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Introduction to SDTMIG v4.0: Key Updates and What's New

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29 October 2026

Agenda

1. Background & Restructuring
2. Non-standard Variables
3. Multiple Subject Instances
4. Additional SDTM and SDTMIG Updates
5. Review Instructions

Speaker



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Director
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Hyunsoo Lee is clinical research professional with over 20 years of experience in the pharmaceutical and CRO industries, specializing in Data Management and Biostatistics.
Throughout her career, she has held leadership roles at pharmaceutical companies and global CROs, overseeing clinical data management, statistical programming, and clinical trial data analysis across a wide range of therapeutic areas.

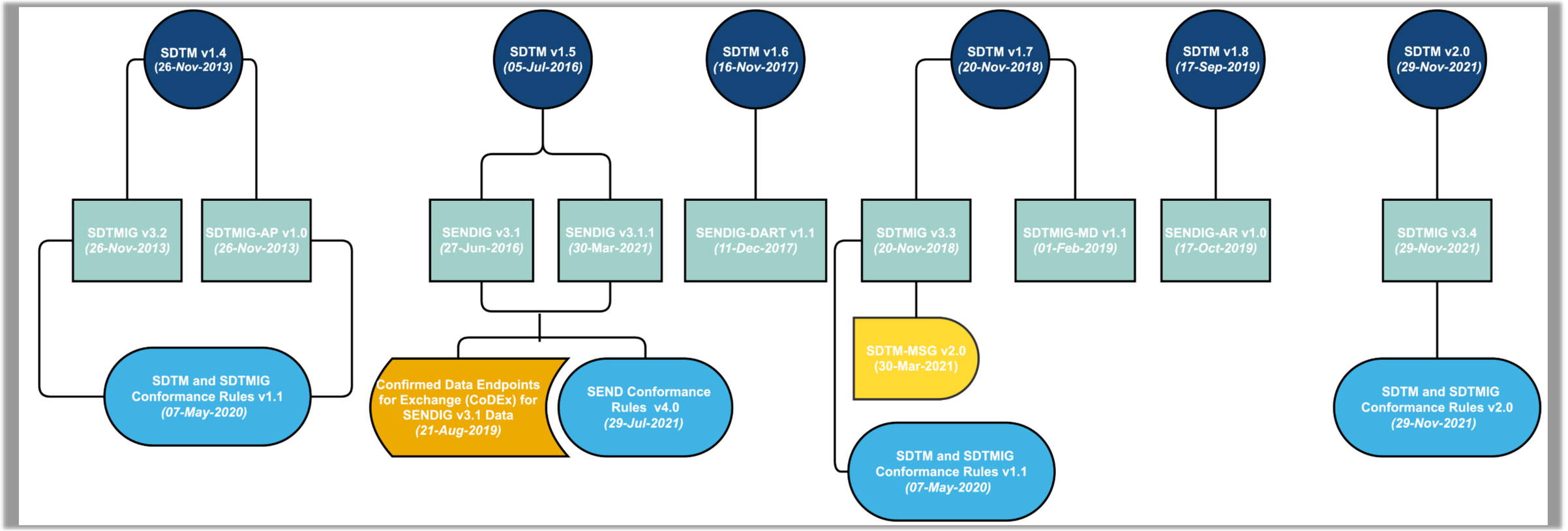
At JNPMEDI, she focuses on developing innovative clinical solutions leveraging Data-Driven Formats (DDF) to advance the digital transformation of clinical research. Her work aims to bridge clinical protocol content and structural clinical data, enabling more standardized, connected, and efficient clinical trial processes.

Disclaimer and Disclosures

This presentation is largely adapted and summarized from official CDISC webinar materials for education and sharing purposes

Background & Restructuring

Background


SDTM v1.4
(26-Nov-2013)
SDTM v1.5
(05-Jul-2016)
SDTM v1.6
(16-Nov-2017)
SDTM v1.7
(20-Nov-2018)
SDTM v1.8
(17-Sep-2019)
SDTM v2.0
(29-Nov-2021)
SDTMIG v3.2
(26-Nov-2013)
SDTMIG-AP v1.0
(26-Nov-2013)
SENDIG v3.1
(27-Jun-2016)
SENDIG v3.1.1
(30-Mar-2021)
SENDIG-DART v1.1
(11-Dec-2017)
SDTMIG v3.3
(20-Nov-2018)
SDTMIG-MD v1.1
(01-Feb-2019)
SENDIG-AR v1.0
(17-Oct-2019)
SDTMIG v3.4
(29-Nov-2021)
SDTM and SDTMIG Conformance Rules v1.1
(07-May-2020)
Confirmed Data Endpoints for Exchange (CoDEx) for SENDIG v3.1 Data
(21-Aug-2019)
SEND Conformance Rules v4.0
(29-Jul-2021)
SDTM-MSG v2.0
(30-Mar-2021)
SDTM and SDTMIG Conformance Rules v1.1
(07-May-2020)
SDTM and SDTMIG Conformance Rules v2.0
(29-Nov-2021)

Background

- **SDTMIG 4.0**
  - Major revision to SDTMIG 3.4
  - Scoping Started 2020

- **SDTM3.0**
  - Revision to 2.0 (SDTMIG 3.4) and 2.1 (Tabacco)
  - Completed Variable Definitions
  - Added Variable Groups
  - Added Variable Relationships

