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

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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

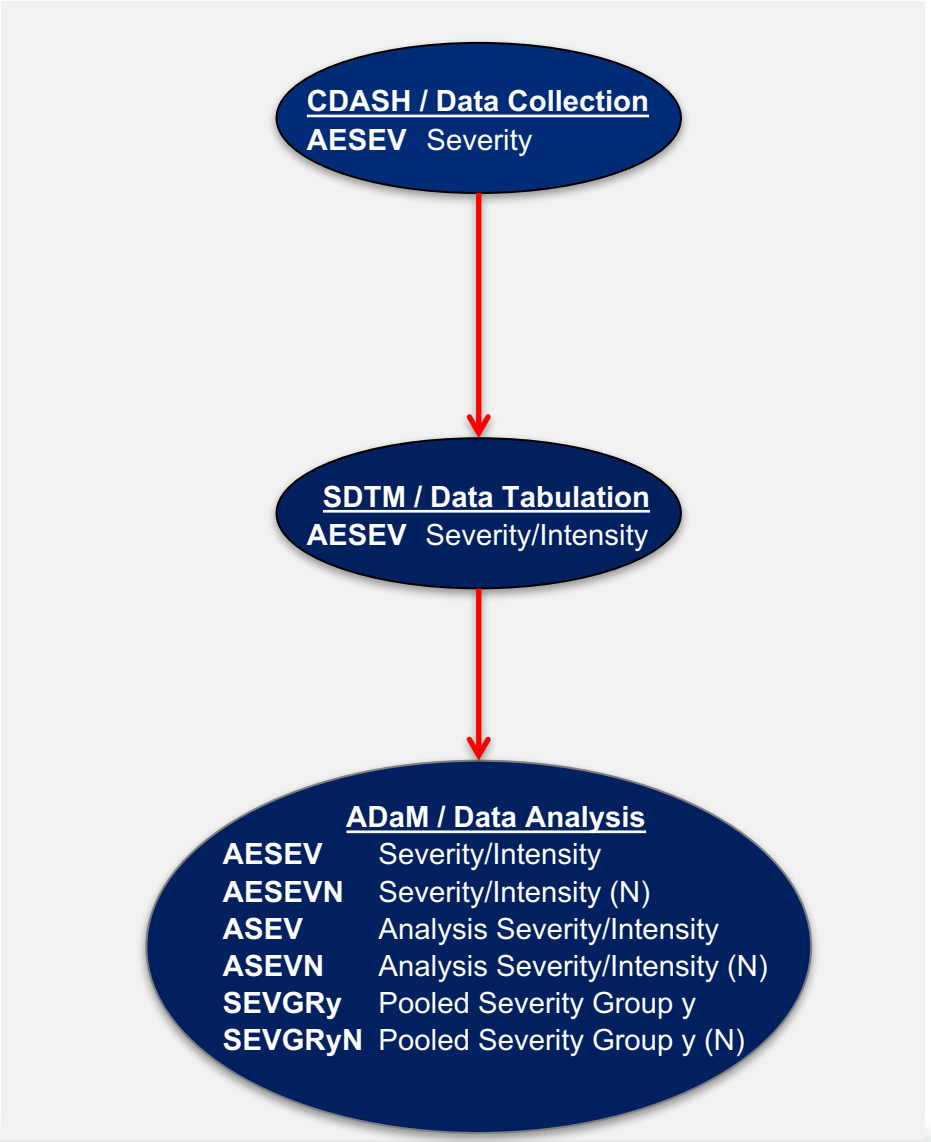
When a data collection form is designed we can know how it will impact the tabulation and analysis data

