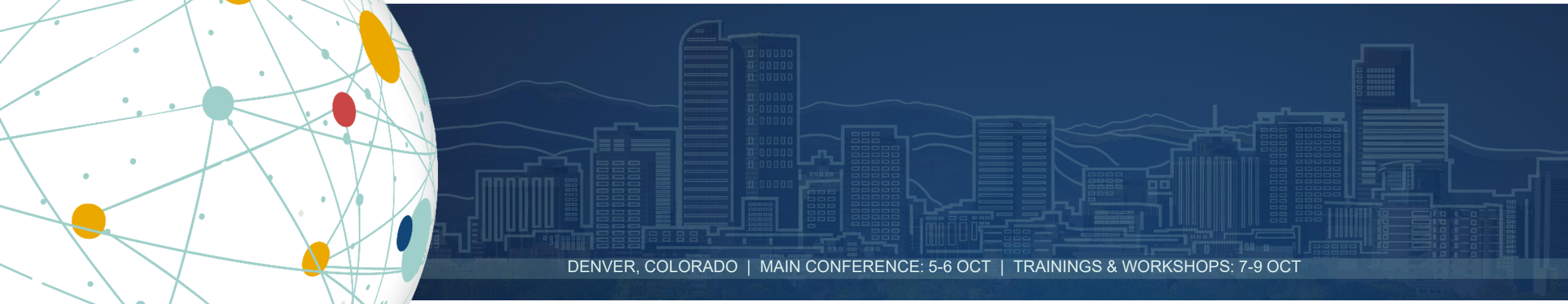


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SDTM 3.0: What's Changed; What's New

Michael Wise, Director, Statistical Programming, Edwards LifeSciences

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

Speakers



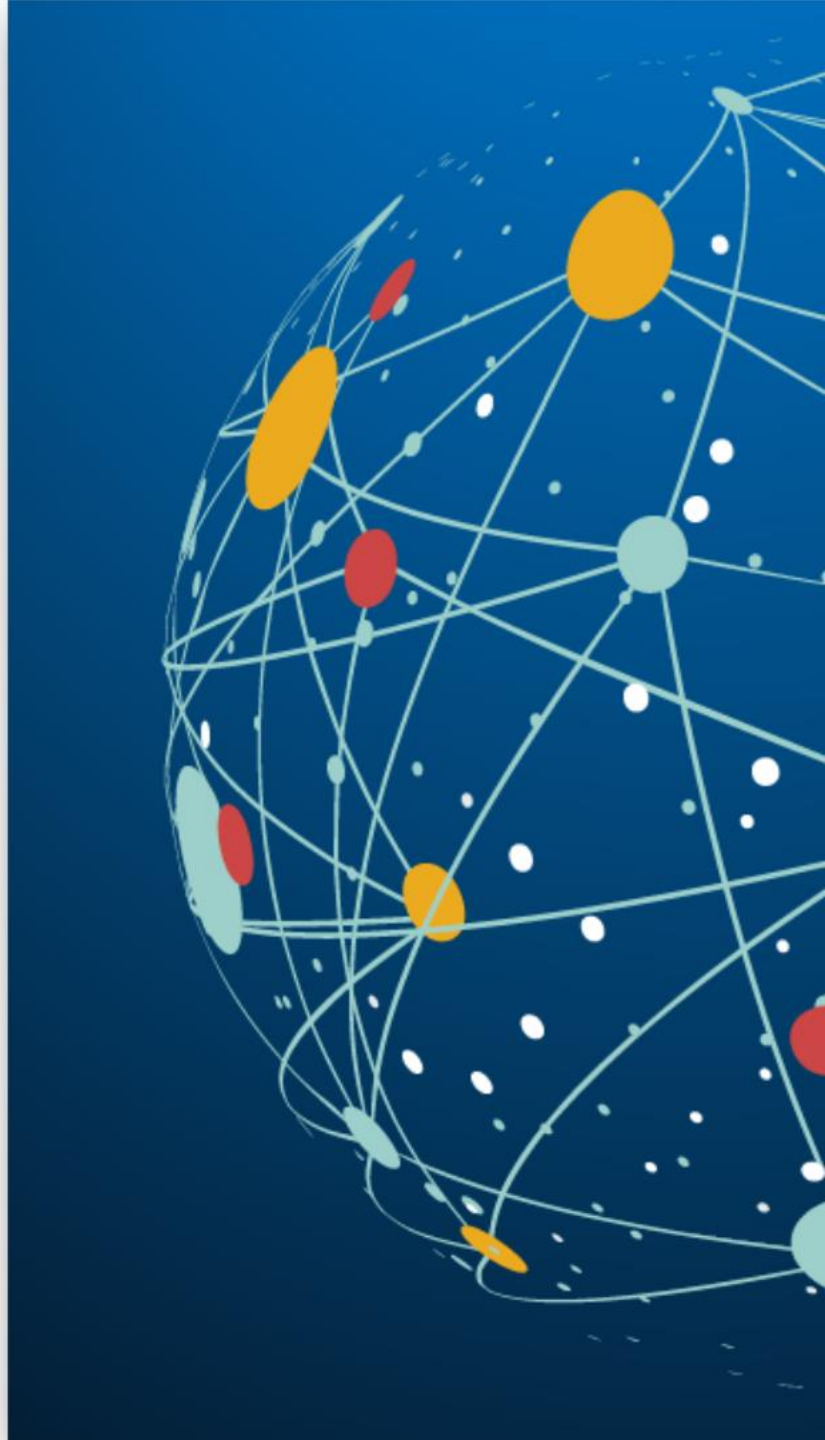
I have been a CDSIC volunteer for over a decade; although I am a member of sub-teams for CDASH and ADaM, SDTM is my main focus. I am the current Medical Devices Team Lead and former SDS Lead. I live in Chicago.

Michael Wise
Director, Statistical Programming
Edwards LifeSciences

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 has been completed; comment resolution in progress.
- 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
  - The “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