High-level changes in SDTMIG v4.0

- Reorganization/ Re-write of Section 1-4
- Metadata Restructuring
- --BLFL variable removal
- Protocol Deviations (DV) updates
- Event Adjudication (EA)
- Gastrointestinal Finding (GI)
- Multiple Subject Instances (MSI)
- SUPPQUAL (SUPP--) to NSV (NS--)

Metadata Restructuring

Old Structure

Deleted

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DD	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DDSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req

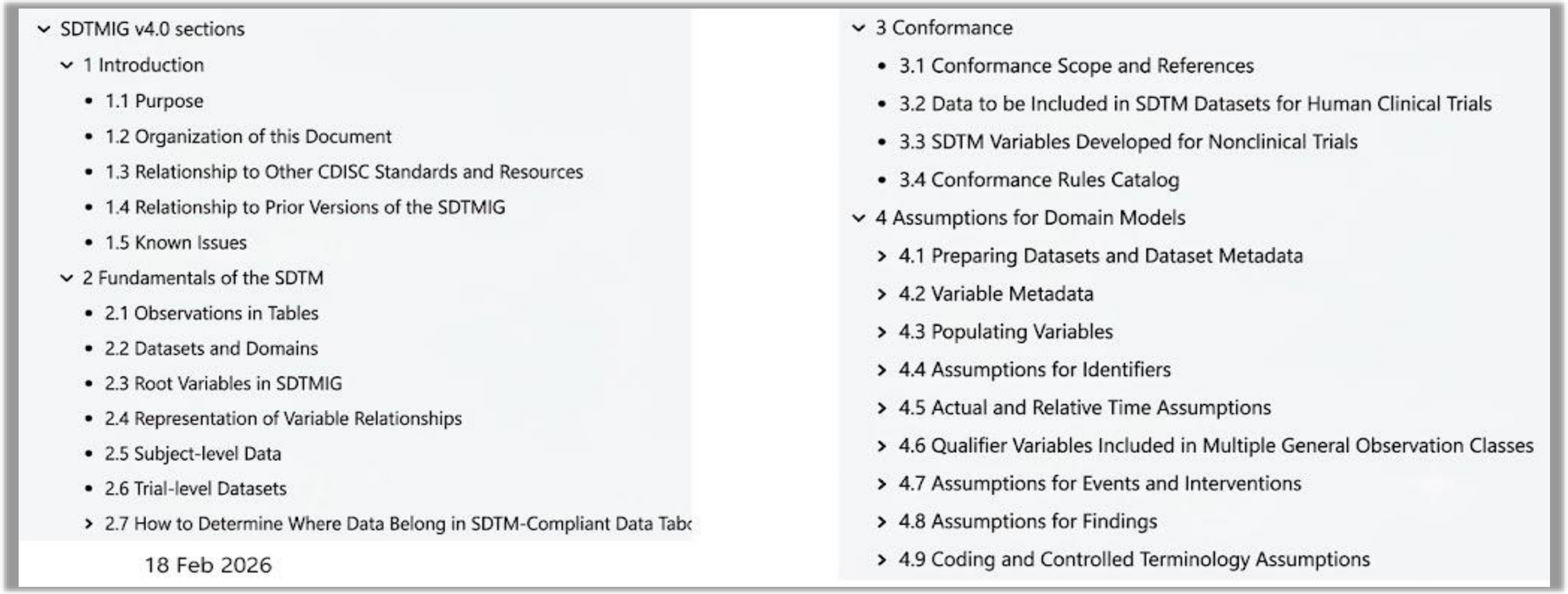
New Structure

Split into | Updated | Added | Added

#	Variable Name	Variable Label	Type	Codelist	Allowed Controlled Terms	Format	Role	Variable Group	Root Variable C-code	Root Variable Definition	Notes	Examples	Core
1	STUDYID	Study Identifier	Char				Identifier	Study	C83082	A sequence of characters used to identify or name the study.			Req
2	DOMAIN	Domain Abbreviation	Char	(DOMAIN)	DD		Identifier	Domain	C49558	An abbreviation for a collection of observations, with a topic-specific commonality.	See Datasets and Domains.		Req

Reorganization and Rewrite of Section 1~4

- to add more clarity
- to improve the content's organization
- to ensure that general assumptions are consistent, and in one place



Reorganization and Rewrite of Section 1~4

Section	Previous Version	New Version	Key Structural Changes
Section 1	1. Introduction 1.1 Purpose 1.2 Organization of this Document 1.3 Relationship Prior CDISC Documents 1.4 How to Read this Implementation Guide	1. Introduction 1.1 Purpose 1.2 Organization of this Document 1.3 Relationship to Other CDISC Standards and Resource 1.4 Relationship to Prior Versions of the SDTMIG 1.5 Known Issues	✓ CDISC 타 표준과의 관계 세분화 ✓ 알려진 문제점 세션 추가
Section 2	2. Fundamentals of the SDTM 2.1 Observations and Variables 2.2 Datasets and Domains 2.3 General Observation Classes 2.4 Datasets Other Than General Observation 2.5 Standard Domain Model 2.6 Creating a New Domain 2.7 SDTM Variables Not Allowed	2. Fundamentals of the SDTM 2.1 Observations in Tables 2.2 Datasets and Domains 2.3 Root Variables in SDTMIG 2.4 Representation of Variable Relationships 2.5 Subject-level Data 2.6 Trial-level Datasets 2.7 How to Determine Where Data Belong in SDTM-Compliant Data Tabulations	✓ 메타데이터 관전 (Root Variables, 변수 간 관계 등) 으로 기초 개념 전면 재정비

