

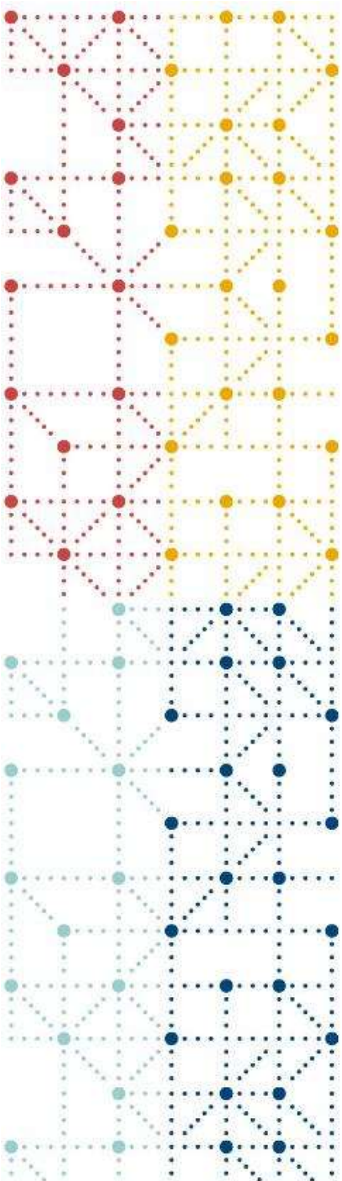


Upcoming Changes to the SDTM and SDTMIG

Diane Wold

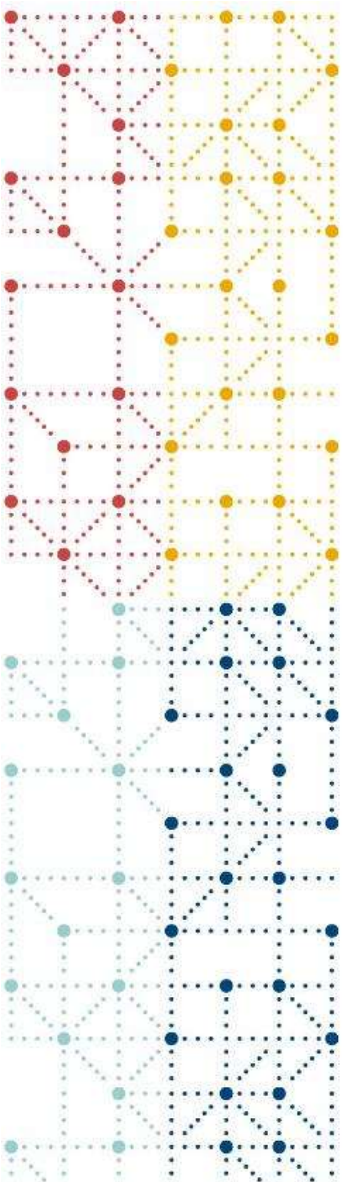
2025-10-02





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Structural Changes to the SDTM

Qualifier types removed

Variable groups introduced

Variable relationships introduced

Root variables and variable definitions



Qualifier sub-roles removed

- Role for all qualifiers now just “Qualifier”
- Removed
 - Grouping Qualifiers -- only variables with this role were –CAT and –SCAT
 - Result Qualifier -- only variables were –ORRES, --STRESC, and –STRESN
 - Synonym Qualifier and Variable Qualifier – unclear distinctions between these two roles
 - Record Qualifier – a sort of dumping ground for everything else
- Impact should be minimal. Qualifier sub-types were always intended as informative and are not submitted.



