

**CAMP**  
**Limited Access Database Documentation**  
**(February 2008 version)**

**Dataset Specifications**

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1. These are the Limited Access Database files for the Childhood Asthma Management Program (CAMP) trial and CAMP Continuation Study (CAMPCS) as of October 2004.
2. Data files and this documentation are included on the CD. Data files are:

aa1.xpt	fef.xpt	nm2.xpt
ah1.xpt	fi3.xpt	pe3.xpt
bd2.xpt	finasste.xpt	pe5pp5.xpt
bd5.xpt	fract_db.xpt	pf3.xpt
bestfevf.xpt	fx5.xpt	pf5.xpt
bestpffu.xpt	hospsfu.xpt	ph1.xpt
bh1.xpt	hospstr.xpt	pm5.xpt
boneaged.xpt	hs2.xpt	pq5.xpt
ca1.xpt	hs5.xpt	predfutr.xpt
cq5.xpt	ia1.xpt	rg1.xpt
cx1.xpt	icspred.xpt	sb2_all.xpt
cy2.xpt	ih7.xpt	sb2_idt.xpt
dcallcli.xpt	im1.xpt	sb6.xpt
ds2.xpt	in4.xpt	serum.xpt
dust.xpt	it2.xpt	septim.xpt
ec1.xpt	kf1.xpt	ue1.xpt
en5.xpt	mc2.xpt	va1.xpt
er1.xpt	mc6.xpt	valids.xpt
erfu.xpt	mcpostbd.xpt	xr1.xpt
ertr.xpt	medcodes.xpt	
es1.xpt	medstefi.xpt	
es5.xpt	mv2.xpt	
	mv5.xpt	
	mvpdat.xpt	

Other files included on the CD are: limacc1doc.pdf (this documentation).

3. Data file format: SAS transport files
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# CAMP

## Limited Access Database Documentation (February 2008 version)

### General Comments on Database

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**Introduction:** This version of the CAMP Limited Access Database is derived from the October 2004 version of the CAMP Master Database. The Limited Access Database includes Childhood Asthma Management Program (CAMP) trial screening, followup and transition data and CAMP Continuation Study (CAMPCS) followup data for randomized patients. CAMP trial data were collected from 1 November 1993 through 31 October 1999. CAMPCS data were collected from 1 November 1999 through 30 April 2004.

The data are too voluminous to provide one record per patient with all data included. Instead, files are provided for specific data forms or for types of data. A SAS Proc Contents listing of each file is provided in this documentation. In the case of files that correspond to specific CAMP or CAMPCS forms, early form revisions have been recoded to the last revision of the form; copies of the last revision of a form are included with this documentation.

Edits obtained since locking the CAMP baseline data files and since publication of the CAMP primary outcomes paper have been applied to these files. These edits include corrections to birthdate discovered on enrollment of the patient in the CAMPCS or CAMP Continuation Study/Phase 2 (CAMPCS/2); these edits are current to October 2004.

We have tried to eliminate duplication of data across forms. Forms were constructed with some duplication of information to make completion easier and less error-prone. To the extent possible, this redundancy has been eliminated in these data files.

**File formats, variable names, and variable formats:** All files are SAS transport files. Each variable on each file has an associated SAS label. Variables which are in direct correspondence to a form item (and the response categories on the form) are named ffxiii where ffx is the form abbreviation and revision number and iii is the item number. For example, ah1110 is item 110 on form AH1. A variable that is in direct correspondence with a form item remains in the format that it was keyed, ie, character data and without a decimal point. These character data have to be transformed into numeric data: you must divide by 10, 100, or other appropriate denominator depending on the format of the item on the CAMP form. If there is no denominator (ie, the item was recorded in a whole number format), then add 0 to the item to transform the data from character to numeric. If the variable name is not in the format ffxiii, then it most likely has already been put into analysis ready format.

**Deletions and edits to protect patient confidentiality:** The Limited Access Database does not include these items of information, even though they were collected on CAMP or CAMPCS forms: Clinic, data in response to Other (specify) items, data in response to administrative information sections on forms (staff PIN, date and time of next appointment, form review date), and comment fields. Permission was received from NHLBI to retain age, height, weight, body mass index, and other continuous variables without identification properties. Adverse event forms and death report forms are not included in the Limited Access Database. All dates have been converted to a number of days before or after randomization (i.e., enrolldt, the date of randomization, is 0 and dates before randomization are negative numbers and dates after randomization are positive numbers). Thus age is available, but the calendar time the participant was that age is masked. Spirometer and flow meter identification codes have been deleted.

