6 Domain Models Based on the General Observation Classes

6.2 Events

Environmental Risk Factors (ER)

ER – Description/Overview for Environmental Risk Factors Domain Model

The Environmental Risk Factors (ER) domain is an events domain for representing data collected to assess potential exposures to, or risk factors associated with, diseases by way of environmental contact or through participation in activities associated with risk.

ER – Specification for Environmental Risk Factors Domain Model

er.xpt, Environmental Risk Factors — Events, Version 3.x.x. One record per event per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	ER	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
ERSEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness of records within a dataset for a subject (or within a parameter, in the case of the Trial Summary domain). May be any valid number (including decimals) and does not have to start at 1.	Req
ERGRPID	Group ID	Char		Identifier	Optional group identifier, used to link together a block of related records within a subject in a domain. Also used to link together a block of related records in the Trial Summary dataset.	Perm
ERREFID	Reference ID	Char		Identifier	Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image.	Perm
ERSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier. Example: pre-printed line identifier on a Concomitant Medications page.	Perm

ERLNKID	Link ID	Char		Identifier	Identifier used to link related records across domains. This may be a one-to-one or a one-to-many relationship. For Example: A single tumor may have multiple measurements/assessments performed at each study visit.	Perm
ERLNKGRP	Link Group ID	Char		Identifier	Identifier used to link related records across domains. This will usually be a many-to-one relationship. For example: Multiple tumor measurements/assessments will contribute to a single response to therapy determination record.	Perm
ERTERM	Reported Term	Char		Topic	Topic variable for an event observation, which is the verbatim or pre-specified name of the event.	Req
ERMODIFY	Modified Reported Term	Char		Synonym Qualifier	If the value for ERTERM is modified for coding purposes, then the modified text is placed here.	Perm
ERDECOD	Dictionary-Derived Term	Char		Synonym Qualifier	Dictionary or sponsor-defined derived text description of the topic variable, ERTERM, or the modified topic variable (ERMODIFY), if applicable. Equivalent to the Preferred Term (PT in MedDRA).	Perm
ERCAT	Category	Char		Grouping Qualifier	Used to define a category of topic-variable values.	Perm
ERSCAT	Subcategory	Char		Grouping Qualifier	Used to define a further categorization of ERCAT values.	Perm
ERPRESP	Pre-specified	Char		Variable Qualifier	Used to indicate whether the event described by ERTERM was pre-specified on a CRF. Value is Y for pre-specified events, null for spontaneously reported events.	Perm
EROCCUR	Occurrence	Char		Record Qualifier	Used to record whether a pre-specified event occurred when information about the occurrence of a specific event is solicited.	Perm
ERSTAT	Completion Status	Char		Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified event was not answered. Should be null or have a value of NOT DONE.	Perm
ERREASND	Reason Not Done	Char		Record Qualifier	Reason not done. Used in conjunction with ERSTAT when its value is NOT DONE.	Perm
ERBODSYS	Body System or Organ Class	Char		Record Qualifier	Body system or system organ class assigned for analysis from a standard hierarchy (e.g. MedDRA) associated with an event. Example: GASTROINTESTINAL DISORDERS.	Perm
ERBDSYCD	Body System or Organ Class Code	Num		Variable Qualifier	MedDRA System Organ Class code corresponding to ERBODSYS assigned for analysis.	Perm
ERPATT	Pattern of Event	Char		Record Qualifier	Used to indicate the pattern of the event over time. Examples: INTERMITTENT, CONTINUOUS, SINGLE EVENT.	Perm
VISITNUM	Visit Number	Num		Timing	Clinical encounter number. Numeric version of VISIT, used for sorting.	Perm
VISIT	Visit Name	Char		Timing	Protocol-defined description of a clinical encounter.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of VISIT. Should be an integer.	Perm
EPOCH	Epoch	Char		Timing	Epoch associated with the start date/time of the observation, or the date/time of collection if start date/time is not collected.	Perm
ERDTC	Date/Time of Collection	Char	ISO 8601	Timing	Collection date and time of an observation.	Perm
ERSTDTC	Start Date/Time of Observation	Char	ISO 8601	Timing	Start date/time of an observation.	Perm

