6 Domain Models Based on the General Observation Classes

6.3 Events

Adverse Events (AE)

AE - Description/Overview for Adverse Events Domain Model

Adverse events may be captured either as free text or a pre-specified list of terms.

AE - Specification for Adverse Events Domain Model

ae.xpt, Adverse Events — Events, Version 3.2, One record per adverse 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	AE	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
AESEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
AEGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
AEREFID	Reference ID	Char		Identifier	Internal or external identifier such as a serial number on an SAE reporting form.	Perm
AESPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier. It may be pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on an Adverse Events page.	Perm
AETERM	Reported Term for the Adverse Event	Char		Topic	Verbatim name of the event.	Req
AEMODIFY	Modified Reported Term	Char		Synonym Qualifier	If AETERM is modified to facilitate coding, then AEMODIFY will contain the modified text.	Perm
AELLT	Lowest Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the Lowest Level Term.	Exp
AELLTCD	Lowest Level Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the Lowest Level Term.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
AEDECOD	Dictionary-Derived Term	Char	MedDRA	Synonym Qualifier	Dictionary-derived text description of AETERM or AEMODIFY. Equivalent to the Preferred Term (PT in MedDRA). The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.	Req
AEPTCD	Preferred Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the Preferred Term.	Exp
AEHLT	High Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the High Level Term for the primary System Organ Class.	Exp
AEHLTCD	High Level Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the High Level Term for the primary System Organ Class.	Exp
AEHLGT	High Level Group Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the High Level Group Term for the primary System Organ Class.	Exp
AEHLGTCD	High Level Group Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the High Level Group Term for the primary System Organ Class.	Exp
AECAT	Category for Adverse Event	Char	*	Grouping Qualifier	Used to define a category of related records. Example: BLEEDING, NEUROPSYCHIATRIC.	Perm
AESCAT	Subcategory for Adverse Event	Char	*	Grouping Qualifier	A further categorization of adverse event. Example: NEUROLOGIC.	Perm
AEPRESP	Pre-Specified Adverse Event	Char	(NY)	Variable Qualifier	A value of "Y" indicates that this adverse event was pre-specified on the CRF. Values are null for spontaneously reported events (i.e., those collected as free-text verbatim terms)	Perm
AEBODSYS	Body System or Organ Class	Char	*	Record Qualifier	Dictionary derived. Body system or organ class used by the sponsor from the coding dictionary (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables which may not necessarily be the primary SOC.	Exp
AEBDSYCD	Body System or Organ Class Code	Num	MedDRA	Variable Qualifier	Dictionary derived. Code for the body system or organ class used by the sponsor. When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables, which may not necessarily be the primary SOC.	Exp
AESOC	Primary System Organ Class	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the primary System Organ Class. Will be the same as AEBODSYS if the primary SOC was used for analysis.	Exp
AESOCCD	Primary System Organ Class Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the primary System Organ Class. Will be the same as AEBDSYCD if the primary SOC was used for analysis.	Exp
AELOC	Location of Event	Char	(LOC)	Record Qualifier	Describes anatomical location relevant for the event (e.g., ARM for skin rash).	Perm
AESEV	Severity/Intensity	Char	(AESEV)	Record Qualifier	The severity or intensity of the event. Examples: MILD, MODERATE, SEVERE.	Perm
AESER	Serious Event	Char	(NY)	Record Qualifier	Is this a serious event?	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
AEACN	Action Taken with Study Treatment	Char	(ACN)	Record Qualifier	Describes changes to the study treatment as a result of the event. AEACN is specifically for the relationship to study treatment. AEACNOTH is for actions unrelated to dose adjustments of study treatment. Examples of AEACN values include ICH E2B values: DRUG WITHDRAWN, DOSE REDUCED, DOSE INCREASED, DOSE NOT CHANGED, UNKNOWN or NOT APPLICABLE.	Exp