**Identifiers:** Every record includes a recoded ID number for the patient that the record refers to. The variable corresponding to the recoded patient ID number (variable name newcamp) is a 4 character numeric text string. Name code (which appears on forms) has been deleted from all files.

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**Visit codes:** CAMP visit codes are s1, s2, s3, s4, rz, n, and fxx, where xx is the number of months from randomization. CAMPCS visit codes are c54, c60, c66, c72, c78, c84, c90, c96, c02, c08, c14, c20, and c26 where the number after the c is the number of months from randomization; for c02, c08, c14, c20 and c26, add 100 to the number after the c to get the number of months from randomization. Be careful when sorting on visit code -- f8 will sort after f12 and c02 will sort before c60. If you sort on followup visit code, you may want to recode f2, f4, and f8 to f02, f04, and f08 respectively and c54, c60, etc to c054, c060, and c02, c08 etc to c102, c108, etc.

**Visit time windows:** The procedures for a visit could be spread over several days so long as all dates were within the time window for the visit. The ideal dates and time windows for the visits were:

f2: E+61, E+30 – E+91  
f4: E+122, E+92 – E+183  
f8: E+244, E+184 – E+304  
f12: E+365, E+305 – E+426  
f16: E+487, E+427 – E+548  
f20: E+609, E+549 – E+670  
f24: E+731, E+671 – E+791  
f28: E+852, E+792 – E+913  
f32: E+974, E+914 – E+1035  
f36: E+1096, E+1036 – E+1157  
f40: E+1218, E+1158 – E+1278  
f44: E+1339, E+1279 – E+1400  
f48: E+1461, E+1401 – E+1522  
f52: E+1583, E+1523 – E+1644  
f56: E+1705, E+1645 – E+1765  
f60: E+1826, E+1766 – E+1887  
f64: E+1948, E+1888 – E+2009

c54: E+1643, E+1552 – E+1734  
c60: E+1826, E+1735 – E+1917  
c66: E+2008, E+1918 – E+2100  
c72: E+2191, E+2101 – E+2282  
c78: E+2374, E+2283 – E+2465  
c84: E+2556, E+2466 – E+2648  
c90: E+2739, E+2649 – E+2830  
c96: E+2922, E+2831 – E+3013  
c02: E+3104, E+3014 – E+3195  
c08: E+3287, E+3196 – E+3378  
c14: E+3469, E+3379 – E+3561  
c20: E+3652, E+3562 – E+3652  
c26: E+3835, E+3653 – E+3926

where E=enrolldt (date of randomization).

**Baseline visits/values:** The baseline visit for height and spirometry is the randomization visit. The baseline visit for methacholine, hematology, and skin testing is visit s3. The baseline visit for psychological testing is s4. The baseline visit for Tanner stage is s3. The baseline values for diary card measures are those obtained during the 28 day screening period.

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**Dates:** Dates are recoded to a number of days before or after randomization.

**1st and 2nd keyings and subsequent transactions:** All data were keyed twice in succession during data entry, and all subsequent transactions are present in the Coordinating Center's database. Only the final transaction is included in this Database.

**STOP items:** Some screening forms contained STOP items (items that are associated with a STOP sign on the form). Responses that corresponded to a STOP could not be keyed. Since these files include randomized patients only, none of the STOP items will include responses that correspond to a STOP. In general, STOP items are not be useful for analysis, since the patient could have only the non STOP response.

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Specific Comments on Database Files

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**aa1.xpt (CAMP):** All AA forms in AA1 format.

**ah1.xpt (CAMP):** All AH forms in AH1 format. Edits received subsequent to locking of baseline data were applied.

**bd2.xpt (CAMP):** All BD forms in BD2 format. Edits received subsequent to locking of baseline data were applied. Machine type, model number, and beam type data have been added for each scan.

**bd5.xpt (CAMPCS):** All BD forms in BD5 format. Machine type, model number, and beam type data have been added for each scan.

