

This page contains the working list of errata for the final version 3.2 of the SDTMIG.

Overall: Intra-document cross-references should be changed from bold italic to plain text.

## Section 2 - Fundamentals of the SDTM

- Page 6 (noportfolio page 16) / Section 2.6, step 2: The extraneous H in front of the URL should be deleted.
- Page 7 (noportfolio page 17) / Section 2.7:
  - The title of this section should be renamed from "SDTM variables Allowed in SDTMIG" to "SDTM Variables Not Allowed in SDTMIG".
  - The text in parentheses after --DETECT should be changed from "Findings" to "Timing".

## Section 3 - Submitting Data in Standard Format

- Page 1 (noportfolio page 19) / Section 3.1:
  - The fifth item in the first bulleted list (which starts, "The origin or source...") should be deleted.
  - In the paragraph preceding the second bulleted list, in the phrase "the CDISC domain models include three other shaded columns...", the word "three" should be changed to "two".
  - The third (and final) item in the second bulleted list should be deleted.

## Section 4 - Assumptions For Domain Models

- Page 22 (noportfolio page 46) / Section 4.1.4.7, Examples of --STRPT, --STTPT, --ENRPT, and --ENTPT, 2. Adverse Events: The final line of this example, "AEENRPT = "U" ", should be followed by an additional line that reads: "AEENTPT = final subject contact date, e.g., "2006-11-02" "

The second half of this example (starting with "Example when...") as it is currently and as it should be is as follows:

Currently:	Should be:
Example when "Unknown" is checked: AESTDTC = start date, e.g., "2006-10-01" AEENDTC = [null] AEENRPT = "U"	Example when "Unknown" is checked: AESTDTC = start date, e.g., "2006-10-01" AEENDTC = [null] AEENRPT = "U" AEENTPT = final subject contact date, e.g., "2006-11-02"

- Page 23 (noportfolio page 47) / Section 4.1.4.8: The title of this section should be changed from "AEENTPT = final subject contact date, e.g., "2006-11-02"Date and Time Reported in a Domain Based on Findings" to "Date and Time Reported in a Domain Based on Findings"
- Page 24 (noportfolio page 48) / Section 4.1.4.10, second table: The value in for LBDC in Row 1 should be changed from "2006-08-01T08:30" to "2006-08-01T07:45".

## Section 5 - DM Domain

- Page 3 (noportfolio page 64) / DM – Specification for the Demographics Domain Model: The value in the "Variable Label" column for ACTARM should be "Description of Actual Arm".
- Page 6 (noportfolio page 67) / DM – Examples for the Demographics Domain Model, Example 1: The values in the "SUBJID" column should be changed for each row as follows:
  - Row 1: "001" should be changed to "01001"
  - Row 2: "002" should be changed to "01002"
  - Row 3: "003" should be changed to "01003"
  - Row 4: "004" should be changed to "01004"
  - Row 5: "001" should be changed to "02001"
  - Row 6: "002" should be changed to "02002"

## Section 5 - SE Domain

- Page 2 (noportfolio page 75) / SE – Specification for the for the Subject Elements Domain Model: TAETORD and EPOCH should come before SESTDTC in the table.

The final six variables in the SE domain, in their current order and in the order they should be in:

Currently:	Should be:

ELEMENT	Description of Element	ELEMENT	Description of Element
SESTDTC	Start Date/Time of Element	TAETORD	Planned Order of Element within Arm
SEENDTC	End Date/Time of Element	EPOCH	Epoch
TAETORD	Planned Order of Element within Arm	SESTDTC	Start Date/Time of Element
EPOCH	Epoch	SEENDTC	End Date/Time of Element
SEUPDES	Description of Unplanned Element	SEUPDES	Description of Unplanned Element

## Section 6.1 - EX and EC Domains

- Page 21 (noportfolio page 110) / EX-EC – Examples for Exposure and Exposure as Collected Domain Models, Example 7, ec.xpt:
  - EXSTDY should be changed to ECSTDY
  - EXENDY should be changed to ECENDY
  - In row 4, the value for ECADJ should be "Injection Site Reaction".

## Section 6.2 - AE Domain

- Page 1 (noportfolio page 125) / 6.3 Events: The numbering for this section heading should be changed to 6.2. In the portfolio edition, the corresponding bookmark should be changed likewise.

## Section 6.2 - MH Domain

- Page 2 (noportfolio page 153) / MH - Specification for Medical History Domain Model: The value in the "Role" column for MHPRESP should be changed from "Variable Qualifier of --TERM" to "Variable Qualifier".

