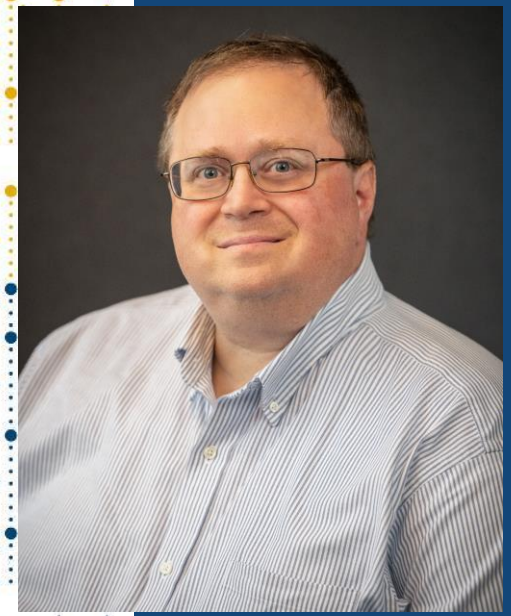
What's New in SDTM 3.0

Presented by Dave Scocca, Principal Statistical Programmer, Rho, Inc.



Meet the Speaker

Dave Scocca

Title: Principal Statistical Programmer

Organization: Rho, Inc.

I have been a programmer for Rho for 26 years now, and I have worked with CDISC data standards since 2010. As a CDISC volunteer since 2018, I have worked on the SDTM and SDS, including on the SDS subteams for multiple subject instances and Jira issue management. I'm currently serving in the Future Lead role on the SDS Leadership Team.

I live in Durham NC.

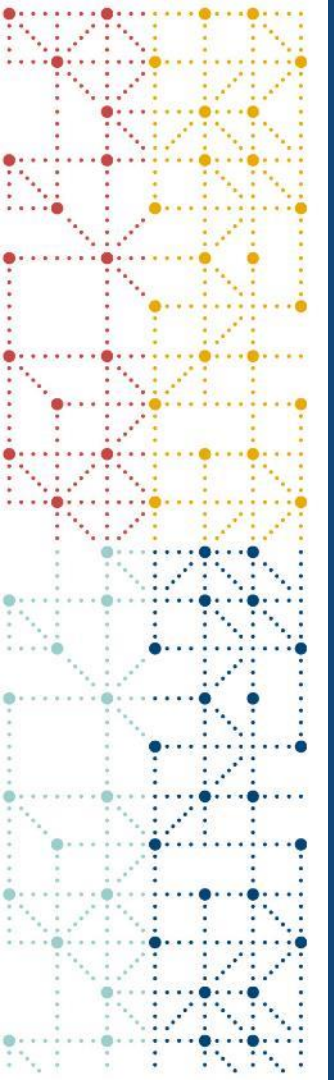
Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author has no real or apparent conflicts of interest to report.*

Agenda

1. Welcome to SDTM 3.0
2. New Sections and Updated Tables
3. SUPP becomes NS
4. Multiple Subject Instances
5. New Domains and Variables



Welcome to SDTM 3.0

Welcome to Study Data Tabulation Model 3.0

- Updates to support SENDIG v4.0, SDTMIG v4.0, and SDTMIG-MD v2.0
  - Planned for release with SDTMIG and SENDIG in 2026, with SDTMIG-MD following close behind
  - Internal review completed alongside both SDTMIG 4.0 and SENDIG 4.0.
  - Public review expected to start late 2025
- SDTM 2.0 was the previous major version
- SDTM 2.1 had revisions specifically to support the Tobacco Implementation Guide
  - Additional identifier variables
  - One new variable for Findings
  - New RELREF relationship table
  - Generalized labels and updated definitions for a “product” that was not a treatment and to support some in vitro assays

New Sections and Updated Tables

Updated Tables

- Qualifiers Simplified
  - In the “Role” column, “Qualifier” replaces separate Grouping, Result, Synonym, Variable, and Record Qualifier Roles
  - “Variable(s) Qualified” column has been removed
  - Qualifier sub-types were informative and are not submitted
- Variable Groups Added
  - A new “Variable Group” column assigns each variable to a defined group
- Root Variable Definitions Completed
  - Version 2.0 definitions were incomplete
  - Definitions managed as terminology
  - Root Variable C-codes included

