

CDISC SHARE Requirements Workshop

PhUSE SDE

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Strength *through Collaboration*

Consider: categories of standards metadata available in SHARE

Categories of Standards Metadata Content in SHARE	
1. Existing Metadata	2. Metadata Gaps
3. New Formats	4. New Technology
5. New Standards Content	6. Semantics
7. Normative + Non-normative	8. Bundles or Packages
9. Computable Rules	10. Examples & Test data
11. Healthcare Alignment	12. Federated MDRs
13. New Reports	14. Relationships
15. Models	

Consider: possible automation use cases

- EDC Development
 - eCRF & edit check specifications
 - Blank CRF
 - Team review and approval
 - EDC system generation
- SDTM Dataset Generation
 - SDTM Annotated CRF
 - Derivations
 - Value Level Metadata
 - Metadata-driven programs to generate datasets
 - Validation
 - Define.xml

Consider: current challenges with the CDISC standards

- CDASH
 - User interface vs data extract
 - Model for adding domains
 - Terminology sources
 - Mappings to/from SDTM
- Terminologies
 - Unique identifiers/keys
 - Change requests
 - Sponsor/CRO implementations
 - Release timing
 - External terminology sources

Starter Questions

- How do you want to see terminologies released (e.g., by terminology, bundled, etc.)?
- How should value-level metadata be bundled for use by industry?
- How do you intend to consume the metadata?
- Is continued packaging by standard sufficient or is something different needed?

Starter Questions

- What additional metadata is needed for eCRF generation (in general and/or from the standards)?
- When new versions come out, do you only want diff files or full versions?
- What metadata is missing between EDC specifications and SDTM (e.g., raw output in different formats from different vendors)?
 - When/how do you map from that to SDTM?
 - Would ODM export make it more consistent rather than using vendor proprietary extract formats?

Thanks!





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