

**Data Set Name: aeclin.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	CAE_1020	Num	8		Description of adverse event
5	CAE_1030	Char	6		ICD9 Code
6	CAE_1040	Num	8		Date started (number of days since enrollment date)
7	CAE_1050	Num	8		Date stopped (number of days since enrollment date)
8	CAE_1060	Num	8	YESF.	Flag: Ongoing at current visit?
9	CAE_1070	Num	8		Duration in hours if < 24 hours
10	CAE_1080	Num	8	CAE_1080F.	Event type (intermittent or continuous)
11	CAE_1090	Num	8	CAE_1090F.	Event severity
12	CAE_1100	Num	8	YNF.	Serious Adverse Event?
13	CAE_1110	Num	8	CAE_1110F.	Likelihood of relationship to study drug
14	CAE_1120	Num	8	CAE_1120F.	Change in study medications
15	CAE_1130	Num	8	CAE_1130F.	Event outcome
16	CAE_1140	Num	8	CAE_1140F.	Treatment required

**Data Set Name: aelab.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	LAE_1000	Num	8		Test date (number of days since enrollment date)
5	LAE_1010	Num	8	LAE_1010F.	Laboratory test
6	LAE_1020	Num	8	LAE_1020F.	Abnormality observed
7	LAE_1030	Num	8	YNF.	Was this Laboratory Adverse Event considered serious?
8	LAE_1040	Num	8	LAE_1040F.	Likelihood of relationship to study drug
9	LAE_1050	Num	8	YNF.	Did the subject require treatment with medication other than study drugs for this Laboratory Adverse Event?
10	LAE_1060	Num	8	YNF.	Did the subject require any other type of treatment for this Laboratory Adverse Event?
11	LAE_1070	Num	8	LAE_1070F.	Adverse Event status
12	LAE_1080	Num	8		Date Adverse Event resolved (number of days since enrollment date)

**Data Set Name: ast\_hx.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	AHX_1000	Num	8	AHX_1000F.	1. What is your relationship to the child?
5	AHX_1010	Num	8		2. How old was the child when chest symptoms suggesting asthma first began? (years)
6	AHX_1020	Num	8		2. How old was the child when chest symptoms suggesting asthma first began? (months)
7	AHX_1030	Num	8		3. How old was the child when a doctor first said he or she had asthma? (years)
8	AHX_1040	Num	8		3. How old was the child when a doctor first said he or she had asthma? (months)
9	AHX_1050	Num	8	YNF.	4. Has the child ever been hospitalized overnight for asthma?
10	AHX_1060	Num	8		4a. If YES, during the past 12 months, how many times has the child been hospitalized overnight for asthma?
11	AHX_1070	Num	8	YNF.	5. Has the child ever been admitted to an intensive care unit for asthma?
12	AHX_1080	Num	8		5a. If YES, during the past 12 months, how many times has the child been admitted to an intensive care unit for asthma?
13	AHX_1090	Num	8		6a. During the past 12 months, how many times has the child been seen in an emergency department for asthma?
14	AHX_1100	Num	8		6b. During the past 12 months, how many times has the child been seen at a doctor's office for asthma? (Include both routine visits and visits for acute problems)
15	AHX_1110	Num	8		6c. During the past 12 months, how many days of work or school did the child miss because of asthma?
16	AHX_1120	Num	8		6d. During the past 12 months, how many days of work did you miss because of the child's asthma?
17	AHX_1130	Num	8	AHX_1130TO1250F.	7. Is the child's asthma provoked on exposure to house dust?
18	AHX_1140	Num	8	AHX_1130TO1250F.	8. Is the child's asthma provoked on exposure to animals?
19	AHX_1150	Num	8	AHX_1130TO1250F.	9. Is the child's asthma provoked by emotional factors? (e.g., stress)
20	AHX_1160	Num	8	AHX_1130TO1250F.	10. Is the child's asthma provoked by exercise/play?
21	AHX_1170	Num	8	AHX_1130TO1250F.	11. Is the child's asthma provoked on exposure to damp, musty area? (e.g., damp basement)
22	AHX_1180	Num	8	AHX_1130TO1250F.	12. Is the child's asthma provoked on exposure to tobacco smoke?
23	AHX_1190	Num	8	AHX_1130TO1250F.	13. Is the child's asthma provoked on exposure to a change in the weather?
24	AHX_1200	Num	8	AHX_1130TO1250F.	14. Is the child's asthma provoked on respiratory infections?
25	AHX_1210	Num	8	AHX_1130TO1250F.	15. Is the child's asthma provoked on exposure to chemicals? (e.g., perfume, household cleaners)
26	AHX_1220	Num	8	AHX_1130TO1250F.	16. Is the child's asthma provoked by food?
27	AHX_1230	Num	8	AHX_1130TO1250F.	17. Is the child's asthma provoked on exposure to cold air?
28	AHX_1240	Num	8	AHX_1130TO1250F.	18. Is the child's asthma provoked by aspirin?
29	AHX_1250	Num	8	AHX_1130TO1250F.	19. Is the child's asthma provoked on exposure to spring and fall pollens?

