SDTM_ADaM Harmonisation

Question

How Should Multiple Subject Instances Be Handled in SDTM Domains?

PHUSE Team Response: 08 October 2024

The FDA Study Data Technical Conformance Guide provides clear guidance on this issue. According to the Study Data Technical Conformance Guide_v4.9_March 2022 (fda.gov) page 10:

"Subject Identifier (SUBJID) The variable SUBJID uniquely identifies each subject that participates in a study. If a single subject is screened and/or enrolled more than once in a study, then the subject's SUBJID should be different for each unique screening or enrolment. For a study with multiple screenings and/or multiple enrolments per subject, SUBJID should be included in other related domains besides DM, even though it may cause validation errors. It is recommended to include a table linking each SUBJID for a single subject to that subject's USUBJID with any additional necessary explanation included in the relevant RG."

The upcoming SDTMIG version 4.0, currently in development, will implement this FDA guideline. Additionally, a new DC (Demographics as Collected) domain, featuring one record per subject, can be added if it helps facilitate the study.

To establish a connection between USUBJID and SUBJIDs, the design of the case report form (CRF) should accommodate multiple prior enrolments within the same or different studies. The data fields collected must be adequate to determine if an individual already possesses a USUBJID. The assignment of USUBJID could be achieved by concatenating STUDYID-SITEID-FIRST STUDY SUBJID or other combinations, depending on the requirements of the study.

It's important to highlight that the configuration of ADSL and DM maintains one record for each USUBJID.