*

CDISC Members Drive Global Standards

Thank you for your support!



Learn CDISC from CDISC!
Authoritative. Global. Vendor neutral.