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

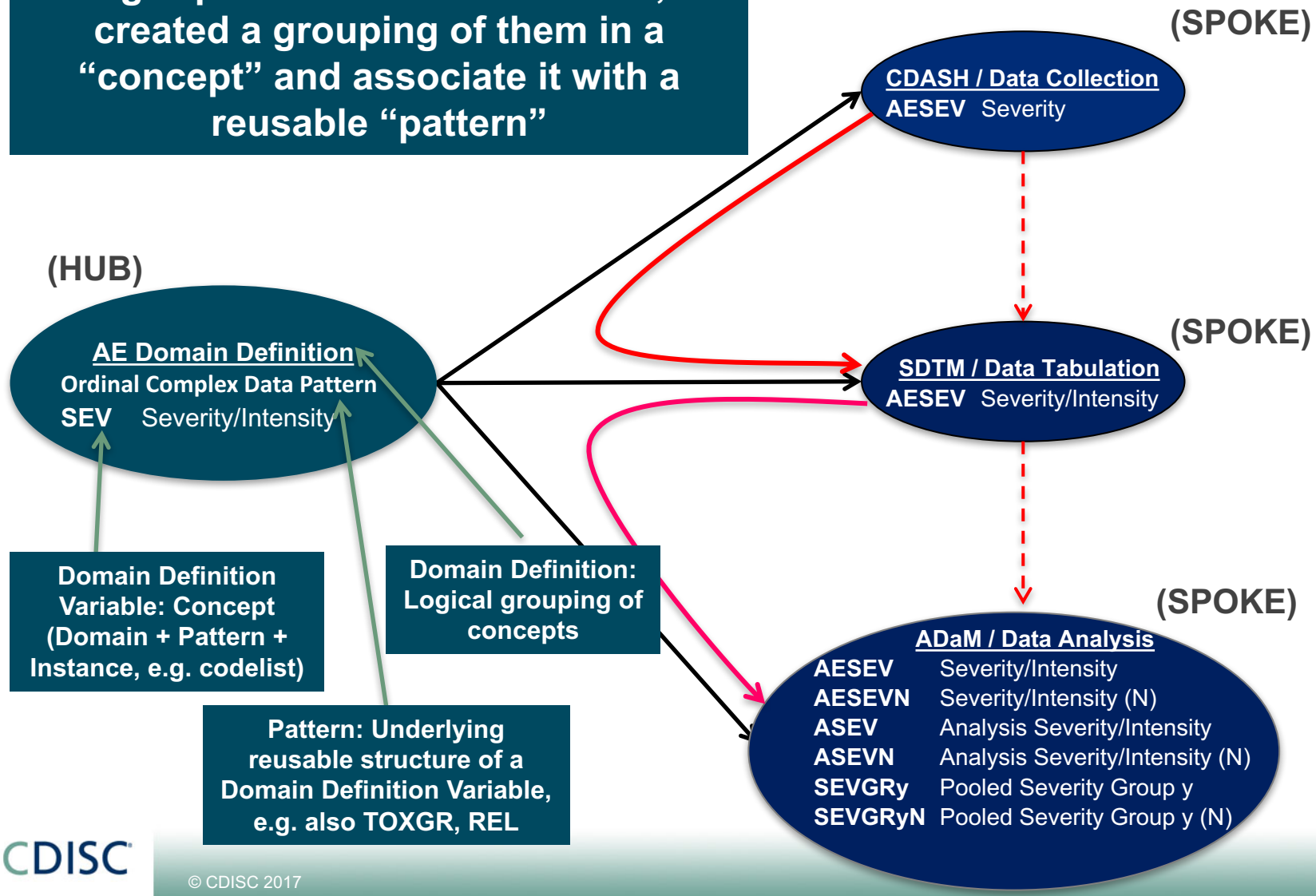
Example: Severity Concept in Adverse events

- 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

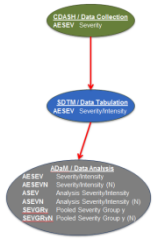
After identifying the different unique "things" present in the AE module, we created a grouping of them in a "concept" and associate it with a reusable "pattern"



