Paper PP17

Associated Persons Mapping in SDTM

Sadiya Ait M'Bark, IQVIA, Strasbourg, France

ABSTRACT

The poster will delve into the use and representation of non-study subject participants. Study subjects' information/data is collected and mapped in Study Data Tabulation Model (SDTM) datasets. However, in some clinical studies, information about persons other than the study participant may also be collected and these needs to be included in SDTM models. These non-study subjects can include, but is not limited to a family member, an organ donor, a caregiver, etc. They are classified as Associated Persons (AP). CDISC has specific guidelines that deals with AP data and this poster will share some best practices in handling this type of data.

INTRODUCTION

CDISC has developed a specific guideline for data collected about subjects other than study subjects. These subjects are considered as Associated Persons and their data need to be included in SDTM models as per SDTM Implementation Guide for Associated Persons (SDTMIG-AP).

WHO ARE ASSOCIATED PERSONS?

Associated Persons are defined as non-study participant in a clinical study. They can be associated to a specific subject study but can also be associated to the study or a device used in the study. An AP may be a family member, an organ donor, accidental study treatment exposure, etc.

MAPPING OF AP DATA IN SDTM MODELS

AP DATASET

When collected, AP data should be mapped in AP datasets. The AP datasets have the same structure as those for study subjects' domains defined in SDTM-IG, apart variables that are only applicable to study subjects (USUBJID, ARM/ARMCD, ACTARM/ACTARMCD, RFSTDTC, RFENDTC, etc.).

APRELSUB DATASET

Relationships between AP and study subject(s) are reported in APRELSUB dataset.

APRELSUB is required when an AP has relationships to multiple subjects or devices or when an AP has multiple relationships to a single subject or device. This dataset can be also helpful, even when not required, to report all individual relationships.

POOLDEF DATASET

A pool of individually identified persons can be represented as an AP. In that case, APID (Associated Persons Identifier identifier) contains the identifier of the pool and POOLDEF dataset identifies each individual associated subjects included within a pool.

CAUTION

It is important to clearly identify if a subject should be considered as an Associated Person and to clearly understand the relationship between this non-study subject with the study or with study subject.

Some study subject variables would not be used in AP datasets as these data are study related. Some other SDTM variables (as EPOCH, study days) need to be used with caution in AP datasets. Timing variables may be ambiguous when one AP is related to multiple study subjects.

AP domains are not recognized in Pinnacle 21 check. So further manual compliance check needs to be performed.

CONCLUSION

Data collected in clinical studies is often data of study subject's participant. Non-study subjects' data may be also planned to be collected in the protocol or can be collected even if not planned. We must be familiar with CDISC SDTMIG-AP to be prepared to map these non-study subject data when this occurs.

REFERENCES

Study Data Tabulation Model Implementation Guide: Human Clinical Trials. Clinical Data Interchange Standards Consortium (CDISC) Submission Data Standards (SDS) Team. Version 3.3. November 2018

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Author Name: Sadiya Ait M'Bark
Company: IQVIA
Address: Parc d'Innovation, 260 rue Léon Foucault, 67400 Illkirch, France
Email: Sadiya.aitmbark2@iqvia.com