Variable Groups Added

- Variables with similar functions are now grouped together.
- Variable groups have definitions
- No impact on submissions. Variable Groups are informative



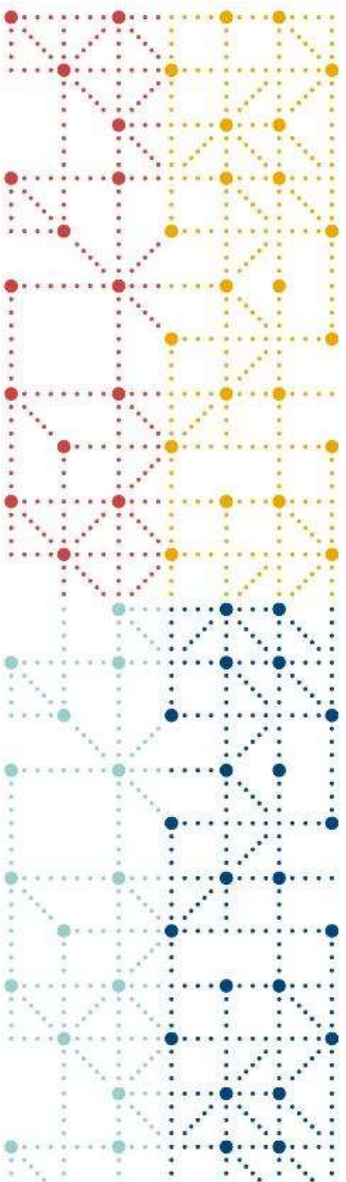
Variable Relationships Added

- Variable relationships provide a linking phrase describing the relationship between a Subject Variable and an Object Variable
- Examples:
 - --TEST decodes the value in --TESTCD
 - --ORRESU is the unit for the value in --ORRES
 - --ORRESU is the unit for the value in --ORNRLO
 - --ORRESU is the unit for the value in --ORNRHI
 - --ORRESU is the unit for the value in --ORREF
 - --CSMRKS specifies the markers used to identify the cell state in --CELSTA
- While in SDTM 2.0
 - --TEST was a synonym qualifier qualifying --TESTCD
 - --ORRESU was a variable qualifier qualifying --ORRES, --ORNRLO, --ORNRHI, --ORREF
 - --CSMRKS was a variable qualifier qualifying --TESTCD
- The set of variable relationships is not complete. Expect more in future.
- Variable relationships are informative.



Variable Definitions and Root Variables

- SDTM v2.0 included definitions for some, but not all variables.
- SDTM v3.0 includes definitions for all variables
- Variable definitions are at the root variable level (e.g., --ORRES, not LBORRES, --PARMCD, not TSPARMCD)
- Variable Definitions were developed at the root variable level, but the SDTM did not use the term “root variable”. A new section explains the concept.
- Column headers in tables use “Root Variable C-code” and “Root Variable Definition”
- Variable definitions and C-codes are informative.



SDTMIG Organizational Changes

Sections 1-4

Domain Specifications



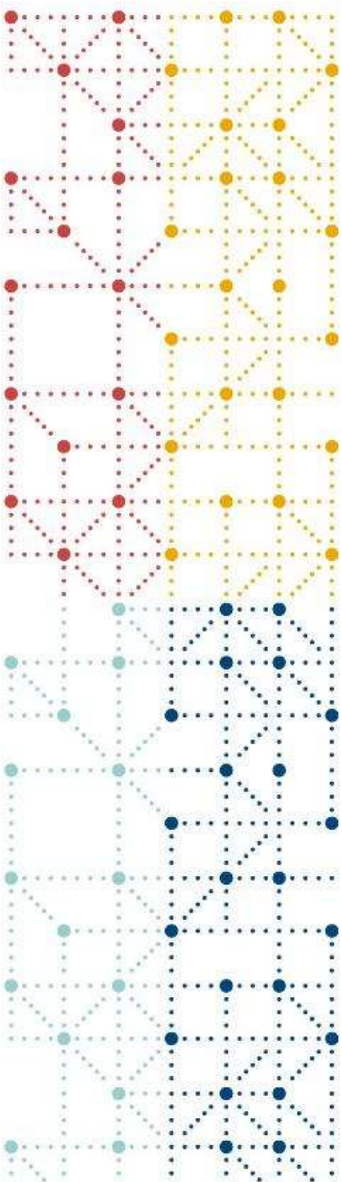
Sections 1-4

- Much of the text was written years ago.
- No mention was made of conformance rules.
- Assumptions were added to Section 4 piecemeal, many under the heading “Other Assumptions”.
- Information was updated.
- Section on conformance was completely rewritten.
- Subsections within Section 4 were completely reorganized.
- Assumptions that appeared in CDISC Notes for multiple domains were moved to Section 4.