**bestfevf.xpt (CAMP):** Best pre-bronchodilator FEV<sub>1</sub> from rz through last CAMP trial visit. One record per new best pre-bronchodilator FEV<sub>1</sub>. The value changed when a larger pre-bronchodilator FEV<sub>1</sub> was observed at a regularly scheduled CAMP visit (ie, visit code=rz or fxx).

**bestffu.xpt (CAMP):** Best post-bronchodilator peak flow (obtained by peak flow meter) from s3 through last CAMP trial visit. One record per new best peak flow. The value changed when a larger post-bronchodilator peak flow was observed at a regularly scheduled CAMP visit (ie, visit code=rz or fxx). The initial best peak flow is the peak flow used for eligibility evaluation at visit s3 and is assigned visit code s3. This value remained the best peak flow until at least visit rz, when it could begin to change.

**bh1.xpt (CAMP):** All BH forms in BH1 format.

**boneaged.xpt (CAMP):** This file contains one record per child who had the bone age x-ray done and read. Meanbage is the bone age in months; it is either the mean of the 2 readers' assessments or the adjudicated reading (if adjudication was required). The chronologic age at the time of x-ray (in months) is also provided. Projected adult height was calculated using the methods of Tanner et al (Tanner JM et al. Assessment of skeletal maturity and prediction of adult height (TW2 method). New York: Academic Press, 1983).

**ca1.xpt (CAMP):** All CA forms in CA1 format.

**cq5.xpt (CAMPCS):** All CQ forms in CQ5 format.

**cx1.xpt (CAMP):** All CX forms in CX1 format. Treatment data items (items 39-41) have been dropped; treatment data are in special files described below.

**cy2.xpt (CAMP):** All CY forms in CY2 format.

**dcalleli.xpt (CAMP):** Diary card records for patients. Each record corresponds to one day of data (the original diary keying included up to 14 days of data -- these records have been deconstructed into up to 14 records). To be included in the file, the diary day had to have at least 1 item of data completed (completely blank days are not included). Each record includes an indicator whether the day is part of the 28 day screening period, pre-randomization but before the 28 day screening period, pre-randomization but after the 28 day screening period, the randomization day, a post randomization day, or a transition day. The 28 day screening period could actually be 24-28 days in duration. Children continued to complete diaries after the 28 day screening period, but the data recorded did not affect eligibility except by physician discretion. Children could not use prednisone during the 28

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day screening period but could use it afterwards, but they had to be off it on the day of randomization. The 28 day screening period took place between visits s2 and s3. Because some children took 2 or more tries to get through the 28 day screening period without a flare, there sometimes were more than 28 days between s2 and s3. The best peak flow applicable to the diary day has been included in each record, as have am and pm percent of personal best and an indicator denoting whether the day was asthma episode-free. A day with a night awakening, am peak flow less than 80% personal best, pm peak flow less than 80% personal best, any albuterol use for symptoms, any prednisone use, absence from school due to asthma, a physician contact due to asthma, or symptom code greater than 0 was considered to be a day with an asthma episode. An episode free day was any day with diary data that was not an asthma episode day. Only diary card data are considered for this determination. Daily peak flow variability has been added ( $(\text{am}-\text{pm})/(\text{am}+\text{pm})/2$ ). In the primary outcome paper, change in diary outcomes was determined as the average value for the period from the last visit to the next to last visit (120 days on average) minus the average value during the 28 day screening period. Missing diary data were ignored (we did not assume that missing data represented days without asthma). The denominator for the average was the number of non missing days. Also in the primary outcome paper, diary data were primarily analyzed by diary card average (up to 14 days of data are included in each diary card); a different approach has been taken in this file (each record corresponds to a day of diary data. For no. of days/month, we used total no. of days/30.4375 (a standard month). For no. of puffs/week, we used total no. of puffs/7. Missing symptom codes were edited as follows: coded as 3 if the diary item pertaining to physician contact for asthma was checked, or coded as 2 if the diary item pertaining to school absence was checked. Peak flow values have had minimal editing; peak flow values less than 10 have been set to missing. All other peak flow values remain as keyed since they were queried during editing and were reported to have been recorded as keyed; it may be appropriate during analysis to do further editing of the peak flow values.

**ds2.xpt (CAMP):** All DS forms in DS2 format. No attempt has been made to assess correspondence between the observation (DS) forms and the dust specimen analysis results files.

