
Revision History

Version Number	Effective Date	Reason for Version	Standard this Version is Based on (if applicable)
1.0	7-NOV-2012	Initial Core Standards Release.	SDTM 3.1.2 and CDASH v1.1-1
2.0	19-JUL-2013	Added I.AERELNSTCMDVC, I.AERELDVC and deleted I.AERELNSTDVC. Changed question texts for I.AESDTH, I.AESLIFE, I.AESHOSP, I.AESDISAB, I.AESCONG, I.AESINV, and I.AESMIE. RS-00238. mjlw_tjs	SDTM 3.1.2 and CDASH v1.1-1

: Adverse Events () - Repeating Form [AE3001]													
#	Any AEs?		AE Group ID		Adverse Event				Adverse Events Details				
1													
igAE3000 [igAE3000]													
1.*	Were any adverse events experienced? [Any AEs?]				[AEYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No								
igAE3001 [igAE3001]													
2.	AE Group ID <i>[read-only]</i> [AE Group ID]				[AEGRPID] N4								
3.*	What is the adverse event term? [Adverse Event]				[AETERM] A200								
4.*	Dictionary-Derived Term <i>[hidden]</i> [Dictionary-Derived Term]				[AEDECOD] A200								
5.*	MedDRA Lowest Level Term <i>[hidden]</i> [Lowest Level Term]				[AELLT] A250								
6.*	MedDRA Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term code]				[AELLTCD] A20								
7.*	MedDRA Preferred Term Code <i>[hidden]</i> [Preferred Term Code]				[AEPTCD] A20								
8.*	MedDRA High Level Term <i>[hidden]</i> [High Level Term]				[AEHLT] A250								
9.*	MedDRA High Level Term Code <i>[hidden]</i> [High Level Term Code]				[AEHLTCD] A20								
10.*	MedDRA High Level Group Term <i>[hidden]</i> [High Level Group Term]				[AEHLGT] A250								
11.*	MedDRA High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]				[AEHLGTCD] A20								
12.*	Body System or Organ Class <i>[hidden]</i> [Body System or Organ Class]				[AEBODSYS] A250								
13.*	MedDRA Body System or Organ Class Code <i>[hidden]</i> [Body System or Organ Class Code]				[AEBDSYCD] A20								
14.*	MedDRA Primary System Organ Class <i>[hidden]</i> [Primary System Organ Class]				[AESOC] A250								
15.*	Primary System Organ Class Code <i>[hidden]</i> [Primary System Organ Class Code]				[AESOCCD] A20								
	AE Group ID	AE Number	Start Date	Start Time	Ongoing?	Severity	Relationship to Study Treatment	Relationship to Study Device	Relationship to Non-Study Treatment	Serious	Action Taken with Study Treatment	Outcome	
16.													
Adverse Events Details Entry [igAE3002]													
16.1	AE Group ID <i>[read-only]</i> [AE Group ID]							[AEGRPID] N4					
16.2*	AE Number <i>[read-only]</i> [AE Number]							[AESPID] N5					

16.3*	What is the date the adverse event started? [Start Date]	[AESTDAT] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2013-2013)
16.4	At what time did the adverse event start? [Start Time]	[AESTTIM] Req <input type="text"/> : Req <input type="text"/> 24-hour clock
16.5*	Is the adverse event still ongoing? [Ongoing?]	[AEONGO] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No End Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2013-2013) [AEENTIM] End Time Req <input type="text"/> : Req <input type="text"/> 24-hour clock
16.6*	What was the severity of the adverse event? [Severity]	[AESEV] [A:MILD] <input type="radio"/> Mild [A:MODERATE] <input type="radio"/> Moderate [A:SEVERE] <input type="radio"/> Severe
16.7*	Is this event related to study treatment? [Relationship to Study Treatment]	[AEREL] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
16.8	Is this event related to a study device? [Relationship to Study Device]	[AERELDVC] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
16.9	Relationship to Non-Study Treatment (Select all that apply) [Relationship to Non-Study Treatment]	[AERELNST_CMPD] [AERELNSTADJ] [A:ADJUNCT THERAPY] <input type="checkbox"/> Adjunct Therapy [AERELNSTCM] [A:CONCOMITANT THERAPY] <input type="checkbox"/> Concomitant Therapy [AERELNSTCMDVC] [A:CONCOMITANT DEVICE] <input type="checkbox"/> Concomitant Device [AERELNSTDIS] [A:STUDY DISEASE] <input type="checkbox"/> Study Disease [AERELNSTOMC] [A:OTHER MEDICAL CONDITION] <input type="checkbox"/> Other Medical Condition [AERELNSTPROC] [A:STUDY PROCEDURE] <input type="checkbox"/> Study Procedure [AERELNSTNONE] [A:NONE] <input type="checkbox"/> None
16.10*	Is the adverse event serious? [Serious]	[AESER] [A:Y] <input type="radio"/> [AESER_CMPD] Yes Serious Event Categories [AESDTH] Death [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [AESLIFE] Life-threatening [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [AESHOSP] Hospitalization (initial or prolonged) [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [AESDISAB] Disability or Permanent Damage [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [AESCONG] Congenital Anomaly / Birth Defect [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [AESINV] Required Intervention to Prevent Permanent Impairment or Damage (Devices) [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [AESMIE] Other Serious (Important Medical Events) [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [A:N] <input type="radio"/> No
16.11*	What action was taken with study treatment? [Action Taken with Study Treatment]	[AEACN] [c]AEACN <input type="text"/>
16.12*	What was the outcome of this adverse event? [Outcome]	[AEOUT] [c]OUT <input type="text"/>

