2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION





What's Coming in SDTMIG v4.0 (and new information since the last interchange)



Monday, 05-Oct-2026, 16:30 (*Session 4, Track A*)

About Me….



- I love data
- Proud metadata nerd
- Spreadsheet enthusiast
- Passionate about standards & traceability
- Stickler for documenting the “why”
- Love training & mentoring others
- 26 years in pharma + proud CDISC contributor
- Resides in New Jersey

Maria Sekac
Director, Clinical Data Standards
Merck & Co., Inc., USA

Agenda

1. Introduction
2. Major Scope Changes
   - Reorganization and Revision of Sections 1-4
   - Metadata Restructuring
   - Changing Supplemental Qualifiers to Non-Standard Variables
   - New Domains (+ new expanded scope domains)
3. Knowledge Base Articles
4. Other References
5. Progress & Milestones

Introduction

SDTMIG v4.0 Next Version, succeeding v3.4

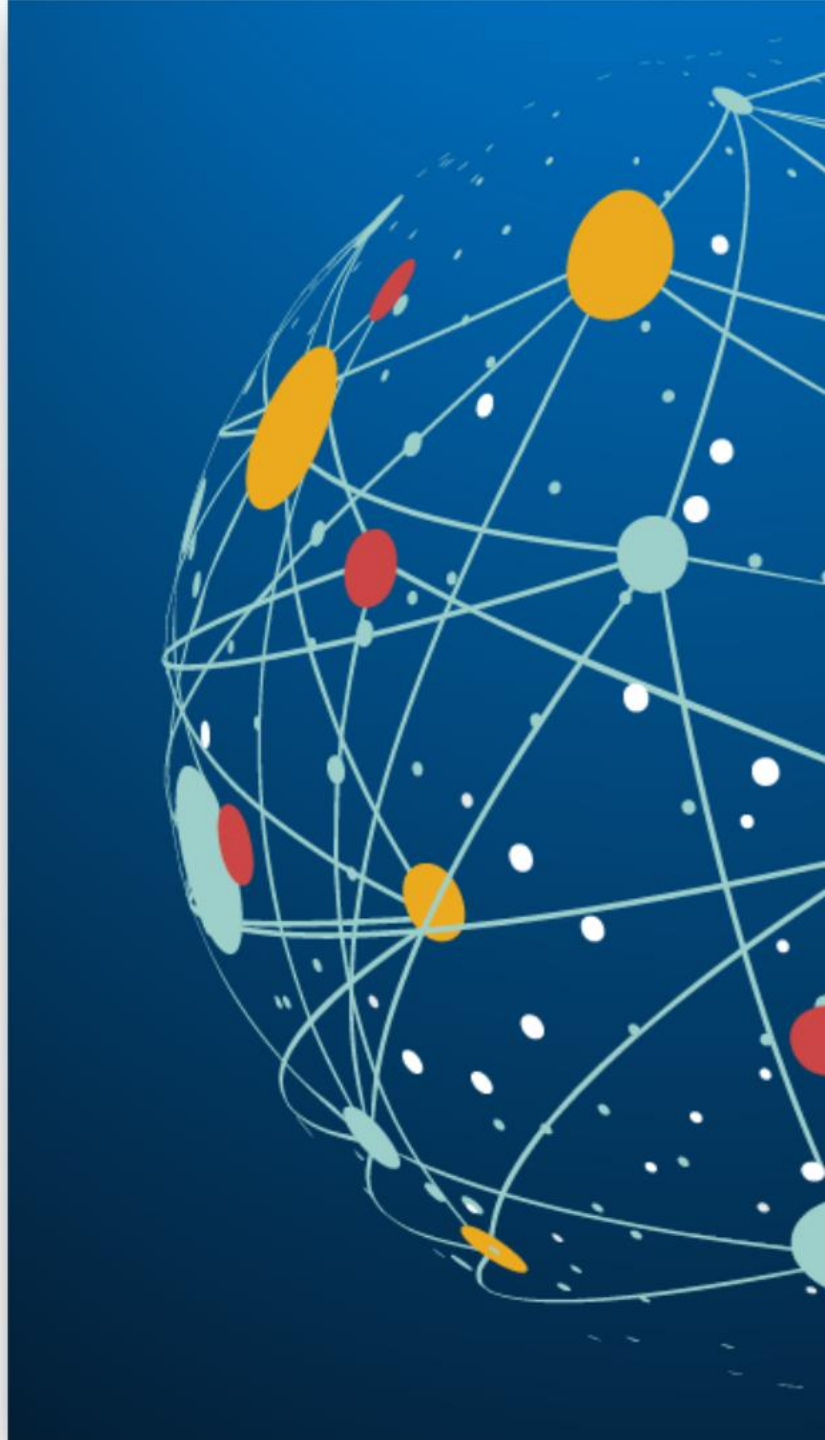
Significant changes introduced.

Developed by industry experts

Led by CDISC and shaped by volunteers and stakeholders across the industry since 2021.

Vetted by the wider standards community

CDASH and ADaM teams, CDISC Governance, and Health Authorities, across internal and public review cycles.