**dust.xpt (CAMP):** DACI dust sample analysis results for baseline visits (visit code=rz) and f36 visits (visit code=f36) and samples taken outside of any visit window. If multiple samples were obtained within the window for the baseline sample, the earliest sample is retained (the rationale is that sample is closest in time to randomization). If multiple samples were obtained in the f36 window, the record retained has the average values for the multiple samples. *Can fi* analysis replaced *Bla g ii* analysis early in CAMP. Most patients are missing *Bla g ii* results at baseline. *Bla g ii* analysis was not done on f36 samples.

**ec1.xpt (CAMP):** All EC forms in EC1 format.

**en5.xpt (CAMPCS):** All EN forms in EN5 format. Date of birth and age at last birthday have been dropped from the data file. Date of birth should be obtained from the valids.xpt file and age at various dates should be calculated as needed.

**er1.xpt (CAMP):** Includes only non STOP items from ER forms: these include use of prednisone since s3.

**erfu.xpt (CAMP):** One record per child with total number of ER/urgent care visits due to asthma during the CAMP trial followup. Count is zero if child had no ER/urgent care visits due to asthma.

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**ertr.xpt (CAMP):** One record per child with total number of ER/urgent care visits due to asthma during the transition period. Count is zero if child had no ER/urgent care visits due to asthma.

**es1.xpt (CAMP):** All ES forms in ES1 format. Parent smoking status variables have been clarified. The ES form asks who the respondent(s) is(are) and queries the smoking status of the respondent and his/her partner, but does not explicitly ask about the mother's or father's smoking status. We have translated responses from the mother into variables referring to the mother and have translated the mother's responses about her partner into variables referring to the father and similarly for responses from the father. When both the mother and father were respondents, it was assumed that the mother was the primary respondent.

**es5.xpt (CAMPCS):** All ES forms in ES5 format. The ES5 form is very similar but not identical to the ES1 form used in CAMP.

**fef.xpt (CAMP and CAMPCS):** This file contains pre- and post bronchodilator FEF measures retrieved from the spirometry system files. Each FEF record also includes FEV, FVC, MMEF, and PEFR measures. These FEV and FVC measures may not match the measures reported on the PF form for the session. If you want to analyze FEV<sub>1</sub> or FVC, use the values in the pf3.xpt file (for CAMP data) and the values in the pf5.xpt file (for CAMPCS data).

**fi3.xpt (CAMP):** All FI forms in FI3 format. Nasal steroid items, prednisone items, and treatment change items have been eliminated since special files were created for these data.

**finasste.xpt (CAMP):** This file contains data on nasal steroid use during the CAMP trial (not during transition). The nasal steroid item on the FI form was poorly constructed; the item asked about prescriptions for nasal steroids since the previous FI form. Some interpreted the item as enquiring about new prescription and some interpreted it as asking about refills of continuing prescriptions. The judgment was that information about ever using nasal steroids during the CAMP trial would be valid. This information is included in this file.

**fract\_db.xpt (CAMP):** This file contains data on occurrence of broken bones during CAMP followup.

**hospsfu.xpt (CAMP):** One record per child with total number of overnight hospitalizations due to asthma during the CAMP trial followup. Count is zero if child had no overnight hospitalizations due to asthma.

**hospstr.xpt (CAMP):** One record per child with total number of overnight hospitalizations due to asthma during the transition period. Count is zero if child had no overnight hospitalizations due to asthma.

**hs2.xpt (CAMP):** All HS forms in HS2 format. Note that IgE is provided in the serum.xpt file (being an assessment provided by the DACI lab).

**hs5.xpt (CAMPCS):** All HS forms in HS5 format. Note that IgE is provided in the serum.xpt file (being an assessment provided by the DACI lab).

**ia1.xpt (CAMP):** All IA forms in IA1 format.

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**icspred.xpt (CAMP):** Cumulative ICS dose by category of ICS (study drug, beclomethasone, other ICS), cumulative days on ICS, cumulative prednisone dose, and cumulative days on prednisone during the CAMP trial.

**ih7.xpt (CAMPCS):** All IH forms in IH7 format.

**im1.xpt (CAMP):** All IM forms in IM1 format. Edits identified subsequent to locking of baseline data and deletions of records for baseline testing done after randomization have been applied.