ERENDTC	End Date/Time of Observation	Char	ISO 8601	Timing	End date/time of the observation.	Perm
ERDY	Study Day of Visit/Collection/Exam	Num		Timing	Actual study day of visit/collection/exam expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.	Perm
ERSTDY	Study Day of Start of Observation	Num		Timing	Actual study day of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.	Perm
ERENDY	Study Day of End of Observation	Num		Timing	Actual study day of end of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.	Perm
ERDUR	Duration	Char	ISO 8601	Timing	Collected duration of an event, intervention, or finding. Used only if collected on the CRF and not derived.	Perm
ERTPT	Planned Time Point Name	Char		Timing	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See ERTPTNUM and ERTPTREF.	Perm
ERTPTNUM	Planned Time Point Number	Num		Timing	Numeric version of planned time point used in sorting.	Perm
ERELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned Elapsed time relative to a planned fixed reference (ERTPTREF) such as "Previous Dose" or "Previous Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval, represented as ISO duration.	Perm
ERTPTREF	Time Point Reference	Char		Timing	Description of the fixed reference point referred to by ERELTM, ERTPTNUM, and ERTPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
ERRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time for a fixed reference time point defined by ERTPTREF.	Perm
EREVLINT	Evaluation Interval	Char	ISO 8601	Timing	Duration of interval associated with an observation such as a finding ERTESTCD. Example: -P2M to represent a period of the past 2 months as the evaluation interval for a question from a questionnaire such as SF-36.	Perm
EREVINTX	Evaluation Interval Text	Char		Timing	Evaluation interval associated with an observation, where the interval is not able to be represented in ISO 8601 format. Examples: LIFETIME, LAST NIGHT, RECENTLY, OVER THE LAST FEW WEEKS.	Perm
ERSTRTPT	Start Relative to Reference Time Point	Char		Timing	Identifies the start of the observation as being before or after the sponsor-defined reference time point defined by variable ERSTTPT.	Perm
ERSTTPT	Start Reference Time Point	Char		Timing	Description or date/time, in ISO 8601 or other character format, of the sponsor-defined reference point referred to by ERSTRTPT. Examples: "2003-12-15" or "VISIT 1".	Perm
ERENRTPT	End Relative to Reference Time Point	Char		Timing	Identifies the end of the observation as being before or after the sponsor-defined reference time point defined by variable ERENTPT.	Perm
ERENTPT	End Reference Time Point	Char	ISO 8601	Timing	Description or date/time in ISO 8601 or other character format of the sponsor-defined reference point referred to by ERENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm
ERSTINT	Planned Start of Assessment Interval	Char	ISO 8601	Timing	The start of a planned evaluation or assessment interval in ISO 8601 character format relative to the Time Point Reference (ERTPTREF).	Perm

ERENINT	Planned End of Assessment Interval	Char	ISO 8601	Timing	The end of a planned evaluation or assessment interval in ISO 8601 character format relative to the Time Point Reference (ERTPTREF).	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

ER – Assumptions for Environmental Risk Factors Domain Model

1. The Environmental Risk Factors (ER) domain is an events domain for representing data collected to assess potential exposures to, or risk factors associated with, diseases through environmental contact or through participation in activities associated with risk. In the case of infectious diseases this includes known exposures to infected persons or animals as well as potential exposures via environmental circumstances or high-risk behaviors. For non-infectious diseases it may include other risk factors such as participation in contact sports, exposure to pesticides or other hazardous materials, etc.

2. Risk factors not directly associated with exposure to environmental factors, such as genetic risk factors, age, sex, or weight, would not be represented in the ER domain.

3. The contact event is represented in ERTERM, with appropriate timing variables used to represent the timeframe of the contact event. ERTERM should be a brief description of the contact event (e.g., DIRECT CONTACT WITH LIVESTOCK, PARTICIPATION IN CONTACT SPORTS, etc.).

4. Additional details further characterizing the event in ERTERM should be represented in Findings About (FAER) (e.g., Livestock species handled, contact sports participated in, etc.).

5. The following variables would generally not be used in the ER domain: --SER, --ACN, --ACNOTH, --REL, --RELNST, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE.

ER – Examples for Environmental Risk Factors Domain Model

Example 1

The following example shows the results of an environmental risk factors assessment for one subject. The responses were collected via a CRF with pre-specified questions then represented as Environmental Risk Factors (ER) data. These data are categorized as "TB RISK FACTORS" in ERCAT to enable sorting.

