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**CTN-0010 Database Descriptions**

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**CTN-0010 CRF Level Data De-Identification Notes  
and  
Database Descriptions**

**Updated: December 12, 2011**

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## CTN-0010 Database Descriptions

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The Case Report Form (CRF)-level de-identified data sets were prepared by reviewing the CRFs and the data dictionary to identify a list of variables that contained, or could potentially contain, identifying information, such as dates and free text fields. The variables were programmatically removed or modified in the raw dataset, resulting in de-identified datasets. All dates were converted to “days on study,” where the date of randomization (BASEDATE) = 0. A negative value for days on study refers to an event that occurred prior to randomization (e.g., date of birth) and a positive value for days on study refers to an event that occurred after randomization (e.g., 12-month visit date).

The following free text fields were emptied:

- Any responses derived from “Other. Please specify” or “Specify other reason”. For example, other races, marital status, therapy sessions, SAE categories, reasons study drug not given, abnormalities on ECG and Urine Analysis forms.
- Comment fields
- AE/SAE terms were retained in the database, but any detailed descriptions in a separate field providing additional information the AE or SAE were erased. This includes relevant labs, medical history and medications, drug/alcohol use description, probable cause of death.
- On dosing logs: lot numbers, who administered dose.
- All medical history information.
- Concomitant medication names, purposes, and start year were *retained* in the database, but start dates and months were dropped.
- All protocol violations
- Type of work; job description/parents' type of work; school program name and major; descriptions of living situation, illnesses, concerns, drug/alcohol use, feelings/interests.

Following is a list of all variables in the dataset that were modified or emptied in order to de-identify the data, based on the following commands:

PATIDDEID assigns to each patient a unique value in a variable called PATIDDEID.

BASEDATE names the variable that is used as the base date to calculate days on study. In this study, BASEDATE is date of randomization.

DOS names a variable that is to be converted from a date into days on study.

EMPTY defines a variable to fill with missing values.

DROPPFILE defines a data set to drop.

The following documentation presents information on the variable based on the name within the database. To get the corresponding label of the variable, one must look within the data dictionary in Excel that is also provided on the CTN Data Share web site.

**For all the datasets dates were changed to days of study and site was emptied.**

**Inc010:** Removed exc015a (Clinician Name) and exc015b (Clinician signed date)

**bc010:** Removed bc003a (Clinician Name) and bc003a (Clinician signed date)

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**ab010:** Removed ab003 (Comments)

**cbc010:** Removed cbc003a (Clinician Name) and bc003a (Clinician signed date)

**dem010:** Removed dem00326 (Other specify), dem00309 (Other specify), dem00318 (Other specify) and dem00324 (other specify)

**ecg010:** Removed ecg009a (Clinician name), ecg009b (Clinician signed date) and ecg006 (Specify abnormal)

**hbc010:** Removed hbc005a (Clinician name) and hbc005b (clinician signed date)

**phy010:** Removed phy022a (Clinician name), phy022b (Clinician signed date) and phy021 (Comments)

**le010:** Removed le003a (clinician name) and le003b (clinician signed date)

**pcm010:** Removed PCM001JM (Month), PCM001JD (Day), PCM001JY (Year), PCM002JM (Month), PCM002JD (Day), PCM002JY (Year), PCM003JM (Month), PCM003JD (Day), PCM003JY (Year), PCM004JM (Month), PCM004JD (Day), PCM004JY (Year), PCM005JM (Month), PCM005JD (Day), PCM005JY (Year), PCM006JM (Month), PCM006JD (Day), PCM006JY (Year), PCM007JM (Month), PCM007JD (Day), PCM007JY (Year), PCM008JM (Month), PCM008JD (Day), PCM008JY (Year), PCM009JM (Month), PCM009JD (Day), PCM009JY (Year), PCM010JM (Month), PCM010JD (Day), PCM010JY (Year), PCM011JM (Month), PCM011JD (Day), PCM011JY (Year), PCM012JM (Month), PCM012JD (Day) and PCM012JY (Year)

**sdl010:** Removed sdl051a (clinician name), sdl051b (clinician signed date) and sdl000 (time begun)

**ua010:** Removed ua003a (clinician name), ua003b (clinician signed date) and ua001 (Specify reason)

**vs010:** Removed vs007 (comments)

**ran010:** Removed ran005 (comments), ran006a (clinician name) and ran006b (clinician signed date)

**sae010:** Removed SAE003 (group assignment), SAE006a (name), SAE006b (phone number), SAE006bx (phone extension), SAE009b (other specify), SAE012c1 (event description), SAE012c2 (event description), SAE012c3 (event description), SAE012c4 (event description), SAE012c5 (event description), SAE012c6 (event description), SAE012c7 (event description), SAE012c8 (event description), SAE013a (test data), SAE013b (test data), SAE013c (test data), SAE014a (other condition), SAE014b (other condition), SAE014c (other condition), SAE017 (describe use), SAE018 (amount of use), SAE011h (Other specify), SAE025b (lot number), SAE025cm (month), SAE025cy (year), SAE025do (other), SAE025fo (other), SAE025go (other), SAE025ho (other), SAE026b (lot number), SAE026cm (month), SAE026cy (year), SAE026do (other), SAE026eo (other), SAE026fo (other), SAE026go (other), SAE026ho (other), SAE027b (lot number), SAE027cm (month), SAE027cy (year), SAE027do (other), SAE027eo (other), SAE027fo (other), SAE027go (other), SAE027ho (other), SAE028b (lot number), SAE028cm (month), SAE028cy (year), SAE028do (other), SAE028eo (other), SAE028fo (other), SAE028go, SAE028ho (other), SAE029b (lot number), SAE029cm (month), SAE029cy (year), SAE029do (other), SAE029eo (other), SAE029fo (other), SAE029go (other), SAE029ho (other), SAE029im, SAE029id, SAE030b (lot number), SAE030cm (month), SAE030cy (year), SAE030do (other), SAE030eo (other), SAE030fo (other), SAE030go (other), SAE030ho (other), SAE030im, SAE030id, SAE031b, SAE031cm