**in4.xpt (CAMP):** All IN forms in IN4 format.

**it2.xpt (CAMP):** All IT forms in IT2 format.

**kf1.xpt (CAMP):** All KF forms in KF1 format.

**mc2.xpt (CAMP):** File includes screening (visit code=s3), followup (visit code=fxx) and transition methacholine data (visit code=t1 or t2). Data from forms MS and MC have been combined. In general, data items have been renamed or have been assigned to the corresponding variable on form MC2. Percent predicted values for pre-bronchodilator FEV<sub>1</sub> and FVC were calculated using equations of Knudson et al (Am Rev Respir Dis 1983;127:725-34) for Caucasians and others, Knudson et al (Am Rev Respir Dis 1983;127:725-34) with a 0.88 correction factor for African-Americans, and Coultas et al for Hispanics (Am Rev Respir Dis 1988;135:1386-92). FEV<sub>1</sub>/FVC ratio x 100 has been calculated from the values of FEV<sub>1</sub> and FVC. SOL0FEV1-SOL9FEV1 are the FEV<sub>1</sub> values at solution 0 through 9, respectively; these variables are numeric (no arithmetic manipulation is required), with untested solutions having the corresponding variable set to missing. PC<sub>20</sub> values have been corrected for an error in the spirometry software. Patients whose PC<sub>20</sub> occurred while inhaling diluent have been assigned a PC<sub>20</sub> value of 0.023 which is half the value of the lowest non-zero PC<sub>20</sub> at visit s3. If the challenge was completed but there was no 20% drop at the highest level of methacholine, the patient was assigned a PC<sub>20</sub> value of 37.5 (this applies to followup data only). Methacholine PC<sub>20</sub> data should be analyzed using a natural log transformation since they are log normal in this population.

**mc6.xpt (CAMPCS):** All MC forms in MC6 format. Percent predicted values for pre-bronchodilator FEV<sub>1</sub> and FVC were calculated using equations of Knudson et al (Am Rev Respir Dis 1983;127:725-34) for Caucasians and others, Knudson et al (Am Rev Respir Dis 1983;127:725-34) with a 0.88 correction factor for African-Americans, and Coultas et al for Hispanics (Am Rev Respir Dis 1988;135:1386-92). FEV<sub>1</sub>/FVC ratio x 100 has been calculated from the values of FEV<sub>1</sub> and FVC. COMPLIC concatenates the 5 specify lines in item 51 on MC6. SOL0FEV1-SOL9FEV1 are the FEV<sub>1</sub> values at solution 0 through 9, respectively; these variables are numeric (no arithmetic manipulation is required), with untested solutions having the corresponding variable set to missing. PC<sub>20</sub> values have been corrected for an error in the spirometry software. Patients whose PC<sub>20</sub> occurred while inhaling diluent have been assigned a PC<sub>20</sub> value of 0.023 which is half the value of the lowest non-zero PC<sub>20</sub> at visit s3. If the challenge was completed but there was no 20% drop at the highest level of methacholine, the patient was assigned a PC<sub>20</sub> value of 37.5 (this applies to followup data only). Methacholine PC<sub>20</sub> data should be analyzed using a natural log transformation since they are log normal in this population. The variable MCDONE is set to 1 if the challenge was done and is 0 otherwise.



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**mcpstbd.xpt (CAMP and CAMPCS):** Post methacholine challenge, post-bronchodilator FEV<sub>1</sub> and FVC have been retrieved from the spirometry system files if available. The test with the highest FEV<sub>1</sub>+FVC sum was selected. FEV<sub>1</sub>/FVC ratio x 100 has been calculated from the values of FEV<sub>1</sub> and FVC. Percent predicted values for pre-bronchodilator FEV<sub>1</sub> and FVC were calculated using equations of Knudson et al (Am Rev Respir Dis 1983;127:725-34) for Caucasians and others, Knudson et al (Am Rev Respir Dis 1983;127:725-34) with a 0.88 correction factor for African-Americans, and Coultas et al for Hispanics (Am Rev Respir Dis 1988;135:1386-92). Please note that, per the CAMP Manual for Methacholine Challenge Testing, measurement of post-bronchodilator FEV<sub>1</sub> was not required if FEV<sub>1</sub> at the end of the challenge was at least 90% of the baseline, pre-diluent FEV<sub>1</sub>; the protocol is not stated correctly on the MC6 form.