Row 1: Shows that the subject was asked about incarceration. The subject has not been incarcerated as indicated by EROCCUR=N.
Row 2: Shows that the subject has not been homeless in the year preceding the date of assessment (ERDTC) as indicated by EREVLINT= -P1Y.
Row 3: Shows that the subject traveled internationally between the dates indicated in ERSTDTC and ERENDTC. Details about the countries to which the subject traveled were also collected and are represented in FA (example follows).
Row 4: Shows that the subject reported a history of alcohol abuse within the 3 years prior to the date of assessment.

er.xpt

Row	STUDYID	DOMAIN	USUBJID	ERSEQ	ERLNKID	ERTERM	ERCAT	ERPRESP	EROCCUR	ERDTC	ERSTDTC	ERENDTC	EREVLINT
1	ABC	ER	ABC-01-701	1		Incarceration	TB RISK FACTORS	Y	N	2014-04-07			
2	ABC	ER	ABC-01-701	2		Homeless	TB RISK FACTORS	Y	N	2014-04-07			-P1Y

Row	STUDYID	DOMAIN	USUBJID	ERSEQ	ERLNKID	ERTERM	ERCAT	ERPRESP	EROCCUR	ERDTC	ERSTDTC	ERENDTC	EREVLINT
3	ABC	ER	ABC-01-701	3	1	International Travel	TB RISK FACTORS	Y	Y	2014-04-07	2014-03-10	2014-03-25	
4	ABC	ER	ABC-01-701	4		Alcohol Abuse	TB RISK FACTORS	Y	Y	2014-04-07			-P3Y

Details regarding destinations of international travel–collected as part of the environmental risk factors above–are represented as Findings About Environmental Risk Factors and linked via RELREC.

Rows 1-2: Show that the subject's international travel (represented in er.xpt Row 3, above) included the destination countries of Djibouti and Eritrea. FAOBJ matches the ERTERM to which these records are related. FASTRESC contains the ISO-3166 alpha-3 code for these countries. Note that the specific dates spent in each country were not collected.

faer.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC
1	ABC	FA	ABC-01-701	1	1	COUNTRY	Country	International Travel	TB RISK FACTORS	Djibouti	DJI
2	ABC	FA	ABC-01-701	2	1	COUNTRY	Country	International Travel	TB RISK FACTORS	Eritrea	ERI

Row	FASTRSN	FADTC
1 (cont)		2014-04-07
2 (cont)		2014-04-07

Rows 1-2: Show how to represent the relationship between international travel and countries visited. The data are linked via --LNKID.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	ER		ERLNKID		ONE	1
2	ABC	FAER		FALNKID		MANY	1

Example 2

Source case investigations collect information primarily about non-study subjects (the source of the subject's TB exposure). The example tables below show how to represent data collected from a source case investigation. This investigation resulted in the identification of an educator at a child care center as the source of the subject's exposure to TB during the time period represented between ERSTDTC and ERENDTC in the er.xpt table. A --CAT of "SOURCE CASE INVESTIGATION" is used to indicate that this information is part of a source case investigation.
A table of additional examples of the types of data collected on the identified source case follows this example.

er.xpt

Row	STUDYID	DOMAIN	USUBJID	ERSEQ	ERLNKID	ERTERM	ERCAT	ERDTC	ERSTDTC	ERENDTC
1	ABC	ER	ABC-01-301	1	1	Exposure to TB	SOURCE CASE INVESTIGATION	2012-10-01	2012-08-06	2012-08-10

This example table shows the setting of the subject's exposure to TB identified through the source case investigation. FAOBJ matches the ERTERM in the example above. This record indicates that a child care center was the setting of the exposure to TB during the date range indicated in the mh.xpt example above.

faer.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC
1	ABC	FA	ABC-01-301	1	1	SETTING	Setting	Exposure to TB	SOURCE CASE INVESTIGATION	Child Care Center		Child Care Center

Relating the record of the TB Exposure event in MH to the setting of the exposure in FAER is handled via RELREC.

Rows 1-2: Show the relationship between exposure to TB and further details about the exposure. The data are linked via --LNKID. While the above example shows a ONE to ONE relationship between ER and FA, a ONE to MANY relationship may be also occur.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	ER		ERLNKID		ONE	1
2	ABC	FAER		FALNKID		MANY	1

The following tables show data collected from the subject's suspected source case (the non-study subject from whom the study subject likely contracted TB). The APRELSUB dataset is used to represent the source case's relation to the study subject. Additional data from non-study subjects associated with study subjects are represented in Associated Persons (APxx) datasets.

aprelsub.xpt

Row	STUDYID	APID	RSUBJID	SREL
1	ABC	AP-01	ABC-01-301	EDUCATOR

All subsequent data collected on the source case is handled in Associated Persons (APxx) datasets, where "xx" is the 2-letter domain code for the corresponding domain where data of the matching type from the subject would be handled (i.e, source case medical history would be represented in the APMH domain). All APxx records make use of the APID assigned in APRELSUB dataset above as unique identifier for this person.