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(month),SAE031cy (year),SAE031do (other),SAE031eo, SAE031fo,SAE031go (other),SAE031ho (other),SAE031im,SAE031id,SAE032b (lot number),SAE032cm (month),SAE032cy (year), SAE032do (other),SAE032eo (other),SAE032fo (other),SAE032go (other),SAE032ho (other),SAE032im (month),SAE032id (day),SAE035d1 (Probable cause of death), SAE035d2 (Probable cause of death), SAE035d3 (Probable cause of death),SAE038 (PI name),SAE039 (PI date signed),SAE040 (Name of physician),SAE041 (Date physician signed),SAE042a (comments),SAE042b (comments),SAE042c (comments),SAE042d (comments),SAE042e (comments),SAE042f (comments),SAE042g (comments)and SAE042h (comments)

**saa010:** Removed SAA01C (lot), SAA01DM (month), SAA01DY (year), SAA01EO (other), SAA01FO (other), SAA01GO (other), SAA01HO (other), SAA01IO (other), SAA01JM (month), SAA01JD (day), SAA02C (Lot), SAA02DM (month), SAA02DY (year), SAA02EO (other), SAA02FO (other), SAA02GO (other), SAA02HO (other), SAA02IO (other), SAA02JM (month), SAA02JD (day), SAA03C (Lot), SAA03DM (month), SAA03DY (year), SAA03EO (other), SAA03FO (other), SAA03GO (other), SAA03HO (other), SAA03IO (other), SAA03JM (month), SAA03JD, SAA04C (Lot), SAA04DM (month), SAA04DY (year), SAA04EO (other), SAA04FO (other), SAA04GO (other), SAA04HO (other), SAA04IO (other), SAA04JM, SAA04JD

**haqp010:** Removed haqp000 (comments)

**ae010:** Removed AE014b (time), AE002b (AE description), AE009 (comments), AE015a (Clinician name) and AE015b (Clinician date signed)

**com010:** Removed COM004A (Other session), COM004B (Other session) and COM004C (Other session)

**dos010:** Removed DOS004 (BUP level), DOS003 (Dr Number), DOS008 (BUP lot), DOS012 (BUP lot), DOS017 (Administer by) and DOS018A (Other)

**eos010:** Removed eos005 (comments)

**tac010 :** Removed tacc312s (Other) , TAC0A1C9 (Other) and TAC0B1B (Other)

**yas010:** Removed YASD000B (Type of work), YAS006A (Use drug describe), YASD007 (Concern describe), YASD008 (best things), YASD006A (Illness describe) , YAS009A (thoughts), YAS029A (Describe), YAS040A (Describe), YAS046A (Describe), YAS056D1 (Describe), YAS056J1 (Describe), YAS058A (Describe), YAS066A (Describe), YAS070A (Describe), YAS077A (Describe), YAS079A (Describe), YAS081A (Describe), YAS083A (Describe), YAS084A (Describe), YAS085A (Describe), YAS092A (Describe), YAS100A (Describe), YAS120, YAS120A (Describe), YASD0051 (Marital status), YASD0053 (Describe), YASD0021 (School), YASD0022 (Degree), YASD0023 (Major), YASD0024 (Month), YASD0025 (year) and YASD0031 (Degree jobs)

**ysr010:** Removed YSRD000C (Type of work), YSRD000D (Type of work), YSRD000E (Type of work), YSRD001A (Sport A), YSRD001B (Sport B), YSRD001C (Sport C), YSRD002A (Hobbies A), YSRD002B (Hobbies B), YSRD002C (Hobbies C), YSRD003A (Organization A), YSRD003B (Organization B), YSRD003C (Organization C), YSRD004A (Job A), YSRD004B (Job B), YSRD004C (Job C) , YSRD0071 (Reason), YSRD0072 (Other), YSRD0073 (Other), YSRD0074 (Other), YSRD008A (Describe), YSRD009 (Concerns), YSRD010 (Other concern), YSRD011 (Best thing about yourself), YSR002A (Describe), YSR009A (Describe), YSR029A (Describe), YSR040A (Describe), YSR046A (Describe), YSR056D1 (Describe), YSR056H1 (Describe), YSR058A (Describe), YSR066A (Describe), YSR070A (Describe), YSR077A v, YSR079A(Describe), YSR083A (Describe), YSR084A (Describe), YSR085A (Describe), YSR100A (Describe), YSR105A (Describe), YSR113 (Describe) and YSR113A (Describe)

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## CTN-0010 Database Descriptions

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Databases for this protocol are available for download in both SAS and ASCII/comma separated value (CSV) format. When you retrieve the datasets from the data download page on the CTN Data Share website, a ZIP file will be provided containing the datasets.

Note that when you download the SAS datasets, the files will be SAS transport files. The [transport.xpt](#) contains all the SAS datasets available. The following code can be executed in SAS to retrieve the individual SAS databases.

```
libname newlib "[Name of Path where you want to store the SAS datasets. E.g.:  
c:\temp\CTN0030] ";
```

```
filename tranfile "[Name of path where you store transport.xpt. E.g.: C:\temp\  
transport.xpt";
```

```
proc cimport library=newlib infile=tranfile; run;
```

Also in the SAS ZIP file are SAS transport files corresponding to each individual database. These files are provided to allow import into SPSS and differ slightly from the SAS datasets in the Transport.xpt and from the data dictionaries provided.