Reorganization and Revision of Sections 1-4

Reorganization and Revision of Sections 1-4:

SDTMIG v3.4 sections

- 1 Introduction
  - 1.1 Purpose
  - 1.2 Organization of this Document
  - 1.3 Relationship to Prior CDISC Documents
  - 1.4 How to Read this Implementation Guide
  - 1.5 Known Issues
- 2 Fundamentals of the SDTM
  - 2.1 Observations and Variables
  - 2.2 Datasets and Domains
  - 2.3 The General Observation Classes
  - 2.4 Datasets Other than General Observation Class Domains
  - 2.5 The SDTM Standard Domain Models
  - 2.6 Creating a New Domain
  - 2.7 SDTM Variables Not Allowed in the SDTMIG
- 3 Submitting Data in Standard Format
  - 3.1 Standard Metadata for Dataset Contents and Attributes
  - 3.2 Using the CDISC Domain Models in Regulatory Submissions – Dataset M
- 4 Assumptions for Domain Models
  - 4.1 General Domain Assumptions
  - 4.2 General Variable Assumptions
  - 4.3 Coding and Controlled Terminology Assumptions
  - 4.4 Actual and Relative Time Assumptions
  - 4.5 Other Assumptions

SDTMIG v4.0 sections

- 1 Introduction
  - 1.1 Purpose
  - 1.2 Organization of this Document
  - 1.3 Relationship to Other CDISC Standards and Resources
  - 1.4 Relationship to Prior Versions of the SDTMIG
  - 1.5 Known Issues
- 2 Fundamentals of the SDTM
  - 2.1 Datasets and Domains
  - 2.2 Root Variables in SDTMIG
  - 2.3 Representation of Variable Relationships
  - 2.4 Subject-level Datasets
  - 2.5 Trial-level Datasets
  - 2.6 How to Determine Where Data Belong in SDTM-Compliant Data Tabula
- 3 Conformance
  - 3.1 Conformance Scope and References
  - 3.2 Data to be Included in SDTM Datasets for Human Clinical Trials
  - 3.3 SDTM Variables Developed for Nonclinical Trials
  - 3.4 Conformance Rules Catalog
- 4 Assumptions for Domain Models
  - 4.1 Preparing Datasets and Dataset Metadata
  - 4.2 Variable Metadata
  - 4.3 Populating Variables
  - 4.4 Assumptions for Identifiers
  - 4.5 Actual and Relative Time Assumptions
  - 4.6 Qualifier Variables Included in Multiple General Observation Classes
  - 4.7 Assumptions for Events and Interventions
  - 4.8 Assumptions for Findings
  - 4.9 Coding and Controlled Terminology Assumptions

- ✓ Improves the orientation, foundational concepts, conformance, and implementation assumptions into a more usable structure.
- ✓ More organized and centralizes information to reduce duplication of the same information across each domain assumption.
- ✓ Goal is to help implementers find the information easier and more quickly.

METADATA RESTRUCTURING

Metadata Restructuring of Domain Tables

- Old Structure

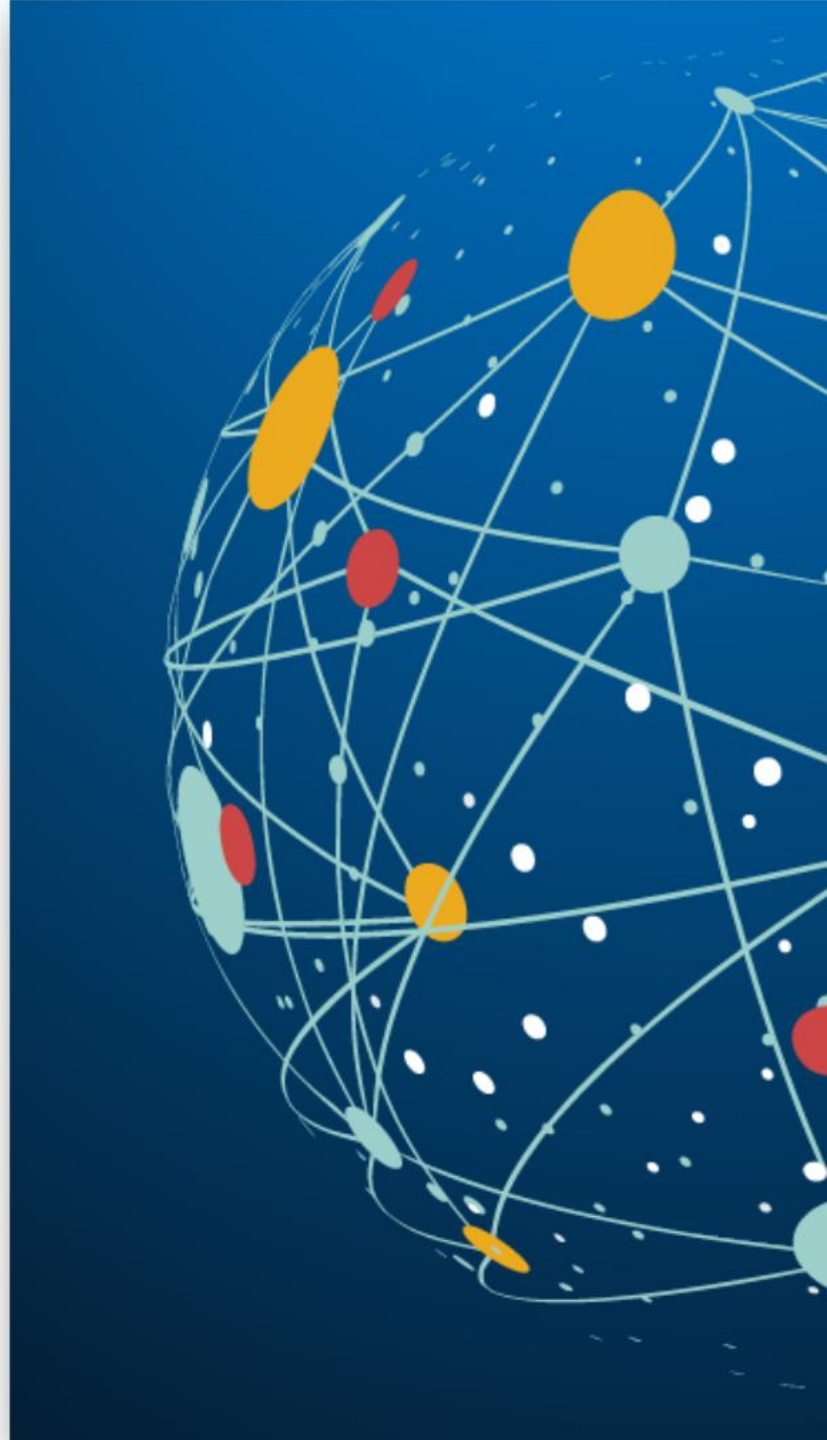
Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
DOMAIN	Domain Abbreviation	Char	CM	Identifier	Two-character abbreviation for the domain.	Req
CMDOSE	Dose per Administration	Num		Record Qualifier	Amount of CMTRT given. Not populated when CMDOSTXT is populated.	Perm
CMDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for CMDOSE, CMDOSTOT, or CMDOSTXT. Examples: "ng", "mg", "mg/kg".	Perm
CMSTDTC	Start Date/Time of Medication	Char	ISO 8601 datetime or interval	Timing	Start date/time of the medication administration represented in ISO 8601 character format.	Perm