Key: [*] = Item is required [✓] = Source verification required

Study Object Descriptions: Adverse Events

Type	RefName	Description
Section	igAE3000	Yes/No section (Item Group) of the Adverse Events form.
Section	igAE3001	Event Term and MedDRA coding section (Item Group) of the Adverse Events form.
Item	AEGRPID	AEGRPID
Item	AETERM	AETERM
Item	AEDECOD	AEDECOD
Item	AELLT	AELLT
Item	AELLTCD	AELLTCD

Item	AEPTCD	AEPTCD
Item	AEHLT	AEHLT
Item	AEHLTCD	AEHLTCD
Item	AEHLGT	AEHLGT
Item	AEHLGTCD	AEHLGTCD
Item	AEBODSYS	AEBODSYS
Item	AEBDSYCD	AEBDSYCD
Item	AESOC	AESOC
Item	AESOCCD	AESOCCD
Item	AEGRPID	AEGRPID
Item	AESPID	AESPID
Item	AESTDAT	AESTDTC
Item	AESTTIM	AESTDTC
Item	AEONGO	Used to derive AEENRTPT. If AEONGO = 'Y'; then set AEENRTPT to 'ONGOING' where AEENTPT = 'STUDY INFORMED CONSENT'.
Item	AEENDAT	AEENDTC
Item	AEENTIM	AEENDTC
Item	AESV	AESV
Item	AEREL	AEREL
Item	AERELDVC	SUPPAE.QVAL where QNAM = AERELDVC
Item	AERELNST_CMPD	AERELNST
Item	AERELNSTADJ	AERELNST
Item	AERELNSTCM	AERELNST
Item	AERELNSTCMDVC	AERELNST
Item	AERELNSTDIS	AERELNST
Item	AERELNSTOMC	AERELNST
Item	AERELNSTPROC	AERELNST
Item	AERELNSTNONE	AERELNST
Item	AESER	AESER
Item	AESDTH	AESDTH
Item	AESLIFE	AESLIFE
Item	AESHOSP	AESHOSP
Item	AESDISAB	AESDISAB
Item	AESCONG	AESCONG
Item	AESINV	SUPPAE.QVAL where QNAM = AESINV
Item	AESMIE	AESMIE
Item	AEACN	AEACN
Item	AEOUT	AEOUT

Codelist Values and Tables: Adverse Events					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clAEACN	String	Dose Increased	DOSE INCREASED	clitmAEACN_1	AEACN
		Dose Not Changed	DOSE NOT CHANGED	clitmAEACN_2	
		Dose Reduced	DOSE REDUCED	clitmAEACN_3	
		Drug Interrupted	DRUG INTERRUPTED	clitmAEACN_4	
		Drug Withdrawn	DRUG WITHDRAWN	clitmAEACN_5	
		Not Applicable	NA	clitmAEACN_96	
		Unknown	U	clitmAEACN_97	
clOUT	String	Recovered/Resolved	RECOVERED/RESOLVED	clitmOUT_1	AEOUT
		Recovering/Resolving	RECOVERING/RESOLVING	clitmOUT_2	
		Not Recovered/Not Resolved	NOT RECOVERED/NOT RESOLVED	clitmOUT_3	
		Recovered/Resolved With Sequelae	RECOVERED/RESOLVED WITH SEQUELAE	clitmOUT_4	
		Fatal	FATAL	clitmOUT_5	
		Unknown	UNKNOWN	clitmOUT_97	

RDE Analytics: RD_AE3001		
Data Variable RefName	RD Column Name	Column Data Type
AEYN	AEYN_C	VARCHAR2
	AEYN	VARCHAR2
	AEYN_ND	VARCHAR2
AEGRPID	AEGRPID	NUMBER

