Adjudication Data – How Would You Map in SDTM?

Adjudication is performed in clinical trials to ensure independent, accurate, and consistent assessments of important study events, such as cardiovascular outcomes or oncology endpoints. The results of these assessments are critical to the validation of clinical study results, so the data must be stored in an efficient and effective manner within the SDTM database. Findings observations collected from the adjudication events or safety and efficacy endpoints are mapped to the FA domain, which are related to the Event (AE/CE) or Interventions (PR) domains using RELREC or supplemental qualifiers in SDTM. This approach allows for the data to be consistently stored and easily referenced for analysis purposes and for later regulatory review.

Examples:

Events and Findings About (Case 1)

Often times, the adjudication or endpoint data collected is related to a study event (CE or AE), but does not fit in the Event domain structure. In these situations, the FA domain is an ideal place to store these findings.

PR and FA Example

In this example, the FA domain is used as a way to accomplish this need.

Related Records (RELREC) Domain

Findings About (FA) Domain

The relationship between CE and FA is maintained via CESPID and FAGRPID - FAGRPID for multiple records is equal to the CESPID of one record. RELREC helps to build the relationship between CE and FA.

Related Records (RELREC) Domain

Findings About (FA) Domain

PR and FA Example

In this example, the FA domain is used as a way to accomplish this need.

Stand Alone FA

In this example, the FA domain was used in reference to a surgical event. The data was collected in reference to a surgical site assessment (such as date/time). In this case, the data is stored in FA with FACAT indicating the records refer to a SURGERY. RELREC is not created because there is no relationship with an Event or Intervention record. SUPPFA is used to hold non-standard data.

Conclusion

The use of a Findings About domain allows for consistent and compliant storage of the adjudication and endpoint data collected in clinical trials. Per the SDTM IG, the FA domain is used to hold findings about events or interventions when the data cannot be represented within an Event or Intervention record, or as a Supplemental Qualifier to such record. The above examples show three cases where this can apply when collecting findings data: different timing from an associated event/intervention as a whole, qualifiers of their own that can be represented in Findings variables, data about an event/intervention for which no event/intervention record has been created. Regulatory authorities are placing increasing focus on the unbiased and consistent reporting that adjudication data provides, and the SDTM structure provides the FA domain as a way to accomplish this need.