- New Structure

#	Variable Name	Variable Label	Type	Codelist	Allowed Controlled Terms	Format	Role	Variable Group	Root Variable C-code	Root Variable Definition	Notes	Examples	Core
2	DOMAIN	Domain Abbreviation	Char	(DOMAIN)	CM		Identifier	Domain	C49558	An abbreviation for a collection of observations, with a topic-specific commonality.	See Datasets and Domains.		Req
21	CMDOSE	Dose per Administration	Num				Qualifier	Dose Amount	C25488	The quantity of an agent (e.g., drug, product, substance, radiation) within a single administration.			Perm
23	CMDOSU	Dose Units	Char	(UNIT)			Qualifier	Dose Amount	C166259	The unit of measure for the administered agent (e.g., drug, substance, radiation).		"ng", "mg", "mg/kg"	Perm
33	CMSTDTC	Start Date/Time of Medication	Char			ISO 8601 datetime or interval	Timing	Date/Time	C82517	The start date or date and time of a subject intervention, event, visit, element, disease	See Date/time Variables.		Perm

Benefits for Restructuring the Metadata Domain Tables

- Parse out overloaded columns of text
- Better organized and more informative
- Machine readable
  - With Variable Groups, Root C-Codes, and Root Definitions, variables are now semantic entities and eliminates manual mapping steps.
- Normative constraints live in machine-testable columns and centralized assumption sections, while informative content is clearly bounded in descriptive columns.



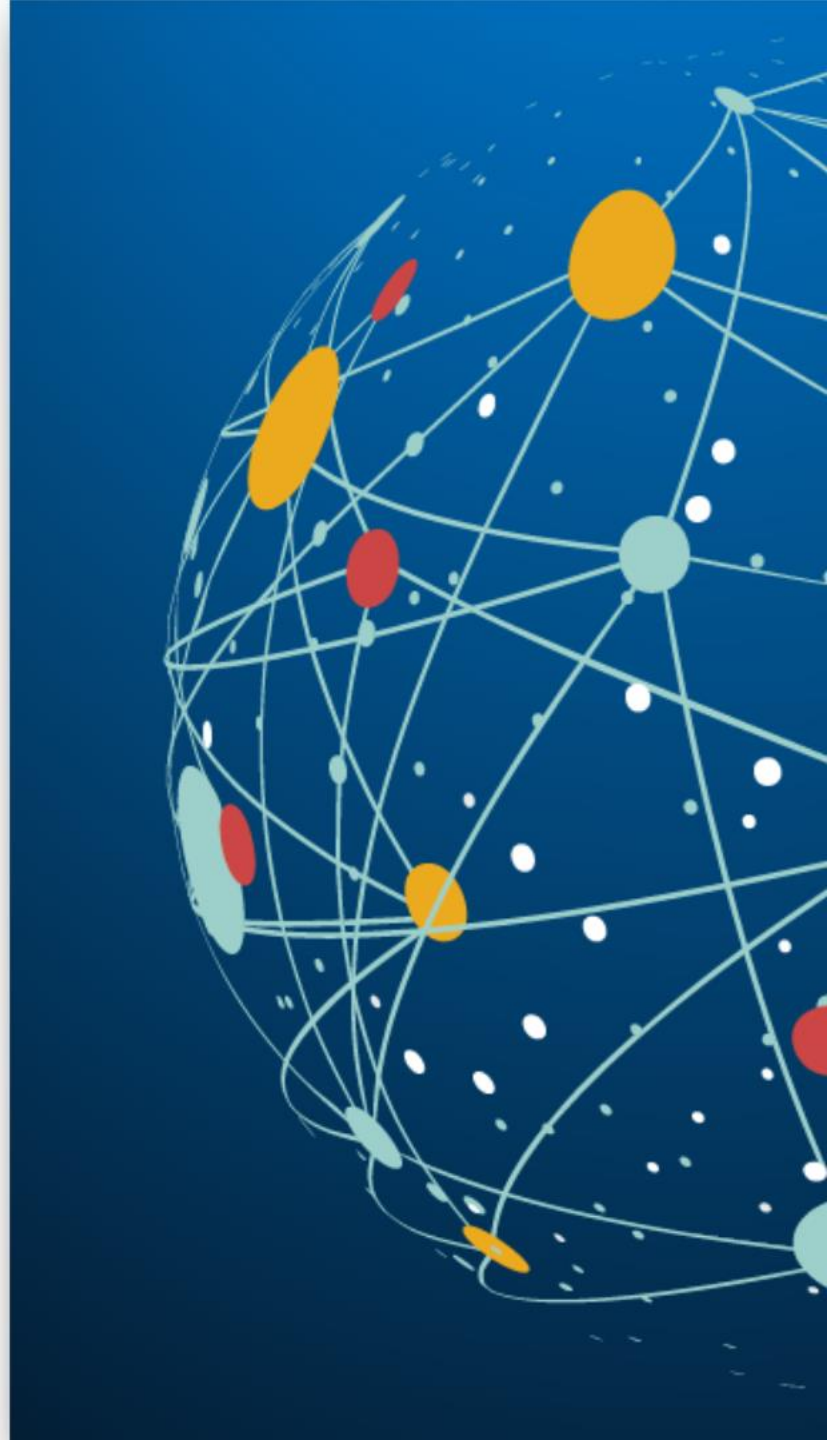
Variable Groups and Variable Relationships