AEACNOTH	Other Action Taken	Char		Record Qualifier	Describes other actions taken as a result of the event that are unrelated to dose adjustments of study treatment. Usually reported as free text. Example: "TREATMENT UNBLINDED. PRIMARY CARE PHYSICIAN NOTIFIED."	Perm
AEREL	Causality	Char	*	Record Qualifier	Records the investigator's opinion as to the causality of the event to the treatment. ICH E2A and E2B examples include NOT RELATED, UNLIKELY RELATED, POSSIBLY RELATED, RELATED. Controlled Terminology may be defined in the future. Check with regulatory authority for population of this variable.	Exp
AERELNST	Relationship to Non-Study Treatment	Char		Record Qualifier	Records the investigator's opinion as to whether the event may have been due to a treatment other than study drug. May be reported as free text. Example: "MORE LIKELY RELATED TO ASPIRIN USE.".	Perm
AEPATT	Pattern of Adverse Event	Char	*	Record Qualifier	Used to indicate the pattern of the event over time. Examples: INTERMITTENT, CONTINUOUS, SINGLE EVENT.	Perm
AEOUT	Outcome of Adverse Event	Char	(OUT)	Record Qualifier	Description of the outcome of an event.	Perm
AESCAN	Involves Cancer	Char	(NY)	Record Qualifier	Was the serious event associated with the development of cancer?	Perm
AESCONG	Congenital Anomaly or Birth Defect	Char	(NY)	Record Qualifier	Was the serious event associated with congenital anomaly or birth defect?	Perm
AESDISAB	Persist or Signif Disability/Incapacity	Char	(NY)	Record Qualifier	Did the serious event result in persistent or significant disability/incapacity?	Perm
AESDTH	Results in Death	Char	(NY)	Record Qualifier	Did the serious event result in death?	Perm
AESHOSP	Requires or Prolongs Hospitalization	Char	(NY)	Record Qualifier	Did the serious event require or prolong hospitalization?	Perm
AESLIFE	Is Life Threatening	Char	(NY)	Record Qualifier	Was the serious event life threatening?	Perm
AESOD	Occurred with Overdose	Char	(NY)	Record Qualifier	Did the serious event occur with an overdose?	Perm
AESMIE	Other Medically Important Serious Event	Char	(NY)	Record Qualifier	Do additional categories for seriousness apply?	Perm
AECONTRT	Concomitant or Additional Trtmnt Given	Char	(NY)	Record Qualifier	Was another treatment given because of the occurrence of the event?	Perm
AETOXGR	Standard Toxicity Grade	Char	*	Record Qualifier	Toxicity grade according to a standard toxicity scale such as Common Terminology Criteria for Adverse Events v3.0 (CTCAE). Sponsor should specify name of the scale and version used in the metadata (see Assumption 6d). If value is from a numeric scale, represent only the number (e.g., "2" and not "Grade 2").	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
AESTDTC	Start Date/Time of Adverse Event	Char	ISO 8601	Timing		Exp
AEENDTC	End Date/Time of Adverse Event	Char	ISO 8601	Timing		Exp
AESTDY	Study Day of Start of Adverse Event	Num		Timing	Study day of start of adverse event relative to the sponsor-defined RFSTDTC.	Perm
AEENDY	Study Day of End of Adverse Event	Num		Timing	Study day of end of event relative to the sponsor-defined RFSTDTC.	Perm
AEDUR	Duration of Adverse Event	Char	ISO 8601	Timing	Collected duration and unit of an adverse event. Used only if collected on the CRF and not derived from start and end date/times. Example: P1DT2H (for 1 day, 2 hours).	Perm
AEENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the event relative to the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point (RFSTDTC) and a discrete ending point (RFENDTC) of the trial.	Perm
AEENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the event as being before or after the reference time point defined by variable AEENTPT.	Perm
AEENTPT	End Reference Time Point	Char		Timing	Description of date/time in ISO 8601 character format of the reference point referred to by AEENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

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

AE - Assumptions for Adverse Events Domain Model

1. AE Definition
   The Adverse Events dataset includes clinical data describing "any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment" (ICH E2A). In consultation with regulatory authorities, sponsors may extend or limit the scope of adverse event collection (e.g., collecting pre-treatment events related to trial conduct, not collecting events that are assessed as efficacy endpoints). The events included in the AE dataset should be consistent with the protocol requirements. Adverse events may be captured either as free text or via a pre-specified list of terms.