Reorganization and Rewrite of Section 1~4

Section	Previous Version	New Version	Key Structural Changes
Section 3	3. Submitting Data in Standards Format 3.1 Standard Metadata for Dataset Contents and Attributes 3.2 Using the CDISC Domain Models in Regulatory Submissions Dataset Metadata	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	✓ 섹션 명칭 변경 ✓ 단순 데이터 제출 안내에서 규정 준수 기준 및 검증 규칙 (Conformance Rules)체계로 모듈화
Section 4	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	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 Finding 4.9 Coding and Controlled Terminology Assumptions	✓ 가장 결정적 변화 ✓ V3.4까지 각 도메인(AE, LB등) Specifications 하단 주석 (CDISC Notes) 및 4.5에 파편화 되어 있던 작성 규칙을 4.1~4.9 소단원으로 전면 통합정리

Non-standard Variables

No more SUPPQUAL

AE Example: Comparing SUPPAE to NSAE

ae.xpt Convert IDVARVAL from character to numeric

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

Transpose

suppae.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	1996001	AE	99-401	AESEQ	1	AESOSP	Other Medically Important SAE	SPONTANEOUS ABORTION	CRF	
2	1996001	AE	99-401	AESEQ	1	AETRTEM	Treatment Emergent Flag	Y	Derived	
3	1996001	AE	99-567	AESEQ	1	AETRTEM	Treatment Emergent Flag	N	Derived	

nsae.xpt

Row	STUDYID	DOMAIN	USUBJID	IDVAR	IDVARVLN	AESOSP	AETRTEM
1	1996001	AE	99-401	AESEQ	1	SPONTANEOUS ABORTION	Y
2	1996001	AE	99-567	AESEQ	1		N

NSAE metadata

Variable	Label	Type	Codelist	Role	Origin Type	Origin Source
AESOSP	Other Medically Important SAE	Char		Non-Standard Qualifier	Collected	Investigator
AETRTEM	Treatment Emergent Flag	Char	(NY)	Non-Standard Qualifier	Derived	Sponsor

Non-Standard Variables (NS--)

Previous Versions	SDTM 3.0 and SDTMIG 4.0
Dataset named SUPP--, one per parent dataset	Dataset named NS--, one per parent dataset
Vertical: one row per populated nonstandard variable value	Horizontal: one row, per row in the parent dataset with at least one nonstandard variable populated
A row in SUPP– may match more than one row in the parent dataset (IDVAR could be –GRPID) and IDVARVAL is character	Each row in NS– matches exactly one row in the parent dataset. IDVAR is always –SEQ and IDVARVLN is numeric
QVAL is always a character field	Nonstandard variable columns can be character or numeric
Value-level metadata in Define-xml for QVAL, based on value of QNAM	Variable-level metadata in Define-xml for nonstandard variables
Merge requires transposing and often converting IDVARVAL from character to numeric	Can merge without transposing or character-to-numeric conversion

Multiple Subject Instances

SUBJID Everywhere, and DC Domain

SUBJID Everywhere

- **SDTM 3.0**
  - SUBJID has been added to “Identifiers for all Classes”

- **SDTMIG 4.0**
  - 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

SUBJID Everywhere

6.1.2 Concomitant/Prior Medications (CM)

CM – Description/Overview

An interventions domain that contains concomitant and prior medications used b
medications.

CM – Specification

cm.xpt, Concomitant/Prior Medications — Interventions. One record per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes
STUDYID	Study Identifier	Char		Identifier	Unique identifier fo
DOMAIN	Domain Abbreviation	Char	CM	Identifier	Two-character abb
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to u the product.
CMSEQ	Sequence Number	Num		Identifier	Sequence number
CMGRPID	Group ID	Char		Identifier	Used to tie togethe
CMSPID	Sponsor-Defined	Char		Identifier	Sponsor-defined re

CM Specification

작성자: Dana Booth, 마지막 업데이트: Dianna DiRusso, 업데이트 날짜: 2026-08-24 • 6분 읽기

General Assumptions
In addition to the domain-specific assumptions listed here, implementers should follow the gener

Metadata Check for SDTMIG SENDIG Domain Specification Table Beta 1
Metadata check macro is applied and detected no issues. This notice is provided as a visual reminder. It w

#	Variable Name	Variable Label	Type	Codelist	Allowed Controlled Terms	Format	Role
1	STUDYID	Study Identifier	Char				Identifier
2	DOMAIN	Domain Abbreviation	Char	(DOMAIN)	CM		Identifier
3	USUBJID	Unique Subject Identifier	Char				Identifier
4	SUBJID	Subject Identifier for the Participation	Char				Identifier
5	CMSEQ	Sequence Number	Num				Identifier

4.4.3 USUBJID and SUBJID

USUBJID and SUBJID

작성자: Diane Wold, 마지막 업데이트: Dianna DiRusso, 업데이트 날짜: 2026-01-18 • 1분 읽기

This section was previously part of the section, Use of "Subject" and "USUBJID." The explanation for the use of "subject" rather than "patient" has been moved into a separate section.