This example table shows the results of a bacteriological identification test performed on a sputum sample provided by the source case identified through the source case investigation. Data of this type is represented in the MB domain (for study subjects), therefore source case data of this type is represented in APMB. APID is the unique identifier for the non-study subject (source case) whereas RSUBJID is the USUBJID of the study subject.

apmb.xpt

Row	STUDYID	DOMAIN	APID	MBSEQ	RSUBJID	SREL	MBREFID	MBTESTCD	MBTEST	MBEXTRG
1	ABC	APMB	AP-01	1	ABC-01-301	EDUCATOR	100	TRGMBEXM	Targeted Microbiology Examination	Mycobacterium tuberculosis

Row	MBCAT	MBORRES	MBORRESU	MBSTRESC	MBSTRESU	MBSPEC	MBLOC	MBMETHOD	MBDTC
1 (cont)	SOURCE CASE INVESTIGATION	PRESENT		PRESENT		SPUTUM	LUNG	MICROBIAL CULTURE, SOLID	2012-08-10

Example 3

The following example is based on the Centers for Disease Control and Prevention case report form (CRF) for Viral Hemorrhagic Fever (VHF). It shows the results of an environmental risk factors assessment for one subject. The responses were collected via the CRF with pre-specified questions then represented as Environmental Risk Factors (ER) data. These data are categorized as "EVD RISK FACTORS" in ERCAT. These questions were asked about the one month preceding the date of assessment (ERDTC) as indicated by EREVLINT= -P1M.

Row 1:   Shows that the subject was asked about contact with a known or suspect case, or contact with any sick person before becoming ill. The subject did not have specified contact as indicated by EROCCUR=N.
Row 2:   Shows that the subject attended a funeral.
Row 3:   Shows that the subject traveled outside their home or village/town before becoming ill.
Row 4:   Shows that the subject was not hospitalized, and did not go to a clinic or visit anyone in the hospital before becoming ill.
Row 5:   Shows that the subject did not consult a traditional/spiritual healer before becoming ill.
Row 6:   Shows that the subject did not have direct contact with animals of uncooked meat before becoming ill.

er.xpt

Row	STUDYID	DOMAIN	USUBJID	ERSEQ	ERLNKID	ERTERM	ERCAT	ERPRESP	EROCCUR	ERDTC	ERSTDTC	ERENDTC	EREVLINT
1	CDC-11	ER	ABC-01-101	1		Contact with a known or suspect case, or with any sick person	EVD RISK FACTORS	Y	N	2015-02-10			-P1M
2	CDC-11	ER	ABC-01-101	2	2	Attend a funeral	EVD RISK FACTORS	Y	Y	2015-02-10	2014-01-15	2014-01-15	-P1M
3	CDC-11	ER	ABC-01-101	3	3	Travel outside their home or village/town	EVD RISK FACTORS	Y	Y	2015-02-10	2014-01-13	2014-01-18	-P1M
4	CDC-11	ER	ABC-01-101	4		Hospitalized or go to a clinic or visit anyone in the hospital	EVD RISK FACTORS	Y	N	2015-02-10			-P1M
5	CDC-11	ER	ABC-01-101	5		Consult a traditional/spiritual healer	EVD RISK FACTORS	Y	N	2015-02-10			-P1M
6	CDC-11	ER	ABC-01-101	6		Direct contact (hunt, touch, eat) with animals or uncooked meat	EVD RISK FACTORS	Y	N	2015-02-10			-P1M

Details regarding destinations of funeral attendance and travel outside their village/town–collected as part of the environmental risk factors above–are represented as Findings About Environmental Risk Factors and linked via RELREC. There will only be records in FA for questions where EROCCUR=Y.

Rows 1-5: Show that the subject's funeral attendance (represented in er.xpt Row 2, above) included information about the name of the deceased person, relation to the patient, village and county names, and patient participation in the funeral. FAOBJ matches the ERTERM to which these records are related. FASTRESC contains the two-letter ISO-3166 alpha-3 code for the country (Liberia) and the UN/LOCODE for the specific County and Village names (Grand Bassa and Lower Buchanan). Note that the specific dates spent at the funeral were not collected.