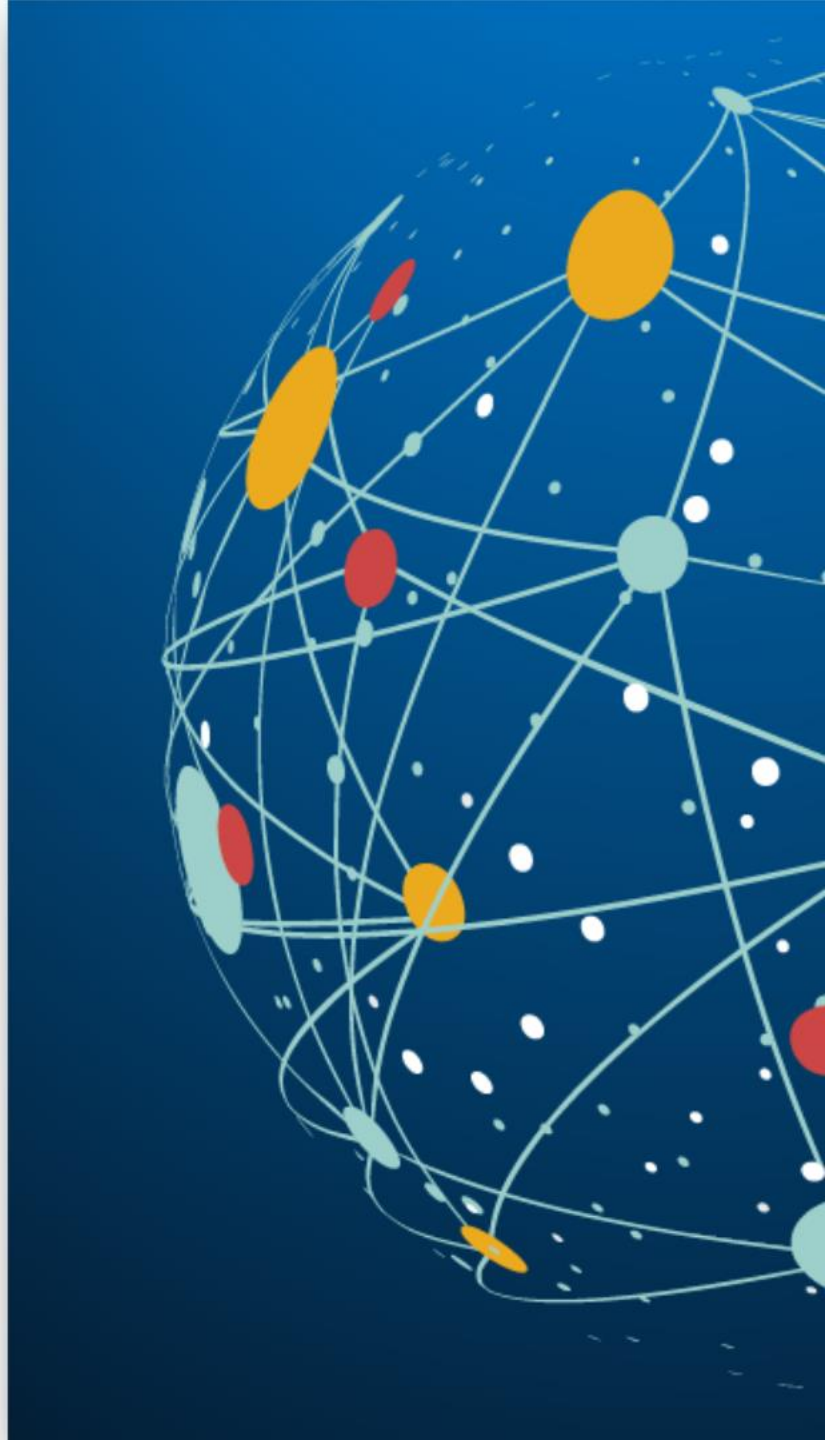
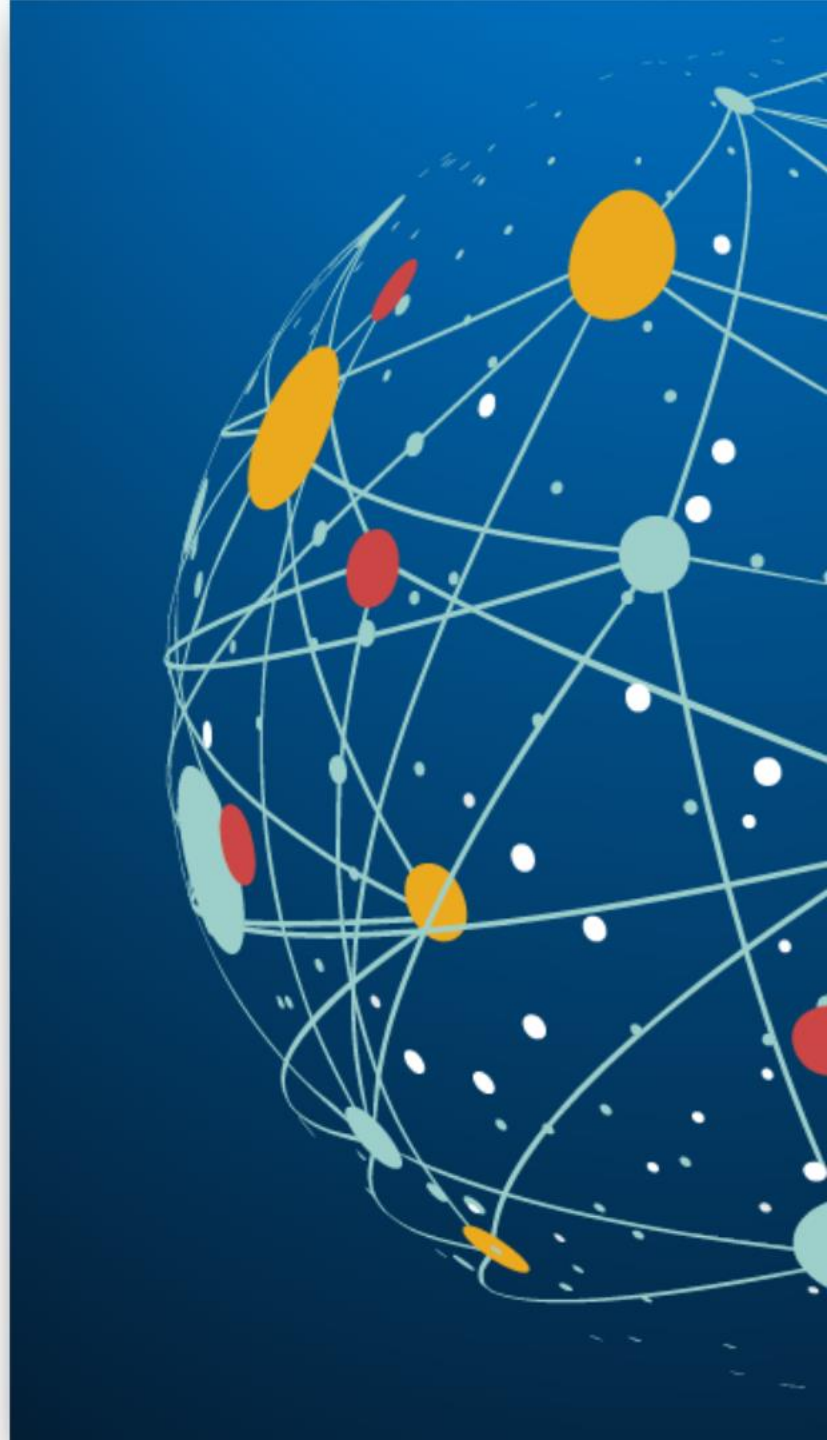