USUBJID

The unique subject identifier (USUBJID) is required in all datasets containing subject-level data, unless the dataset includes records that use POOLID (see Section 4.4.2, Identifying the Subject of an Observation). USUBJID values must be unique for each trial participant (subject) across all trials in the submission. This means that no 2 or more subjects, across all trials in the submission, may have the same USUBJID. In addition, the same person who participates in multiple clinical trials (when this is known) must be assigned the same USUBJID value in all trials.

CDISC does not recommend any specific format for the values of USUBJID, only that the values need to be unique for all subjects in the submission, and across multiple submissions for the same compound. Many sponsors concatenate values for the study, site, and subject into USUBJID, but this is not a requirement. It is acceptable to use any format for USUBJID, as long as the values are unique across all subjects.

SUBJID

For subjects who have multiple participations in a study (e.g., are screened multiple times), subject records (i.e., general observation class domain and special-purpose domain records) should include SUBJID, which identifies the participation, as well as USUBJID, which identifies the person. SUBJID is often the ID of the subject as recorded on a CRF, although the value of SUBJID may be derived as necessary to ensure uniqueness.

4.4.3 USUBJID and SUBJID

- **USUBJID**
  - 필수조건: Subject-level data가 포함된 모든 데이터셋이 Required로 들어가야 함
  - Uniqueness: 모든 임상시험을 통틀어 각 대상자마다 고유한 값
  - 동일한 사람이 여러 임상시험에 참여한 경우 모든 임상시험에서 동일한 USUBJID 값을 부여해야 함
- **SUBJID**
  - 다중 참여 시 구분: 한 임상시험 내에서 여러 번 참여/ 등록하는 경우 USUBJID 뿐만 아니라 SUBJID를 함께 포함해야 함

4.4.3 USUBJID and SUBJID

The following dm.xpt sample rows illustrate a single subject who participates in 2 studies, first in ACME01 and later in ACME14. Note that this is only one example of the possible values for USUBJID.

dm.xpt

dm.xpt

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	SITEID	INVNAM
1	ACME01	DM	ACME01-05-001	001	05	John Doe

dm.xpt

dm.xpt

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	SITEID	INVNAM
1	ACME14	DM	ACME01-05-001	017	14	Mary Smith

Multiple Participations: DM and DC (Demographics for Multiple Participations)

- **FDA Request**
  - "A custom domain with a structure similar to DM"
- **New Special Purpose domain in SDTM 3.0 and SDTMIG 4.0**
  - Model restricts use to human clinical trials
- **DC Domain: Demographics for Multiple Participations**
  - One record per participation for all subjects: no need to combine with DM
  - Structure matches DM
  - Required when (and only when) there are multiple enrollments
  - DM can often be derived from DC
    - Strategy 1: Always create DC and do not submit DC if not needed
    - Strategy 2: Create DM first and then only create DC when needed

Multiple Participations: DM and DC

- **Shared Demographics Assumptions**
  - All DM assumption are shared
  - Additional assumptions specific to DC

- **FDA: “the primary enrollment should be submitted in DM”**
  - Per FDA, if multiple screenings and single enrollment, enrollment is “primary”
  - No CDISC definition of “primary” in other instances
    - Multiple screenings without enrollment
    - Multiple enrollments over time

- **All study day variables are still derived form DM.RFSTDTC**

Difference between DC and DM

- **DCSEQ is required**
  - NSDC will have IDVAR=DCSEQ
  - NSDM will still have IDVAR and IDVARVLN missing

- **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)**

Difference between DC and DM

DM Specification

23	SEX	Sex	Char	(SEX)			Qualifier	Subject Demographics	C28421	The assemblage of properties or qualities by which male is distinguished from female.			Req
36	DMDY	Study Day of Collection	Num				Timing	Study Day	C170993	The number of days from the sponsor-defined reference start date to the date of collection (--DTC), used in study data tabulation.	See Demographics Data Shared Assumption 11.		Perm

DC Specification

25	SEX	Sex	Char	(SEX)			Qualifier	Subject Demographics	C28421	The assemblage of properties or qualities by which male is distinguished from female.	See DC Assumption 5.		Exp

dc.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	DCSEQ	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
ABC123	DC	ABC12301001	1001	1	2006-01-14	2006-01-28	2006-01-14	2006-01-28	2006-01-05	2006-02-25
ABC123	DC	ABC12301002	1002	1	2006-01-12	2006-01-26	2006-01-12	2006-01-26	2006-01-04	2006-02-23
ABC123	DC	ABC12301003	1003	1	2006-01-08	2006-01-20	2006-01-08	2006-01-20	2006-01-02	2006-02-17
ABC123	DC	ABC12301004	1004	1					2005-09-13	2005-09-21
ABC123	DC	ABC12301004	1004B	2					2005-11-14	2005-11-16
ABC123	DC	ABC12301004	1004C	3	2006-01-16	2006-02-01	2006-01-16	2006-02-01	2006-01-07	2006-03-02

BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS
1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO	A	Drug A	A	Drug A	
1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC OR LATINO	P	Placebo	P	Placebo	
1938-01-19	67	YEARS	F	BLACK OR AFRICAN AMTERICAN	NOT HISPANIC OR LATINO	P	Placebo	P	Placebo	
1941-07-02			M	ASIAN	NOT HISPANIC OR LATINO					SCRENN FAILURE
										SCRENN FAILURE
	64	YEARS				A	Drug A	A	Drug A	

dm.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC
ABC123	DM	ABC12301001	1001	2006-01-14	2006-01-28	2006-01-14	2006-01-28	2006-01-05	2006-02-25
ABC123	DM	ABC12301002	1002	2006-01-12	2006-01-26	2006-01-12	2006-01-26	2006-01-04	2006-02-23
ABC123	DM	ABC12301003	1003	2006-01-08	2006-01-20	2006-01-08	2006-01-20	2006-01-02	2006-02-17
ABC123	DM	ABC12301004	1004C	2006-01-16	2006-02-01	2006-01-16	2006-02-01	2006-01-07	2006-03-02

BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS
1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO	A	Drug A	A	Drug A	
1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC OR LATINO	P	Placebo	P	Placebo	
1938-01-19	67	YEARS	F	BLACK OR AFRICAN AMTERICAN	NOT HISPANIC OR LATINO	P	Placebo	P	Placebo	
1941-07-02	64	YEARS	M	ASIAN	NOT HISPANIC OR LATINO	A	Drug A	A	Drug A	

Effects in Other Domains

- **All study days are still derived from DM.RFSTDTC**
  - There is no DCDY to avoid interdependency
  - For other relative days, use NSVs or derive in ADaM

- **Subject Visits (SV) now requires SVSEQ**
  - Assigned in a chronological sequence
  - Cannot assume USUBJID and VISITNUM uniquely identify a record

SVSEQ	Sequence Number	Num				Identifier	Record	C70710	A number used in combination with the identifier of the subject of the observation to uniquely identify a record within a domain.	See Record Identifiers.		Req

- **Subject Elements (SE) allows gaps between participations only**

Additional SDTM and SDTMIG Updates

Additional updates to DM (and DC)

- **Addition of CRACE and CETHNIC variables**
  - Collected values
  - CRACE and CETHNIC have extensive, extensible codelists
  - RACE and ETHNIC no longer have assigned codelists
    - Previously had assigned codelists matching FDA requirements
    - Now will use terminology as defined by data recipient (e.g. FDA)
  - All four race and ethnicity variables are now permissible

- **Age updates**
  - Added AGERLO and AGERHI for when precise age is unknown
  - Removed AGETXT

Additional updates to DM (and DC)

RACE	Race Category	Char		Qualifier	Not in nonclinical trials	Subject Demographics	C227356	An administrative classification of race specified by the data recipient (e.g., a regulatory authority). SDTM-974 TEAM APPROVED
CRACE NEW	Collected Race	Char		Qualifier	Not in nonclinical trials	Subject Demographics	C227305	A classification of race as specified by the sponsor in the data collection field.
ETHNIC	Ethnicity Category	Char		Qualifier	Not in nonclinical trials	Subject Demographics	C227309	An administrative classification of ethnicity specified by the data recipient (e.g., a regulatory authority).
CETHNIC NEW	Collected Ethnicity	Char		Qualifier	Not in nonclinical trials	Subject Demographics	C227296	A classification of ethnicity as specified by the sponsor in the data collection field.

Additional updates to DM (and DC)

20	AGERLO NEW	Age Range Lower Limit	Num		Qualifier		Subject Demographics	C227290	A numeric representation of the lowest possible value for the age of the subject at a specific point in time defined for the trial.	Either the AGE variable or the AGERLO and AGERHI variables should be populated, but not both.
21	AGERHI NEW	Age Range Upper Limit	Num		Qualifier		Subject Demographics	C227289	A numeric representation of the highest possible value for the age of the subject at a specific point in time defined for the trial.	Either the AGE variable or the AGERLO and AGERHI variables should be populated, but not both.

Other New Domains

- **Event Adjudication (EA)**
  - Use Findings About structure
  - EAOBJ is the event being adjudicated
  - Uses EAEVAL, EAEVALID, and EAACPTEL
  - Terminology will be available for EATEST and EATESTCD
  - Examples show adjudication of event occurrence, relationship to treatment, event start date, event type, event classification

- **Gastrointestinal Findings (GI)**
  - Additional morphology/ physiology body system domain
  - Already used in Therapeutic Area User Guides

EA Example

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

DILI

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

Updates to Protocol Deviations (DV)

