Ensuring USUBJID is Unique for an Individual within an Application

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Introduction

- FDA identified issues with implementation of USUBJID in applications
- PhUSE Working Group formed March 2014 to investigate, brainstorm solutions, and draft a White Paper to describe the best practice for handling USUBJID

Problem Statement

Sponsors are required to ensure a consistent single USUBJID value is assigned to each individual with data in an application

Important Considerations

1. The word “subject” is often used to mean two related but different constructs:
   a. Individual person
   b. Participant in a clinical trial

2. Relationship of USUBJID to SUBJID
   a. At the time USUBJID was defined, it was anticipated there would be a 1:1 relationship of USUBJID to SUBJID within a study
   b. In reality, there is often a 1:m relationship of USUBJID to SUBJID (e.g., when a screen failure rescens in the same study)

3. Characteristics of the SDTM DM domain
   a. Topic variable is SUBJID (specifies the focus of the observation)
   b. Record structure of the SDTM DM domain is “one record per subject”
      i. “Subject” is not overtly defined as a unique individual, nor as a trial participant
      ii. Practical implementation has been to define “one record per subject” as “one record per USUBJID”

   “If the same subject is screened more than once in a trial, then the subject’s SUBJID should be different.”

First Recommendation

Challenge: Identify individuals enrolled in more than one study, or individuals enrolled more than once in the same study

Recommendation 1: Design database to track previous enrollments

Typically use a Case Report Form (CRF)
Information needed:
- If previously enrolled in current study, SITEID and SUBJID of previous enrollment
- If previously enrolled in other study in the same application, STUDYID, SITEID, and SUBJID from other studies

Recommendation 2: Create a new record in DM for each screening event

First Recommendation

Challenge: Determine how to link assessments done during screening with the specific screening event data in the DM domain

Recommendation 3: Allow SUBJID as a permissible identifier variable on General Observation Class domains

Second Recommendation

Challenge: Develop a proposal for the best way to record data in the SDTM DM domain when an individual has multiple enrollments in a single study

Recommendation 2: Create a new record in DM for each screening event

Considerations

1. CRF design needs to allow for multiple previous enrollments within the same study (e.g., re-screens)
2. CRF design needs to allow for enrollments from multiple previous studies
3. Data fields collected must be sufficient to identify whether individual has existing USUBJID

Discussion

(1) Key to the concepts presented within this Proposal for Best Practice, is that all of the CDISC and FDA documentation is consistent in the requirement of “one record per subject” in the DM domain, but “subject” is not overtly defined. In practice, industry implementation of this requirement has been to define “one record per subject” as one record per USUBJID in the DM domain, which has proven to be problematic.

(2) Sponsors should realize that the proposed solution may not accurately identify USUBJID for all individuals, as the solution often relies on the accuracy and validity of the data provided by screened subjects.

(3) The actual submission of screen failure data within an application should be a conscious decision based either on internal sponsor decision or through discussion with the regulatory authority responsible for reviewing the application.

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