

Enhancing Metadata, Documenting Relationships

cdisc



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Meet the Speaker

Diane Wold

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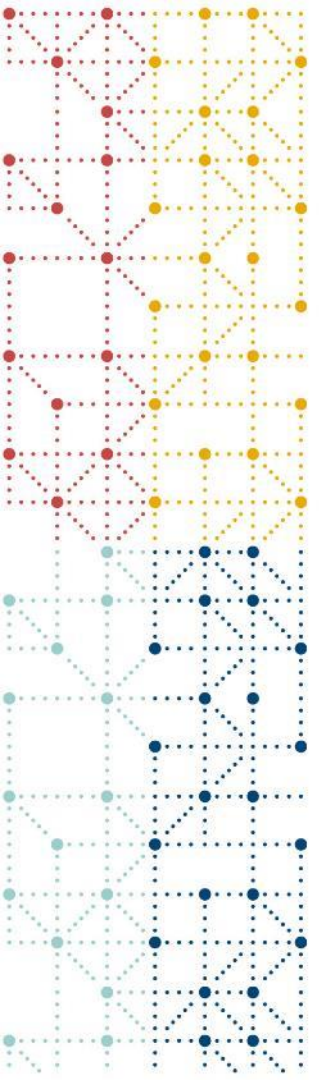
Organization: CDISC

Diane Wold received her Ph.D. in Statistics from the University of North Carolina at Chapel Hill. She worked for Burroughs Wellcome/Glaxo Wellcome/Glaxo Smith Kline in a variety of roles for over 30 years. At the Glaxo Smith Kline merger, she joined the data standards group, and in 2002 she joined the CDISC SDS team. She was also involved in other CDISC teams, including the Protocol Representation Group and SHARE. In 2012 she became involved in the CFAST initiative to develop therapeutic area standards. In 2015 she joined CDISC as an employee. Among other activities, she is currently working on SDTM variable definitions, SDTM variable roles, and the CDISC Knowledge Base.

A decorative graphic on the left side of the slide, consisting of a grid of dots and lines. The dots are colored in red, yellow, and blue, and the lines are colored in red, yellow, and blue. The grid is composed of horizontal, vertical, and diagonal lines, creating a complex pattern of squares and triangles.

