

Dataset-Level Metadata for *AE_R*

Variable	Value
DESCRIPTION	
KEYFIELDS	
STRUCTURE	
INPUT_NOTES	<ol style="list-style-type: none">1. For all data sets with "Raw." libnames, the library location is: "S:\RhoFED\CSCC\Protocol Committees\Arginine\data\derive"2. For all data sets with "Der." libnames, the library location is: "S:\RhoFED\CSCC\Protocol Committees\Arginine2\data\derive"3. Merge Der.Add_Pt with: Raw.AE, by CSCC_ID --> Der.AE_R
OUTPUT_NOTES	

Variable-Level Metadata for 33 Variables in Table AE_R
 Metadata last updated [26JUN2009:10:40:36] Most recent change made [26JUN09:10:40]
 Display order [Alphabetical] Filtering [] Key Fields [unknown]

Var #	name8 [1]	Order	Type/ Len	Label	Definition, Notes, et al.	Format	Latest Update	Use
1	ACTION_DOSEADJUST	16	N8	Action - Study drug dose adjusted	Notes: #Imported from CSCC, ARGININE, dataset [AE]	1.	17JUN09:17:02	Yes
2	ACTION_DRUGDISCONTIN	15	N8	Action - Study drug discontinued	Notes: #Imported from CSCC, ARGININE, dataset [AE]	1.	17JUN09:17:02	Yes
3	ACTION_DRUGINTERRUPT	14	N8	Action - Study drug interrupted	Notes: #Imported from CSCC, ARGININE, dataset [AE]	1.	17JUN09:17:02	Yes
4	ACTION_HOSPITAL	18	N8	Action - Hospitalization	Notes: #Imported from CSCC, ARGININE, dataset [AE]	1.	17JUN09:17:02	Yes
5	ACTION_MEDINTERVENTION	17	N8	Action - Medical Intervention	Notes: #Imported from CSCC, ARGININE, dataset [AE]	1.	17JUN09:17:02	Yes
6	ACTION_NONE	19	N8	No Action Taken	Notes: #Imported from CSCC, ARGININE, dataset [AE]	1.	18JUN09:12:47	Yes
7	AECOM	9999	C150	AE comments	Notes: #Imported from CSCC, ARGININE, dataset [AE]	\$150.	12JUN09:13:16	No
8	AETEXT	6	C80	Adverse Event Text	Notes: #Imported from CSCC, ARGININE, dataset [AE]	\$80.	18JUN09:12:48	Yes
9	AE_END_DAY	8	I8	Number of days before (-) or after 1st day on study med, that AE ended	=Raw.AE_Stop_Date-Der.Pt_Start_Date+1 Notes: This is a new variable created for this version of the AE data	8.	18JUN09:12:47	Yes
10	AE_ONSET_DATE	999	N8	Adverse Event Onset Date (number of days prior to 1st day on study med)	Notes: #Imported from CSCC, ARGININE, dataset [AE]	Date9.	18JUN09:12:48	No
11	AE_START_DAY	7	I8	Number of days before (-) or after 1st day on study med, that AE was first reported	=Raw.AE_Onset_Date-Der.Pt_Start_Date+1 Notes: This is a new variable created for this version of the AE data	8.	18JUN09:12:48	Yes
12	AE_STOP_DATE	999	N8	Adverse Event Stop Date (number of days prior to 1st day on study med)	Notes: #Imported from CSCC, ARGININE, dataset [AE]	Date9.	18JUN09:12:48	No
13	AGE_GROUP	1	C5	Age Group	Notes: #Imported from CSCC, ARGININE, dataset [AE]	\$5.	18JUN09:12:48	Yes
14	CENTER	9999	C3	Center	Notes: #Imported from CSCC, ARGININE, dataset [AE]	\$3.	12JUN09:13:16	No

