Variable	Value
DESCRIPTION	Analysis dataset useful for analysis of hematology or chemistry lab data
KEYFIELDS	
STRUCTURE	One observation per subject per visit
INPUT_NOTES	Keep only subjects in Patient_II dataset 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 in 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.

Program [S:\RhoFED\CSCC\Protocol Committees\Neuropsych\Prog\Derive\run_printSpecs.sas]

This file [S:\RhoFED\CSCC\Protocol Committees\Neuropsych\MetaData\Analysis\Specs\printSpecs_LABS_II_2012_02_28_16_53.PDF]   *User id [plebeau] Run time [Tuesday, February 28, 2012 4:53 PM]*

Variable-Level Metadata for 41 Variables in Table   LABS_II
Metadata last updated   [12JAN2012:17:25:54]   Most recent change made   [24AUG11:14:08]
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.	08AUG11:15:20	Yes
▮	▮	▮	▮	▮	▮	▮	▮	▮
▮	▮	▮	▮	▮	▮	▮	▮	▮
4	RANDTRTARM	4	C40	Randomized group, phase 2	=DERIVE.PATIENT_II.RANDTRTARM	$40.	08AUG11:15:21	Yes
5	ITT	4.1	C3	ITT Population	=DERIVE.PATIENT_II.ITT	$3.	08AUG11:16:29	Yes
6	SAFETY	4.2	C3	Safety Population	=DERIVE.PATIENT_II.SAFETY	$3.	08AUG11:16:30	Yes
7	RANDOM	4.3	C3	Randomized Subjects	=DERIVE.PATIENT_II.RANDOM	$3.	09AUG11:12:04	Yes
8	ANLY	4.4	C3	Full Analysis Population	=DERIVE.PATIENT_II.ANALY	$3.	09AUG11:12:04	Yes
9	PP	4.5	C3	Per Protocol Population	=DERIVE.PATIENT_II.PP	$3.	09AUG11:12:05	Yes
10	COMPLETE	4.6	C3	Completed Study	=DERIVE.PATIENT_II.COMPLETE	$3.	09AUG11:12:05	Yes
11	GENDER	4.7	C6	Subject Gender	=DERIVE.PATIENT_II.GENDER	$6.	09AUG11:12:02	Yes
12	AGE	4.8	N8	Subject Age	=DERIVE.PATIENT_II.AGE	2.	09AUG11:12:03	Yes
13	PHASE	5	C4	Phase	=CLINICAL.LAB2MSTR.PHASE (I & II)	$4.	08AUG11:15:21	Yes
14	PROJECT	6	C16	Project	=CLINICAL.LAB2MSTR.PROJECT (I & II)	$16.	08AUG11:15:21	Yes
15	HEMADT	7	N8	Hematology Collection Date	=CLINICAL.LAB2MSTR.HEMADT (I & II)	DATE9.	08AUG11:15:23	Yes
▮	▮	▮	▮	▮	▮	▮	▮	▮
▮	▮	▮	▮	▮	▮	▮	▮	▮
▮	▮	▮	▮	▮	▮	▮	▮	▮
19	CHEMDT	11	N8	Serum Chemistry Collection Date	=CLINICAL.LAB2MSTR.CHEMDT (I & II)	DATE9.	08AUG11:15:27	Yes
▮	▮	▮	▮	▮	▮	▮	▮	▮

Program [S:\RhoFED\CSCC\Protocol Committees\Neuropsych\Prog\Derive\run_printSpecs.sas]

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User id [plebeau] Run time [Tuesday, February 28, 2012 4:53 PM]

Variable-Level Metadata for 41 Variables in Table LABS_II

Metadata last updated   [12JAN2012:17:25:54]   Most recent change made   [24AUG11:14:08]
Display order   [ORDER, NAME8] Filtering [] Key Fields   [unknown]

3

Var #	name8 [1]	Order	Type/ Len	Label	Definition, Notes, et al.	Format	Latest Update	Use
21	██████	█	█	███████	█████████████	█	████████	█
█	██████	█	█	██████	█████████████	█	████████	█
23	HGB	15	N8	Hemoglobin (g/dL)	=CLINICAL.LAB2MSTR.HGB(I & II)	4.1	08AUG11:15:29	Yes
24	HGBS	16	N8	Hemoglobin S (%)	=CLINICAL.LAB2MSTR.HGBS (I & II)	5.1	08AUG11:15:30	Yes
25	HCT	17	N8	Hematocrit (%)	=CLINICAL.LAB2MSTR.HCT (I & II)	4.1	08AUG11:15:31	Yes
26	WBC	18	N8	WBC (x10-3/mm3)	=CLINICAL.LAB2MSTR.WBC (I & II)	5.2	08AUG11:15:32	Yes
27	NEUT	19	N8	Neutrophils (%)	=CLINICAL.LAB2MSTR.NEUT (I & II)	5.1	08AUG11:15:32	Yes
28	PLATE	20	N8	Platelet Count (x10-3/mm3)	=CLINICAL.LAB2MSTR.PLATE (I & II)	7.2	08AUG11:15:33	Yes
29	CREAT	21	N8	Creatinine (mg/dL)	=CLINICAL.LAB2MSTR.CREAT (I & II)	4.1	08AUG11:15:34	Yes
30	BUN	22	N8	BUN (mg/dL)	=CLINICAL.LAB2MSTR.BUN (I & II)	2.	08AUG11:15:34	Yes
31	GLUCFAS	23	C11	Glucose	=CLINICAL.LAB2MSTR.GLUCFAS (I & II)	$11.	08AUG11:15:35	Yes
32	GLUC	24	N8	Glucose (mg/dL)	=CLINICAL.LAB2MSTR.GLUC (I & II)	3.	08AUG11:15:35	Yes
33	AST	25	N8	AST (IU/L)	=CLINICAL.LAB2MSTR.AST (I & II)	4.	08AUG11:15:36	Yes
34	ALT	26	N8	ALT (IU/L)	=CLINICAL.LAB2MSTR.ALT (I & II)	4.	08AUG11:15:36	Yes
35	TOTBILI	27	N8	Total Bilirubin (mg/dL)	=CLINICAL.LAB2MSTR.TOTBILI (I & II)	5.2	08AUG11:15:37	Yes
36	LDH	28	N8	LDH (U/L)	=CLINICAL.LAB2MSTR.LDH (I & II)	4.	08AUG11:15:38	Yes
37	FERRITN	29	N8	Ferritin (ng/mL)	=CLINICAL.LAB2MSTR.FERRITN (I & II)	4.	08AUG11:15:39	Yes
38	██████	█	█	███████	█████████████	█	████████	█

