How to Assess the Quality of your eCRF Library

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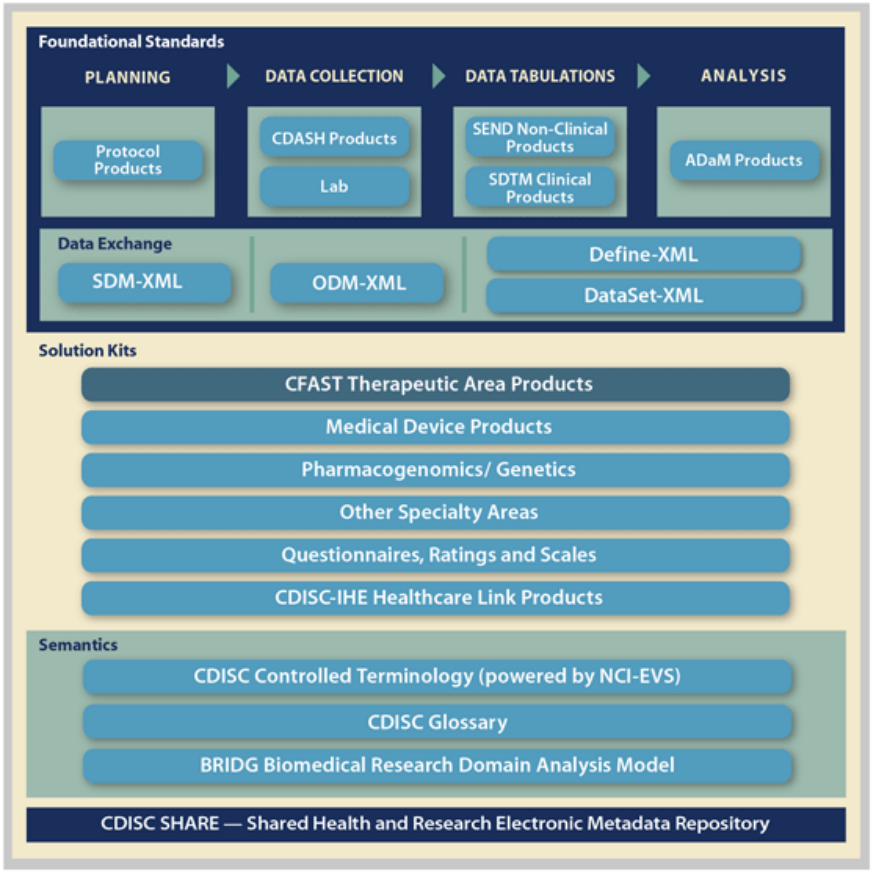
Introduction

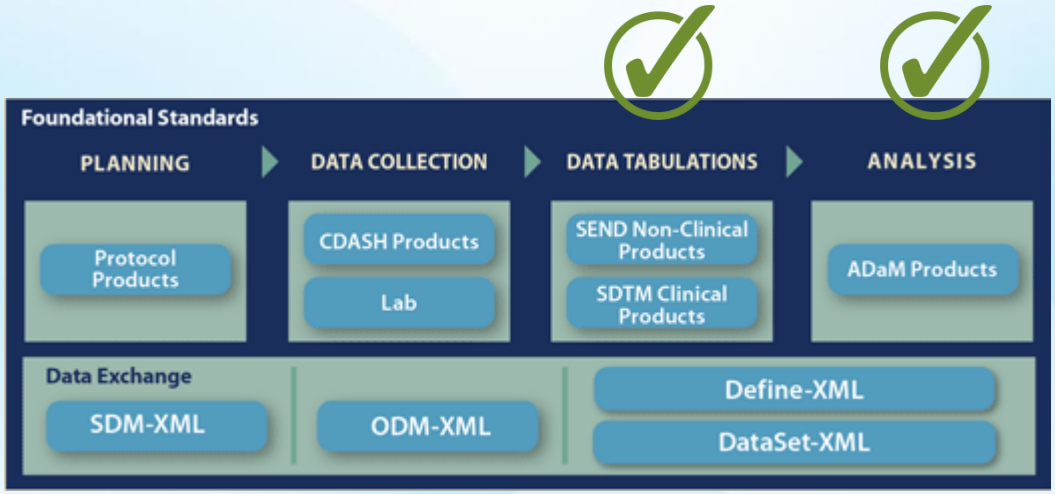
- CDISC standards are rapidly expanding and evolving
- Efficient Data Governance is required
  - Data should be standardized by default
  - Need for upfront CDISC implementation at each step of the clinical study
  - Proper tools are a necessity



http://www.cdisc.org/standards-and-implementations

Electronic Compliance Checking

- Well-established for SDTM/ADaM/Define.xml
  - Readily available
  - Objective quality assessment