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Var #	name8 [1]	Order	Type/ Len	Label	Definition, Notes, et al.	Format	Latest Update	Use
15	CONTINUING	9	C3	AE Continuing	= 'Yes' if AEXPCODE.OUTCOME='3=Ongoing' Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$3.	18JUN09:12:48	Yes
16	CSCC_ID	9999	C7	CSCC ID number	Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$7.	12JUN09:13:15	No
17	DEATH	20	C3	Did patient die?	= 'Yes' if AEXPCODE.OUTCOME='5=Death due to AE' or AEXPCODE.SEVER='5=Death' ~='No' otherwise Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$3.	18JUN09:12:48	Yes
18	ITT	2	C3	Intent-To-Treat Population	Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$3.	18JUN09:12:48	Yes
19	LOWLEVELNAME	23	C100	LowLevelName - coding	Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$100.	18JUN09:12:48	Yes
20	OUTCOME	12	C45	Outcome of Adverse Event	= 'Resolved without sequelae' if AEXPCODE.OUTCOME='1=Resolved without sequelae' ~='Resolved with sequelae' if AEXPCODE.OUTCOME='2=Resolved with sequelae' ~='Ongoing' if AEXPCODE='3=Ongoing' ~='Present at death, not contributing to death' if AEXPCODE.OUTCOME='4=Present at death, not contributing to death' ~='Death due to AE' if AEXPCODE.OUTCOME='5=Death' Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$45.	18JUN09:12:48	Yes
21	PREFERRED_TERM	22	C100	Preferred_Term	Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$100.	18JUN09:12:48	Yes
22	PT_ID	0	C7	New Patient ID	=Der.Add_Pt.PT_ID Notes: New Variable	\$7.	26JUN09:10:40	Yes
23	RANDOMIZED	3	C3	Was patient randomized?	Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$3.	18JUN09:12:48	Yes
24	RELATIONSHIP	13	C25	Relationship to Study Drug	= 'Unrelated' if AEXPCODE.RELATED='1=Unrelated' ~='Probably not/remote if AEXPCODE.RELATED='2=Probably not/remote' ~='Possibly related' if AEXPCODE.RELATED='3=Possibly related' ~='Probably related' if AEXPCODE.RELATED='4=Probably related' ~='Definitely related' if AEXPCODE.RELATED='5=Definitely related' Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$25.	18JUN09:12:48	Yes
25	SAE	10	C3	Serious Adverse Event	= 'Yes' if AEXPCODE.SAE='Yes' ~='No' if AEXPCODE.SAE='No' Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$3.	18JUN09:12:48	Yes
26	SEVERITY	11	C20	Severity of AE	= 'Mild' if AEXPCODE.SEVER='1=Mild' ~='Moderate' if AEXPCODE.SEVER='2=Moderate' ~='Severe' if AEXPCODE.SEVER='3=Severe' ~='Life Threatening' if AEXPCODE.SEVER='4=Life threatening' ~='Death' if AEXPCODE.SEVER='5=Death' Notes: #Imported from CSCC, ARGinine, dataset [AE]	\$20.	18JUN09:12:49	Yes

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Var #	name8 [1]	Order	Type/ Len	Label	Definition, Notes, et al.	Format	Latest Update	Use
27	SITE	9999	C3	Site	Notes: #Imported from CSCC, ARGININE, dataset [AE]	\$3.	12JUN09:13:15	No
28	STUDY_ DRUG_ STARTDT	9999	N8	Study Drug Start Date	Notes: #Imported from CSCC, ARGININE, dataset [AE]	Date9.	12JUN09:13:15	No
29	SYSTEM_ ORGAN_ CLASS	21	C100	System Organ Class	Notes: #Imported from CSCC, ARGININE, dataset [AE]	\$100.	18JUN09:12:49	Yes
30	TEAE	24	C3	Treatment Emergent Adverse Event	= 'No' if AE_Onset_Date LT Study_Drug_StartDt ~='Yes' otherwise Notes: #Imported from CSCC, ARGININE, dataset [AE]	\$3.	18JUN09:12:49	Yes
31	TRAE	25	C3	Treatment-Related Adverse Event	= 'Yes' if AEXPCODE.RELATED in (4,5) ~='No' otherwise Notes: #Imported from CSCC, ARGININE, dataset [AE]	\$3.	18JUN09:12:49	Yes
32	TREATGRP	4	C9	Treatment Group, Actual	Notes: #Imported from CSCC, ARGININE, dataset [AE]	\$9.	18JUN09:12:49	Yes
33	TREATMENT	5	C1	Treatment Group	Notes: #Imported from CSCC, ARGININE, dataset [AE]	\$1.	18JUN09:12:49	Yes

[1] Shaded variable names indicate a variable identified in DATASETS.KEYFIELDS