Metadata Component	SDTMIG v3.4 (Legacy Approach)	SDTMIG v4.0 & SDTM v3.0 (Modern Approach)
Role of CMDOSE	Record Qualifier	Qualifier
Role of CMDOSU	Variable Qualifier	Qualifier
Functional Categorization	Inferred vaguely from the role subtype name.	Defined in Variable Group: "Dose Amount"
Variable Connection	Free-text sentence in CDISC Notes: "Units for CMDOSE, CMDOSTOT, or CMDOSTXT."	Explicit triplet in Variable Relationships Table: CMDOSU → QUALIFIES_DOSE_AMOUNT_OF → CMDOSE

Non-standard Variables

Nonstandard Variables Dataset

SDTMIG v4.0	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
Can merge without transposing or character-to-numeric conversion.	Merge requires transposing and often converting IDVARVAL from character to numeric.
Each row in NS-- matches exactly one row in the parent dataset. IDVAR is almost always --SEQ (except for NSDM) 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 variables can now 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.



AE Example: Comparing SUPPAE to NSAE

ae.xpt

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AESEV	AESER	AESMIE	AESTDTC	AEENDTC
1	1996001	AE	99-401	1	UTERINE FIBROIDS	SEVERE	Y	Y	2023-01-05	2023-01-12
2	1996001	AE	99-567	1	FEVER	MILD	N		2023-09-25	2023-09-25

old

suppae.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	1996001	AE	99-401	AESEQ	1	AESOSP	Other Medically Important SAE	Severe, Acute Pelvic Pain
2	1996001	AE	99-401	AESEQ	1	AETRTEM	Treatment Emergent Flag	Y
3	1996001	AE	99-567	AESEQ	1	AETRTEM	Treatment Emergent Flag	N

To merge with parent AE domain, Transpose, and convert IDVARVAL AESEQ from character to numeric.

new

nsae.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVALN	AESOSP	AETRTEM
1	1996001	AE	99-401	AESEQ	1	Severe, Acute Pelvic Pain	Y
2	1996001	AE	99-567	AESEQ	1		N

Metadata for nsae.xpt

NSAE Variable Metadata

Variable	Label	Type	Codelist	Role
AESOSP	Other Medically Important SAE, Specify	Char		Non-standard Qualifier
AETRTEM	Treatment Emergent Flag	Char	(NY)	Non-standard Qualifier

NSVs can also be numeric

New Domains

New Domains

Domain	Title	Observation Class	Expanded Scope
CC	Clinical Classifications	Findings	*
DC	Demographics for Multiple Participations	Special Purpose	
EA	Event Adjudication	Findings About	
LC	Laboratory Test Results in Conventional Units	Findings	*

Domain	Title	Observation Class	Expanded Scope
AU	Auricular System Findings	Findings	*
ED	Endocrine System Findings	Findings	*
GI	Gastrointestinal System Findings	Findings	
HM	Hematopoietic System Findings	Findings	*
IG	Integumentary System Findings	Findings	*

*Expanded Scope

Clinical Classification (CC) Domain

- Description:
  - A findings domain that contains data for named instruments whose output is an ordinal or categorical score that serves as a surrogate for, or ranking of, disease or disorder status, or other physiological or biological status.
  - **Previously, Clinical Classifications and Disease Response criteria were mapped in a single domain. Now Clinical Classification instruments should be represented in the Clinical Classifications (CC) domain while Disease Response criteria are represented in the Disease Response (RS) domain.**
- Rationale:
  - Community feedback showed RS was overloaded, mixing disease-response assessments with clinical classification instruments has led to significant confusion, complexity, and implementation challenges.
- Benefits:
  - Brings greater clarity, consistency, and ease of implementation by giving classification instruments their own domain and keeping RS focused on disease response assessment.

Clinical Classification (CC) Domain

- Clinical Classifications are based on a trained healthcare professional's observation and clinical judgement of a subject's health condition and may rely on objective data from clinical records or interpretation of directly observable signs and physical manifestations.
- Follows QRS Naming Conventions and Business Rules

cc.xpt

Row	STUDYID	DOMAIN	USUBJID	CCSEQ	CCTESTCD	CCTEST	CCCAT	CCORRES	CCSTRESC	CCSTRESN	CCSTAT	CCLOBXFL	VISITNUM	CCDTC
1	STUDYX	CC	P0001	1	GCS0101	GCS01-Best Eye Response	GCS NINDS V1.0	No eye opening	1	1		Y	1	5/15/2012
2	STUDYX	CC	P0001	2	GCS0102	GCS01-Motor Response	GCS NINDS V1.0	Abnormal extension	2	2		Y	1	5/15/2012
3	STUDYX	CC	P0001	3	GCS0103	GCS01-Verbal Response	GCS NINDS V1.0	Incomprehensible sound	2	2		Y	1	5/15/2012
4	STUDYX	CC	P0001	4	GCS0104	GCS01-Total Score	GCS NINDS V1.0	5	5	5		Y	1	5/15/2012

- Key Differences Between Disease Response and Clinical Classification

Feature	Disease Response Data (RS)	Clinical Classification Data (CC)
Purpose and Primary End Point Measured	Measures how a disease (e.g. cancer) responds to treatment (e.g., tumor shrinkage, progression, no response, stable disease etc.).	Provides a surrogate score or ranking for a patient's disease status, severity, or prognosis.
Clinical Question Answered	"How well does the disease respond to therapy?"	"How severe is the disease?" or "What is the prognosis?"
Data Mapping Strategies	Uses standardized, generic, reusable tests and results across different criteria (e.g., RECIST 1.1, RANO).	Employs instrument-specific tests and results with no reusability between different clinical classifications (e.g., Child-Pugh, APACHE).
Controlled Terminology	Governed by the oncology SDS team. A small number of codelists (4) are used with broad applicability.	Governed by the QRS teams. A large and growing number of codelists (271+) exist, each specific to an instrument. Follows the QRS Naming and Business Rules.