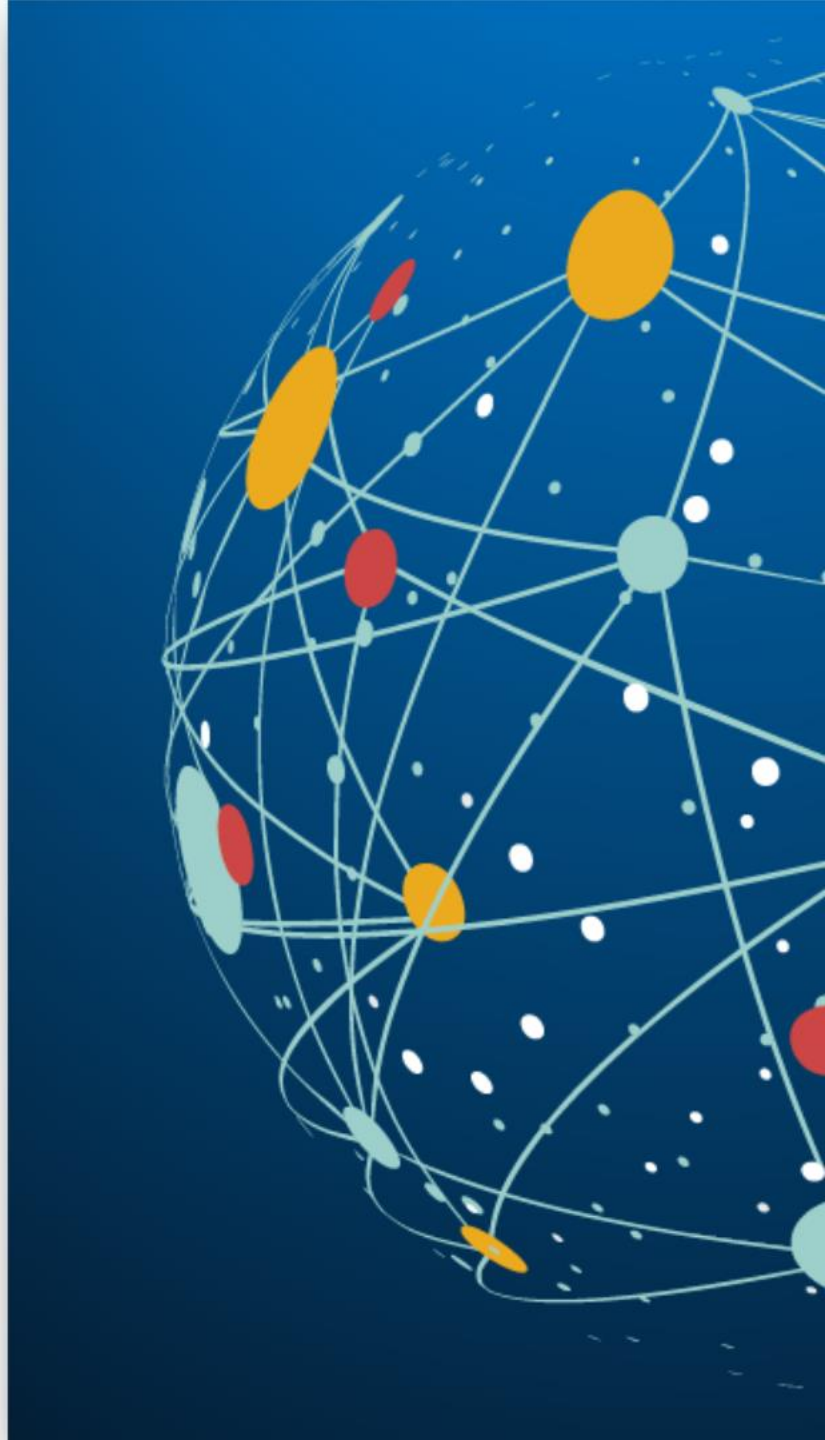
Table Example — Events

#	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"



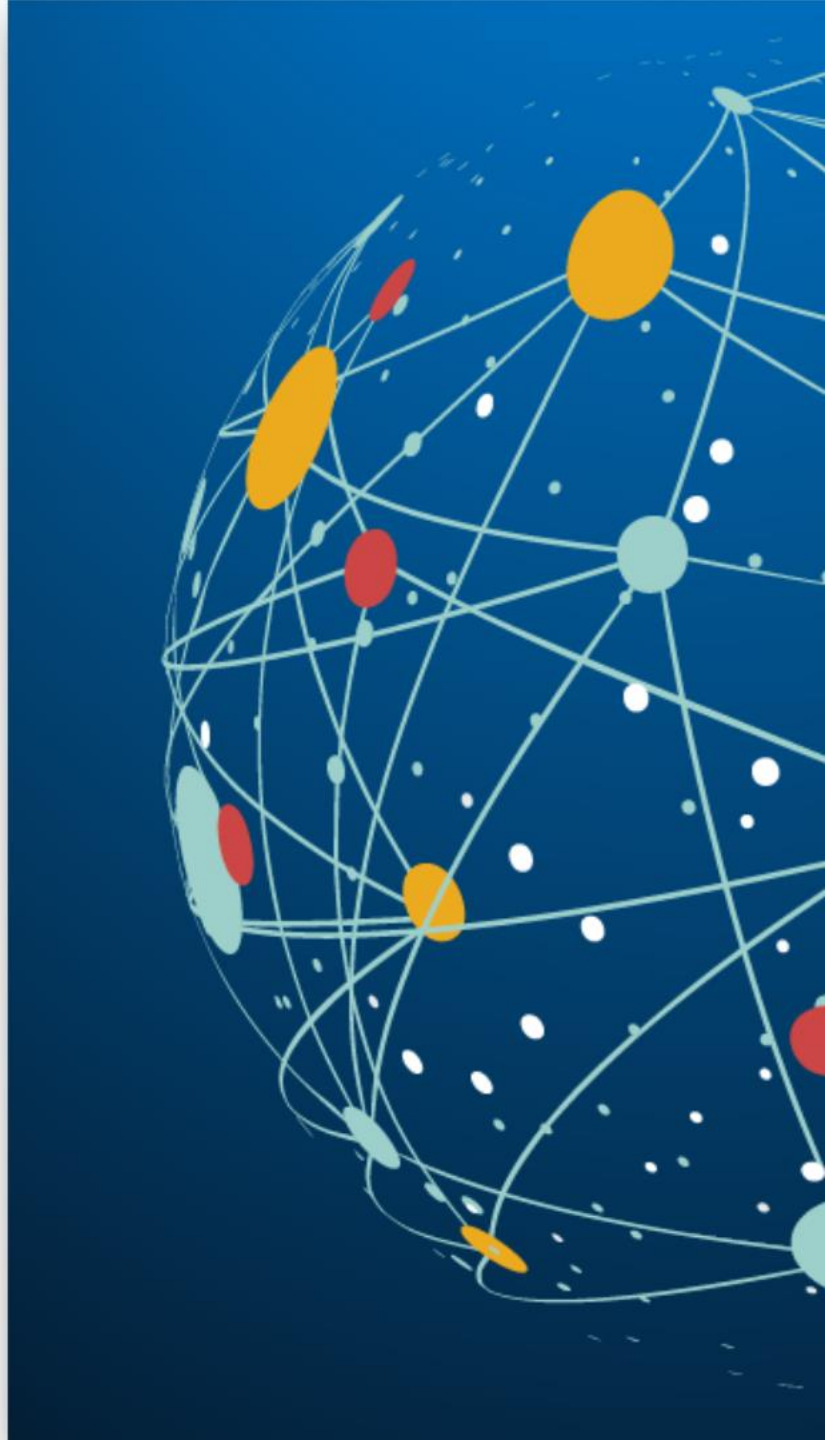
Additions to Section 2: Model Concepts and Terms

- 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, both 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



