Clinipace
CLINICAL RESEARCH

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Handling of Re-Sreens in SDTM
(Sabine Erbslöh, Clinipace)

At Clinipace, it's personal.

Procedure at Clinipace

- Identify subjects with re-screens (or second site)
- Establish a unique USUBJID that is corresponding to the primary screening
- DM domain is containing demographic data based on the primary screening (SITEID/SUBJID)
- Create additional domain following the structure of DM, e.g. XM, for the re-screens only with the other screening information
- Add SUBJID to all affected domains to clarify to which SUBJID the records are corresponding to
- Amend EPOCH where needed (re-screening)

Example

- Subjid 100-001, re-screened 100-099
- USUBJID X-100-001
- Use DM Variables as template for XM

DOMAIN	USUBJID	SUBJID	SITEID	SEX	RFSTDTC	RFICDTC	DMDTC XMDTC
DM	X-100-001	100-001	100	F		2020-01-01	2020-01-01
XM	X-100-001	100-099	100	F	2020-04-01	2020-03-05	2020-03-05

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4.1.1 Study Data Tabulation Model

4.1.1.2 SDTM General Considerations

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 enrollment.
- For a study with multiple screenings and/or multiple enrollments 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.

4.1.1 Study Data Tabulation Model

4.1.1.2 SDTM General Considerations

Unique Subject Identifier (USUBJID) (I)

- The variable USUJID is an identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
- Each individual subject should be assigned a single unique identifier across the entire application.
- This is in addition to the subject ID (SUBJID) used to identify subjects in each study and its corresponding study report
- An individual subject should have the exact same unique identifier across all datasets, including between SDTM and ADaM datasets.
- Subjects that participate in more than one study should maintain the same USUBJID across all studies. It is important to follow this convention to enable pooling of a single subject's data across studies (e.g., a randomized control trial and an extension study).

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4.1.1 Study Data Tabulation Model

4.1.1.2 SDTM General Considerations

Unique Subject Identifier (USUBJID) (II)

- Sponsors should not add leading or trailing spaces to the USUBJID variable in any dataset. For example, applications have been previously submitted in which the USUBJID variable for each individual subject appeared to be the same across datasets; however, in certain datasets, the actual entry had leading zeros added, or zeros added elsewhere in the entry.
- This does not allow for machine-readable matching of individual subject data across all datasets. Improper implementation of the USUBJID variable is a common error with applications and often requires sponsors to re-submit their data.

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4.1.1 Study Data Tabulation Model

4.1.1.3 SDTM Domain Specifications

DM Domain (Demographics) (I)

- In the DM domain, each subject should have only one single record per study.
- Screen failures, when provided, should be included as a record in DM with the ARM, ARMCD, ACTARM, and ACTARMCD field left blank.
- For subjects who are randomized in treatment group but not treated, the planned arm variables (ARM and ARMCD) should be populated, but actual treatment arm variables (ACTARM and ACTARMCD) should be left blank.
- For subjects with multiple enrollments within a single study, the primary enrollment should be submitted in DM.

4.1.1 Study Data Tabulation Model

4.1.1.3 SDTM Domain Specifications

DM Domain (Demographics) (II)

- Additional enrollments should be included in a custom domain with a similar structure to DM. Clarifying statements in the RG would be helpful.
- For subjects with multiple screenings and no subsequent enrollment, include the primary screening in DM with additional screenings in a custom domain with a structure similar to DM.
- For subjects with multiple screenings and subsequent enrollment, include the enrollment in DM with screenings in a custom domain with a structure similar to DM.

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4.1.4 General Considerations: SDTM, SEND, and/or ADaM

4.1.4.1 Variables in SDTM and SEND: Required, Expected, and Permissible

EPOCH

- 2. EPOCH designators in SDTM. Please follow CDISC guidance for terminology.
- The variable EPOCH should be included for clinical subject-level observation (e.g., adverse events, laboratory, concomitant medications, exposure, and vital signs).
- This will allow the reviewer to easily determine during which phase of the study the observation occurred (e.g., screening, on-therapy, follow-up), as well as the actual intervention the subject experienced during that phase.

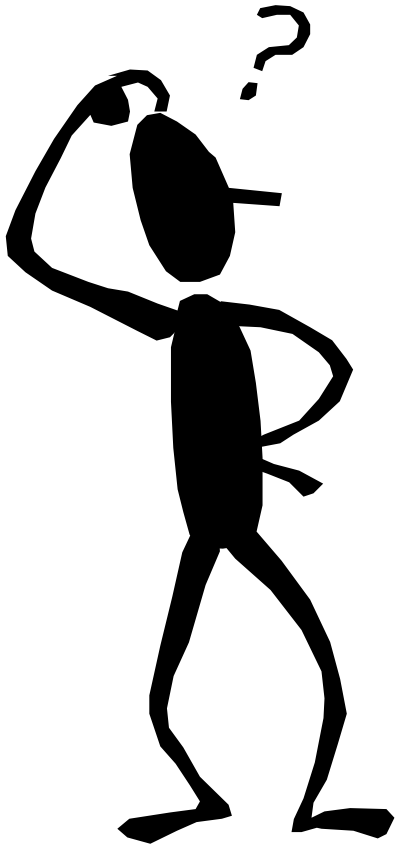
Discussion

- CDISC Guidance?
- Clarify which entry to use for USUBJID
- XM vs SUPPDM

Reference

- *Study Data Technical Conformance Guide v4.5 (March 2020)*
  - This guide provides technical specifications, study data standardization plan, and general considerations on how to submit standardized electronic study data.

Questions



Sabine Erbslöh
Associate Director Statistical Programming

Helfmann-Park 10
D-65760 Eschborn, Germany
mailto: serbsloeh@Clinipace.com