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Question

Do you create a TA and TE domain for Observation Studies? There is no intervention/medication given to the subject in this type of study. There are two types of observational study:
1) Retrospective trial. For example, a study to observe subjects who had taken medication in past.
2) Prospective study. For example, a study to observe biomarkers in subjects with certain traits compared to those without those traits.

PHUSE Team Response: 12 May 2020

TA and TE, as described in the SDTM, were conceived of in the context of a prospective trial, usually an interventional trial. The concepts may be of interest in observational studies, but applying them will require some thought. There may be specific time periods of interest in a retrospective trial, and data collection may be structured to coincide with those time periods. For example, a study of subjects who took a particular medication might collect data about the subjects before, during, and after they took the medication. For a prospective study, there might be only one arm and one epoch (observation), but a plan for data collection would be in place. Trial Sets may help represent groups of subjects with different preexisting characteristics. Trial Sets are described in the SENDIG, but can be adapted for use in human clinical trials. There is a webinar in the CDISC archive on this topic.

Question

According to SDTM-IG 3.3, Example 2, Row 2: https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Trial+Summary, when TSPARMCD=TPHASE and the value is not applicable, 'NA' should be mapped to TSVALNF.

If this is the case, then why is there CDISC SDTM Terminology of 'NOT APPLICABLE' in the TPHASE CodeList? These are the cases I found in CDISC SDTM Terminology where a TSPARMCD CodeList value matches a value in ISO 21090 Version: SDTM Terminology 2019-06-28 CodeList: CL.C66737.TPHASE CodeList Value: NOT APPLICABLE CodeList Value ID: C48660 CodeList: CL.C99078.INTTYPE CodeList Value: OTHER CodeList Value ID: C17649.

PHUSE Team Response: 9 January 2020

The team have decided that it is the simplest for implementers to use the value from CT rather than mapping to TSVALNF. This will also be noted as a known issue with SDTMIG v3.3. CDISC are working towards publishing these known issues on their website.

Question

In SDTM-IG 3.3, there is an inconsistency with TSVAL when TSPARMCD is set to FCNTRY. In the IG example dataset at 7.4.2 Trial Summary, TS-examples, TSVAL is assigned the full country name, and

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TSVALCD is assigned the alpha-3 code:https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Trial+Summary.
IG Appendix C1 states that TSVAL should be assigned the alpha-3 code: https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Trial+Summary+Codes.
For reference, in SDTM-IG 3.2, the example dataset assigns both TSVAL and TSVALCD the alpha-3 code. Appendix C! is consistent for FCNTRY across 3.2 and 3.3. It appears that they deliberately changed this in the 3.3 examples but forgot to update it in the Appendix. For FCNTRY, should the full country name or the alpha-3 code be mapped to TSVAL?

PHUSE Team Response: 7 January 2020

CDISC has verified that TSVAL was changed to the full country name in error. It should have been the alpha-3 code. CDISC has noted this as a known issue for SDTMIG v3.3 and will correct it in a subsequent version?

Question

Storing dictionary versions in the Trial Summary dataset (TS). As per SDTM Terminology_29Mar2019, we have the following code list (C66788). We are required to store MedDRA and WHODrug dictionary versions in SDTM and ultimately reflect in analysis TLFs. DICTNAM Dictionary Name C43820 MedDRA Medical Dictionary for Regulatory Activities C49475 WHODD World Health Organisation Drug Dictionary. The current solution is to store in supplemental datasets; however, this means repeating the same data for every record. As an alternate solution, will the below be in violation of CDISC guidelines?
TSPARMCD TSPARM TSVAL TSVALCD TSVCDREF
DICTNAM Dictionary Name MedDRA 22.0 Medical Dictionary for Regulatory Activities

PHUSE Team Response: 31 July 2019

Not a violation if recorded in SUPP or in TS, as they are not required in either, as per CDISC SDTM IG. They should be included in the SDSP and in Define. XML. It's also optional to add to DRGs. DICTNAM is not a valid CT for TSPARMCD as per the most recent NCI SDTM CT.

Question

Why are Screen Failures and Not Assigned not represented in TA?

PHUSE Team Response:

TA represents only paths where things happen as desired. There are many circumstances where things don't happen as desired, including screen failures, drop-outs before study completion, and the study being terminated before completion. Although a protocol may deal with handling some of such circumstances, including all these in TA could overwhelm the desired paths with all the undesired

paths. This scope (desired paths, rather than all paths) was part of the original proposal from Norman Stockbridge at the FDA.

Question

How should a subject that is incorrectly dosed be represented in SE (i.e. a subject is randomised to Drug A, but receives Drug B)? Unplanned element?

PHUSE Team Response: 7 June 2017

An element which does not occur in the Trial Elements (TE) dataset should be represented as unplanned.

An element which is not part of the arm to which a subject was assigned but does appear in the TE dataset should be represented using the appropriate ETCD value.

If Drug B was an element in TE, then for a subject who received the treatment described in the Drug B element, their SE records would include a record for the Drug B element, regardless of whether they were assigned to an arm that included that element, as defined in the Trial Arms (TA) dataset.

Improvements to the examples for DM and SE were included in the Public Review of SDTMIG v3.3 Batch 3, and are expected to be included in the final standard. The revised examples include values for ACTARM and ACTARMCD, which help to represent the situation when subjects are not treated as planned.

Question

How to define an unplanned Element in SE? Example: unexpected washout.

PHUSE Team Response: 7 June 2017

If an element was unplanned for the subject but still a planned element for the trial, then in the SE dataset for that subject, the actual element name should be used rather than ETCD = UNPLAN. ETCD = UNPLAN would be used when the element does not exist in TA/TE.