**medcodes.xpt (CAMP):** SAS file containing code and description of treatment represented by the code.

**medstefi.xpt (CAMP):** This file includes records for medication step at each fxx visit and at each TE form that indicated a change in treatment (note that a record for the rz visit is not included). Records with identical step information are not combined since this file was created to provide information about step status at each visit. The step codes used in this file distinguish between different non inhaled corticosteroid (ICS) controller medications (although dose of non ICS controller medications is ignored) and as well as different doses of specific ICS medications. The codes are defined in medcodes.xpt.

**mv2.xpt (CAMP):** All MV forms in MV2 format.

**mv5.xpt (CAMPCS):** All MV forms in MV5 format.

**mvpatdat.xpt (CAMP):** One record per patient, containing information about missed and completed visits in the CAMP trial. This file includes the pattern of visit completion in CAMP, the number of required visits in CAMPCS and the code for the last required visit, as well as other counts related to completion of visits. Since patients had different dates of randomization, the last required visit varied.

**nm2.xpt (CAMP):** All NM forms in NM2 format. Edits identified subsequent to locking of baseline data and deletions of records for baseline testing done after randomization have been applied.

**pe3.xpt (CAMP):** File includes screening (visit code=s3), followup (visit code=fxx) and transition (visit code=t1 or t2). Data from forms PX, PE, and PP have been combined. For visits where PP was completed (non annual visits), the items that are included on PE are set to missing. In general, data items have been renamed or have been assigned to the corresponding variable on form PE3. Several items were collected only at screening. These items have variable names that start with PX and were taken from the PX form and will be missing in records for followup visits. If the patient was assessed at Tanner stage 5 for 2 consecutive visits, Tanner stage assessment halted; Tanner stage data for such children has been set to 5 for those visits where it was skipped due to maturity. Height and weight percentiles and z scores are provided for the 1978 CDC/WHO standards (Sullivan KM and Gorstein J, Centers for Disease Control: ANTHRO, version 1.01, December 1990) and for the 2000 CDC standards ([www.cdc.gov/epiinfo](http://www.cdc.gov/epiinfo)). The 1978 standards provide standards for up to age 18; so as to get a z-score and percentile for all observations, observations age 18 or over had age set to 17.99.

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Similarly, the 2000 standards provide standards for up to age 20; so as to get a z score and percentile for all observations, observations age 20 or over had age set to 19.99.

**pe5pp5.xpt (CAMPCS):** Data from CAMPCS PE and PP forms have been combined. Tanner staging was skipped for fully mature participants. Tanner stage data (pubic hair and genital stage for males, pubic hair and breast stage for females) for these participants are set to 5 and last assessed testicular volume (while at Tanner 5 for pubic hair and genital stage) has been carried forward for males and age at menarche has been carried forward for females. To get height at spirometry or methacholine challenge, match to the spirometry or methacholine file on camp and visit. Height and weight percentiles and z scores are provided for the 1978 CDC/WHO standards (Sullivan KM and Gorstein J, Centers for Disease Control: ANTHRO, version 1.01, December 1990) and for the 2000 CDC standards ([www.cdc.gov/epiinfo](http://www.cdc.gov/epiinfo)). The 1978 standards provide standards for up to age 18; so as to get a z-score and percentile for all observations, observations age 18 or over had age set to 17.99. Similarly, the 2000 standards provide standards for up to age 20; so as to get a z score and percentile for all observations, observations age 20 or over had age set to 19.99.

**pf3.xpt (CAMP):** File includes screening (visit code=s2), randomization (visit code=rz), followup (visit code=fxx) and transition data (visit code=t1 or t2). Data from forms PS and PF have been combined. In general, data items have been renamed or have been assigned to the corresponding variable on form PF3. Percent predicted values for FEV<sub>1</sub> and FVC were calculated using equations of Knudson et al (Am Rev Respir Dis 1983;127:725-34) for Caucasians and others, Knudson et al (Am Rev Respir Dis 1983;127:725-34) with a 0.88 correction factor for African-Americans, and Coultas et al for Hispanics (Am Rev Respir Dis 1988;135:1386-92). FEV<sub>1</sub>/FVC ratio x 100 has been calculated from the values of FEV<sub>1</sub> and FVC.