Agenda

1. Introduction
2. Metadata Changes in SDTM v2.0
3. Changes proposed for SDTM with SDTMIG v4.0



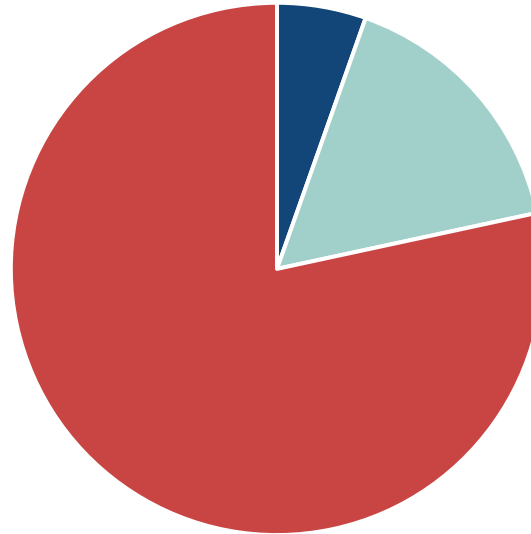
Introduction

The SDTM is mostly variable metadata

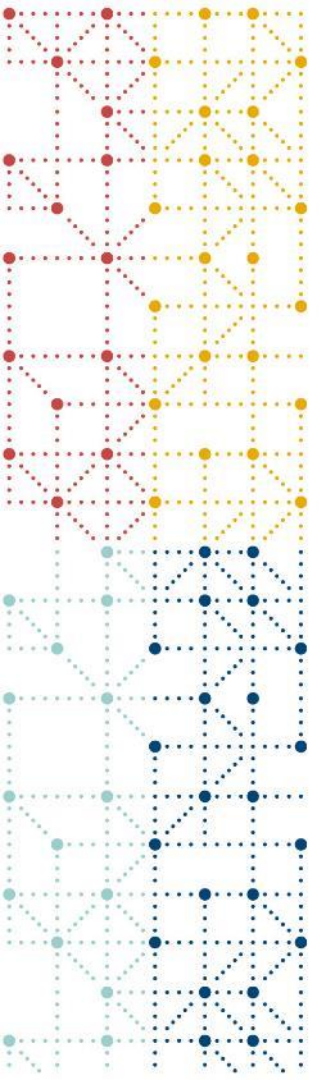
Introduction

The SDTM is Mostly Variable Metadata

SDTM v2.0 Pages



■ Front & End Matter ■ Text Sections ■ Table Sections



SDTM v2.0

Big Changes to Variable Metadata



SDTM v2.0 Changes

- Domain-specific variables rolled into General Observation Class tables
- All tables have the same metadata items
- Role: split out Variable(s) Qualified
- C-code and Definition added
- Description replaced by Usage Restrictions, Notes, Examples

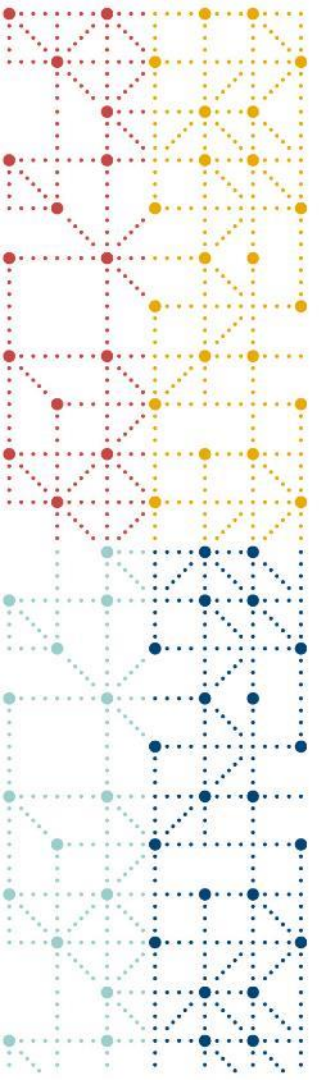
- Motivated in part by desire for more usable metadata in CDISC Library

SDTM 2.0 Variable Metadata

3.1.1 The Interventions Observation Class

Interventions—Topic and Qualifier Variables—One Record per Constant-dosing Interval or Intervention Episode

#	Variable Name	Variable Label	Type	Format	Role	Variable(s) Qualified	Usage Restrictions	Variable C-code	Definition	Notes	Examples
1	--TRT	Name of Treatment	Char		Topic			C82542	The reported name of the drug, procedure, or therapy.	The topic for the intervention observation, usually the verbatim name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.	
2	--MODIFY	Modified Treatment Name	Char		Synonym Qualifier	--TRT		C170998	A value which represents an alteration to a collected value for coding purposes.	If the value for --TRT is modified for coding purposes, then the modified text is placed here.	
3	--DECOD	Standardized Treatment Name	Char		Synonym Qualifier	--TRT		C170991	Standardized or dictionary-derived text for the description of an event or intervention.	Equivalent to the generic drug name in WHODrug, or a term in SNOMED, ICD-9, or other published or sponsor-defined dictionaries.	
4	--MOOD	Mood	Char		Record Qualifier			C117051	The state that may be applied to a record to indicate its phase in a life cycle or business process (e.g., scheduled, performed).		"SCHEDULED", "PERFORMED"
5	--CAT	Category	Char		Grouping Qualifier			C25372	A grouping or classification of the topic of the finding, event, or intervention.		
6	--SCAT	Subcategory	Char		Grouping Qualifier				A further grouping or classification of the category for the topic of the finding, event, or intervention.	The category is in --CAT.	
7	--PRESP	Pre-Specified	Char		Variable Qualifier	--TRT	Not in nonclinical trials	C82510	An indication that the event or intervention was prospectively stated or detailed on the CRF.	Values should be "Y" or null.	