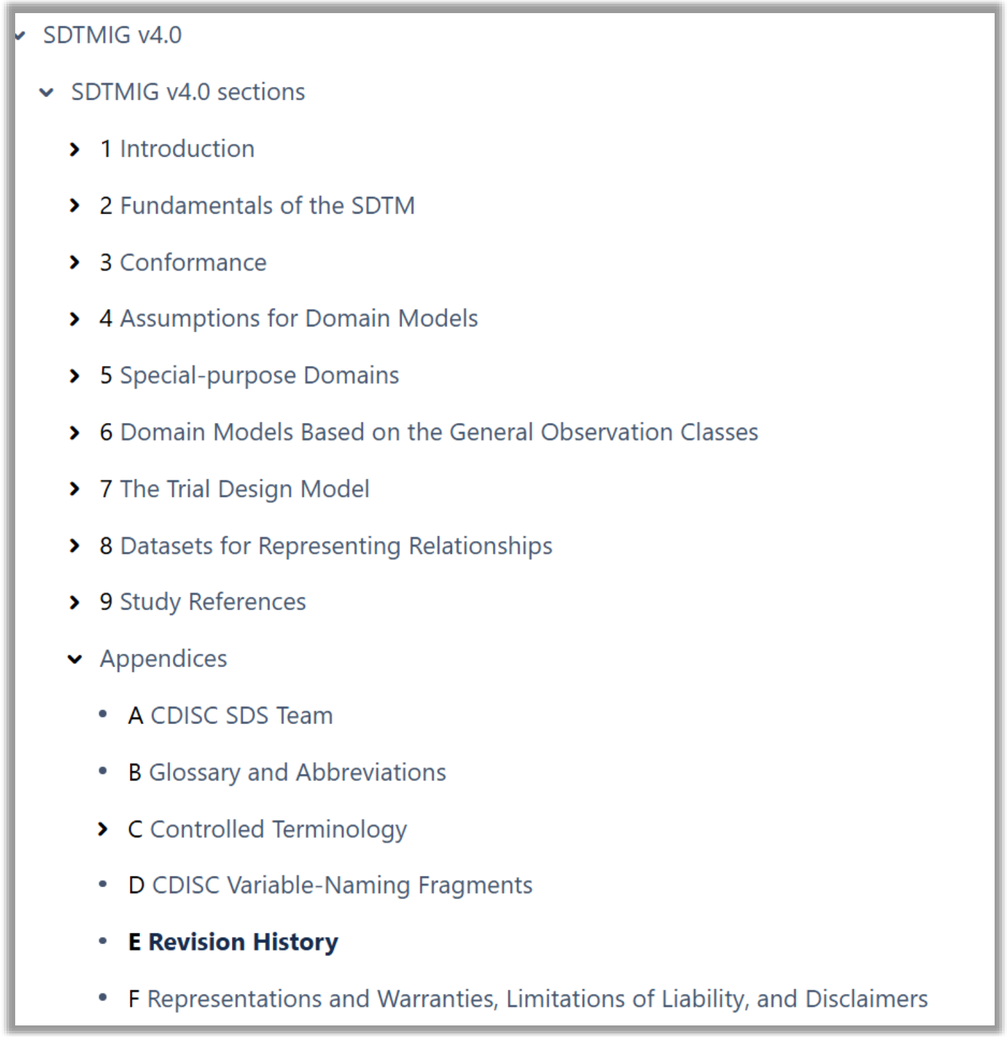
- **New variables, DVCLASI**
  - Retrospective classification of deviations
    - No assigned Controlled Terminology
    - Examples:
      MAJOR/ MINOR,
      IMPORTANT/ NON-IMPORTANT
      CRITICAL/ NON_CRITICAL

- **Controlled terminology for DVDECOD and DVCAT**

12	DVCLASI NEW	Classification of Protocol Deviation	Char				Qualifier	Event Impact	C227300	A classification of protocol deviations based on the potential impact to the completeness, accuracy, and/or reliability of the study data, or to a subject's rights, safety, or well-being. (ICH E3 Q&As (R1))	See DV Assumption 3.	"IMPORTANT"/ "NON-IMPORTANT"; "MAJOR"/ "MINOR"; "CRITICAL"/ "NON-CRITICAL".	Perm

General Observation Class New Variables

cdisc Wiki



General Observation Class New Variables: --RSCNT

Variable	Label	Observation Class	Definition
--RSCNT	Result Count	Findings, EG domain only	The number of occurrences of a result

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGCAT	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGRSCNT
1	123	EG	VYR2FMCh9003	1	EGEVALQL	ECG Evaluation, Qualitative	INTERPRETATION	UNCONSTRAINED	Premature Ventricular Contraction, 1, Single		PREMATURE VENTRICULAR COMPLEX			1
2	123	EG	VYR2FMCh9003	2	EGEVALQL	ECG Evaluation, Qualitative	INTERPRETATION	UNCONSTRAINED	Sinus Tachycardia, 1, Single		SINUS TACHYCARDIA			1
3	123	EG	VYR2FMCh11002	3	EGEVALQL	ECG Evaluation, Qualitative	INTERPRETATION	UNCONSTRAINED	Premature Ventricular Contraction, 1, Single		PREMATURE VENTRICULAR COMPLEX			1
4	123	EG	VYR2FMCh11002	4	EGEVALQL	ECG Evaluation, Qualitative	INTERPRETATION	UNCONSTRAINED	Premature Atrial Contraction, 3, Triple		PREMATURE VENTRICULAR COMPLEX			3
5	123	EG	VYR2FMCh11008	5	EGEVALQL	ECG Evaluation, Qualitative	INTERPRETATION	UNCONSTRAINED	Premature Ventricular Complexes Unifocal, 4, Run		PREMATURE VENTRICULAR COMPLEXES UNIFOCAL			4
6	123	EG	VYR2FMCh11009	6	EGEVALQL	ECG Evaluation, Qualitative	INTERPRETATION	UNCONSTRAINED	Normal Sinus Rhythm		NORMAL SINUS RHYTHM			

