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 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.

Interventions and Findings About (Case 2)

Similarly, data may be collected about Interventions (PR) that do not fit in the parent domain. FA is used in the same manner as with Events domains to store the Findings About the Intervention.

Stand Alone Findings About (Case 3)

The FA domain can also be used without a related domain, if the findings relate to an event/intervention that is not stored in the clinical database.

CE and FA Example

In this example, the findings observations are collected for the subjects from hypoglycemic events. These findings do not fit into the Event domain, hence they are mapped to Findings About (FA). The value of the required variable FAOBJ should match the value of CETERM in CE.

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

Clinical Events (CE) Domain

STUDYID	DOMAIN	USUBJID	CESEQ	CESPID	CETERM	CEDECOD	CECAT	CEPRESP	CEOCCUR	CESTDTC
AXBY	CE	AXBY-01-0135	1	3	HYPOGLYCAEMIA	HYPOGLYCAEMIA	HYPOGLYCEMIC EVENTS	Y	Y	2014-08-20T12:51

Findings About (FA) Domain

STUDYID	DOMAIN	USUBJID	FASEQ	FAGRPID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FADTC
AXBY	FA	AXBY-01-0135	1	3	HYPOR1	When did the hypoglycemic event occur	HYPOGLYCAEMIA	HYPOGLYCEMIC EVENTS	BETWEEN WAKING AND BEDTIME	BETWEEN WAKING AND BEDTIME	2014-08-20T12:51
AXBY	FA	AXBY-01-0135	2	3	HYPOR2	Awareness of hypoglycemic event	HYPOGLYCAEMIA	HYPOGLYCEMIC EVENTS	UNAWARE	UNAWARE	2014-08-20T12:51
AXBY	FA	AXBY-01-0135	3	3	HYPOR3	Hypoglycemia Signs and Symptoms Present	HYPOGLYCAEMIA	HYPOGLYCEMIC EVENTS	N	N	2014-08-20T12:51

Related Records (RELREC) Domain

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
AXBY	CE	AXBY-01-0135	CESPID	3		FACE1
AXBY	FA	AXBY-01-0135	FAGRPID	3		FACE1

PR and FA Example

In this example, the FA domain is necessary because the adjudication data collected has different timing than the associated intervention. The Stent Implantation (PRTRT) was completed on 2010-03-17 and evaluated by the Investigator on the same day, but the adjudicator determined the urgency and success on a later date.

RELREC is used to tie the records together by the --LNKID variable. One PR record has multiple related FA records, which can have differing FADTC values.

Procedures (PR) Domain

STUDYID	DOMAIN	USUBJID	PRSEQ	PRLNKD	PRTRT	PRDECOD	PRCAT	PRLOC	PRSTDTC	PRENDTC
AXBY	PR	AXBY-01-0135	1	1	STENT IMPLANTATION	STENT IMPLANTATION	PERCUTANEOUS CORONARY INTERVENTION	PROXIMAL RIGHT CORONARY ARTERY	2010-03-17 T08:10	2010-03-17T09:25

Findings About (FA) Domain

STUDYID	DOMAIN	USUBJID	FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FAMETHOD	FAEVAL	FADTC
AXBY	FA	AXBY-01-0135	1	1	PRSTTYPE	Procedure Urgency Status Type	STENT IMPLANTATION	PERCUTANEOUS CORONARY INTERVENTION	Urgent	URGENT	CORONARY ANGIOGRAPHY	INVESTIGATOR	2010-03-17
AXBY	FA	AXBY-01-0135	2	1	PRSUCIND	Procedure Success Indicator	STENT IMPLANTATION	PERCUTANEOUS CORONARY INTERVENTION	Y	Y	CORONARY ANGIOGRAPHY	INVESTIGATOR	2010-03-17
AXBY	FA	AXBY-01-0135	3	1	PRSTTYPE	Procedure Urgency Status Type	STENT IMPLANTATION	PERCUTANEOUS CORONARY INTERVENTION	Urgent	URGENT	CORONARY ANGIOGRAPHY	CEC ADJUDICATOR	2010-04-18
AXBY	FA	AXBY-01-0135	4	2	PRSUCIND	Procedure Success Indicator	STENT IMPLANTATION	PERCUTANEOUS CORONARY INTERVENTION	Y	Y	CORONARY ANGIOGRAPHY	CEC ADJUDICATOR	2010-04-18

Related Records (RELREC) Domain

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
AXBY	PR		PRLNKID		ONE	FAPR1
AXBY	FA		FALNKID		MANY	FAPR1

Stand Alone FA

In this example, data was collected in reference to a surgical site, yet there was no specific information collected to create a “surgery” event in the database (such as date/time). In this case, the records are stored in FA with FAOBJ indicating the records refer to a SURGERY. RELREC is not created because there is no relationship with an Event or Intervention domain. SUPPFA is used to hold non-standard data.

Findings About (FA) Domain

STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FADTC
AXBY	FA	AXBY-01-0135	1	1	SUSIASPE	Was the surgical site assessment performed?	SURGERY	SURGICAL SITE ASSESSMENT	Y	Y	2016-07-21
AXBY	FA	AXBY-01-0135	2	1	ASSESS	Surgical site assessment	SURGERY	SURGICAL SITE ASSESSMENT	Major complication	Major complication	2016-07-21

Supplemental Qualifiers for FA (SUPPFA) Domain

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
AXBY	FA	AXBY-01-0135	FASEQ	2	ADINSUSA	Additional Investigator Site Assessment	Hematoma requirement aspiration	CRF	INVESTIGATOR

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.

References

SDTM Implementation Guide v3.2
[http://www.cdisc.org/system/files/all/standard_category/application/pdf/sdtmig_20v3.2_20noportfolio.pdf]

Which clinical trials need a Clinical Endpoint Adjudication Committee?
[https://www.georgeclinical.com/resources/research/clinical-trials-need-clinical-endpoint-adjudication-committee]

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