Benefits and Conclusion

INDEPENDENTLY MAINTAINED STANDARDS

MANUAL MAPPING



FLEXIBILITY

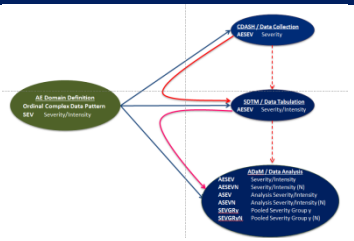
STEPPED APPROACH

MAPPING INCONSISTENCIES

WORKLOAD TO GENERATE HIGH QUALITY E2E LINEAGE

CONCEPT LINKED STANDARDS

REUSABLE TEMPLATES



CONSISTENCY

INCREASED QUALITY

INCREASED EFFICIENCY

DEFINITIONS OF PATTERNS

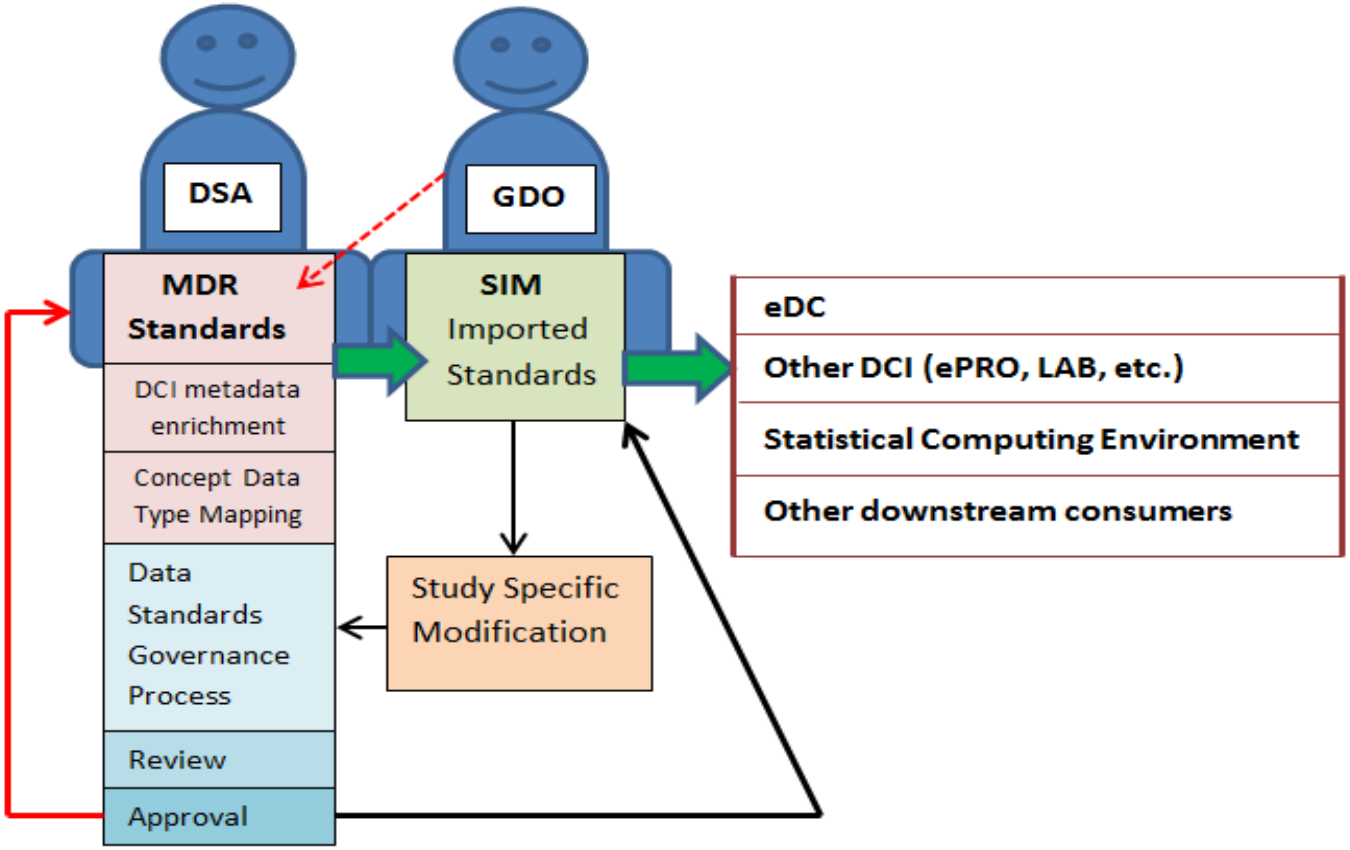