Rows 6-7: Show that the subject's travel outside of their village or county (represented in er.xpt Row 3, above) included information about the village and county names. FAOBJ matches the ERTERM to which these records are related. FASTRESC contains the two-letter ISO-3166 alpha-3 code for the country (Liberia) and the UN/LOCODE for the specific County and Village names (Grand Bassa and Lower Buchanan).

faer.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FADTC
1	CDC-11	FA	ABC-01-101	1	2	NAMDC	Name of Deceased Person	Attend a funeral	EVD RISK FACTORS	Ariana Barnes	Ariana Barnes	2015-02-10
2	CDC-11	FA	ABC-01-101	2	2	RELSUB	Relation to Patient	Attend a funeral	EVD RISK FACTORS	COUSIN, BIOLOGICAL	COUSIN, BIOLOGICAL	2015-02-10
3	CDC-11	FA	ABC-01-101	3	2	VILLNAM	Village	Attend a funeral	EVD RISK FACTORS	Lower Buchanan	Lower Buchanan	2015-02-10
4	CDC-11	FA	ABC-01-101	4	2	CNTYNAM	County	Attend a funeral	EVD RISK FACTORS	Grand Bassa	LR-GBS	2015-02-10
5	CDC-11	FA	ABC-01-101	5	2	BDYCNTC	Patient participate (carry or touch body)	Attend a funeral	EVD RISK FACTORS	N	N	2015-02-10
6	CDC-11	FA	ABC-01-101	6	3	VILLNAM	Village	Travel outside their home or village/town	EVD RISK FACTORS	Lower Buchanan	Lower Buchanan	2015-02-10
7	CDC-11	FA	ABC-01-101	7	3	CNTYNAM	County	Travel outside their home or village/town	EVD RISK FACTORS	Grand Bassa	LR-GBS	2015-02-10

Relating the record of the Ebola exposure event in ER to the setting of the exposure in FAER is handled via RELREC.

Rows 1-2: Show the relationship between exposure to Ebola and further details about the exposure. The data are linked via --LNKID.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	CDC-11	ER		ERLNKID		ONE	3
2	CDC-11	FA		FALNKID		MANY	3

Example 4

The example below illustrates various information that may be collected to assess a person's risk for a traumatic brain injury (TBI). Participation in various activities associated with the potential for cumulative TBI (e.g. contact sports such as football, soccer, skiing, judo), and information regarding military service (e.g. branch, number and average length of deployments, number of blast exposures).

Row 1: Shows that the subject was asked about participation in football. The start and stop dates of participation were not collected, only the total number of years played. The subject played football for 3 years.

Row 2: Shows that the subject was asked about participation in martial arts, but the subject has not participated in martial arts at the time of the study visit.

Row 3: Shows that the subject was asked about participation in football. The start and stop dates of participation were not collected, only the total number of years played. The subject played soccer for 7 years.

Row 4: Shows that the subject was asked about military service. The subject was in the military from September 30, 1998 until June 26, 2012.

er.xpt

Row	STUDYID	DOMAIN	USUBJID	ERSEQ	ERLNKID	ERTERM	ERCAT	ERPRESP	EROCCUR	ERDTC	ERSTDTC	ERENDTC	ERDUR
1	TBI-001	ER	ABC-123	1		Football	TBI RISK FACTORS	Y	Y	2015-09-09			P3Y
2	TBI-001	ER	ABC-123	2		Martial Arts	TBI RISK FACTORS	Y	N	2015-09-09			
3	TBI-001	ER	ABC-123	3		Soccer	TBI RISK FACTORS	Y	Y	2015-09-09			P7Y
4	TBI-001	ER	DEF-456	4	1	Military Service	TBI RISK FACTORS	Y	Y	2015-09-17	1998-09-30	2012-06-26	

Details regarding the subject's military service, such as the branch of service, number and average length of deployments and number of blast exposures are represented as Findings About Environmental Risk Factors and linked via RELREC. There will only be records in FA for questions where EROCCUR=Y.

faer.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU	FADTC
1	TBI-001	FA	DEF-456	1	1	MILBRNCH	Branch of Military Service	Military Service	TBI RISK FACTORS	UNITED STATES ARMY		UNITED STATES ARMY			2015-09-17
2	TBI-001	FA	DEF-456	2	1	DPLOYNO	Number of Deployments	Military Service	TBI RISK FACTORS	4		4	4		2015-09-17
3	TBI-001	FA	DEF-456	3	1	AVLDPLOY	Average Length of Deployment	Military Service	TBI RISK FACTORS	8	MONTHS	8	8	MONTHS	2015-09-17
4	TBI-001	FA	DEF-456	4	1	BLASTNO	Number of Blast Exposures	Military Service	TBI RISK FACTORS	3		3	3		2015-09-17

Relating the record of the TBI Risk Factor exposure event in ER to the details of the exposure in FAER is handled via RELREC.

Rows 1-2: Show the relationship between the TBI Risk Factor of Military Service and further details about the military service. The data are linked via --LNKID.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	TBI-001	ER		ERLNKID		ONE	1

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
2	TBI-001	FA		FALNKID		MANY	1