

SDTM 2.0 & SDTM IG 3.4

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OVERVIEW



- **SDTM 2.0**
- **SDTM IG 3.4**
- **Version Date:** 29-Nov-2021
- Pinnacle Validator: version not yet included

OVERVIEW



- **FDA:**
 - not yet supported by authorities
 - Refer to FDA Data Stds Catalog

Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Supported Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY) [10] [11]	Date Requirement Ends (MM/DD/YYYY)
Study Data Tabulation Model (SDTM)	XPT	Clinical Data Interchange Standards Consortium (CDISC)	1,1	3.1.1	CDER, CBER	Ongoing	01.28.2015		
SDTM	XPT	CDISC	1,2	3.1.2	CDER, CBER	30.10.2009	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]
SDTM	XPT	CDISC	1,2	Version 3.1.2 Amendment 1	CDER, CBER	08.07.2013	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]
SDTM	XPT	CDISC	1,3	3.1.3	CDER, CBER	12.01.2012	03.15.2021	12/17/2016 [1] 12/17/2017 [2]	03.15.2021
SDTM	XPT	CDISC	1,4	3,2	CDER, CBER	08.17.2015		03/15/2018 [1] 03/15/2019 [2]	
SDTM	XPT	CDISC	1,7	3,3	CDER, CBER	03.15.2021		03.15.2023	

SDTM 2.0 VS SDTM 1.8



- **New domain RELSPEC (related specimens):** copied from SDTMIG-PGx

- **Role of LOINC variable:** A single variable of --TESTCD may be associated with multiple values of --LOINC, depending on the values of other variables, such as --SPEC and --METHOD.

- **New variables: Section 3.1.1 (interventions), 3.1.2 (events) and 3.1.3 (findings)**
 - --REASOC = Reason for Occur Value (promoted from supplemental qualifier)
 - --CNTMOD = Contact Mode
 - --EPCHGI = Epi/Pandemic Change Indicator
 - --SINTV = Needs Intervention to Prevent Impairment (in medical-device related studies, “Y”/ “N”/ blank)
 - --UNANT = Unanticipated Adverse Effect/Event (in medical-device related studies)
 - --RLPRT = Rel of AE to Device-Related Procedure (in medical-device related studies)
 - --RLPRC = Rel of AE to Non-Dev-Rel Study Activity (in medical-device related studies)
 - --LLOD = Lower Limit of Detection
 - --CLSIG = Clinically Significant, Collected (promoted from supplemental qualifier)
 - ...

SDTM 2.0 VS SDTM 1.8



- **New variables:**
 - Section 3.1.5 Timing Variables for All Classes
 - --PTFL = Point in Time Flag
 - --PDUR = Planned Duration

 - Section 3.2.3.2 Subject Elements
 - SESTDY = Study Day of Start of Element
 - SEENDY = Study Day of End of Element

 - Section 3.2.3.3 Subject Visits
 - SVPRESP = Pre-Specified
 - SVOCCUR = Occurrence
 - SVREASOC = Reason for Occur Value
 - SVCNTMOD = Contact Mode
 - SVEPCHGI = Epi/Pandemic Related Change Indicator

SDTM 2.0 VS SDTM 1.8



- **Label changes**

- --MODIFY = Modified Result Term
- --SEV = Severity/Intensity
- --DUR = Collected Duration
- --LOC = Location of Administration
- --PRESP = Pre-Specified
- DOMAIN = Domain Abbreviation (corrected for SM and TM domain)

SDTM IG 3.4 VS SDTM IG 3.3



- Names of supplemental qualifier variables have been updated to include 2-character domain abbreviations
- MO (morphology) domain removed
- **New domains:**
 - BE = Biospecimen Events (copied from SDTMIG-PGx)
An events domain that documents actions taken that affect or may affect a specimen (e.g., specimen collection, freezing and thawing, aliquoting, transportation).
 - BS = Biospecimen Findings (copied from SDTMIG-PGx)
A findings domain that contains data related to biospecimen characteristics.
 - CP = Cell Phenotyping Findings
A findings domain that contains data related to the characterization of cell phenotype, lineage, and function based on expression of specific markers in single cell or particle suspensions.

SDTM IG 3.4 VS SDTM IG 3.3



- **New domains:**

- GF = Genomics Findings (replaces PF domain from SDTMIG-PGx)

A findings domain that contains data related to the structure, function, evolution, mapping, and editing of subject and non-host organism genomic material of interest. This domain includes but is not limited to assessments and results for genetic variation and transcription, and summary measures derived from these assessments. The GF domain is used for findings from characteristics assessed from nucleic acids and may include subsequent inferences and/or predictions about related proteins/amino acids.

- RELSPEC = Related Specimens (copied from SDTMIG-PGx)

A dataset used to represent relationships between specimens.