Domain Specifications

- New columns were added to reflect variable metadata in SDTM
 - Variable Group
 - Root Variable C-code
 - Root Variable Definition
- Role column uses simplified set of roles
- Controlled Terms, Codelist or Format column split into 3 columns
- CDISC Notes content moved elsewhere
 - Definition-like text replaced by definition
 - Assumption-like text moved to general or domain-specific assumptions
 - Information on allowed values moved to split controlled terms column
 - Examples moved to new Examples column
- New “Notes” column references general and domain-specific assumptions
- Things were moved around and supplemented rather than changed.



New Domains in SDTMIG

Demographics for Multiple Participations

Event Adjudication

Non-standard Variable datasets replace Supplemental Qualifiers

Gastrointestinal Findings domain



Demographics for Multiple Participations (DC)

- The FDA TCG included a way to handle subjects with multiple participations (commonly multiple screenings)
- New DC domain uses a somewhat different approach
 - All participations in DC
 - No “primary” participation (this was an undefined term in the TCG)
 - Allows documentation of different body parts (e.g., the two eyes) as experimental units with their own participations (especially useful for certain SEND studies)
 - Thorough documentation of assumptions
- This domain includes new normative content.
- Approaches which followed the FDA TCG closely will have to be modified.



Event Adjudication (EA)

- PhUSE issued a white paper on event adjudication
- The SDTMIG Event Adjudication considered this white paper, but did not follow it completely.
- EA has a Findings About structure
- This domain includes new normative content.
- Approaches sponsors developed, including those based on the PhUSE white paper, may have to be modified.



Non-standard variable datasets replace Supplemental Qualifiers datasets

- Non-standard variables in a horizontal, rather than a vertical structure
- One NS-- dataset for each domain with non-standard variables.
- IDVAR is limited
 - --SEQ for general observation class domains and DC
 - --VISITNUM for SV
 - Not needed for DM
- Structure allows easy merging of an NS-- domain with its parent domain
- This is a big change.
- Merging non-standard variables with parent domains requires no transposition and is simple.



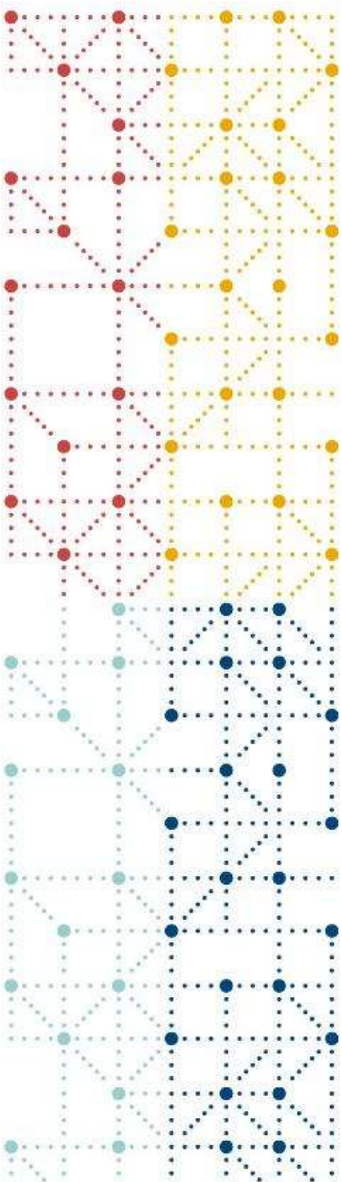
Gastrointestinal System Findings

- Just another body-system based physiology and morphology domain.



There's a lot more, such as

- A bunch of SEND variables in the SDTM marked “Not for human clinical trials”
- A new variable in the Protocol Deviation domain to allow classification of the impact of the deviation, needed to meet regulatory requirements.
- Examples updated
 - Terminology brought up to date
 - Supplemental qualifier datasets changed to use NS-- datasets
 - Errors corrected
- The --LNKID/--LNKGRP Known Issue in SDTMIG v3.4 was resolved, and related examples were updated.



Thank You!