**pf5.xpt (CAMPCS):** All PF forms in PF5 format. Percent predicted values for FEV<sub>1</sub> and FVC were calculated using equations of Knudson et al (Am Rev Respir Dis 1983;127:725-34) for Caucasians and others, Knudson et al (Am Rev Respir Dis 1983;127:725-34) with a 0.88 correction factor for African-Americans, and Coultas et al for Hispanics (Am Rev Respir Dis 1988;135:1386-92). FEV<sub>1</sub>/FVC ratio x 100 has been calculated from the values of FEV<sub>1</sub> and FVC.

**ph1.xpt (CAMP):** All PH forms in PH1 format.

**pm5.xpt (CAMPCS):** All PM forms in PM5 format.

**pq5.xpt (CAMPCS):** All PQ forms in PQ5 format.

**predfutr.xpt (CAMP):** This file was created from data on FI, TE and diary forms. All dose data have been transformed to correspond to a number of 5 mg pills. Each record corresponds to a patient-day of use. The variable itrial indicates whether the record is for the CAMP trial or transition.

**rg1.xpt (CAMP):** All RG forms in RG1 format. Items 7 and 8 have been dropped from the data file since there have been corrections to date of birth since baseline data were locked. Ethnicity (white, black, hispanic or other) is available from the valids.xpt file.

**sb2.xpt (CAMP):** Prick skin test data from all SB forms. Children were tested with the 10 core allergens and site selected allergens. 48 different allergens were tested in CAMP overall. Variables

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Specific Comments on Database Files (cont'd)

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were created for all 48 tests and included on each record (test status=positive, negative, not tested; flare size; wheal size). Hormodendrum and cladosporium are the same mold – in this edition of the Master Database, these variables have been combined under hormodendrum whereas in the earlier editions, hormodendrum and cladosporium were thought to be two different molds.

**sb2\_idt.xpt (CAMP):** Intradermal skin test data from all SB forms.

**sb6.xpt (CAMPCS):** All SB forms in SB6 format. Children were tested with the 10 core allergens and site selected allergens. 48 different allergens were tested in CAMP overall. Variables were created for all 48 tests and included on each record (test status=positive, negative, not tested; flare size; wheal size). Items relating to intradermal testing have been deleted since no intradermal testing was done in CAMPCS.

**serum.xpt (CAMP and CAMPCS):** Total IgE as measured by DACI lab at baseline (visit code=s3) and f48 and c84 and c08.

**steptim.xpt (CAMP):** This file is derived from medstefi.xpt. The CAMP trial protocol “allowed” essentially 6 treatment steps: full dose study drug, half dose study drug by tapering, zero dose study drug by tapering, full dose study drug and 4 puffs beclomethasone *bid*, full dose study drug and 2 puffs beclomethasone *bid*, and other treatment. This file is designed to indicate treatment steps (changes) from the point of view of these 6 steps. The file includes a record for each patient’s starting treatment (step 1 at randomization). Consecutive records indicating the same treatment have been deleted. This file continues through transition for patients who participated in transition. The step variable in steptim.xpt is the child’s CAMP protocol step, with some added detail about the nature of physician discretion treatment: 1 is full dose study drug only; 2 is half dose study drug only; 3 is zero dose study drug by tapering and no other treatment aside from albuterol or prednisone; 4 is full dose study drug and 4 puffs beclomethasone (42 mcg/puff) *bid* only; 5 is full dose study drug and 2 puffs beclomethasone (42 mcg/puff) *bid* only; and 6 and 7 describe physician discretion treatment (which is something other than steps 1-5). If step=6, the physician discretion included an ICS; if step=7, the physician discretion treatment did not include an ICS. Note that 7 could mean albuterol alone but not achieved by tapering.

**ue1.xpt (CAMP):** All UE forms in UE1 format.

**va1.xpt (CAMP):** All VA forms in VA1 format.

**valids.xpt (CAMP and CAMPCS):** ID, demographic, and treatment assignment information are included in this file. Date of birth (as a number of days before randomization) and ethnicity (white, black, hispanic, other) are included in this file.

**xr1.xpt (CAMP):** All XR forms in XR1 format.

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## Items on file at the National Technical Information Service

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### Videos

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