SDTM IG 3.4 VS SDTM IG 3.3



- **Updates for existing domains** (not all listed here)

- Procedures (PR): CT for PRDECOD added

- Adverse Events (AE):

variables for Medical Devices were added (SPDEVID, AEACNDEV, AEUNANT, AERLPRC, AERLPRT, AERLDEV, AESINTV)

varLabel	varName
Action Taken with Device	AEACNDEV
Relationship of Event to Device	AERLDEV
Rel of AE to Device-Related Procedure	AERLPRC
Rel of AE to Non-Dev-Rel Study Activity	AERLPRT
Needs Intervention to Prevent Impairment	AESINTV
Unanticipated Adverse Device Effect	AEUNANT
Sponsor Device Identifier	SPDEVID

- Clinical Events (CE): CETOXGR (Standard Toxicity Grade) added

- ECG Test Results (EG): EGCLSIG (Clinically Significant, Collected) added

SDTM IG 3.4 VS SDTM IG 3.3



- **Updates for existing domains** (not all listed here)

- Laboratory Test Results (LB):

added variables:

LBTSTCND = Test Condition

LBBDAGNT = Binding Agent (The textual description of the agent that is binding to the entity in the LBTEST variable.)

LBTSTOPO = Test Operational Objective (Text description of the high-level purpose of the test at the operational level.)

LBRSLSCL/ LBRESSCL = Result Scale

LBRESTYP = Result Type

LBCOLSRT = Collected Summary Result Type

LBLLOD = Lower Limit of Detection

LBTMTHSN = Test Method Sensitivity

LBCLSIG = Clinically Significant, Collected

LBPTFL = Point in Time Flag

LBPDUR = Planned Duration

removed variables: LBORREF, LBSTREFC, and LBSTREFN

SDTM IG 3.4 VS SDTM IG 3.3



- **Updates for existing domains** (not all listed here)

- Immunogenicity Specimen Assessments (IS):

added variables: ISBDAGNT, ISCNDAGT, ISDRVFL, ISELTM, ISENDTC, ISENDY, ISMSCBCE, ISNRIND, ISORNRHI, ISORNRLO, ISRFTDTC, ISSPCCND, ISSPCUFL, ISSTNRC, ISSTNRHI, ISSTNRLO, ISTPT, ISTPTNUM, ISTPTREF, ISTSTCND, ISTSTDTL, ISTSTOPO, NHOID

Variable Name
Binding Agent
Test Condition Agent
Derived Flag
Planned Elapsed Time from Time Point Ref
End Date/Time of Specimen Collection
Study Day of End of Specimen Collection
Molecule Secreted by Cells
Reference Range Indicator
Reference Range Upper Limit in Orig Unit
Reference Range Lower Limit in Orig Unit
Date/Time of Reference Time Point
Specimen Condition
Specimen Usability for the Test
Reference Range for Char Rslt-Std Units
Reference Range Upper Limit-Std Units

Variable Code
ISBDAGNT
ISCNDAGT
ISDRVFL
ISELTM
ISENDTC
ISENDY
ISMSCBCE
ISNRIND
ISORNRHI
ISORNRLO
ISRFTDTC
ISSPCCND
ISSPCUFL
ISSTNRC
ISSTNRHI

varLabel

Reference Range Lower Limit-Std Units
Planned Time Point Name
Planned Time Point Number
Time Point Reference
Test Condition
Test Detail
Test Operational Objective
Non-host Organism ID

varName

ISSTNRLO
ISTPT
ISTPTNUM
ISTPTREF
ISTSTCND
ISTSTDTL
ISTSTOPO
NHOID

SDTM IG 3.4 VS SDTM IG 3.3



- **Updates for existing domains** (not all listed here)
 - Exposure as Collected (EC): ECREASOC (Reason for Occur Value) added

 - Vital signs (VS):
VSCLSIG (Clinically Significant, Collected), VSTOX (Toxicity) and VSTOXGR (Standard Toxicity Grade) added

 - Functional Tests (FT): FTEVAL (Evaluator) dropped

 - Findings About Events and Interventions (FA):
Explanations/ examples updated
FA domain name updated

 - Trial Summary (TS):
CDISC Note for TSSEQ updated
Appendix C1 deleted, therefore reference to TS codetable on CDISC website added

SDTM IG 3.4 VS SDTM IG 3.3



- **Updates for existing domains** (not all listed here)
 - Questionnaires (QS):
QSEVINTX (Evaluation Interval Text) and QSMETHOD (Method of Test or Examination) added
QSEVAL (Evaluator) dropped
 - Subject Characteristics (SC): VISIT (Visit Name), VISITDY (Planned Study Day of Visit) and VISITNUM (Visit Number) added
 - Subject Elements (SE): SEENDY (Study Day of End of Element) and SESTDY (Study Day of Start of Element) added

SDTM IG 3.4 VS SDTM IG 3.3



- **Variable label changes**

- DOMAIN = Domain Abbreviation (corrected for SM and TM domain)
- DVENDY = Study Day of End of Deviation Event
- FTMETHOD = Method of Test or Examination
- LBTESTCD = Lab Test or Examination Short Name
- SVENDTC = End Date/Time of Observation
- SVENDY = Study Day of End of Observation
- SVSTDTC = Start Date/Time of Observation
- SVSTDY = Study Day of Start of Observation
- TSVALNF = Parameter Value Null Flavor

LINKS / REFERENCES



- **Presentation from Pinnacle**

<https://www.pinnacle21.com/blog/exploring-changes-sdtmig-34-adamig-13>

- **SDTM v2.0**

<https://www.cdisc.org/standards/foundational/sdtm/sdtm-v2-0>

- **SDTM IG v3.4**

<https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-4>

CONTACT DETAILS



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