Proposed Changes

To be introduced with SDTMIG v4.0



Proposed Changes

- Reviewers submitted issues suggesting changes to certain variable roles
- Changes were not made in SDTM 2.0, but a team was formed to consider these issues further.
- Team Recommendations:
 - Remove Qualifier role sub-classes
 - Grouping Qualifier, Result Qualifier, Synonym Qualifier, Variable Qualifier, Record Qualifier
 - All will have a role of simply “Qualifier”
 - Add Variable Groups
 - Add Variable Relationships

Rationale for Proposed Changes

- Role is not submitted, so minimal impact
- Qualifier role subclasses were never well defined
- Qualifier role subclasses were assigned inconsistently
- Assigning qualifier role subclasses was sometimes controversial

- Conclusions:
 - Qualifier role subclasses were little used, poorly understood, and not worth trying to reform
 - A different classification of variables (Variable Groups) could be more useful for understanding how variables are used in the standard
 - The small amount of information in “Variable(s) Qualified” would be better represented by more explicit representation of relationships between variables.



Variable Groups

- Intended as informative
- Reflect concepts and wording already being used informally. e.g.
 - Visit variables
 - Relative timing variables
 - Coding variables
 - Method variables
- Allow grouping of similar groups not grouped in standard variable order
 - For example, several Findings qualifier describe a test's method, but are scattered in order
- May help users more easily pick out the variables needed in a particular case

Variable Relationships

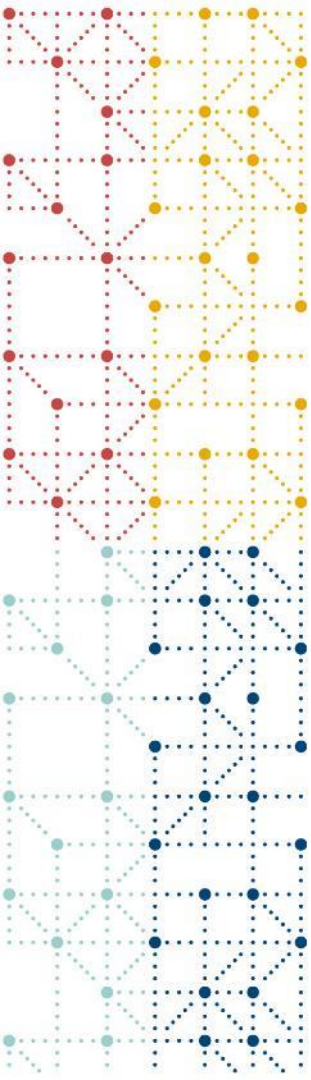
- “Variable(s) Qualified” provides a small amount of information about relationships between variables
 - Does not describe the nature of the relationship
 - Describes only a few of the relationships between variables
- Since a variable can be part of multiple relationships, variable relationships will be in separate tables, something like this:

Source Variable Name	Source Variable Label	Linking Phrase	Target Variable Name	Target Variable Label
--TEST	Name of Measurement, Test, or Exam	Decodes the value in	--TESTCD	Short Name of Measurement, Test, or Exam
--CAT	Category	Groups values in	--TESTCD	Short Name of Measurement, Test, or Exam
--POS	Position of Subject During Observation	Is the subject position during performance of the test in	--TESTCD	Short Name of Measurement, Test, or Exam
--ORRESU	Original Units	Is the unit for the value in	--ORRES	Result or Finding in Original Units



Variable Relationships Strategy

- Uses
 - Enable users to build knowledge graphs
 - Used to construct Biomedical Concepts
 - Enhance understanding and correct use of variables
- Development
 - There are many more relationships than currently reflected in “Variable(s) Qualified”
 - Developing explicit representations of currently implicit relationships will take a lot of work
 - First phase will cover relationships currently reflected in “Variable(s) Qualified,” those needed for initial Biomedical Concept development, and very low-hanging fruit



Thank You!

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