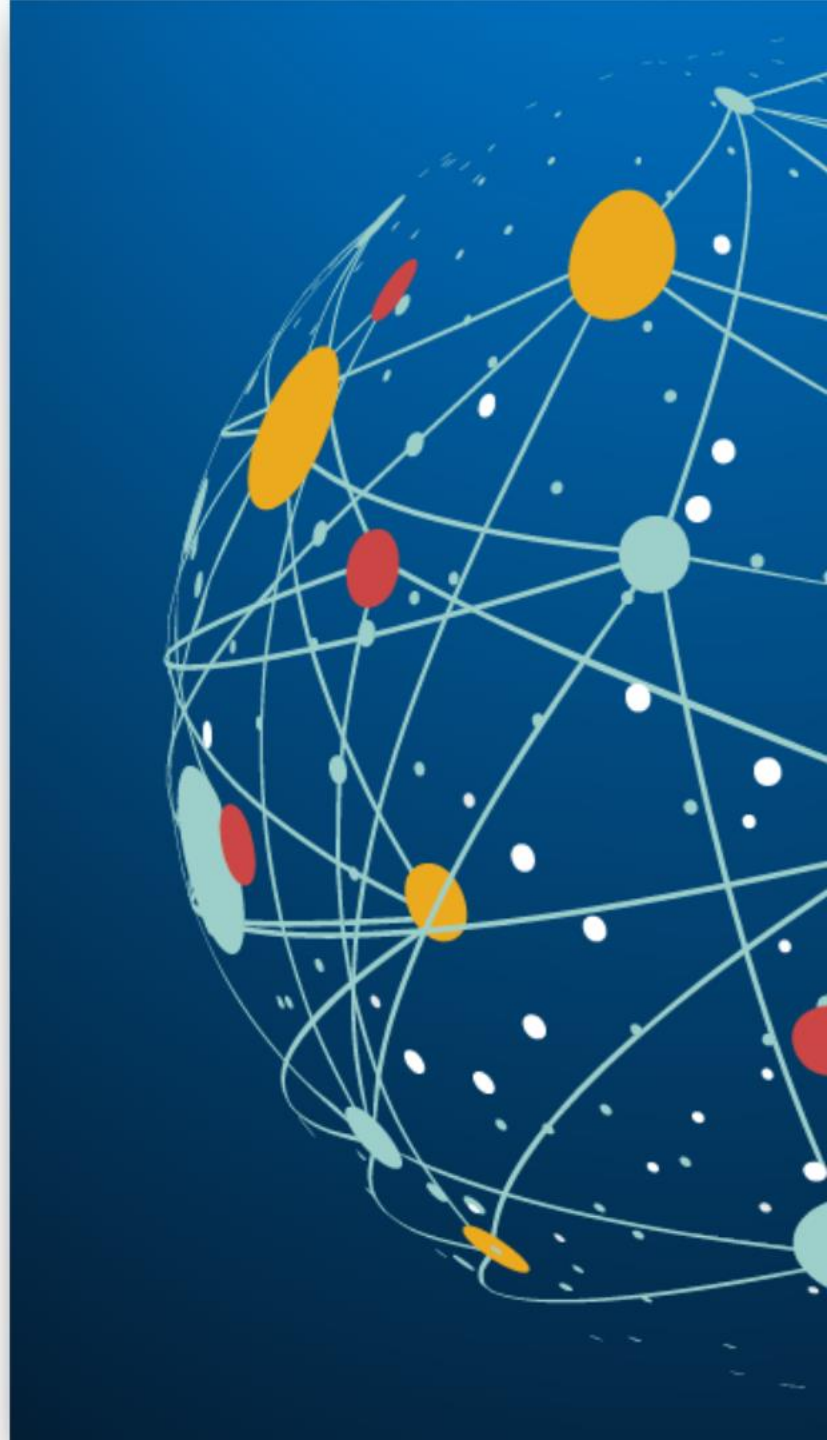
Variable Groups — Examples

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

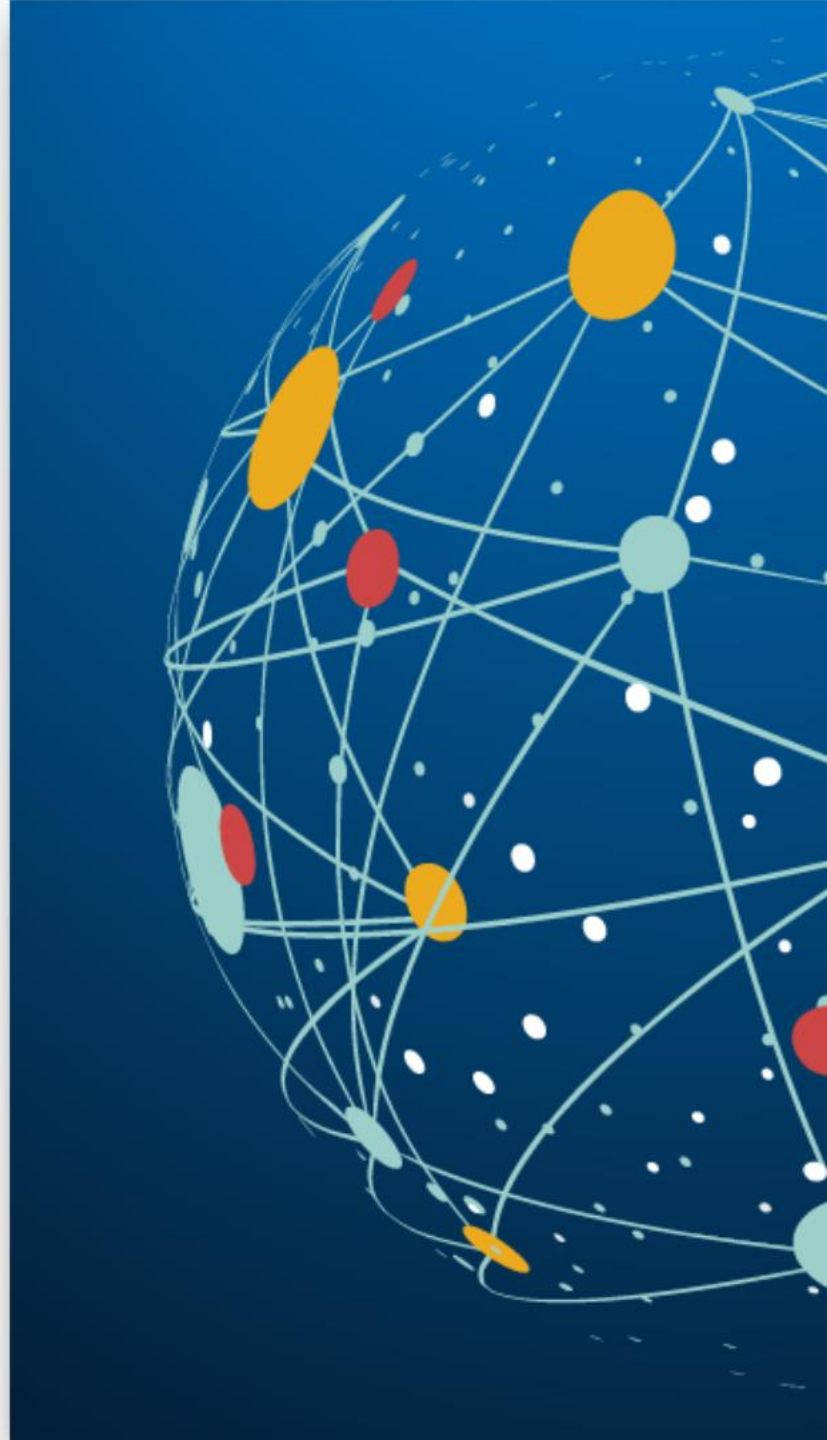
Subject Variable	Subject Var Label	Linking Phrase	Predicate Term	Object Variable	Object Var Label
--DECOD	Dictionary-Derived Term	is a dictionary-derived term for the value in	IS_DERIVED_FROM	--TERM	Reported Term
--PTCD	Preferred Term Code	is a dictionary-derived code for the value in	IS_DERIVED_FROM	--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



NS Replaces SUPP

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.

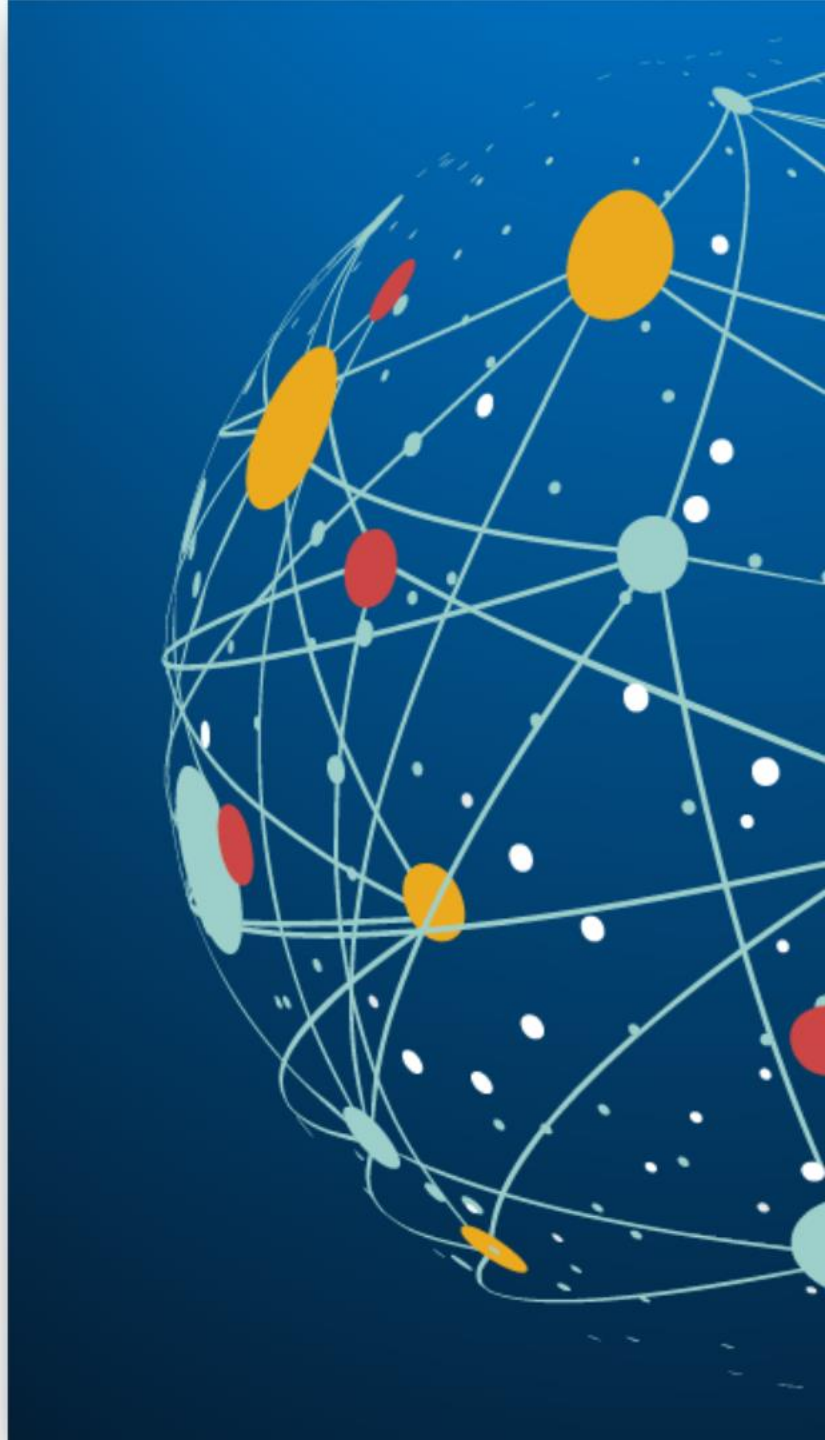


Multiple Subject Participations

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:

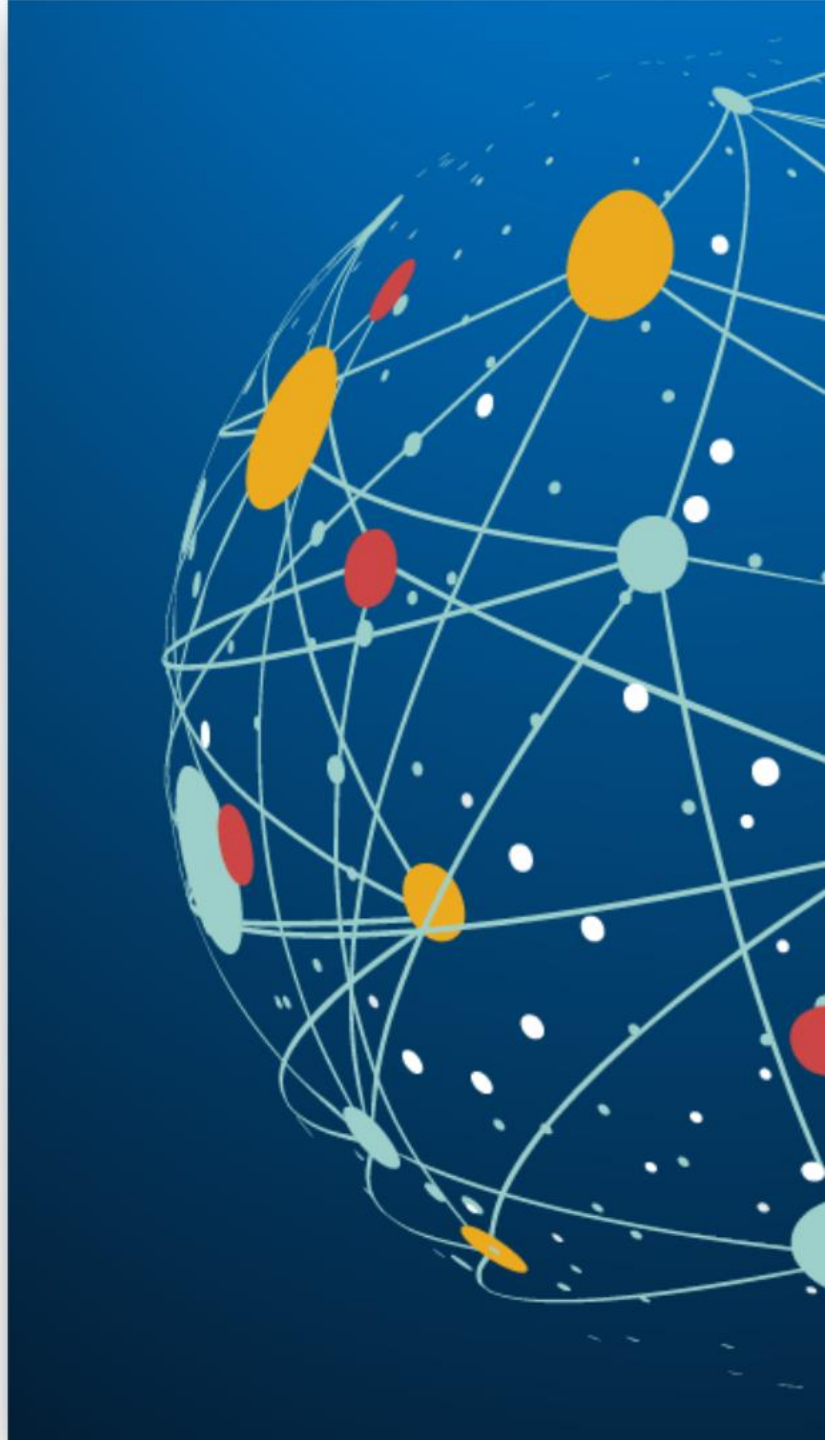
- DC (Demographics for Multiple Participations)

Study Reference:

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

Relationship:

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



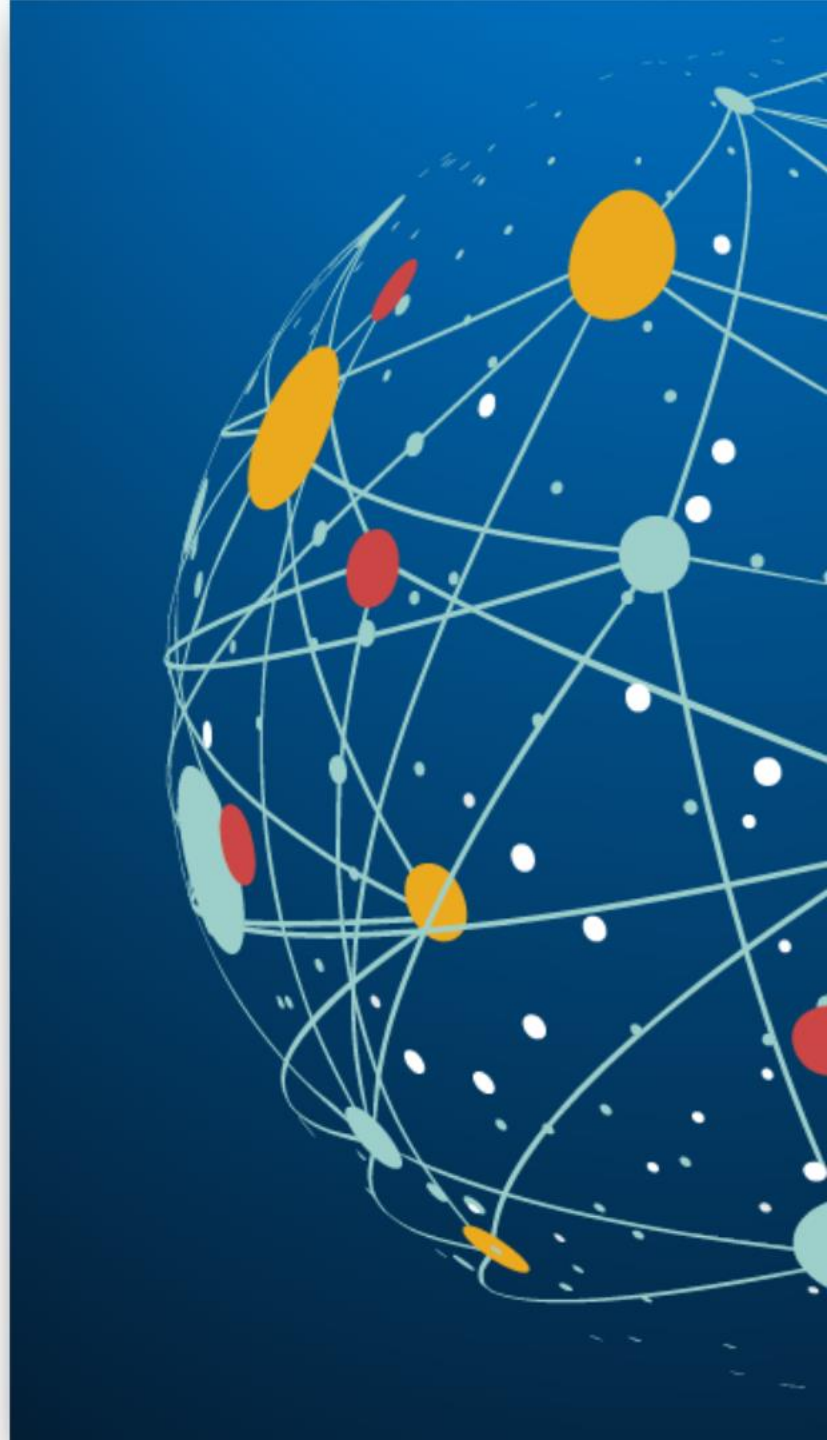
New Variables — All Datasets and Special Purpose Domains

All Datasets:

- SUBJID has been added to identifiers
- MASSID has been 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



New Variables — Findings, Events, and Interventions

Findings:

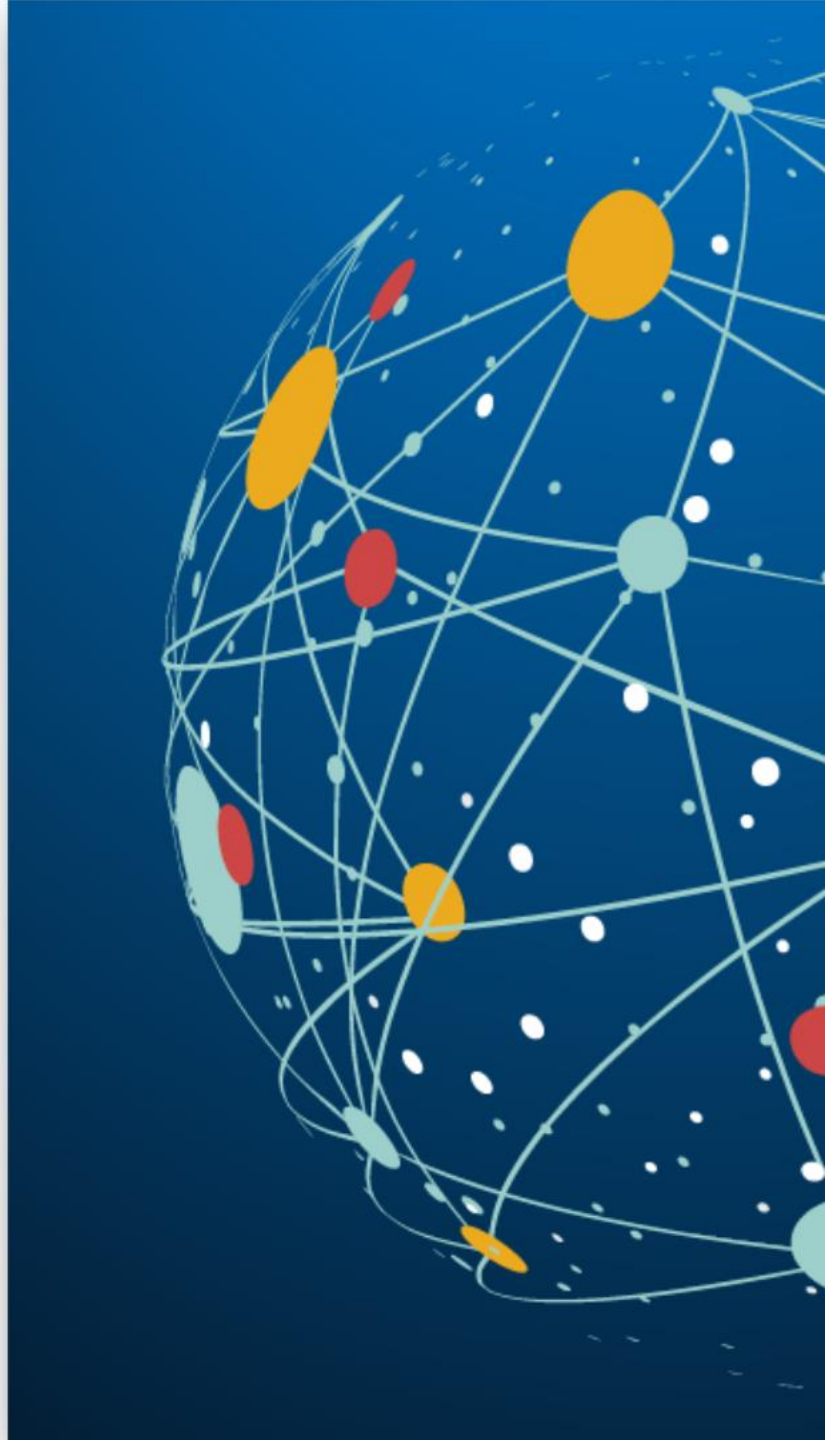
- --RSCNT (Result Count) added
  - restricted to use in EG
- --CBRFL (Conditionally Branched Item Flag) added
  - restricted to use in QS, FT, CC

Events:

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

Interventions:

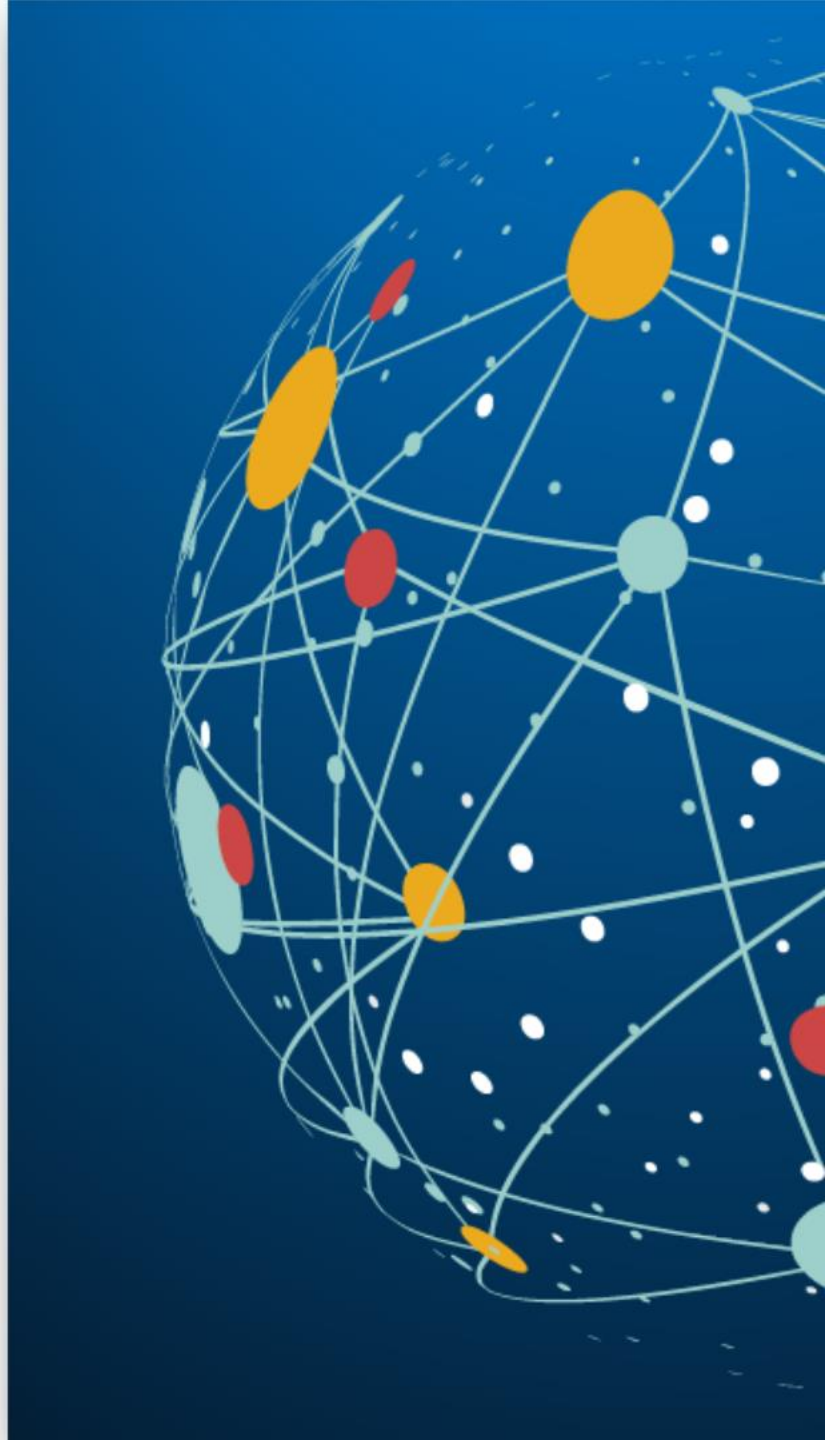
- --TRTCD (Standardized Intervention Code) added
  - can store code associated with --DECOD



New Variables — Relationships

Relationships:

- NS--: new variable IDVARVLN (like IDVARVAL, but numeric)
- IDVARVAL still available but IDVARVALN stores numeric values for the so conversion is not needed to match parent records to –NS records by a numeric ID variable.



Removed Variables - BLFL

- **--BLFL removed**

  --BLFL has been removed; last Observation Before Exposure Flag (--LOBXFL) provides a more defined algorithm for derivation.