PROCESS CHANGE

MDR TOOL REQUIREMENT

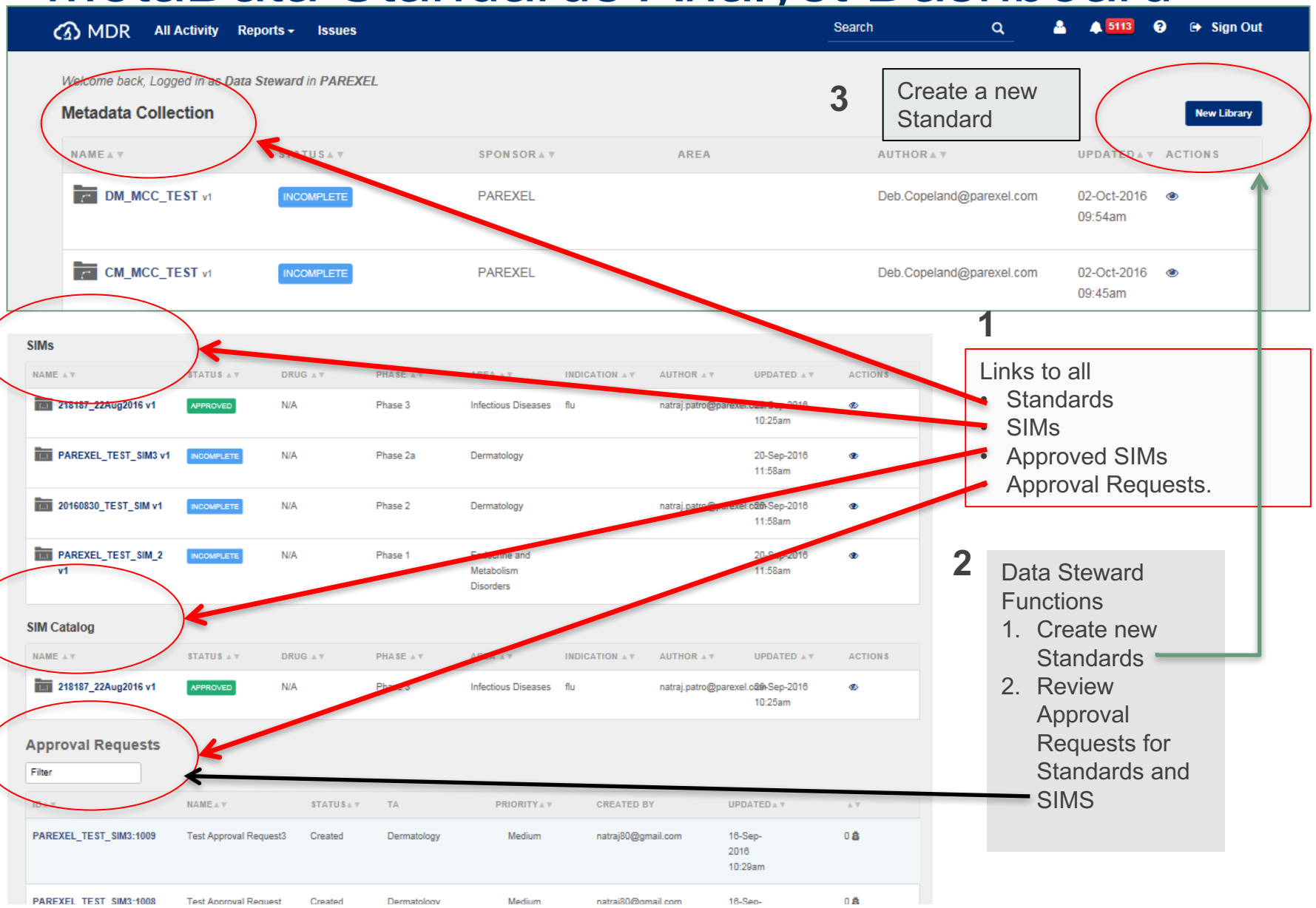
Glossary

- 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

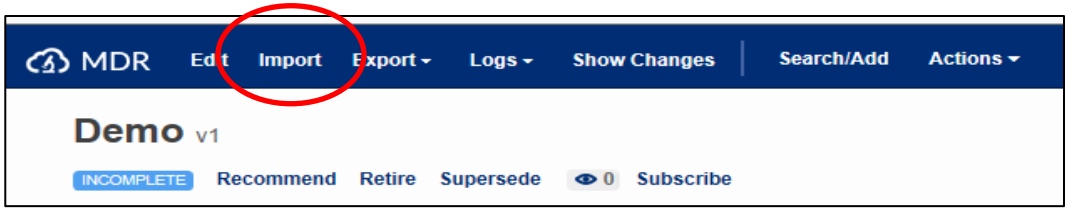
MDR and Data Standards Roles and Process Flow



MetaData Standards Analyst Dashboard

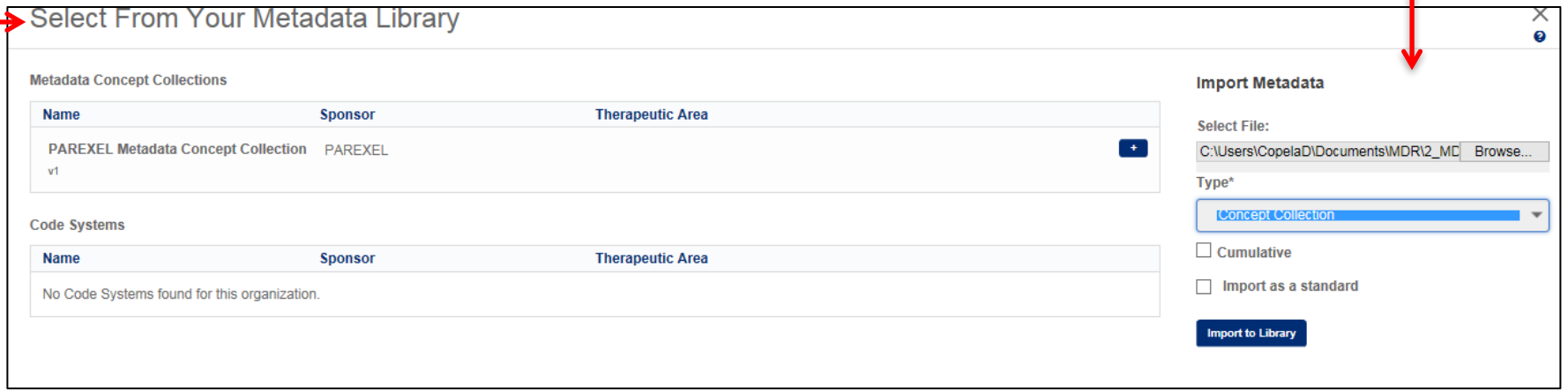


Populating Metadata content in the MDR



Allows Import of metadata standards from:

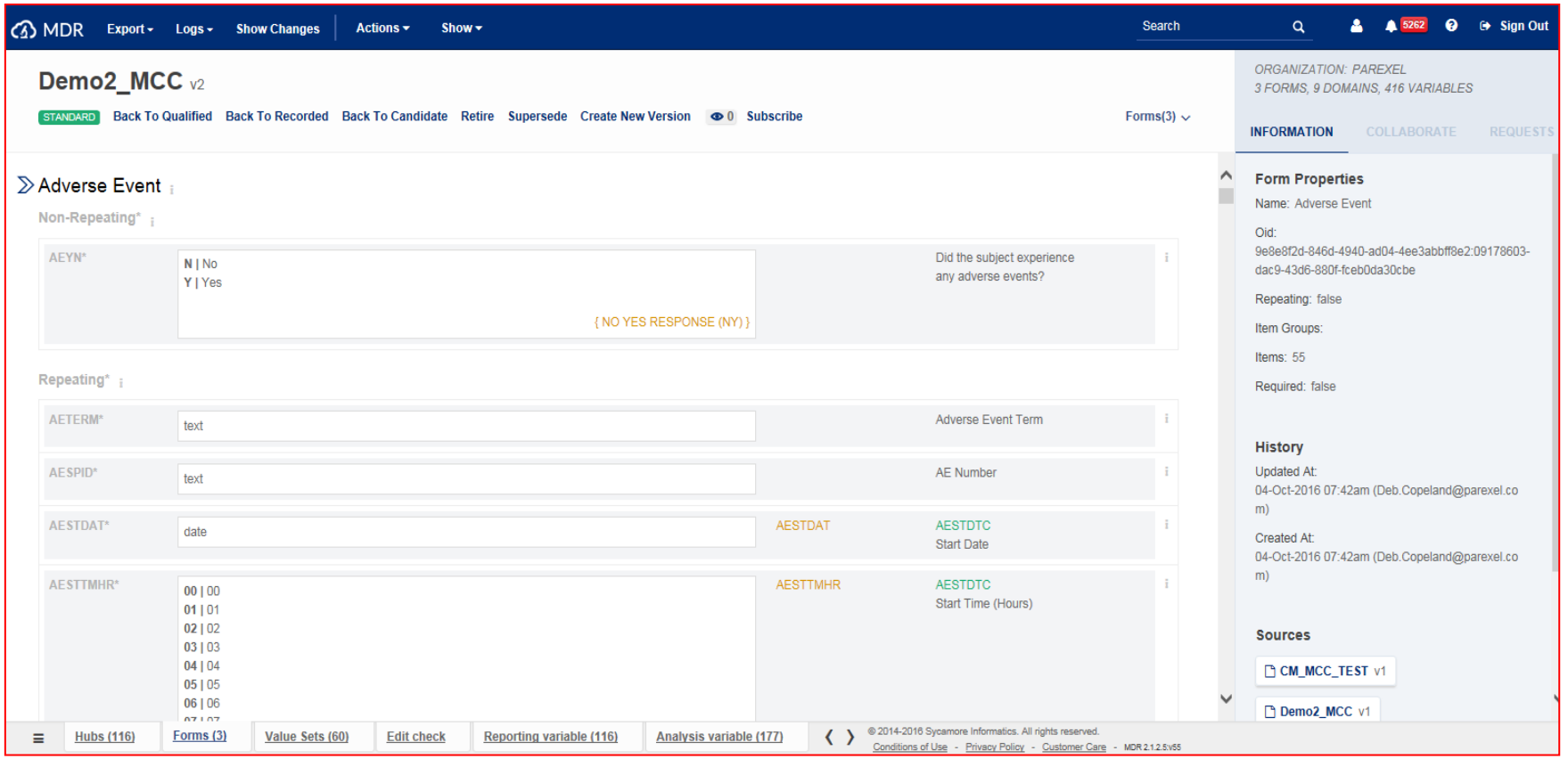
- External Source - NCI controlled terminology, CDISC, Metadata spreadsheet template
- Copy from existing standard or SIM – one already in the MDR



