

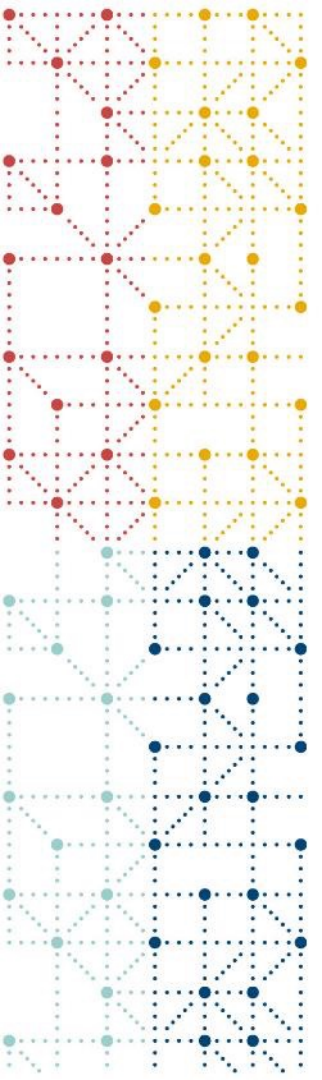


Current and Future Landscape of Analysis Related Metadata in CDISC Library

Presented by Anthony Chow
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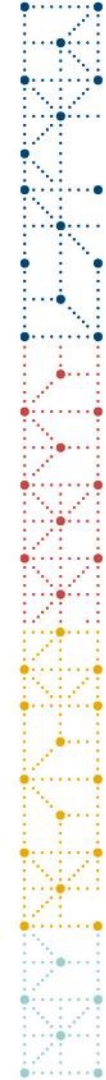
21 May 2021





Agenda

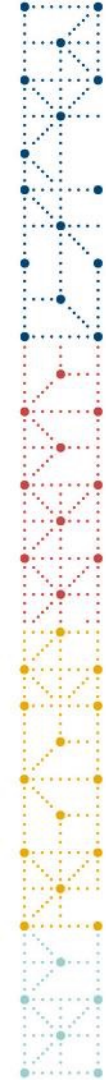
1. What's Available Today
2. ADaM Related Projects
3. Missing Links & Opportunities



Analysis Metadata ~ Now

Content types

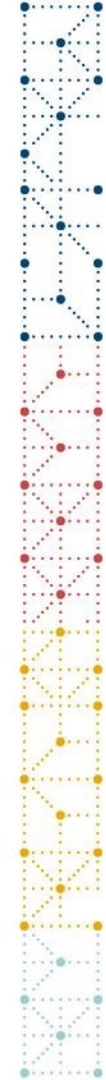
- Normative metadata tables
- Endpoints for the hierarchical patterns
- GET a catalog, e.g., `/mdr/products/Analysis`
- GET a standard, e.g., `/mdr/adam/adam-occds-1-0`
- GET data structures, e.g., `/mdr/adam/adamig-1-2/dataStructures`
- GET variables, e.g., `/mdr/adam/adam/dataStructures/BDS/variables`



Major Adverse Cardiovascular Events (MACE+)

Comprises of

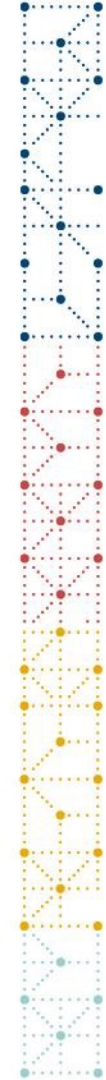
- Concept map
- Codelist subsets
- Derivation logic
- Data lineage: AETRTEM's predecessor: SUPPAE.QNAM EQ "AETRTEM"
- Specialization: OCCDS: ADAE for MACE+



Safety User Guide

Goals

- Standardize statistical outputs such as TLFs through standardizing statistical analysis and tabulation datasets
- Data domain of interest: AE, Lab, Vitals, ECG, ConMeds, etc.
- Disease-specific safety from TAUG
- eDT standards, e.g., CDISC LAB data exchange standard
- Make E2E perspective more clearly: eCRF > SDTM > Analysis > Analysis Results
- Most commonly performed safety analyses, e.g., Drug induced liver injury (DILI), MACE+ (in phases)



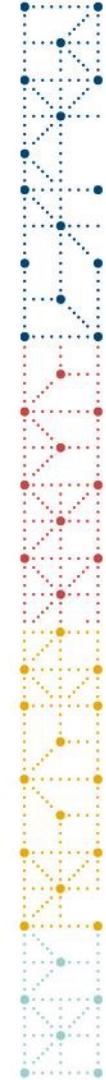
Analysis Results Standard

Goals

- Co-develop with Safety User Guide, e.g., select common safety TLF
- Address automation in generating TLF, and repeatability
- Create metadata to precisely describe each region of a display, e.g.,

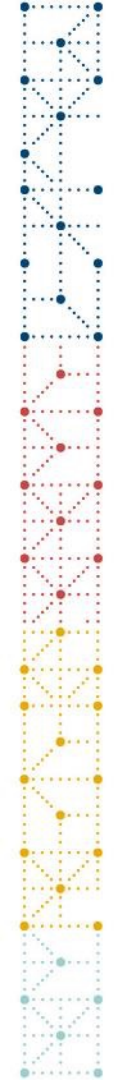
Expand on arm:AnalysisResultDisplays

- Controlled terminology



Basic Premise: Solutions Over Specifications

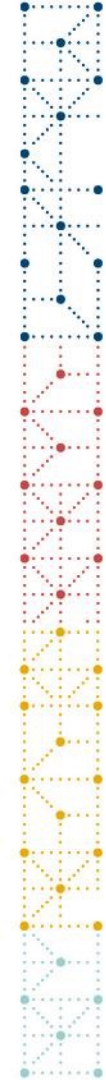
- Standards implementers want solutions to their data processing needs
 - Reduce reliance on standards experts
- Embed standards knowledge in software tools to create solutions
 - Software tools can make CDISC standards implementations easier and more consistent
- CDISC seeks to lower barriers to software tool development
 - Make it simpler to build software that automates standards-based processes



Missing Links

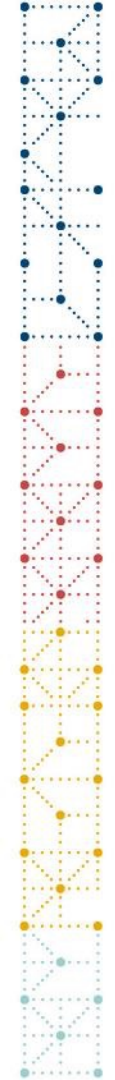
Machine-Readable Metadata

- Data lineage from SDTM, e.g., mapping & derivation
- Analysis section in Therapeutic Areas User Guide
- Codelist subsets
- SuppQuals
- Strong datatyping
- ADQRS



Opportunities

- Explicit metadata
 - Avoid overloading
 - Clear relationships
 - Machine-readable
- ODM extensions
 - arm:
 - library:
- Address standards fragmentation
 - CDISC Library brings them back all and show how they are related
 - Build standards with E2E in mind



Opportunities (Con't)

- Biomedical Concepts
 - Conceptual + Implementation
 - FHIR resources
 - LOINC resources
 - VLM compatible
- For standards vs. for studies
 - Normative vs. informative.
 - Version agnostic vs. version-specific.



Thank You!