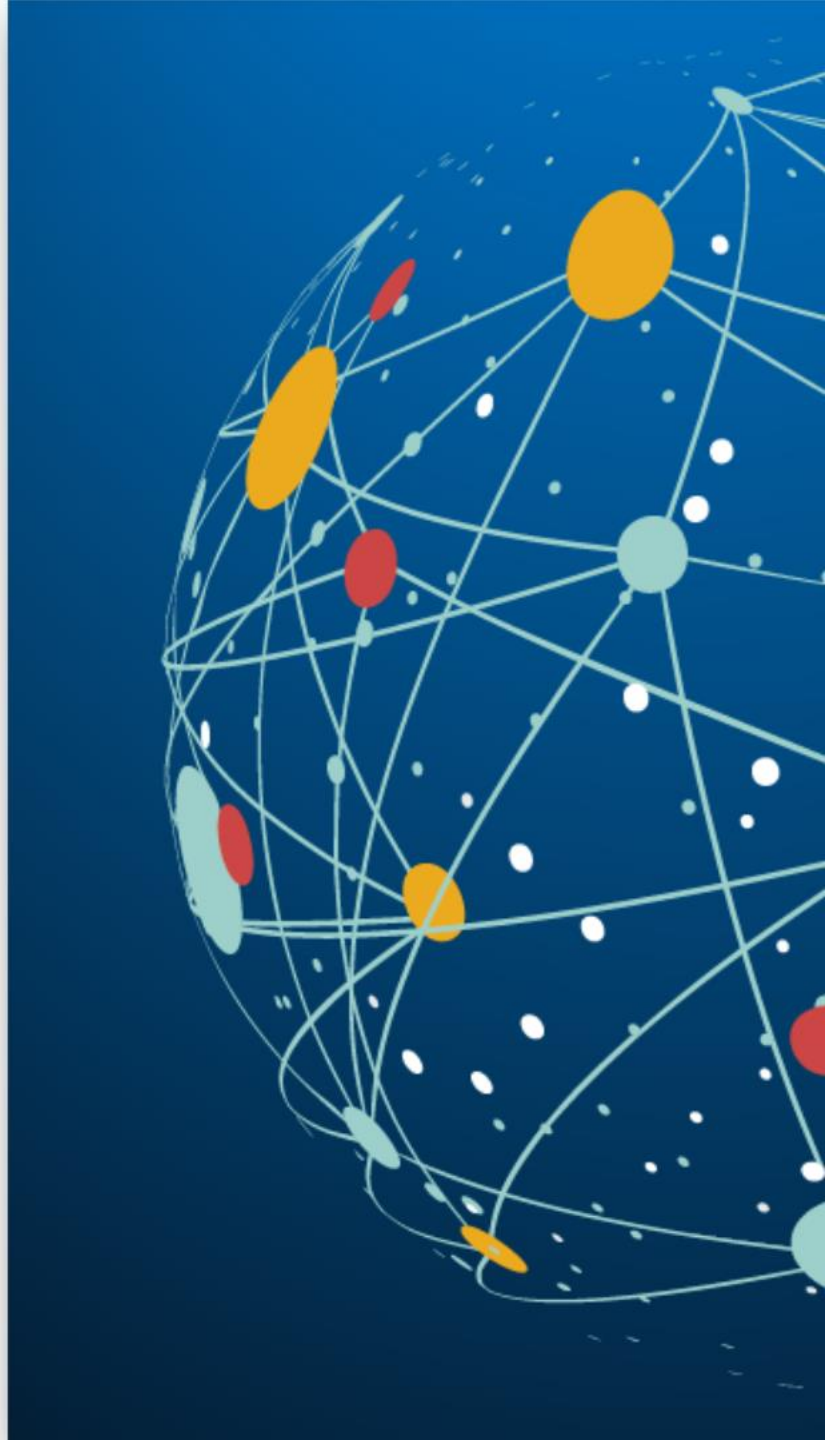
  -LOBXFL Definition: An indication that the record is the last non-missing baseline assessment prior to the date and time of first protocol specified treatment exposure.

  Previously, when operationally defining the baseline was difficult, sponsors could either leave the baseline flag value blank or flag a record that contained an approximation for the true baseline value. Thus, –BLFL did not convey a consistent meaning.

  --LOBXFL was introduced in SDTMIG v3.3 and it is already being implemented.

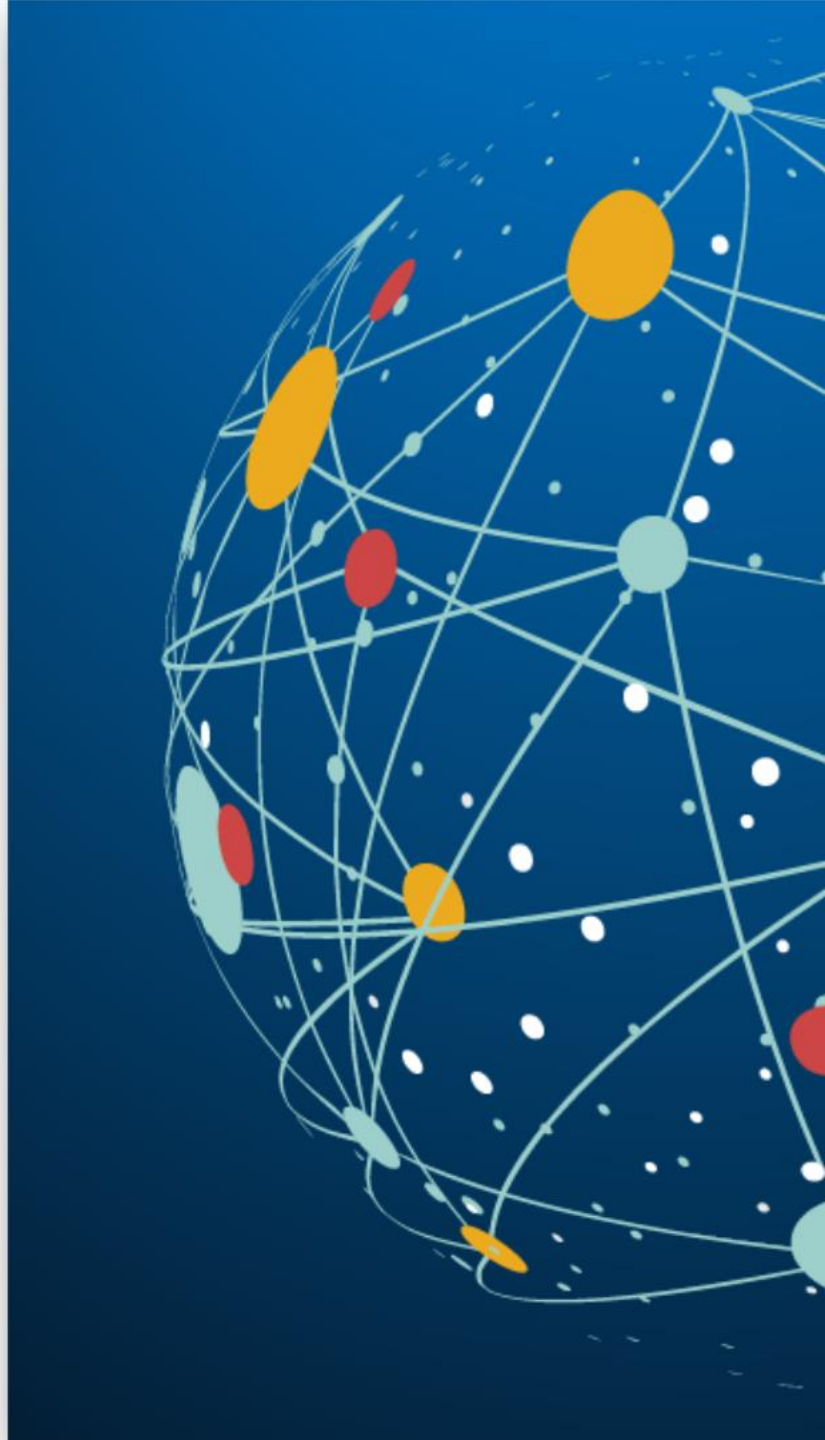
  Core value for --BLFL was already changed from 'Expected' to 'Permissible' in preparation for deprecation, and --LOBXFL is present wherever –BLFL used to be.

  Analysis Baseline (ABLFL) within ADaM is defined within the Statistical Analysis Plan (SAP) according to analysis needs.



Removed Variables -TIRL

- **TIRL (in TI) removed**
  - The variable TIRL was included in the Trial Inclusion/Exclusion Criteria (TI) domain in anticipation of developing a way to represent eligibility criteria in a computer-executable manner. However, such a method has not been developed, and it is not clear that an SDTM dataset would be the best place to represent such a computer-executable representation.