Demographics for Multiple Participations (DC)

- Description:
  - A special-purpose domain that describe each participation of a subject in a clinical study.
- Rationale:
  - Clinical trials historically managed Multiple Subject Instances (MSI) inconsistently.
  - Addresses the FDA sdTCG requirements.
- Benefits:
  - Provides standardized traceability for repeat screenings and enrollments while keeping DM with one record per subject.

Demographics for Multiple Participations (DC) Domain

- One record per participation for all subjects
- Required when (and only when) there are multiple enrollments

- FDA: “the primary enrollment should be submitted in DM”

dc.xpt

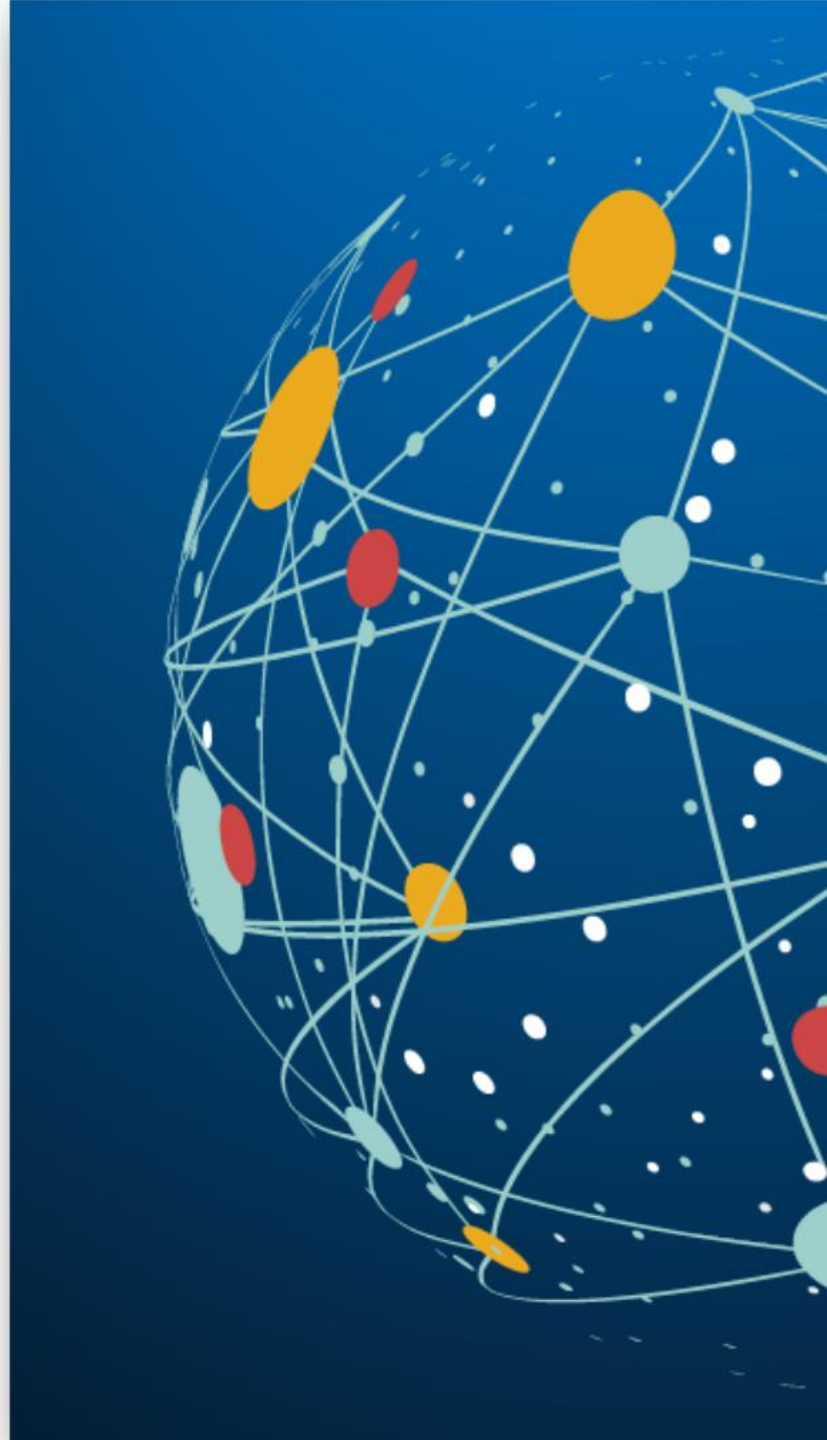
Row	STUDYID	DOMAIN	USUBJID	SUBJID	DCSEQ	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS
1	ABC123	DC	ABC12301001	1001	1	1/14/2006	1/28/2006	1/14/2006	1/28/2006	1/5/2006	A	Drug A	A	Drug A	
2	ABC123	DC	ABC12301002	1002	1	1/12/2006	1/26/2006	1/12/2006	1/26/2006	1/4/2006	P	Placebo	P	Placebo	
3	ABC123	DC	ABC12301003	1003	1					9/13/2005					SCREEN FAILURE
4	ABC123	DC	ABC12301003	1003B	2					11/14/2005					SCREEN FAILURE
5	ABC123	DC	ABC12301003	1003C	3	1/16/2006	2/1/2006	1/16/2006	2/1/2006	1/7/2006	A	Drug A	A	Drug A	