	AEGRPID_ND	VARCHAR2
AETERM	AETERM	VARCHAR2
	AETERM_ND	VARCHAR2
AEDECOD	AEDECOD	VARCHAR2
	AEDECOD_ND	VARCHAR2
AELLT	AELLT	VARCHAR2
	AELLT_ND	VARCHAR2
AELLTCD	AELLTCD	VARCHAR2
	AELLTCD_ND	VARCHAR2
AEPTCD	AEPTCD	VARCHAR2
	AEPTCD_ND	VARCHAR2
AEHLT	AEHLT	VARCHAR2
	AEHLT_ND	VARCHAR2
AEHLTCD	AEHLTCD	VARCHAR2
	AEHLTCD_ND	VARCHAR2
AEHLGT	AEHLGT	VARCHAR2
	AEHLGT_ND	VARCHAR2
AEHLGTCD	AEHLGTCD	VARCHAR2
	AEHLGTCD_ND	VARCHAR2
AEBODSYS	AEBODSYS	VARCHAR2
	AEBODSYS_ND	VARCHAR2
AEBDSYCD	AEBDSYCD	VARCHAR2
	AEBDSYCD_ND	VARCHAR2
AESOC	AESOC	VARCHAR2
	AESOC_ND	VARCHAR2
AESOCCD	AESOCCD	VARCHAR2
	AESOCCD_ND	VARCHAR2
RD_AE3001_IGAE3002		
AEGRPID	AEGRPID	NUMBER
	AEGRPID_ND	VARCHAR2
AESPID	AESPID	NUMBER
	AESPID_ND	VARCHAR2
AESTDAT	AESTDAT	DATE
	AESTDAT_DTS	VARCHAR2
	AESTDAT_ND	VARCHAR2
AESTTIM	AESTTIM	DATE
	AESTTIM_TMS	VARCHAR2
	AESTTIM_ND	VARCHAR2
AEONGO	AEONGO_C	VARCHAR2
	AEONGO	VARCHAR2
	AEONGO_ND	VARCHAR2
AEONGO - AEENDAT	AEENDAT	DATE
	AEENDAT_DTS	VARCHAR2
AEONGO - AEENTIM	AEENTIM	DATE
	AEENTIM_TMS	VARCHAR2
AESEV	AESEV_C	VARCHAR2
	AESEV	VARCHAR2
	AESEV_ND	VARCHAR2
AEREL	AEREL_C	VARCHAR2
	AEREL	VARCHAR2
	AEREL_ND	VARCHAR2
AERELDVC	AERELDVC_C	VARCHAR2
	AERELDVC	VARCHAR2
	AERELDVC_ND	VARCHAR2
AERELNST_CMPD	AERELNST_CMPD_ND	VARCHAR2
AERELNST_CMPD - Adjunct Therapy	*AERELNSTADJ_CLITMAERELNST_1_C	VARCHAR2
	*AERELNSTADJ_CLITMAERELNST_1	VARCHAR2
AERELNST_CMPD - Concomitant Therapy	*AERELNSTCM_CLITMAERELNST_2_C	VARCHAR2
	*AERELNSTCM_CLITMAERELNST_2	VARCHAR2
AERELNST_CMPD - Concomitant Device	*AERELNSTCMDVC_CLITMAERELNST_7_C	VARCHAR2
	*AERELNSTCMDVC_CLITMAERELNST_7	VARCHAR2

AERELNST_CMPD - Study Disease	*AERELNSTDIS_CLITMAERELNST_4_C	VARCHAR2
	*AERELNSTDIS_CLITMAERELNST_4	VARCHAR2
AERELNST_CMPD - Other Medical Condition	*AERELNSTOMC_CLITMAERELNST_6_C	VARCHAR2
	*AERELNSTOMC_CLITMAERELNST_6	VARCHAR2
AERELNST_CMPD - Study Procedure	*AERELNSTPROC_CLITMAERELNST_5_C	VARCHAR2
	*AERELNSTPROC_CLITMAERELNST_5	VARCHAR2
AERELNST_CMPD - None	*AERELNSTNONE_CLITMAERELNST_95_C	VARCHAR2
	*AERELNSTNONE_CLITMAERELNST_95	VARCHAR2
AESER	AESER_C	VARCHAR2
	AESER	VARCHAR2
	AESER_ND	VARCHAR2
AESER - AESDTH	AESDTH_C	VARCHAR2
	AESDTH	VARCHAR2
AESER - AESLIFE	AESLIFE_C	VARCHAR2
	AESLIFE	VARCHAR2
AESER - AESHOSP	AESHOSP_C	VARCHAR2
	AESHOSP	VARCHAR2
AESER - AESDISAB	AESDISAB_C	VARCHAR2
	AESDISAB	VARCHAR2
AESER - AESCONG	AESCONG_C	VARCHAR2
	AESCONG	VARCHAR2
AESER - AESINV	AESINV_C	VARCHAR2
	AESINV	VARCHAR2
AESER - AESMIE	AESMIE_C	VARCHAR2
	AESMIE	VARCHAR2
AEACN	AEACN_C	VARCHAR2
	AEACN	VARCHAR2
	AEACN_ND	VARCHAR2
AEOUT	AEOUT_C	VARCHAR2
	AEOUT	VARCHAR2
	AEOUT_ND	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different.		