

Dataset-Level Metadata for CMED_II

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Variable	Value
DESCRIPTION	Analysis dataset with Conmeds for subjects enrolled in Phase 2
KEYFIELDS	
STRUCTURE	One observation per subject per medication
INPUT_NOTES	Keep only subjects with recorded conmeds who are also part of the Patient_II database 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
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 27 Variables in Table CMED II

Metadata last updated [12JAN2012:17:25:54] Most recent change made [29SEP11:14:05]

Display order [ORDER, NAME8] Filtering // Key Fields [unknown]

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.	09AUG11:14:41	Yes
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
4	RANDTRTARM	4	C40	Randomized group, phase 2	=DERIVE.PATIENT_II.RANDTRTARM	\$40.	09AUG11:14:41	Yes
5	ITT	4.1	C3	ITT Population	=DERIVE.PATIENT_II.ITT	\$3.	09AUG11:14:41	Yes
6	SAFETY	4.2	C3	Safety Population	=DERIVE.PATIENT_II.SAFETY	\$3.	09AUG11:14:41	Yes
7	RANDOM	4.3	C3	Randomized Subjects	=DERIVE.PATIENT_II.RANDOM	\$3.	09AUG11:14:41	Yes
8	ANLY	4.4	C3	Full Analysis Population	=DERIVE.PATIENT_II.ANALY	\$3.	09AUG11:14:41	Yes
9	PP	4.5	C3	Per Protocol Population	=DERIVE.PATIENT_II.PP	\$3.	09AUG11:14:41	Yes
10	COMPLETE	4.6	C3	Completed Study	=DERIVE.PATIENT_II.COMPLETE	\$3.	09AUG11:14:41	Yes
11	GENDER	4.7	C6	Subject Gender	=DERIVE.PATIENT_II.GENDER	\$6.	09AUG11:14:41	Yes
12	AGE	4.8	N8	Subject Age	=DERIVE.PATIENT_II.AGE	2.	09AUG11:14:41	Yes
13	PHASE	5	C4	Phase	=CMEDCODE.PHASE (I & II)	\$4.	09AUG11:14:43	Yes
14	PROJECT	6	C16	Project	=CMEDCODE.PROJECT (I & II)	\$16.	09AUG11:14:44	Yes
15	CMPT	600.1	C80	Conmed Preferred Name	=CMEDCODE.PREFNAME (I & II)	\$80.	11AUG11:15:17	Yes
16	CMNAME	601	C80	Conmed Drug Name	=CMEDCODE.DRUGNAME (I & II)	\$80.	11AUG11:15:17	Yes
17	CMIND	602	C80	Conmed Indication	=CMEDCODE.INDICAT (I & II)	\$80.	11AUG11:15:17	Yes
18	CMSTDT	603	N8	Conmed Start Date	=CMEDCODE.STARTDT (I & II)	DATE9.	11AUG11:15:17	Yes
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
21	CMSTDY	603.3	N8	Conmed Start Day	=DERIVE.TRANS_II.FTRANDT - CMSTDT + 1	8.	29SEP11:14:00	Yes

Variable-Level Metadata for 27 Variables in Table CMED II

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Display order [ORDER, NAME8] Filtering // Key Fields [unknown]

Var #	name8 [1]	Order	Type/ Len	Label	Definition, Notes, et al.	Format	Latest Update	Use
22	CMSTDY_F	603.4	C3	Conmed Start Day Imputed	= "Yes" if (CMST_MYR^=.. or CMST_YR^=..) and CMSTDY=. = "No" otherwise	\$3.	29SEP11:14:05	Yes
23	CMENDT	604	N8	Conmed Stop Date	=CMEDCODE.STOPDT (I & II)	DATE9.	11AUG11:15:17	Yes
24	CMENDY	604.1	N8	Conmed Stop Day	=DERIVE.TRANS_II.FTRANDT - CMENDT + 1	8.	11AUG11:15:18	Yes
25	CMONGO	605	C3	Conmed Ongoing	If CMEDCODE.ONGOING (I & II) =1 then 'Yes' else 'No'	\$3.	11AUG11:15:18	Yes
26	CMINF	606	C14	Conmed Information From	if CMEDCODE.RECORD=1 then CMINF='Medical record' else if CMEDCODE.INTERV=1 then CMINF='Interview' (I & II)	\$14.	11AUG11:15:19	Yes
27	CMMED	607	C80	Conmed Medication Name	=CMEDCODE.MEDICAT (I & II)	\$80.	11AUG11:15:19	Yes

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