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID		RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS
1	ABC123	DM	ABC12301001	1001		1/14/2006	1/28/2006	1/14/2006	1/28/2006	1/5/2006	A	Drug A	A	Drug A	
2	ABC123	DM	ABC12301002	1002		1/15/2006	2/28/2006	1/15/2006	2/28/2006	1/4/2006	P	Placebo	P	Placebo	
3	ABC123	DM	ABC12301003	1003C		1/16/2006	2/1/2006	1/16/2006	2/1/2006	1/7/2006	A	Drug A	A	Drug A	

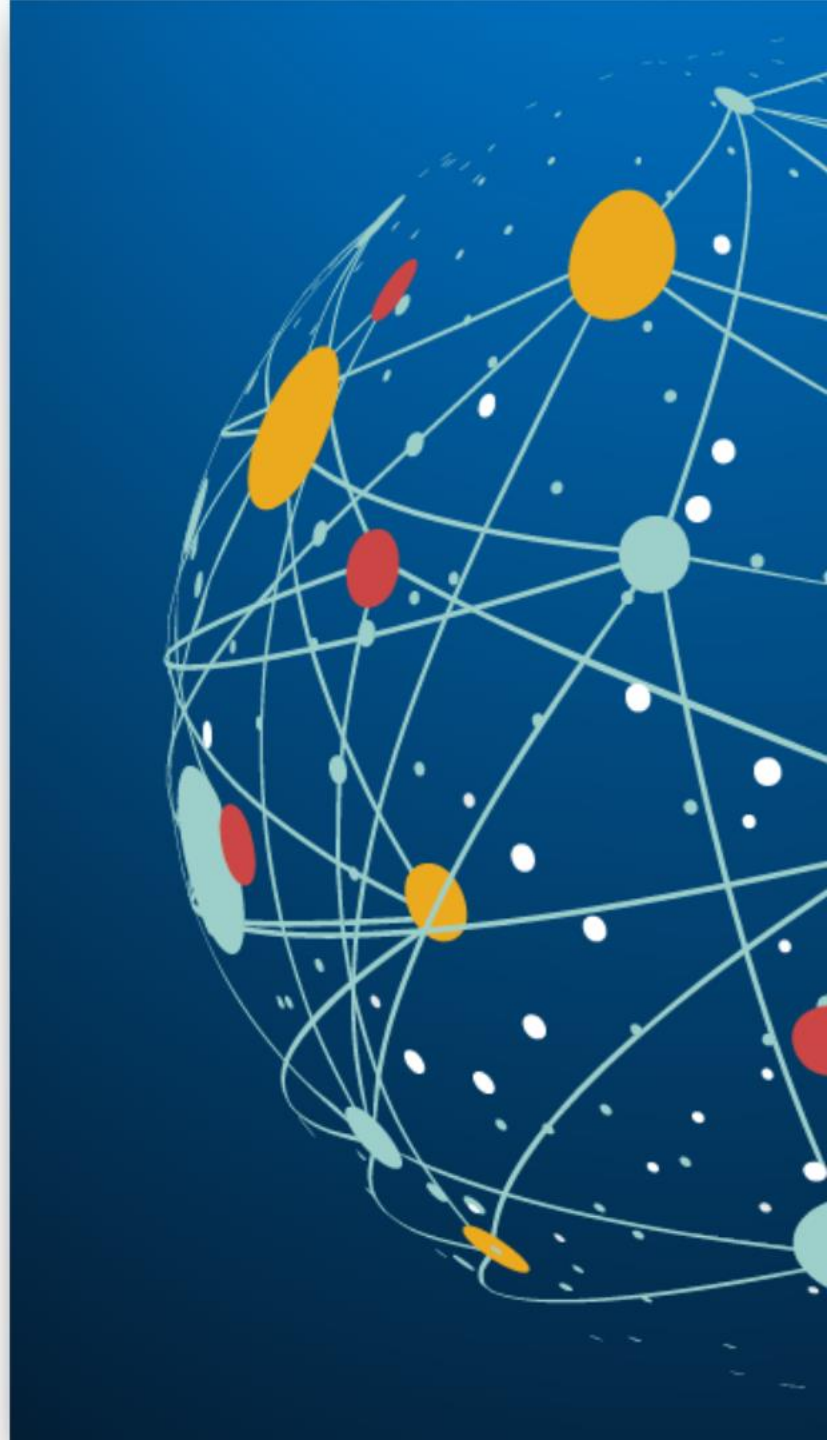
Other Impacts of DC and DM

- All study day variables are still derived from DM.RFSTDTC
- DCSEQ is required
  - If creating NSDC: IDVAR=DCSEQ
  - If creating NSDM: IDVAR and IDVARVLN will still be NULL
- DC.SEX is expected (not required) because it may not be collected at re-screening
- MULTIPLE can be used in DM when responses differ across participations for SEX, RACE, CRACE, ETHNIC, CETHNIC
- DC.RFSTDTC and DC.RFENDTC are permissible (not required)
  - If one is present, both must be present
- No DCDY (avoids DC depending on DM)



Other Impacts of DC and DM

- SUBJID required in DM domain (and new DC domain)
- SUBJID added as permissible variable in all subject domains
- New section 4.4.3 about USUBJID and SUBJID
- SUBJID is used when there are multiple enrollments
- Uniqueness of --SEQ is still relative to USUBJID
- SUBJID is not used in RELREC, RELSUB, or RELSPEC
- Subject Visits (SV) now requires SVSEQ
  - Assigned in a chronological sequence
  - Cannot assume USUBJID and VISITNUM uniquely identify a record
- Subject Elements (SE) allows gaps between participations only