## Section 6.3 Index

- Page 3 (noportfolio page 161) / TU, TR, and RS: "Disease Response (SR)" should be changed to "Disease Response (RS)".

## Section 6.3 - EG Domain

- Page 2 (noportfolio page 169) / EG - Specification for ECG Test Results Domain Model: "EGFXN" should be changed to "EGXFN".
- Page 3 (noportfolio page 170) / EG - Specification for ECG Test Results Domain Model: The value in the "Controlled Terms, Codelist or Form at" column for EGLEAD should be "(EGLEAD)".

## Section 6.3 - IS Domain

- Pages 1-2 (noportfolio pages 177-178) / IS – Specification for the Immunogenicity Specimen Assessment Domain Model:
  - The value in the "Type" column for ISSEQ should be "Num".
  - The value in the "Type" column for ISGRPID should be "Char".
  - The value in the "Role" column for ISTECD should be "Topic"
  - The value in the "Role" column for ISTECD should be "Synonym Qualifier"

## Section 6.3 - LB Domain

- Page 5 (noportfolio page 185) / LB - Examples for Laboratory Test Results Domain Model: The word "Laboratory" in the title of this section should match the font size of the rest of the title.

## Section 6.3 - TU TR and RS Domains

- Pages 6-7 (noportfolio pages 260-261) / TU – Examples for Tumor Identification Domain Model, Example 1:
  - The title of this example should be changed from "TU Example 1" to "Example 1".
  - The text between the second and third tables should be changed from "SUPPTU for Example 1:" to "supptu.xpt" and italicized; the blank line between it and the table following should be removed.
  - The third table should repeat the heading row after the page break.
- Pages 6-7 (noportfolio pages 260-261) / TU – Examples for Tumor Identification Domain Model, Example 2:
  - The title of this example should be changed from "TU Example 2" to "Example 2".
  - The space between tables should be reduced from two blank lines to one blank line.

## Section 6.4 - FA Domain

- Every instance of "Findings About" that is not immediately followed by "Events or Interventions" (except in variable labels) should be changed to "Findings About Events or Interventions".
- Page 1 (noportfolio page 282) / FA – Specification for Findings About Domain Model: In the title of the specification table (the text in bold immediately between the section title and the table), the version number should be changed from "3.1.2" to "3.2".
- Pages 9-10 (noportfolio pages 290-291) / FA - Examples for Findings About Domain Model, Example 6, first table: The first row of this table should be moved to join the rest of the table on the second page.
- Pages 10-11 (noportfolio pages 291-292) / FA - Examples for Findings About Domain Model, Example 6, fa.xpt: The second table should repeat the heading row after the page break.
- Pages 12-13 (noportfolio pages 293-294) / FA - Examples for Findings About Domain Model, Example 8, ae.xpt: The title and first row of this table should be moved to join the rest of the table on the second page.

## Section 6.4 - SR Domain

- Page 1 (noportfolio page 296) / SR – Specification for Skin Response Domain Model: In the title of the specification table (the text in bold immediately between the section title and the table), "SR.xpt" should be changed to "sr.xpt" and the class should be changed from "Findings" to "Findings Sub-Class".

## Section 7.4 - Trial Summary And Eligibility

- Page 1 (noportfolio page 350) / TI – Specification for Trial Inclusion/Exclusion Criteria Dataset:
  - The "I" of "TI" in this section heading should be capitalized.
  - The value in the "Variable Label" column for IETESTCD should be changed from "Incl/Excl Criterion Short Name e" to "Inclusion /Exclusion Criterion Short Name".
- Page 7 (noportfolio page 356) / TS – Examples for Trial Summary Information Dataset, Example 1: The value for TSVCDREF in row 27 should be changed from "EUDRAC" to "EUDRACT".

## Section 8 - Representing Relationships and Data

- Page 6 (noportfolio page 368): In the last sentence of the first paragraph, "(when QORIG="ASSIGNED")" should be changed to "(when QORIG="Assigned")".
- Page 7 (noportfolio page 369) / 8.4.1 Supplemental Qualifiers: SUPP-- Datasets, QORIG, CDISC Notes: "Examples include CRF, ASSIGNED, or DERIVED." should be changed to "Examples include "CRF", "Assigned", or "Derived"."
- Page 8 (noportfolio page 370) / 8.4.3 SUPP-- Examples, Example 1, suppdm.xpt: The value for QORIG in both rows should be changed from "DERIVED" to "Derived".
- Page 8 (noportfolio page 370) / 8.4.3 SUPP-- Examples, Example 2, suppaex.xpt: The value for QORIG in Row 2 should be changed from "DERIVED" to "Derived".