Table Example — Events

#	Variable Name	Variable Label	Type	Format	Role	Usage Restrictions	Variable Group	Root Variable C-code	Root Variable Definition	Notes	Examples
1	--TERM	Reported Term	Char		Topic		Event Name	C82571	The collected name for an event observation.	May not be null.	
2	--MODIFY	Modified Reported Term	Char		Qualifier	Not in nonclinical trials	Coding	C170998	A value which represents an alteration to a collected value for coding purposes.		
3	--LLT	Lowest Level Term	Char		Qualifier	Not in nonclinical trials	Coding	C71886	The lowest-level term assigned to the event from MedDRA.		
4	--LLTCD	Lowest Level Term Code	Num		Qualifier	Not in nonclinical trials	Coding	C117048	The lowest-level term code assigned to the event from MedDRA.		
5	--DECOD	Dictionary-Derived Term	Char		Qualifier		Coding	C170991	Standardized or dictionary-derived text for the description of an event or intervention.	If terms are coded in MedDRA, this is the Preferred Term ("PT").	
6	--EVDTYP	Medical Event Date Type	Char		Qualifier	MH, CE domains only	Event Date Type		A description of a state, stage or instance of a medical event to which distinct timing applies.		"DIAGNOSIS", "SYMPTOM ONSET", "DISEASE RELAPSE"

Additions to Section 2: Model Concepts and Terms

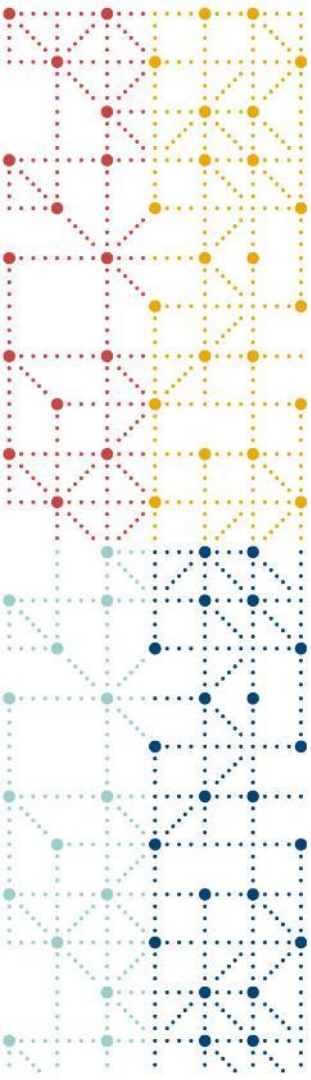
- Root Variables
  - Every variable implemented in a specific domain is an instance of a root variable
    - LBDTC is an instance of the root variable –DTC
    - VISIT, EPOCH, and other variables without domain prefixes are also root variables
  - In the SDTM, definitions and C-codes are at the root variable level
- Variable Groups
  - Each root variable is assigned to a group
  - Group definitions are part of the model
- Variable Relationships
  - Each table of variables is followed by a table of relationships between the variables in that table
  - Describes relationship with both natural language and controlled terminology to support machine use

Variable Groups — Examples

Variable Group	Root Variables	Variable Group Definition
Action Taken in Response to Event	--ACN, --ACNDEV, --ACNOTH, --CONTRT	A group of variables that describes actions taken in response to an event.
Dose Amount	--DOSE, --DOSTOT, --DOSTXT, --DOSU, --FTDOSD, --TDOSD, --VAMT, --VAMTU	A group of variables that describes amount of intervention administered, expressed in absolute or relative terms.
Occurrence	--OCCUR, --PRESP, --REASND, --REASOC, --STAT	A group of variables that describes 1) a question about a pre-specified event or intervention, its response or absence of response and reasons for the response or lack of response or 2) the absence of result for a finding and the reason for the absence.
Category	--CAT, --SCAT	A group of variables that groups or classifies the topic of the observation.

Variable Relationships — Examples

Subject Variable	Subject Var Label	Linking Phrase	Predicate Term	Object Variable	Object Var Label
--DECOD	Dictionary-Derived Term	is a dictionary-derived term for the value in	IS_DERIVED_FROM	--TERM	Reported Term
--PTCD	Preferred Term Code	is a dictionary-derived code for the value in	IS_DERIVED_FROM	--TERM	Reported Term
--PTCD	Preferred Term Code	is the code for the value in	IS_DECODED_BY	--DECOD	Dictionary-Derived Term
--PRESP	Pre-Specified	indicates pre-specification of the value in	IS_INDICATOR_FOR	--TERM	Reported Term