Event Adjudication (EA) Domain

- Description:
  - The Event Adjudication (EA) domain is used to represent data about the adjudication of events using the Findings About specialization of the Findings observation class.
- Rationale:
  - Lack of consistent mapping across sponsors.
- Benefits:
  - Provides a standard domain that expands upon the PHUSE paper from 2019, which is a similar approach described in the FDA "Technical Specification for Submitting Clinical Trial Data Sets for Treatment of Nonalcoholic Steatohepatitis (NASH), 2022“

EA Domain Use Case

- This example depicts the adjudication of a study endpoint.

ae.xpt

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AESPID	AETERM	AEDECOD	AEREL	AESTDTC	AEENDTC
1	ABC	AE	ABC-01-101	4	4	DRUG-INDUCED LIVER INJURY	Drug-induced liver injury	RELATED	2015-02-13	2015-03-13

ea.xpt

Row	STUDYID	DOMAIN	USUBJID	EASEQ	EASPID	EATESTCD	EATEST	EAOBJ	EAORRES	EASTRESC	EASTRESN	EAMETHOD	EAEVAL	EAEVALID	EAACPTFL
1	ABC	EA	ABC-01-101	1	4	REL	Relation to Study Treatment or Product	Drug-induced liver injury	PROBABLE	3	3	FONTANA DILIN NUMERIC SCORE 2009	ADJUDICATOR	ADJUDICATOR 1	
2	ABC	EA	ABC-01-101	2	4	REL	Relation to Study Treatment or Product	Drug-induced liver injury	HIGHLY LIKELY	2	2	FONTANA DILIN NUMERIC SCORE 2009	ADJUDICATOR	ADJUDICATOR 2	
3	ABC	EA	ABC-01-101	3	4	REL	Relation to Study Treatment or Product	Drug-induced liver injury	HIGHLY LIKELY	2	2	FONTANA DILIN NUMERIC SCORE 2009	ADJUDICATION COMMITTEE		Y
4	ABC	EA	ABC-01-101	4	4	EVSTDTC	Start Date/Time of Event	Drug-induced liver injury	2015-02-13	2015-02-13			ADJUDICATOR	ADJUDICATOR 1	
5	ABC	EA	ABC-01-101	5	4	EVSTDTC	Start Date/Time of Event	Drug-induced liver injury	2015-02-13	2015-02-13			ADJUDICATOR	ADJUDICATOR 2	Y

Laboratory Test Results in Conventional Units (LC) Domain

- Description:
  - A specimen-based findings domain that contains laboratory test data, such as hematology, clinical chemistry and urinalysis, with results aligned to uniform regional conventional units.
- Rationale:
  - Directly requested by the FDA (sdTCG June 2023) to review unstandardized native clinical lab values.
- Benefits:
  - Gives medical reviewers immediate access to conventional units without distorting or complicating LB standardization.

Laboratory Test Results in Conventional Units (LC) Domain

- Example for demonstration purposes as variables displayed do not include the domain prefix

Row	STUDYID	DOMAIN	USUBJID	--SEQ	--TESTCD	--TEST	--ORRES	--ORRESU	--ORNRLO	--ORNRHI	--STRESC	--STRESN	--STRESU	--STNRLO	--STNRHI	--DTC
1	ABC	LB	ABC-001-001	1	ALB	Albumin	3.0	g/dL	3.6	5.1	30.0	30.0	g/L	35.0	50.0	2026-07-01
1	ABC	LC	ABC-001-001	1	ALB	Albumin	3.0	g/dL	3.6	5.1	3.0	3.0	g/dL	3.6	5.1	2026-07-01
2	ABC	LB	ABC-002-005	4	CRP	Bilirubin	25.65	umol/L	3.4	20.5	25.65	25.65	umol/L	3.4	20.5	2026-08-05
2	ABC	LC	ABC-002-005	4	CRP	Bilirubin	25.65	umol/L	3.4	20.5	1.5	1.5	mg/dL	0.2	1.2	2026-08-05

- Subject ending in 001:
  - LB domain: original results/units were reported in conventional units; STRESC/STRESN/STRESU converted to SI units
  - LC domain: original value/units from LB copied to ORRES/ORRESU; STRESC/STRESN/STRESU stores the Conventional Units
- Subject ending in 005:.
  - LB domain: original results/units were reported in SI units; STRESC/STRESN/STRESU store the SI units
  - LC domain: original value/units from LB copied to ORRES/ORRESU; STRESC/STRESN/STRESU converted to Conventional Units

New Morphology/Physiology Domains

Domain	Title	Observation Class	Description
AU	Auricular System Findings	Findings	A findings domain for physiological and morphological findings of the ear and auditory system, including otoscopy, audiometry and related assessments.
ED	Endocrine System Findings	Findings	A findings domain for physiological and morphological findings related to the endocrine system and its glands.
GI	Gastrointestinal System Findings	Findings	A findings domain that contains physiological and morphological findings related to the gastrointestinal system, including the esophagus, stomach, small and large intestine, anus, liver, biliary tract and pancreas.
HM	Hematopoietic System Findings	Findings	A findings domain for physiological and morphological findings of the hematopoietic and lymphatic system, such as bone marrow and lymphatic assessments.
IG	Integumentary System Findings	Findings	A findings domain for physiological and morphological findings of the skin, hair, and nails.

- Findings Data
- Part of the Morphology/Physiology Domains
- Supports Various TAUG Use Cases
- SDTM CT test/testcds created to support the domains

Knowledge Base Articles, Other References, Progress & Milestones

Knowledge Base Articles

- Three (3) draft Knowledge Base Articles related to SDTMIG v4.0 new content
- These articles will be finalized and published with SDTMIG v4.0
- Available in the SDTMIG v4.0 Wiki space and via links in the Instructions for Reviewers and Public Review announcement email

  - NS-- Datasets: Why they were built as they were.
  - Why change the structure of SDTMIG metadata?
  - Why does the DC domain differ from what's described in FDA's TCG?