2. Adverse Event Description and Coding
   a. AETERM captures the verbatim term collected for the event. It is the topic variable for the AE dataset. AETERM is a required variable and must have a value.
   b. AEMODIFY is a permissible variable and should be included if the sponsor's procedure permits modification of a verbatim term for coding. The modified term is listed in AEMODIFY. The variable should be populated as per the sponsor's procedures.
   c. AEDECOD is the preferred term derived by the sponsor from the coding dictionary. It is a required variable and must have a value. It is expected that the reported term (AETERM) will be coded using a standard dictionary such as MedDRA. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.

d. AEBODSYS is the system organ class from the coding dictionary associated with the adverse event by the sponsor. This value may differ from the primary system organ class designated in the coding dictionary's standard hierarchy. It is expected that this variable will be populated.

e. Sponsors may include the values of additional levels from the coding dictionary's hierarchy (i.e., High-Level Group Term, High-Level Term, Lower-Level Term) in the SUPPAE dataset as described in ***Appendix C2 - Supplemental Qualifier Name Codes*** and ***Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain***.

3. Additional Categorization and Grouping

a. AECAT and AESCAT should not be redundant with the domain code or dictionary classification provided by AEDECOD and AEBODSYS (i.e., they should provide a different means of defining or classifying AE records). AECAT and AESCAT are intended for categorizations that are defined in advance. For example, a sponsor may have a separate CRF page for AEs of special interest and then another page for all other AEs. AECAT and AESCAT should not be used for after-the-fact categorizations such as clinically significant. In cases where a category of AEs of special interest resembles a part of the dictionary hierarchy (e.g., "CARDIAC EVENTS"), the categorization represented by AECAT and AESCAT may differ from the categorization derived from the coding dictionary.

b. AEGRPID may be used to link (or associate) different records together to form a block of related records at the subject level within the AE domain. See ***Section 4: 4.1.2.6, Grouping Variables and Categorization*** for discussion of grouping variables.

4. Pre-Specified Terms; Presence or Absence of Events

a. Adverse events are generally collected in two different ways, either by recording free text or using a pre-specified list of terms. In the latter case, the solicitation of information on specific adverse events may affect the frequency at which they are reported; therefore, the fact that a specific adverse event was solicited may be of interest to reviewers. An AEPRESP value of "Y" is used to indicate that the event in AETERM was pre-specified on the CRF.

b. If it is important to know which adverse events from a pre-specified list were not reported as well as those that did occur, these data should be submitted in a Findings class dataset such as Findings About Events and Interventions ***[See Section 6.4 - FA Domain]***. A record should be included in that Findings dataset for each pre-specified adverse-event term. Records for adverse events that actually occurred should also exist in the AE dataset with AEPRESP set to "Y."

c. If a study collects both pre-specified adverse events as well as free-text events, the value of AEPRESP should be "Y" for all pre-specified events and null for events reported as free-text. AEPRESP is a permissible field and may be omitted from the dataset if all adverse events were collected as free text.

d. When adverse events are collected with the recording of free text, a record may be entered into the sponsor's data management system to indicate "no adverse events" for a specific subject. For these subjects, do not include a record in the AE submission dataset to indicate that there were no events. Records should be included in the submission AE dataset only for adverse events that have actually occurred.

5. Timing Variables

a. Relative timing assessment "Ongoing" is common in the collection of Adverse Event information. AEENRF may be used when this relative timing assessment is made coincident with the end of the study reference period for the subject represented in the Demographics dataset (RFENDTC). AEENRTPT with AEENTPT may be used when "Ongoing" is relative to another date such as the final safety follow-up visit date. See ***Section 4: 4.1.4.7, Use of Relative Timing Variables***.

b. Additional timing variables (such as AEDTC) may be used when appropriate.

