



What's New in SDTMIG 3.1.2

by

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What is new in SDTM model?



- The model itself has not changed much from version 1.1 to 1.2.
- Changes will be documented in section 6.3.
- It has 26 pages.

What is new in SDTMIG 3.1.2?



SDTMIG 3.1.1 – 183 pages

SDTMIG 3.1.2 – 299 pages

Appendix E in SDTMIG 3.1.2 has revision histories of all versions. Specifically, Appendix E4 will document changes of the IG from version 3.1.1 to version 3.1.2.



What's New in 3.1.2 ?

Major changes and additions

General Assumptions



- **Splitting domains - Domains can be split into multiple datasets (by --CAT or --OBJ in the case of FA) to make it easier to work with. Specific dataset naming conventions and rules (4.1.1.7)**
- **Use of USUBJID comment change The same subject in 2 or more studies should have the same USUBJID in all studies (4.1.2.3)**

General assumptions



● Numeric Standardized Results of Findings Preceded by > or < (statement added)

The value with the greater than (>) or less than (<) sign attached should be moved to the --STRESC variable, and --STRESN should be null. The rules for modifying the value for analysis purposes should be defined in the analysis plan and only changed in the ADaM datasets. If the value in --STRESC has different units, the greater than (>) or less than (<) sign should be maintained

General assumptions



Other, Specify: _____” “Submitting Free Text” from the CRF

When the specified value is for:

- The Topic variable (--TRT, --TERM), the specified value goes in the Topic variable.

Acetaminophen
Aspirin
Ibuprofen
Naproxen
Other: _____

- A Result variable (--ORRES), the specified value goes into --ORRES, while either “OTHER” or the specified value can go into --STRESC, depending on the sponsor’s conventions and needs.

Eye Color
Brown Black
Blue Green
Other, specify: _____

- A non-Result Qualifier variable, “OTHER” goes in domain variable, and the specified value goes in SUPP--.QUAL

Location of Injection
Right Arm Left Arm
Right Thigh Left Thigh
Other, Specify: _____

DOMAIN



DM

- **ARMCD length change (from 8 to 20)**
- **Controlled terminology for ARMCD/ARM**

┌ Added ARMCD=« NOTASSGN » and ARM = « Not Assigned » for subjects who are not screening failures but who have not been assigned an arm

SV (subject visit)

- **Added Assumptions**

┌ Unplanned visits (eg lab tests) should be included in the dataset

┌ Only one record per visit/visitnum per subject allowed

DOMAIN



EX (exposure) domain is mandatory

New domains

Previously Posted and Reviewed Domains

- Protocol deviations (DV)
- Microbiology (MB and MS)
- Clinical events (CE)
- PK (PC and PP)
- Drug Accountability (DA)

Other

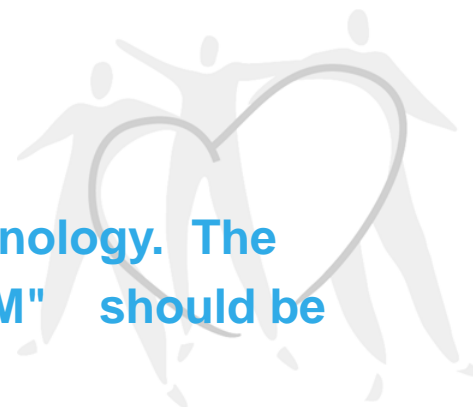
- FA Findings About : domain for Event and Intervention findings

Metadata



- **Various Role changes**
- **Various Variable Order changes**
- **Various Label changes**
- **Various Core changes**
Variables have been revised from Required to Expected and others from Expected to Required or Permissible to Expected
Example : RFSTDTC and RFENDTC are changed in their role as Timing variables to Record Qualifier variables
- **Origin column contents changed**
3.1.1 only CRF and Derived
added Assigned, Protocol, eDT
If multiple Origins, the variable level metadata should separate them with a coma (ex. "Derived, CRF") (4.1.1.8)
(column Origin removed from the domain tables to avoid confusion)

Terminology



SDTMIG only gives examples of controlled terminology. The website "<http://evs.nci.nih.gov/ftp1/CDISC/SDTM>" should be used as the reference for acceptable CT

The use of Yes/No values in section

- **single checkbox to indicate Yes, then OK with blank response**
 - ┌ For some flags such as baseline, blank is permissible
 - Need to document in define document why a value is not populated
- **NA (Not Applicable) added (complete list 'Y','N','U' and 'NA')**

SEX

- **UN (undifferentiated) added**

ETHNICITY

- **« NOT REPORTED » and « UNKNOWN » added**

Other



- Additional examples for Events domains AE, DS and MH.
- Additional examples for Findings domains
- New Substance Use examples
- Data examples appear below the respective domain models (in Sections 5 and 6)
 - Section 9 eliminated