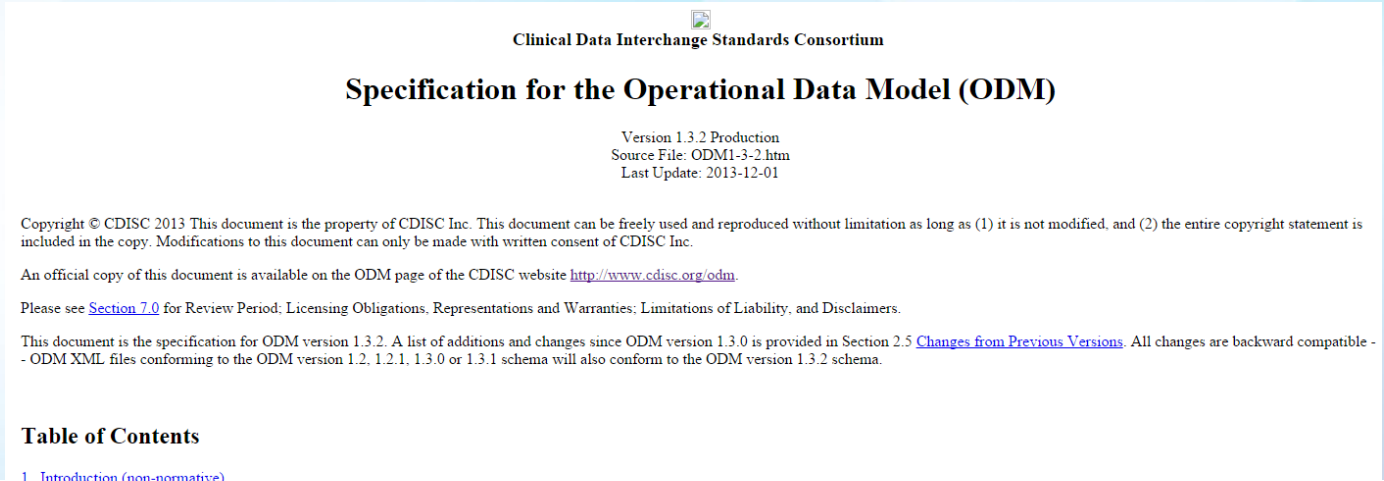


- How to electronically verify a CRF?
  - Wait until there is (dummy) SDTM data available?
  - Retrospective correction of issues?

ODM-XML

- **O**perational **D**ata **M**odel
- Contains CRF definitions
- Platform-independent
- XML = machine-readable + human-readable
- Backbone of all other CDISC XML structures

http://www.cdisc.org/odm



Clinical Data Interchange Standards Consortium

Specification for the Operational Data Model (ODM)

Version 1.3.2 Production
Source File: ODM1-3-2.htm
Last Update: 2013-12-01

An official copy of this document is available on the ODM page of the CDISC website http://www.cdisc.org/odm.

Please see Section 7.0 for Review Period; Licensing Obligations, Representations and Warranties; Limitations of Liability, and Disclaimers.

This document is the specification for ODM version 1.3.2. A list of additions and changes since ODM version 1.3.0 is provided in Section 2.5 Changes from Previous Versions. All changes are backward compatible -- ODM XML files conforming to the ODM version 1.2, 1.2.1, 1.3.0 or 1.3.1 schema will also conform to the ODM version 1.3.2 schema.