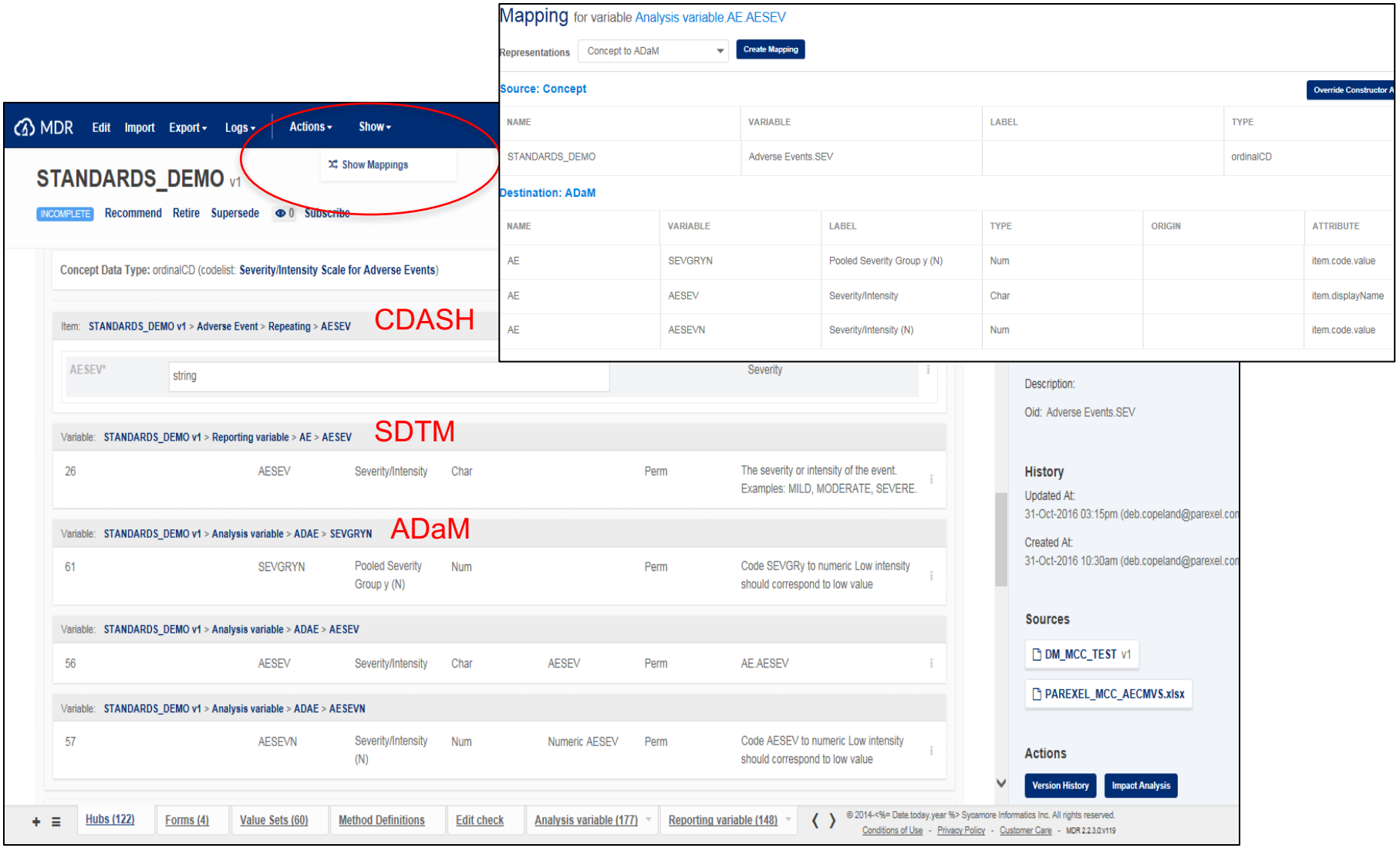
- Build metadata content via the user interface

MDR Display of Metadata Standards Content

Metadata Content: Concept Hubs Spokes: Forms with Value Sets
Reporting variables (SDTM)
Analysis Variables (ADaM)