6. Other Qualifier Variables

a. If categories of serious events are collected secondarily to a leading question, as in the example below, the values of the variables that capture reasons an event is considered serious (i.e., AESCAN, AESCONG, etc.) may be null. For example, if Serious is answered "No, " the values for these variables may be null. However, if Serious is answered "Yes, " at least one of them will have a "Y" response. Others may be N or null, according to the sponsor's convention.

   Serious? [ ] Yes [ ] No
   If yes, check all that apply: [ ] Fatal [ ] Life-threatening [ ] Inpatient hospitalization… [ ] etc.
   On the other hand, if the CRF is structured so that a response is collected for each seriousness category, all category variables (e.g., AESDTH, AESHOSP) would be populated and AESER would be derived.

b. The serious categories "Involves cancer" (AESCAN) and "Occurred with overdose" (AESOD) are not part of the ICH definition of a serious adverse event, but these categories are available for use in studies conducted under guidelines that existed prior to the FDA's adoption of the ICH definition.

c. When a description of Other Medically Important Serious Adverse Events category is collected on a CRF, sponsors should place the description in the SUPPAE dataset using the standard supplemental qualifier name code AESOSP as described in ***Section 8: 8.4, Relating Non-Standard Variables Values to a Parent Domain*** and ***Appendix C2 - Supplemental Qualifier Name Codes***.

d. In studies using toxicity grade according to a standard toxicity scale such as Common Terminology Criteria for Adverse Events v3.0 (CTCAE), published by the NCI (National Cancer Institute) at http://ctep.cancer.gov/reporting/ctc.html)), AETOXGR should be used instead of AESEV. In most cases, either AESEV or AETOXGR is populated but not both. There may be cases when a sponsor may need to populate both variables. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes

e. AE Structure

   The structure of the AE domain is one record per adverse event per subject. It is the sponsor's responsibility to define an event. This definition may vary based on the sponsor's requirements for characterizing and reporting product safety and is usually described in the protocol. For example, the sponsor may submit one record that covers an adverse event from start to finish. Alternatively, if there is a need to evaluate AEs at a more granular level, a sponsor may submit a new record when severity, causality, or seriousness changes or worsens. By submitting these individual records, the sponsor indicates that each is considered to represent a different event. The submission dataset structure may differ from the structure at the time of collection. For example, a sponsor might collect data at each visit in order to meet operational needs, but submit records that summarize the event and contain the highest level of severity, causality, seriousness, etc. Examples of dataset structure:

   1. One record per adverse event per subject for each unique event. Multiple adverse event records reported by the investigator are submitted as summary records "collapsed" to the highest level of severity, causality, seriousness, and the final outcome.
   2. One record per adverse event per subject. Changes over time in severity, causality, or seriousness are submitted as separate events. Alternatively, these changes may be submitted in a separate dataset based on the Findings About Events and Interventions model ***[see Section 6.4 - FA Domain]***.
   3. Other approaches may also be reasonable as long as they meet the sponsor's safety evaluation requirements and each submitted record represents a unique event. The domain-level metadata ***[see Section 3: 3.2, Using The CDISC Domain Models In Regulatory Submissions - Dataset Metadata]*** should clarify the structure of the dataset.

7. Use of EPOCH and TAETORD

   When EPOCH is included in the Adverse Event domain, it should be the epoch of the start of the adverse event. In other words, it should be based on AESTDTC, rather than AEENDTC. The computational method for EPOCH in the define.xml should describe any assumptions made to handle cases where an adverse event starts on the same day that a subject starts an epoch, if AESTDTC and SESTDTC are not captured with enough precision to determine the epoch of the onset of the adverse event unambiguously. Similarly, if TAETORD is included in the Adverse Events domain, it should be the value for the start of the adverse event, and the computational method in the define.xml should describe any assumptions.