General Observation Class New Variables: --CBRFL

Variable	Label	Observation Class	Definition
--CBRFL	Conditionally Branched Item Flag	Findings, Restricted to the QRS domains: QS, FT, RS	An indication that this instance of an item within a QRS instrument was conditionally branched. An item is conditionally branched when the instrument does not solicit a response from the respondent based on a given condition, although for certain instruments, the instrument may provide a result for the item

General Observation Class New Variables: --CBRFL

qs.xpt

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSSTRESC	QSSTRESN	QSSTAT	QSREASND	VISITNUM	QSDTC	QSEVLINT
1	STUDYX	QS	2324-P0001	1	ED102_1	ED1-Able to Communicate Clearly	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY	Consistently	0	0			1	2015-02-16	-P7D
2	STUDYX	QS	2324-P0001	2	ED102_2	ED1-How They Communicate Primarily	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY	Speech	0	0			1	2015-02-16	-P7D
3	STUDYX	QS	2324-P0001	3	ED102_3	ED1-Correct Date and Time	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY	Sometimes	2	2			1	2015-02-16	-P7D
4	STUDYX	QS	2324-P0001	4	ED102_4	ED1-Few Words or Random Answers/Shouting	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY				NOT DONE	CONDITIONALLY BRANCHED			
5	STUDYX	QS	2324-P0001	5	ED102_5	ED1-Moan/Groan/Sounds Not Understandable	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY				NOT DONE	CONDITIONALLY BRANCHED			

19	QSCBRFL	Conditionally Branched Item Flag	Char	(NY)	Y		Qualifier	Test Performer	C227294	An indication that this instance of an item within a QRS instrument was conditionally branched. An item is conditionally branched when the instrument does not solicit a response from the respondent based on a given condition, although for certain instruments, the instrument may provide a result for the item.

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSSTRESC	QSSTRESN	QSSTAT	QSCBRFL	VISITNUM	QSDTC	QSEVLINT
1	STUDYX	QS	2324-P0001	1	ED102_1	ED1-Able to Communicate Clearly	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY	Consistently	0	0			1	2015-02-16	-P7D
2	STUDYX	QS	2324-P0001	2	ED102_2	ED1-How They Communicate Primarily	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY	Speech	0	0			1	2015-02-16	-P7D
3	STUDYX	QS	2324-P0001	3	ED102_3	ED1-Correct Date and Time	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY	Sometimes	2	2			1	2015-02-16	-P7D
4	STUDYX	QS	2324-P0001	4	ED102_4	ED1-Few Words or Random Answers/Shouting	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY				NOT DONE	Y			
5	STUDYX	QS	2324-P0001	5	ED102_5	ED1-Moan/Groan/Sounds Not Understandable	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY				NOT DONE	Y			

General Observation Class New Variables: --TRTCD

Variable	Label	Observation Class	Definition
--TRTCD	Standardized Treatment Code	Interventions, CM domain only	A standardized or dictionary-derived short sequence of characters used to represent the intervention.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMDECOD	CMTRTCD	CMDOSE	CMDOSU	CMDOSFRQ	CMSTDTC	CMENDTC
1	ABC	CM	ABC-0001	1	ASPIRIN	ACETYLSALICYLIC ACID	000027 01 001	100	mg	ONCE	2004-01-01	2004-01-01
2	ABC	CM	ABC-0001	2	ASPIRIN	ACETYLSALICYLIC ACID	000027 01 001	100	mg	ONCE	2004-01-02	2004-01-02
3	ABC	CM	ABC-0001	3	ASPIRIN	ACETYLSALICYLIC ACID	000027 01 001	100	mg	ONCE	2004-01-03	2004-01-03
4	ABC	CM	ABC-0001	4	ASPIRIN	ACETYLSALICYLIC ACID	000027 01 001	100	mg	ONCE	2004-01-07	2004-01-07
5	ABC	CM	ABC-0001	5	ASPIRIN	ACETYLSALICYLIC ACID	000027 01 001	100	mg	ONCE	2004-01-07	2004-01-07
6	ABC	CM	ABC-0001	6	ASPIRIN	ACETYLSALICYLIC ACID	000027 01 001	100	mg	ONCE	2004-01-09	2004-01-09
7	ABC	CM	ABC-0002	1	ASPIRIN	ACETYLSALICYLIC ACID	000027 01 001	100	mg	QD	2004-01-01	2004-01-03
8	ABC	CM	ABC-0002	2	ASPIRIN	ACETYLSALICYLIC ACID	000027 01 001	100	mg	BID	2004-01-07	2004-01-07
9	ABC	CM	ABC-0002	3	ASPIRIN	ACETYLSALICYLIC ACID	000027 01 001	100	mg	QD	2004-01-09	2004-01-09
10	ABC	CM	ABC-0003	1	ASPIRIN	ACETYLSALICYLIC ACID	000027 01 001	100	mg	PRN	2004-01-01	2004-01-09