Other Sources for Reference

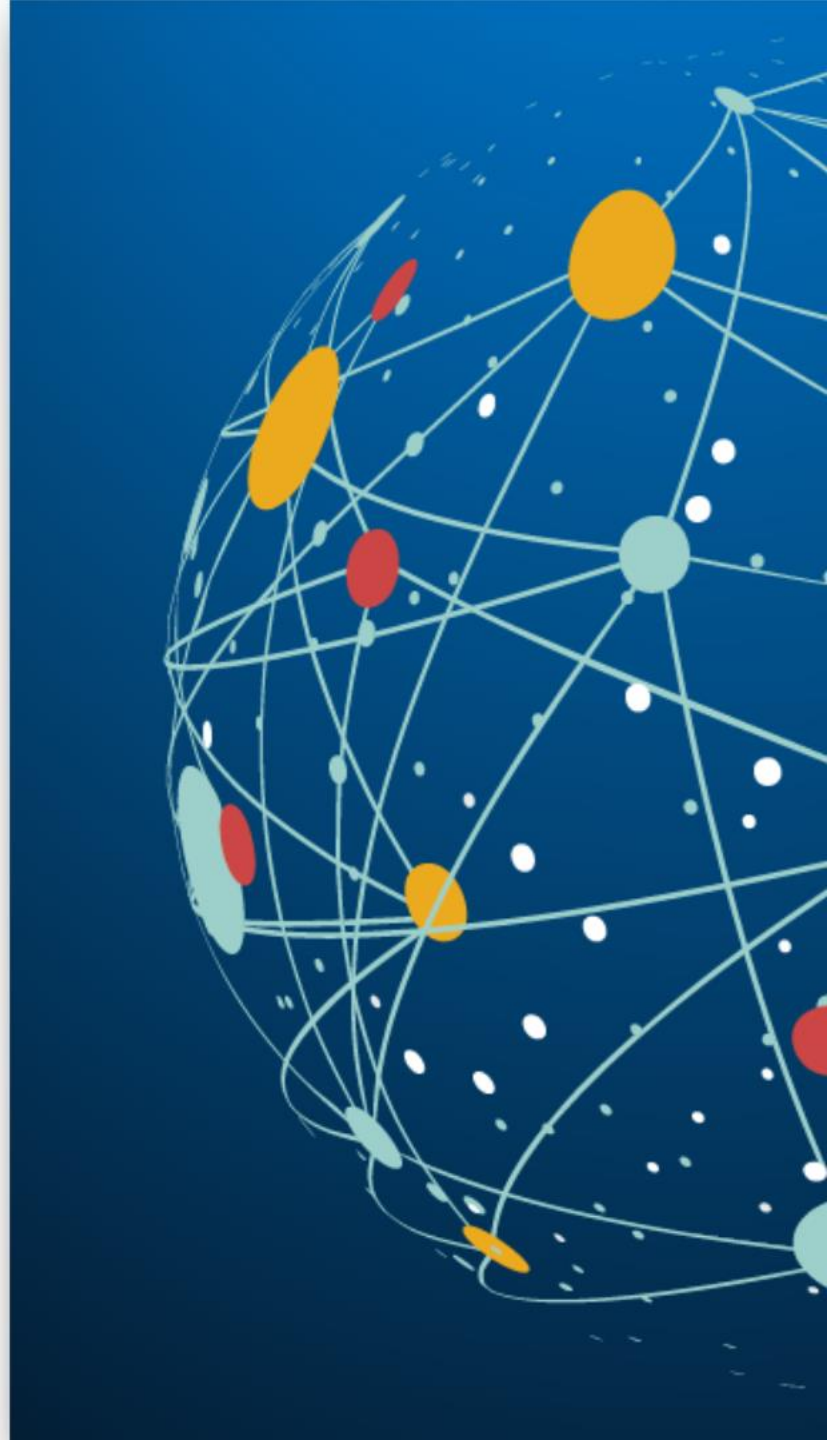
- CDISC Webinar: SDTM v3.0 and SDTMIG v4.0 for Public Review (Feb2026)
  - https://www.cdisc.org/events/webinar/sdtmig-v4-0-sdtm-v3-0-public-review
- PHUSE paper: SDTMIG v4.0: Are You Ready For It? (Mar2026)
  - https://phuse.s3.eu-central-1.amazonaws.com/Archive/2026/Connect/US/Austin/PAP_DS13.pdf
- CDISC Interchange Presentation: An Overview of the New DC Domain (Oct2025)
  - https://www.cdisc.org/sites/default/files/interchange/presentations/public/5B.3%20An%20Overview%20of%20Demographics%20for%20Multiple%20Participations%20%28DC%29.pdf
- CDISC Webinar: Splitting of RS and CC (Apr2026)
  - https://www.cdisc.org/events/webinar/members-only-webinar-sdtmig-v4-0-splitting-rs-domain-rs-and-cc
- CDISC Webinar: New LC Domain (May2026)
  - https://www.cdisc.org/events/webinar/member-webinar-new-sdtmig-v4-0-content-requested-fda

Progress and Milestones

Month/Year	Tasks
Oct 2021 – Mar 2025	Development of Draft Standards
Apr 2025 – Feb 2026	Internal Review and Comment Resolution
Feb 2026 – Oct 2026	Public Review (including expanded scope)
Oct 2026 – Jan 2027	Public Review Comment Resolution
Q2 2027*	Publication

** Pending review and resolution of Public Review comments*

- CDISC Standards Timelines & Scope Changes:
  - https://www.cdisc.org/standards/timeline



Thank you!

Questions?