Program [S:\RhoFED\CSCC\Protocol Committees\Neuropsych\Prog\Derive\run_printSpecs.sas]

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Variable-Level Metadata for 41 Variables in Table   LABS_II

Metadata last updated   [12JAN2012:17:25:54]   Most recent change made   [24AUG11:14:08]
Display order   [ORDER, NAME8]   Filtering   []   Key Fields   [unknown]

4

Var #	name8 [1]	Order	Type/ Len	Label	Definition, Notes, et al.	Format	Latest Update	Use
39	LDH_NLS	31	N8	Normalized LDH	1. Merge Patient_II(keep=ID TRTC GENDER AGE SITE HOSP) and LABS_II(keep=ID HEMADT LDH) by ID. Keep if in both. Rename center=site and site=hosp. Example dataset name: PAT_LAB 2. Import S:\RhoFED\CSCC\Protocol Committees\Neuropsych\Lab Normals\NP Phase I Lab Normals.xlsx, where center is not missing and site is not missing. If Effective_Date__Start_ is missing, then START=., else START= Effective_Date__Start_. If Effective_Date__End_ is missing, then END="&sysdate."d, else END= Effective_Date__End_. If From_Age__Years_____ is missing, then AGE_LOW=0. If From_Age__Years_____ is X and up, then AGE_LOW=X. If From_Age__Years_____=Adult, then AGE_LOW=18. Else AGE_LOW= input(From_Age__Years_____,8.0). If To_Age__Years_____ is missing, then AGE_HIGH=150. Else AGE_HIGH= input(To_Age__Years_____,8.0). Example dataset name: RANGE. 3. Merge PAT_LAB with RANGE by center and site. Only keep observations where center and site are in both datasets, and START<=HEMADT<END, and AGE_LOW<=AGE<=AGE_HIGH. If gender='Male' then HIGH=Male_High and LOW=Male_Low_. Else HIGH=Female_High and LOW=Female_Low. Example dataset name:LABS_RANGES 4. Find frequencies of site/center combinations, and create a dataset of the values from the site/center with the highest frequency. These will be your central lab reference values. C_MALE_LOW=Male_Low_, C_MALE_HIGH=Male_High, C_FEMALE_LOW=Female_Low, C_FEMALE_HIGH=Female_High. Should have 1 observation. Example dataset name: CENTRAL. 5. Merge LABS_RANGES with CENTRAL. If gender='Male' then C_LOW=C_MALE_LOW and C_HIGH=C_MALE_HIGH. Else C_LOW=C_FEMALE_LOW and C_HIGH=C_FEMALE_HIGH. If not missing LDH, LOW, HIGH, C _HIGH, and C _LOW then LDH_NLS=(LDH-LOW)*((C _HIGH-C_LOW)/(HIGH-LOW))+C_LOW. If .z<LDH_NLS<0 then LDH_NLS=0 and LDH_FLS=1. Keep ID, HEMADT, LDH_NLS, LDH_FLS. Example data name: LAB_NORMAL. 6. Merge LAB_NORMAL back with final Labs dataset by ID and HEMADT.	8.	24AUG11:13:35	Yes
40	LDH_FLS	32	N8	Normalized LDH Flag - Negative	=1 if .z<LDH_NLS<=LDH_FLS in LAB_NORMAL dataset (see LDH_NLS definition).	8.	24AUG11:13:35	Yes
41	LDH_NFLAG	33	C60	Normalized LDH Flag - Missing	See LDH_NLS definition for dataset explanation. ='Age out of Range Restrictions' if PAT_LAB.AGE is not between (AGE_HIGH, AGE_LOW) ='Lab Date out of Range Restrictions if PAT_LAB.HEMADT is not between (START,END). ='Age and Lab Date out of Range Restrictions' if PAT_LAB.AGE is not between (AGE_HIGH, AGE_LOW) and PAT_LAB.HEMADT is not between (START,END) ='Site-Hospital not in Range Restrictions Document' if Center and Site are not in RANGES dataset	$60.	24AUG11:14:08	Yes

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

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