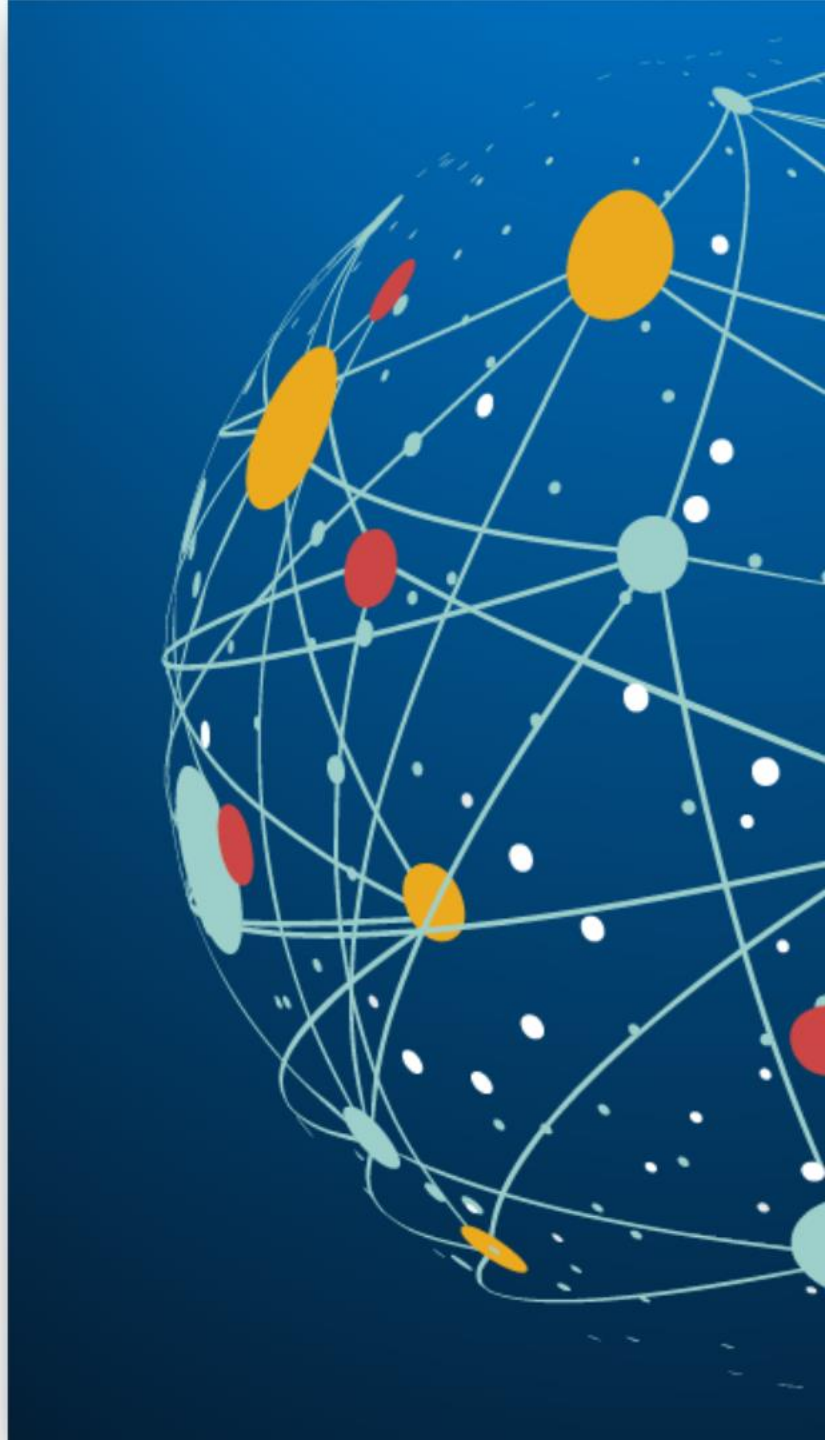


Additional Resources

Support for Implementation

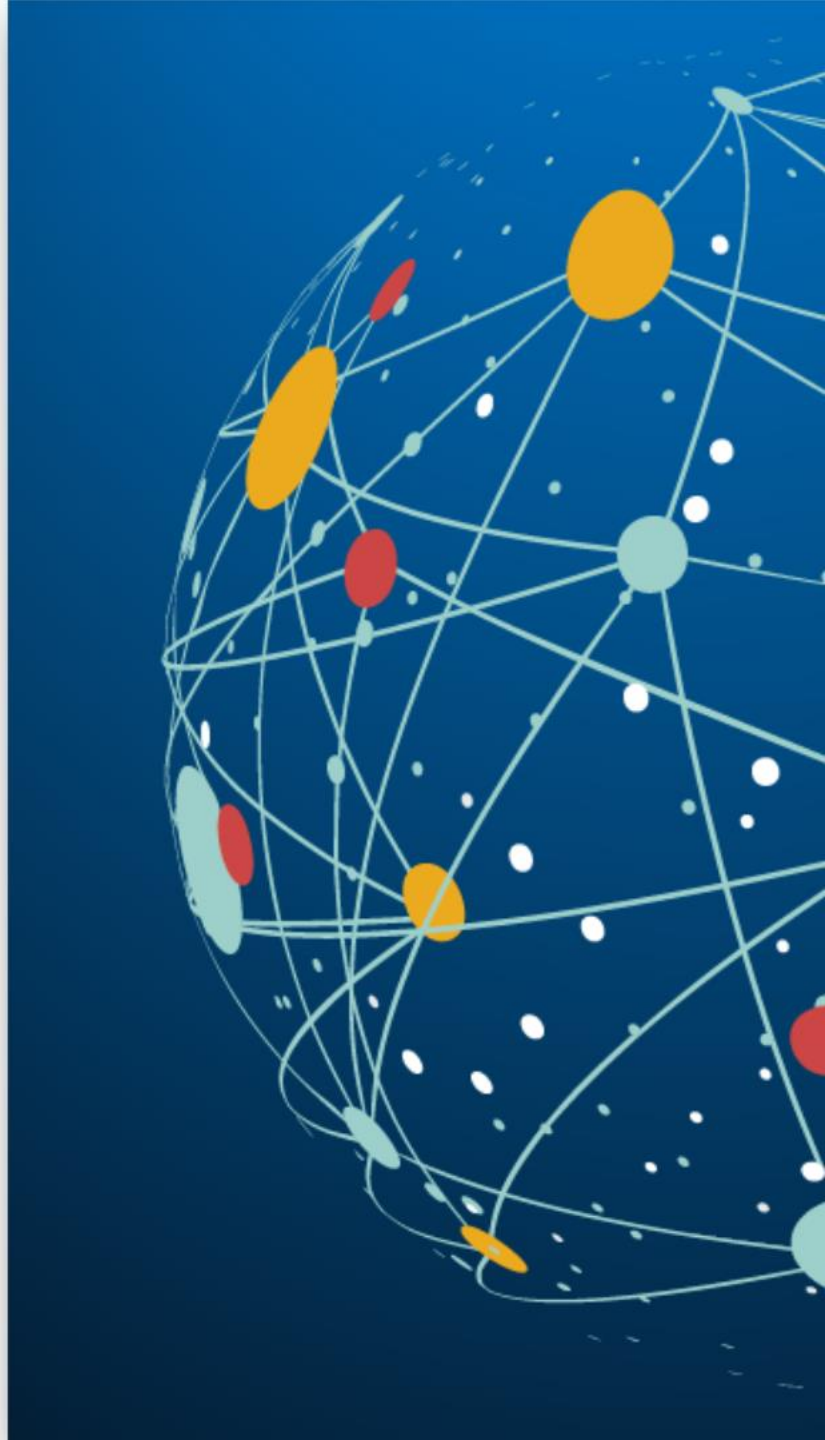
Improving Resources

- Knowledge Base:
  - https://www.cdisc.org/kb
  - General information about using SDTM
- Examples Collection:
  - https://www.cdisc.org/kb/exa
  - “This would really benefit from an example of…”
- Ongoing updates



SDS Activities

- Volunteers welcomed!
  - SDS Home on CDISC Wiki
  - volunteer@cdisc.org
- Work organized by subteams
  - Conformance Rules
  - Comment Resolution
  - Controlled Terminology
  - Specific Topics: Labs, QRS, Oncology
  - May adjust structure as needs become clearer



Thank You!



Questions?