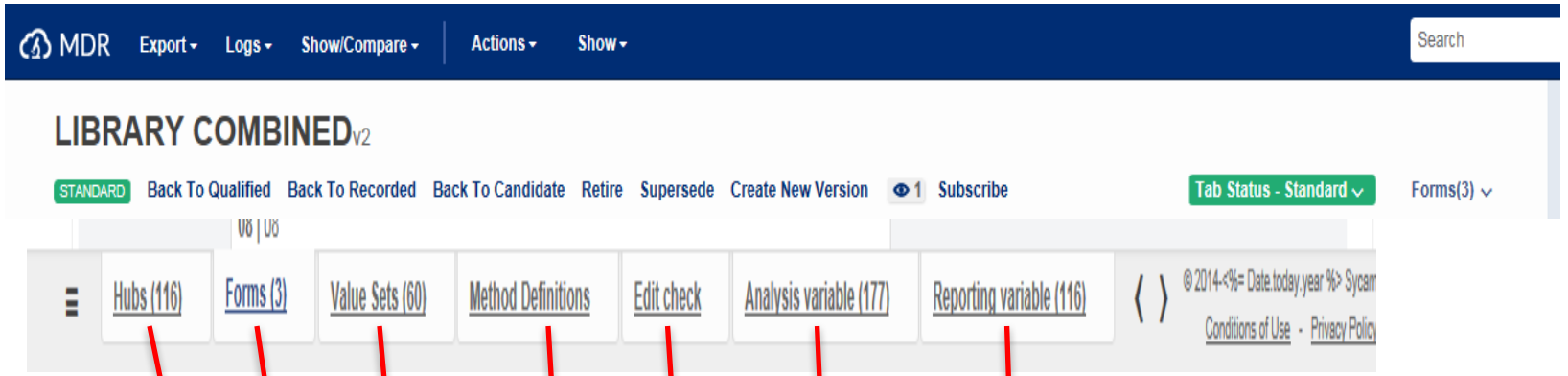


Hub to Spoke (Concept to Variable Representation) Mapping



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

- MCC Standard

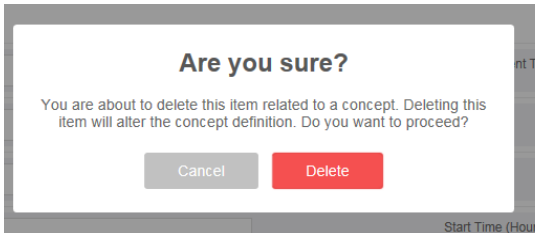


- SIM

MDR facilitated SIM Review

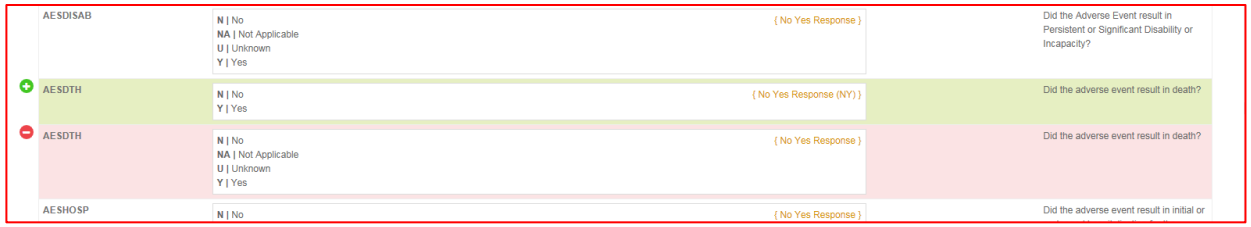
All SIMS undergo Data Standards review and approval process

MDR alerts when required standards are being altered

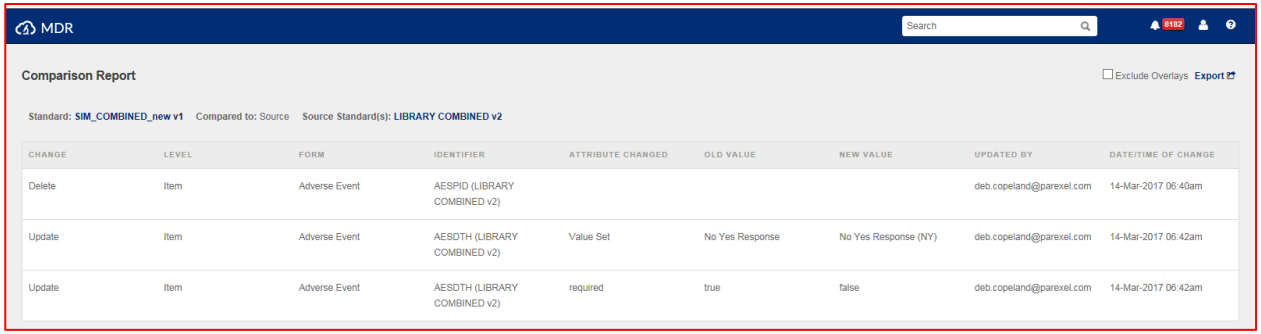


MDR Standards Comparison tools

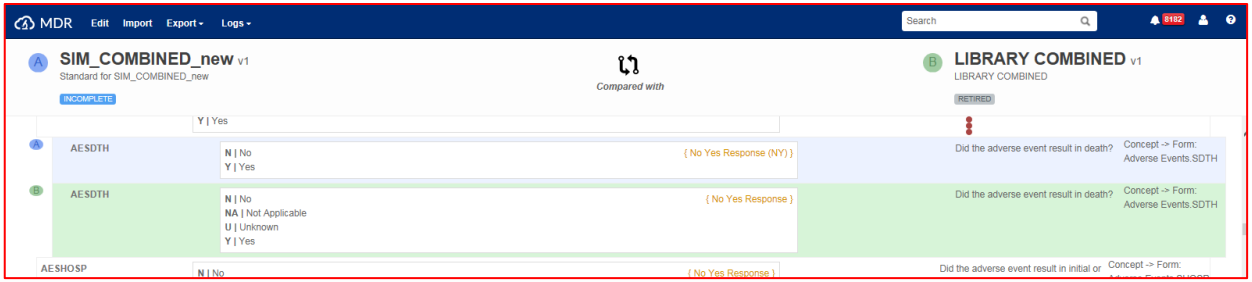
Show changes



Comparison to Source



Comparison to Standard



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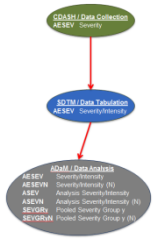

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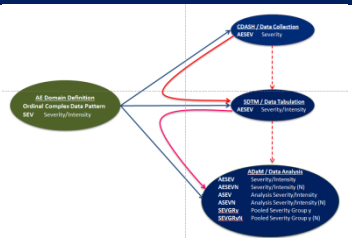


