

Dataset-Level Metadata for AE2

Variable	Value
DESCRIPTION	Analysis data set with Aes for subjects enrolled in Phase 2
KEYFIELDS	
STRUCTURE	One observation per AE per subject
INPUT_NOTES	EDC system I (referred to as (I) in the specs) data sets: S:\RhoFED\CSCC\Protocol Committees\Neuropsych\data\clinical EDC system II (referred to as (II) in the specs) data sets: S:\RhoFED\CSCC\Protocol Committees\Neuropsych\data\clinical\Neuropsych-II Set the I & II data sets together instead of merge. Keep only subjects with AEs
OUTPUT_NOTES	

NOTES:

- All dates were converted to the number of days from the subject's date of informed consent for the phase II pilot transfusion study (variable RANDINFCDT, see description in table below).
- All created study day variable names end with "DY". For example, randomization date (variable name RANDDT was converted to randomization day relative to phase II informed consent data and named RANDDY.
- PT_ID is included in the data instead of ID which is a randomly generated fake ID
- For deidentification purposes, some variables have been removed from the final analysis datasets. These are the variables you'll see crossed out in redacted 'black' in the specifications below to avoid confusion.
- IDs and DATES used as hardcodes in the variable definition fields have also been redacted for the same reasons.
- Red text items: ignore these as they were for internal use and represent the more recent updates.

Variable-Level Metadata for 29 Variables in Table AE2
 Metadata last updated [12JAN2012:17:25:54] Most recent change made [22SEP11:12:58]
 Display order [ORDER, NAME8] Filtering [] Key Fields [unknown]
 5 variable(s) with changes

Var #	name8 [1]	Order	Type/ Len	Label	Definition, Notes, et al.	Format	Latest Update	Use
1	ID	1	C7	Subject ID	=DERIVE.PATIENT_II.ID	\$7.	22FEB10:16:43	Yes
4	RANDTRTARM	4	C40	Randomized group, phase two	= DERIVE.PATIENT_II.RANDTRTARM	\$40.	22FEB10:16:43	Yes
5	RANDDT	5	N8	Date of randomization, phase two	= DERIVE.PATIENT_II.RANDDT	DATE9.	22FEB10:16:43	Yes
6	ITT	5.1	C3	Intent-to-Treat population	DERIVE.PATIENT_II.ITT	\$3.	22FEB10:16:43	Yes
7	RANDOM	5.2	C3	Randomized Subjects	DERIVE.PATIENT_II.RANDOM	\$3.	22FEB10:16:43	Yes
8	SAFETY	5.3	C3	Safety Population	DERIVE.PATIENT_II.SAFETY	\$3.	22FEB10:16:43	Yes
9	ANLY	5.4	C3	Full Analysis population	DERIVE.PATIENT_II.ANLY	\$3.	22FEB10:16:43	Yes
10	PP	5.5	C3	Per Protocol Population	DERIVE.PATIENT_II.PP	\$3.	22FEB10:16:43	Yes
11	COMPLETE	5.6	C3	Completed Study	DERIVE.PATIENT_II.COMPLETE	\$3.	22FEB10:16:43	Yes
13	SAEYN	7	C3	SAE yes/no?	=AEXPCODE.SAEYN (I & II)	\$3.	18DEC08:10:04	Yes
14	ONSETDT	8	N8	AE onset date	=AEXPCODE.ONSETDT (I & II)	DATE9.	18DEC08:10:04	Yes
15	STOPDT	9	N8	AE resolution date	=AEXPCODE.RESOLDT (I & II)	DATE9.	18DEC08:10:04	Yes
16	TEAE	10	C3	Treatment Emergent AE yes/no?	'Yes' if PATIENT_II.EOSDATE>=ONSETDT >= RANDDT and ^missing(ONSETDT) ^missing(RANDDT) and RANDTRTARM ='Standard care based on disease symptoms' ; 'Yes' if PATIENT_II.EOSDATE>=ONSETDT >= PATIENT_II.FTRANDT and ^missing(ONSETDT) ^missing(FTRANDT) and RANDTRTARM ='Chronic transfusion regimen for 6 months' ;	\$3.	22SEP11:12:58	Yes
17	OUTCOME	11	C43	Outcome of AE	=AEXPCODE.OUTCOME (I & II)	\$43.	18DEC08:10:04	Yes
18	SEVERE	12	C16	Severity level of AE	=AEXPCODE.SEVERE (I & II)	\$16.	18DEC08:10:04	Yes

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Var #	name8 [1]	Order	Type/ Len	Label	Definition, Notes, et al.	Format	Latest Update	Use
19	RELATED	13	C19	Relationship to intervention	=AEXPCODE.RELATE (I & II)	\$19.	18DEC08:10:04	Yes
20	ACTION1	14	N8	Action taken - none	=AEXPCODE.ACTION1 (I & II)	1.	18DEC08:10:05	Yes
21	ACTION2	15	N8	Action taken - intervention interrupted	=AEXPCODE.ACTION2 (I & II)	1.	18DEC08:10:05	Yes
22	ACTION3	16	N8	Action taken - intervention discontinued	=AEXPCODE.ACTION3 (I & II)	1.	18DEC08:10:05	Yes
23	ACTION4	17	N8	Action taken - intervention adjusted	=AEXPCODE.ACTION4 (I & II)	1.	18DEC08:10:05	Yes
24	ACTION5	18	N8	Action taken - medical intervention	=AEXPCODE.ACTION5 (I & II)	1.	18DEC08:10:05	Yes
25	ACTION6	19	N8	Action taken - hospitalization	=AEXPCODE.ACTION6 (I & II)	1.	18DEC08:10:05	Yes
26	DEATH	20	C3	AE resulted in Death	='Yes' if OUTCOME='Death due to AE' ='No' otherwise	\$3.	01JUL08:15:07	Yes
27	SOC	21	C100	System Organ Class	=AEXPCODE.SYSTEMORGANCLASSNAME (I & II)	\$100.	18DEC08:10:05	Yes
28	PREF_TERM	22	C100	Preferred Term	=AEXPCODE.PREFERREDNAME (I & II)	\$100.	18DEC08:10:05	Yes
29	ITT	600	C3	ITT population	='Yes' if RANDMSTR.RANDDT > Z. (I & II) ='No' otherwise	\$3.	22FEB10:16:48	Yes

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