Table of Contents

1 Introduction (non-normative)

CDASH

- **C**linical **D**ata **A**cquisition **S**tandards **H**armonization
- Lists best practices and recommendations
- CDASH allows for a smooth conversion from collected data to SDTM
- CDASH vs CDASH UG

http://www.cdisc.org/cdash

CDASH Conformance (Tier 1)

CDASH v1.1:

- All HR and R/C common identifiers and timing vars should be present
- Available CDISC terminology should be used
- Best practice recommendations in section 3.4 of CDASH v1.1 should be followed
- CDASH question text or prompt should be used

http://www.cdisc.org/cdash

CDASH Conformance (Tier 2)

CDASH UG v1:

- All Level 1 conformances are met.
- All data collection fields follow CDASH naming conventions
- All non-CDASH Variable Names in CRFs follow CDASH recommendations for Creating Fields That Do Not Exist in CDASH
- All Best Practice recommendations in Section 3 of CDASH V1.1 are followed

http://www.cdisc.org/cdash

CDASH Hurdles

- CDASH allows for variability
  - Dataset names
  - Variable names
  - Question texts
  - Normalized vs de-normalized scenarios
  - Proprietary data structures
- A single CDASH dataset maps back to different ODM itemgroups
- SDTM domains not (yet) covered by CDASH

Programming Language

- XML Processing has become easy
  - Readily available for many Object Oriented languages
  - Widely supported XML Navigation tools (Xpath, Gpath,…)
  - Boilerplate code has been reduced drastically

    E.g., Groovy (http://www.groovy-lang.org)
  - Well documented tutorials

- Reading ODM.xml and Define.xml is no longer a time-consuming programming effort

Simple eCRF Checker

- Electronic verification
  - Check that all HR and R/C variables are present
  - Check that Controlled Terminology is respected
  - Check if the Question text is conformant
  - Check if the Question prompt is conformant
  - Domain-specific best practices
  - …
- Not everything can be (easily) electronically verified yet

Example eCRF Check Report

	A	B	C	
1	**Domain**	**Variable**	**Issue**	**Name**
2	Adverse Events	AEACN	Value in attached codelist is outside of non-extensible CDISC terminology	Value
3	Adverse Events	AESTDAT	Question text mismatch	CRF Qu
4	Adverse Events	AENY	Variable is not defined in CDASH and/or SDTM	
5	Adverse Events	AESTTIM	Recommended/Conditional variable is missing	

- Reports should be clear
- Reports should be carefully evaluated
  - <<no issues detected>> does not mean a perfect CRF
  - False hits
- Don't be intimidated by the size of the list

eCRF Library Quality Index

- Express the quality of your eCRF library in %
- Assign different weights to different checks

- $$Q = \frac{\sum w_i r_i \quad - \quad \sum w_i e_i}{\sum w_i r_i} \cdot 100\ \%$$

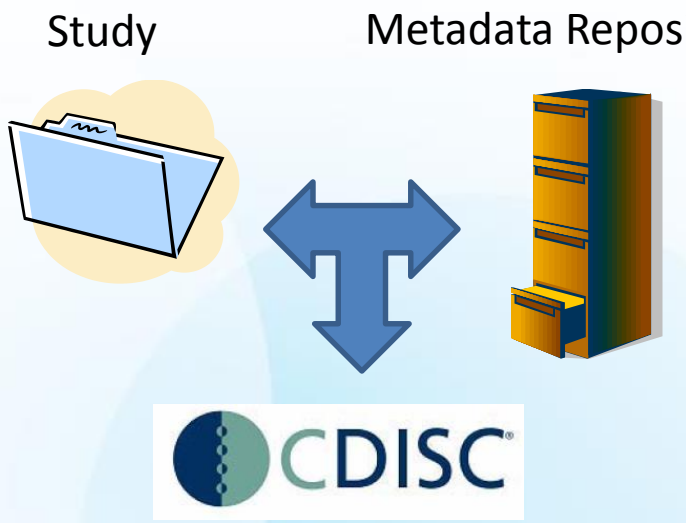
  where

  r_i = number of executions of check i

  w_i= weight of check i

  e_i = number of issues fired by check i

Automation is the Future



Automation requires:

- Standards
- Consistency between standards
- Integrated standards

Conclusion

- Electronic CDISC compliance checking should not only be an end-of-pipe solution
- An eCRF compliance checker can easily be obtained
  - CDISC ODM is a good EDC-independent format
  - XML processing has become easy and readily available
- Automated review allows for more efficient management of your eCRF library and metadata repository
- eCRF quality can be quantified
- QC can focus on data content rather than format
- CDISC SHARE is the future

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