CONSISTENCY

INCREASED QUALITY

INCREASED EFFICIENCY

- ✓ **DEFINITIONS OF PATTERNS**
- ✓ **PROCESS CHANGE**
- ✓ **MDR TOOL REQUIREMENT**

THANK YOU

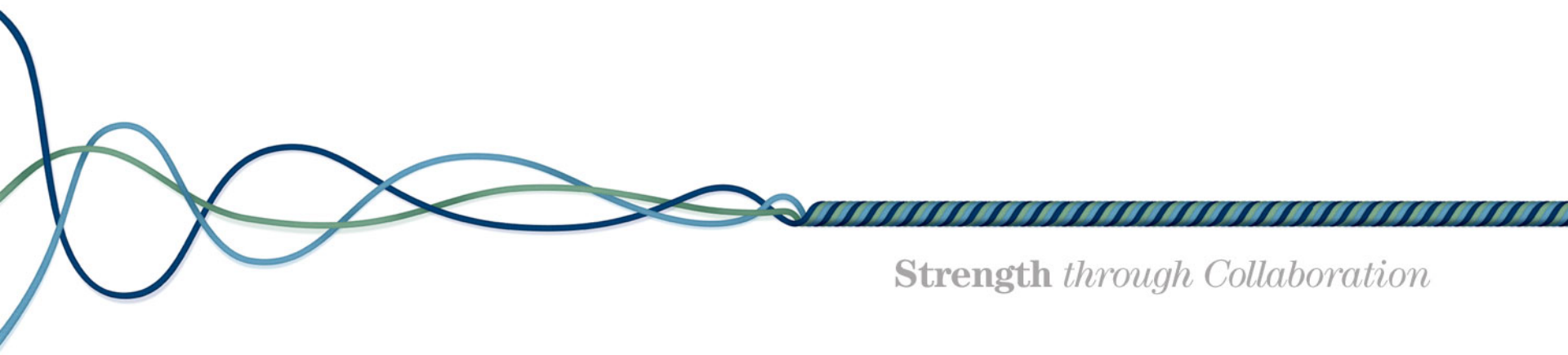
Questions?

Julius Kusserow
Alan Cantrell
Deb Copeland

Q&A

CDISC Online Education & Event Updates

John Ezzell, CDISC



Standard currently out for review

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

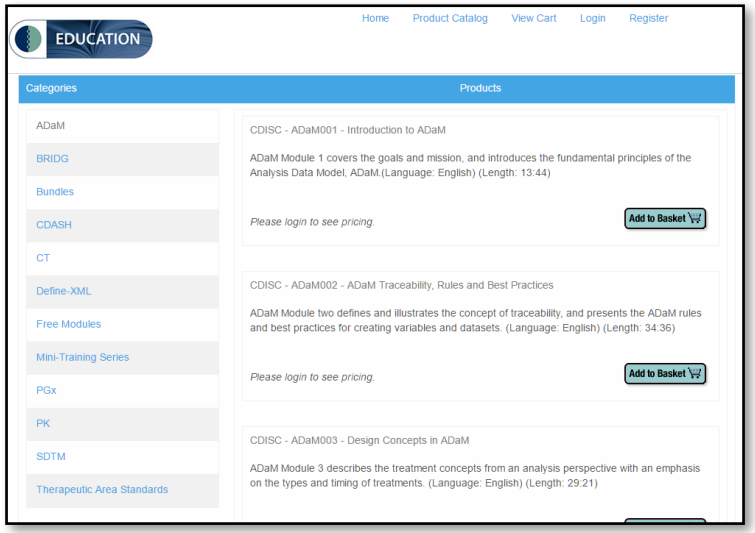
Upcoming Webinars

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

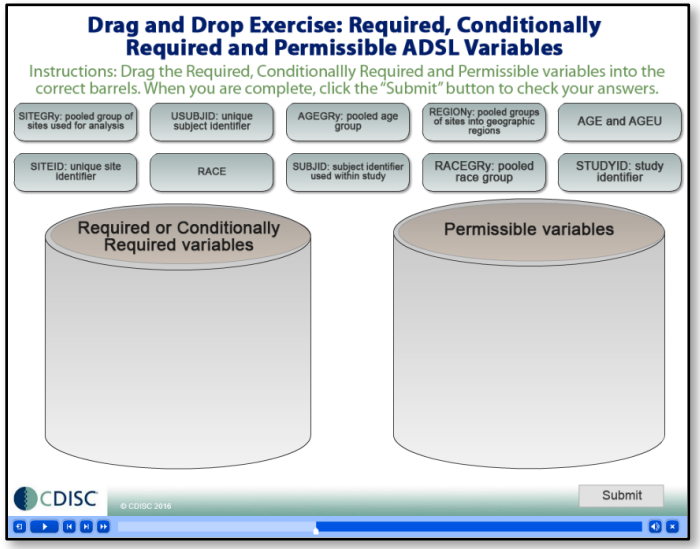


Visit cdisc.trainingcampus.net for more information!

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



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
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

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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	CLINIPACE WORLDWIDE
Leiden, Netherlands	11-15 Sep 2017	SDTM, CDASH, Define-XML, ADaM Primer, ADaM T&A	12 Jun 2017	13 Aug 2017	OCS Consulting
Copenhagen, Denmark	2-10 Nov 2017	SEND, SDTM, ADaM Primer, ADaM T&A, Define-XML	2 Aug 2017	3 Oct 2017	SCUBED

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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	Croit
Beijing, China	18-20 Sep	SDTM, CDASH, ADaM Primer, ADaM T&A, ODM, Define-XML	TBD	TBD	TBD

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Any more questions?

Thank you for attending this webinar.

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Inform Patient Care & Safety Through Higher Quality Medical Research

CDISC Members Drive Global Standards

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