8. Additional Events Qualifiers

   The following Qualifiers would not be used in AE: --OCCUR, --STAT, and--REASND. They are the only Qualifiers from the SDTM Events Class not in the AE domain. They are not permitted because the AE domain contains only records for adverse events that actually occurred. See Assumption 4b above for information on how to deal with negative responses or missing responses to probing questions for pre-specified adverse events.

9. Variable order in the domain should follow the rules as described in ***Section 4: 4.1.1.4, Order Of The Variables*** and the order described in ***Section 1: 1.1, Purpose***.

10. The addition of AELLT, AELLTCD, AEPTCD, AEHLT, AEHLTCD, AEHLGT, AEHLGTCD, AEBDSYCD, AESOC, and AESOCCD is applicable to submissions coded in MedDRA only. Data items are not expected for non-MedDRA coding.

AE - Examples for Adverse Events Domain Model

Example 1

This is an example of data from an AE CRF that collects AE terms as free text. The first study drug was administered to the subject on October 13, 2006 at 12:00. Three AEs were reported. AEs were coded using MedDRA, and the sponsor's procedures include the possibility of modifying the reported term to aid in coding. The CRF is structured so that seriousness category variables (e.g., AESDTH, AESHOSP) are checked only when AESER is answered "Y."

Rows 1-2: Show the following: (1) an example of modifying the reported term for coding purposes. The modified value is in AEMODIFY. (2) An example of the overall seriousness question AESER answered with an "N" and corresponding seriousness category variables (e.g., AESDTH, AESHOSP) left blank.

Row 3: Shows an example of the overall seriousness question AESER answered with a "Y" and the relevant corresponding seriousness category variables (AESHOSP and AESLIFE) answered with a "Y". The other seriousness category variables are left blank. This row also shows an example of AEENRF being populated because the AE was marked as "Continuing" as of the end of the study reference period for the subject ***[see Section 4: 4.1.4.7, Use Of Relative Timing Variables]***.

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AESTDTC	AEENDTC	AEMODIFY	AEDECOD
1	ABC123	AE	123101	1	POUNDING HEADACHE	2005-10-12	2005-10-12	HEADACHE	Headache
2	ABC123	AE	123101	2	BACK PAIN FOR 6 HOURS	2005-10-13T13:05	2005-10-13T19:00	BACK PAIN	Back pain
3	ABC123	AE	123101	3	PULMONARY EMBOLISM	2005-10-21			Pulmonary embolism

Row	AEBODSYS	AESEV	AESER	AEACN	AEREL
1 (cont)	Nervous system disorders	SEVERE	N	NOT APPLICABLE	DEFINITELY NOT RELATED
2 (cont)	Musculoskeletal and connective tissue disorders	MODERATE	N	DOSE REDUCED	PROBABLY RELATED
3 (cont)	Vascular disorders	MODERATE	Y	DOSE REDUCED	PROBABLY NOT RELATED

Row	AEOUT	AESCONG	AESDISAB	AESDTH	AESHOSP	AESLIFE	AESMIE	AESTDY	AEENDY	AEENRF
1 (cont)	RECOVERED/RESOLVED							-1	-1	
2 (cont)	RECOVERED/RESOLVED							1	1	
3 (cont)	RECOVERING/RESOLVING				Y	Y		9		AFTER

Example 2

In this example, a CRF module occurring at several visits asks whether or not nausea, vomiting, or diarrhea occurred. The responses to the probing questions (Yes, No, or Not done) will be represented in the Findings About (FA) domain ***[see Section 6.4 - FA Domain]***. If "Yes " the investigator is instructed to complete the Adverse Event CRF. In the Adverse Events dataset, data on AEs solicited by means of pre-specified on the CRF will have an AEPRESP value of Y. For AEs solicited by a general question, AEPRESP will be null. RELREC may be used to relate AE records with FA records.

Rows 1-2: Show that nausea and vomiting were pre-specified on a CRF, as indicated by AEPRESP = "Y". The subject did not experience diarrhea, so no record for that term exists in the AE dataset.
Row 3: Shows an example of an AE (headache) that is not pre-specified on a CRF as indicated by a blank for AEPRESP.