SUPP becomes NS

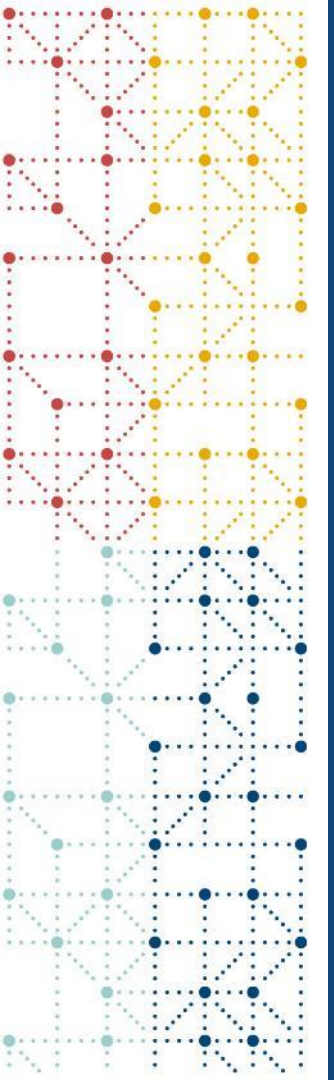
Nonstandard Variables Dataset

SDTM 3.0 and onward	Previous Versions
Dataset named NS--	Dataset named SUPP--
Horizontal: one row per row in the parent dataset with at least one nonstandard variable populated	Vertical: one row per populated nonstandard variable value
Each row in NS-- matches exactly one row in the parent dataset. IDVAR is almost always --SEQ and IDVARVLN is numeric.	A row in SUPP-- may match more than one row in the parent dataset (IDVAR could be --GRPID) and IDVARVAL is character.
Nonstandard variable columns can be character or numeric.	QVAL is always a character field.
Variable-level metadata in Define-xml for nonstandard variables.	Value-level metadata in Define-xml for QVAL, based on value of QNAM.
Can merge without transposing or character-to-numeric conversion.	Merge requires transposing and often converting IDVARVAL from character to numeric.

Multiple Subject Participations

Changes to Support Multiple Subject Participations

- SUBJID has been added to Identifiers for All Classes and to special-purpose tables
- New special-purpose domain DC (Demographics for Multiple Participations)
- USUBJID is still the primary identifier and --SEQ must still be unique per USUBJID
- Many more details to follow in the third presentation of this panel



New Domains and Variables

New Domains

Special Purpose:

- DC (Demographics for Multiple Participations)

Study Reference:

- SX (Scoring Scale)
  - not for human clinical trials

Relationship:

- NS-- (Nonstandard Variables)
- RELDEV (Related Devices)
  - for next version of SDTMIG-MD

New and Changed Variables — Highlights

All Datasets:

- SUBJID added to identifiers
- MASSID added to identifiers (not for human clinical trials)

Special Purpose:

- DM and DC: AGELO and AGEHI replaced AGETXT
- DM and DC: added collected value variables CRACE and CETHNIC

Trial Design:

- TI: removed TIRL

Relationship:

- NS--: new variable IDVARVLN (like IDVARVAL, but numeric)

New and Changed Variables — Highlights

Events:

- --CLASSI (Classification of Protocol Deviation) added
  - restricted to use in DV

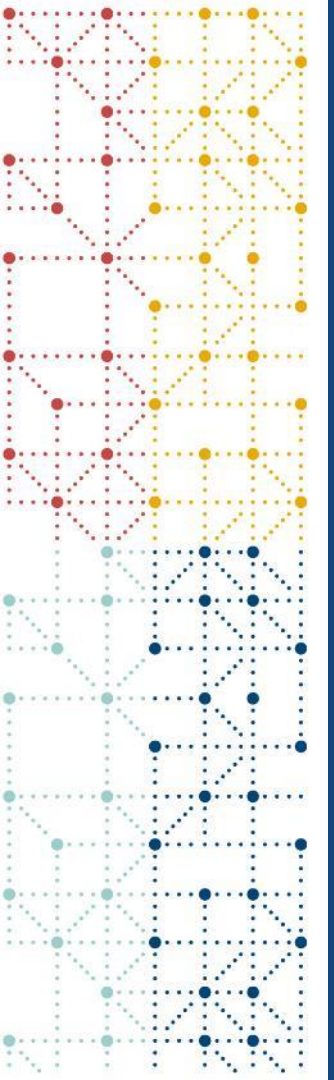
Interventions:

- --TRTCD (Standardized Intervention Code) added
  - can store code associated with --DECOD

New and Changed Variables — Highlights

Findings:

- --CBRFL (Conditionally Branched Item Flag) added
  - restricted to use in QRS domains
- --RESCNT (Result Count) added
  - restricted to use in EG domain
- --BLFL, --MODIFY, and --BODSYS removed
- --PTFL (Point in Time Flag) and --PDUR (Planned Duration) added
  - Previously treated as Timing Variables
- Several additional variables not for use in human clinical trials
  - --RESMOD (Result Modifier)
  - --ROEBE (Reference Observation Before Element)
  - --ROELNM (Reference Observation Element Name)
  - --ROETYP (Reference Observation Group Type)



Questions?

Thank You!