General Observation Class New Variables: CLASI

Variable	Label	Observation Class	Definition
--CLASI	Classification of Protocol Deviation	Events, DV domain only	A classification of protocol deviations based on the potential impact to the completeness, accuracy, and/or reliability of the study data, or to a subject's rights, safety, or well-being. (ICH E3 Q&As (R1))

dv.xpt

Row	STUDYID	DOMAIN	USUBJID	DVSEQ	DVTERM	DVDECOD	DVCAT	DVCLASI	EPOCH	DVSTDTC
1	ABC123	DV	123101	1	IVRS PROCESS DEVIATION - NO DOSE CALL PERFORMED.	TREATMENT DEVIATION	STUDY INTERVENTION	NON-IMPORTANT	TREATMENT	2003-09-21
2	ABC123	DV	123103	1	DRUG XXX ADMINISTERED DURING STUDY TREATMENT PERIOD	EXCLUDED CONCOMITANT MEDICATION	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT	TREATMENT	2003-10-30
3	ABC123	DV	123103	2	VISIT 3 DOSE <15 MG	TREATMENT DEVIATION	STUDY INTERVENTION	IMPORTANT	TREATMENT	2003-10-30
4	ABC123	DV	123104	1	TOOK ASPIRIN	PROHIBITED MEDS	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT	TREATMENT	2003-11-30

Removed Variables

- **Findings**
  - --BLFL removed from model and from all domains
    - Deprecated in SDTMIG 3.4 in favor of --LOBXFL
  - --MODIFY and --BODSYS
    - No expectation that Findings results would be coded
- **Events and Intervention**
  - --PORTOT
- **Trial Inclusion/ Exclusion Criteria (TI)**
  - TIRL

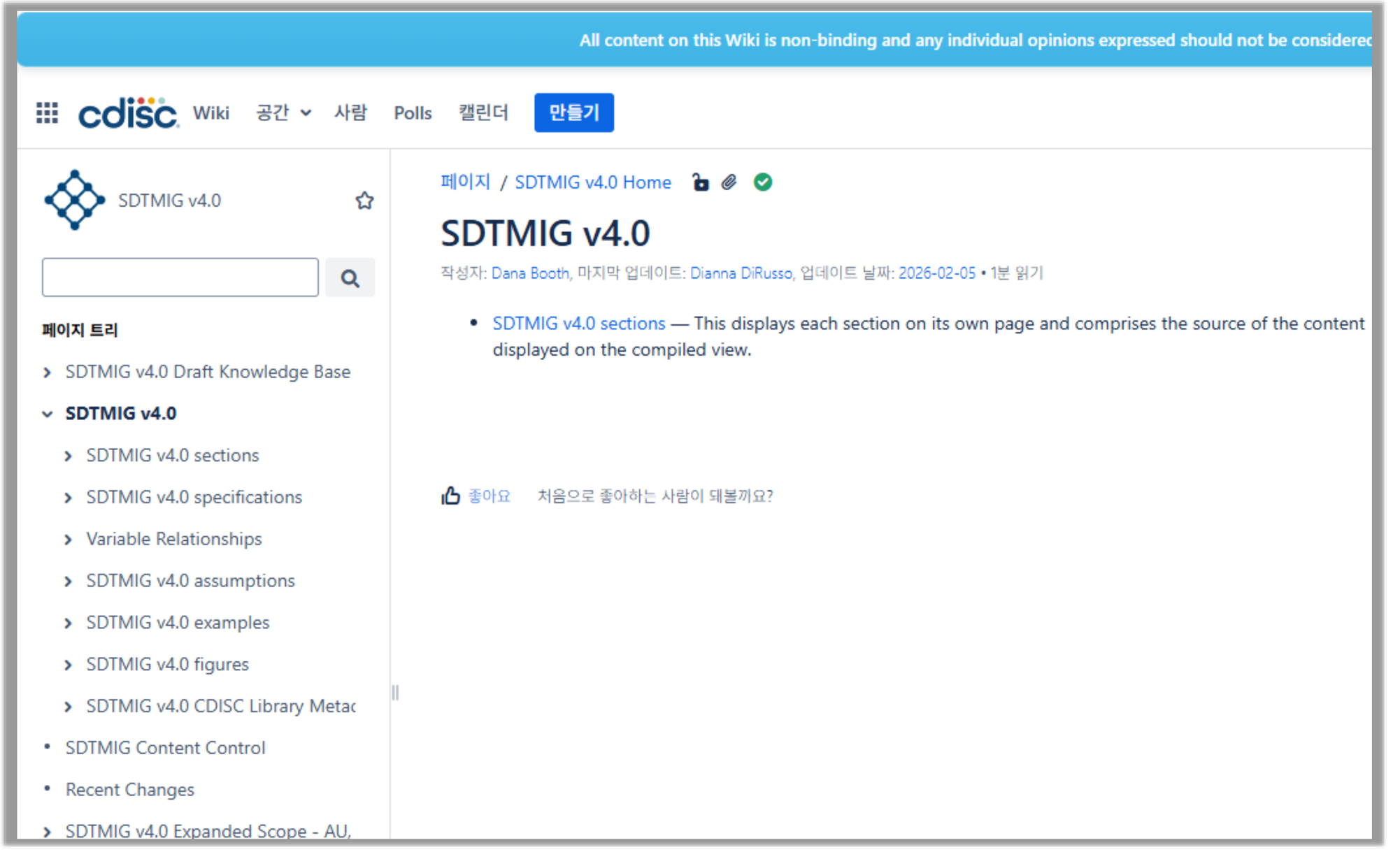
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- Public Review closes **06-April-2026**; targeted Publication: **Q4 2026**
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좋아요
처음으로 좋아하는 사람이 돼볼까요?

Thank You

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2026 Korea CDISC Day · 29 October 2026

