Description

A trial design domain that contains each planned arm in the trial.

ta.xpt, Trial Arms — Trial Design. One record per planned Element per Arm, Tabulation.

Specification

Assumptions

1. TAETORD is an integer. In general, the value of TAETORD is 1 for the first element in each arm, 2 for the second element in each arm, and so on. Occasionally, it may be convenient to skip some values (see Example Trial 6). Although the values of TAETORD need not always be sequential, their order must always be the correct order for the elements in the arm path.

2. Elements in different arms with the same value of TAETORD may or may not be at the same time, depending on the design of the trial. The example trials illustrate a variety of possible situations. The same element may occur more than once within an arm.

3. TABRANCH describes the outcome of a branch decision point in the trial design for subjects in the arm. A branch decision point takes place between epochs, and is associated with the element that ends at the decision point. For instance, if subjects are assigned to an arm where they receive product A through a randomization at the end of element X, the value of TABRANCH for element X would be "Randomized to A."

4. Branch decision points may be based on decision processes other than randomizations (e.g., clinical evaluations of disease response, subject choice).

5. There is usually some gap in time between the performance of a randomization and the start of randomized product. However, in many trials this gap in time is small and it is highly unlikely that subjects will leave the trial between randomization and product. In these circumstances, the trial does not need to be modeled with this time period between randomization and start of product as a separate element.

6. Some trials include multiple paths that are closely enough related so that they are all considered to belong to 1 arm. In general, this set of paths will include a "complete" path along with shorter paths that skip some elements. The sequence of elements represented in the trial arms should be the complete, longest path. TATRANS describes the decision points that may lead to a shortened path within the arm.

7. If an element does not end with a decision that could lead to a shortened path within the arm, then TATRANS will be blank. If there is such a decision, TATRANS will be in a form like, "If condition X is true, then go to epoch Y" or "If condition X is true, then go to element with TAETORD = "Z".

8. EPOCH is not strictly necessary for describing the sequence of elements in an arm path, but it is the conceptual basis for comparisons between arms and also provides a useful way to talk about what is happening in a blinded trial while it is blinded. During periods of blinded product, blinded
participants will not know which arm and element a subject is in, but EPOCH should provide a description of the time period that does not depend on knowing arm.

9. EPOCH should be assigned in such a way that elements from different arms with the same value of EPOCH are "comparable" in some sense. The degree of similarity across arms varies considerably in different trials, as illustrated in the examples.

10. EPOCH values for multiple similar epochs:
   a. When a study design includes multiple epochs with the same purpose (e.g., multiple similar product epochs), it is recommended that the EPOCH values be terms from controlled terminology, but with numbers appended. For example, multiple product epochs could be represented using "PRODUCT 1", "PRODUCT 2", and so on. Because the codelist is extensible, this convention allows multiple similar epochs to be represented without adding numbered terms to the CDISC Controlled Terminology for epoch. The inclusion of multiple numbered terms in the EPOCH codelist is not considered to add value.
   b. Note that the controlled terminology does include some more granular terms for distinguishing between epochs that differ in ways other than mere order, and these terms should be used where applicable, as they are more informative.

11. Note that study cells are not explicitly defined in the TA dataset. A set of records with a common value of both ARMCD and EPOCH constitute the description of a study cell. Transition rules within this set of records are also part of the description of the study cell.

12. EPOCH may be used as a timing variable in other datasets, such as Exposure (EX) and Disposition (DS), and values of EPOCH must be different for different epochs. For instance, in a crossover trial with 3 product epochs, each must be given a distinct name; all 3 cannot be called "PRODUCT".