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AEPRESP	AEBODSYS	AESEV		AESER
1	ABC123	AE	123101	1	NAUSEA	Nausea	Y	Gastrointestinal disorders	SEVERE		N
2	ABC123	AE	123101	2	VOMITING	Vomiting	Y	Gastrointestinal disorders	MODERATE		N
3	ABC123	AE	123101	3	HEADACHE	Headache		Nervous system disorders	MILD		N

Row	AEACN	AEREL	AEOUT	AESTDTC	AEENDTC	AESTDY	AEENDY
1 (cont)	DOSE REDUCED	RELATED	RECOVERED/RESOLVED	2005-10-12	2005-10-13	2	3
2 (cont)	DOSE REDUCED	RELATED	RECOVERED/RESOLVED	2005-10-13T13:00	2005-10-13T19:00	3	3
3 (cont)	DOSE NOT CHANGED	POSSIBLY RELATED	RECOVERED/RESOLVED	2005-10-21	2005-10-21	11	11

Example 3

In this example, a CRF module occurs only once and asks whether or not nausea, vomiting, or diarrhea occurred. In the context of this study, the conditions that occurred are reportable as Adverse Events. No additional data about these events is collected. No other adverse event information is collected via general questions. The responses to the probing questions (Yes, No, or Not done) will be represented in the Findings About (FA) domain ***[see Section 6.4 - FA Domain]***. Since all adverse events must be submitted in AE dataset, this represents an unusual case; the AE dataset will be populated with the term and the flag indicating that it was pre-specified, but timing information is limited to the date of collection, and other expected Qualifiers are not available. RELREC may be used to relate AE records with FA records.

Rows 1-2: Subject was found to have experienced nausea and vomiting by means of the probing questions. The subject did not experience diarrhea, so no record for that term exists in the AE dataset.

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AEPRESP	AEBODSYS	AESER	AEACN	AEREL	AEDTC	AESTDTC	AEENDTC	AEDY
1	ABC123	AE	123101	1	NAUSEA	Nausea	Y	Gastrointestinal disorders				2005-10-29			19
2	ABC123	AE	123101	2	VOMITING	Vomiting	Y	Gastrointestinal disorders				2005-10-29			19

Example 4

In this example, the investigator was instructed to create a new adverse-event record each time the severity of an adverse event changes. AEGRPID can be used to identify the group of records related to a single event for a subject.

Row 1: Shows an adverse event of nausea, whose severity was moderate.
Rows 2-6: Show how AEGRPID can be used to identify the group of records related to a single event for a subject.

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AEGRPID	AETERM	AEBODSYS	AESEV
1	ABC123	AE	123101	1		NAUSEA	Gastrointestinal disorders	MODERATE
2	ABC123	AE	123101	2	1	VOMITING	Gastrointestinal disorders	MILD
3	ABC123	AE	123101	3	1	VOMITING	Gastrointestinal disorders	SEVERE
4	ABC123	AE	123101	4	1	VOMITING	Gastrointestinal disorders	MILD
5	ABC123	AE	123101	5	2	DIARRHEA	Gastrointestinal disorders	SEVERE
6	ABC123	AE	123101	6	2	DIARRHEA	Gastrointestinal disorders	MODERATE

Row	AESER	AEACN	AEREL	AESTDTC	AEENDTC
1 (cont)	N	DOSE NOT CHANGED	RELATED	2005-10-13	2005-10-14
2 (cont)	N	DOSE NOT CHANGED	POSSIBLY RELATED	2005-10-14	2005-10-16
3 (cont)	N	DOSE NOT CHANGED	POSSIBLY RELATED	2005-10-16	2005-10-17
4 (cont)	N	DOSE NOT CHANGED	POSSIBLY RELATED	2005-10-17	2005-10-20
5 (cont)	N	DOSE NOT CHANGED	POSSIBLY RELATED	2005-10-16	2005-10-17
6 (cont)	N	DOSE NOT CHANGED	POSSIBLY RELATED	2005-10-17	2005-10-21