Num	Variable	Type	Len	Format	Label
30	AHX_1260	Num	8	YNF.	20. Has the child ever had hay fever?
31	AHX_1270	Num	8		20a. At what age did the child FIRST have hay fever? (years)
32	AHX_1280	Num	8		20a. At what age did the child FIRST have hay fever? (months)
33	AHX_1290	Num	8	YNF.	20b. During the past 12 months, did the child have hay fever?
34	AHX_1300	Num	8	YNF.	20c. Has the child ever seen a doctor or other health practitioner because of hay fever?
35	AHX_1310	Num	8	YNF.	21. Has the child ever had atopic dermatitis (eczema)?
36	AHX_1320	Num	8		21a. At what age did the child FIRST have atopic dermatitis (eczema)? (years)
37	AHX_1330	Num	8		21a. At what age did the child FIRST have atopic dermatitis (eczema)? (months)
38	AHX_1340	Num	8	YNF.	21b. During the past 12 months, did the child have atopic dermatitis?
39	AHX_1350	Num	8	YNF.	21c. Has the child ever seen a doctor or other health practitioner because of atopic dermatitis?
40	AHX_1360	Num	8	YNF.	22. Has a doctor or other health practitioner ever said that the child has allergies?
41	AHX_1370	Num	8	YNF.	23a. To which of the following did a doctor or other health practitioner say the child was allergic: Medicines
42	AHX_1380	Num	8	YNF.	23b. To which of the following did a doctor or other health practitioner say the child was allergic: Foods
43	AHX_1390	Num	8	YNF.	23c. To which of the following did a doctor or other health practitioner say the child was allergic: Things you breathe in or inhale (e.g., dust, pollens, molds, animal fur, or dander)
44	AHX_1400	Num	8	YNF.	23d. To which of the following did a doctor or other health practitioner say the child was allergic: Stinging insects such as bees or wasps
45	AHX_1410	Num	8	YNF.	23e. To which of the following did a doctor or other health practitioner say the child was allergic: Other
46	AHX_1420	Num	8	AHX_1420F.	24. On average, during the past MONTH, how often has the child had a cough, wheeze, shortness of breath, or chest tightness?
47	AHX_1430	Num	8	AHX_1430TO1450F.	25. On average, during the past MONTH, how often was the child awakened from sleep because of coughing, wheezing, shortness of breath, or chest tightness?
48	AHX_1440	Num	8	AHX_1430TO1450F.	26. On average, during the past MONTH, how often has the child had cough, wheeze, shortness of breath, or chest tightness while exercising or playing?
49	AHX_1450	Num	8	AHX_1430TO1450F.	27. On average, during the past MONTH, how often does asthma keep the child from doing what the child wants?
50	AHX_1460	Num	8	AHX_1460F.	28. In general, during the past MONTH, how bothered was the child by his/her asthma?

**Data Set Name: cap\_feia.sas7bdat**

Num	Variable	Type	Len	Label
1	SUBJ_ID	Num	8	Public Subject ID
2	VNUM	Num	8	Visit Number
3	VDATE	Num	8	Visit Date (number of days since enrollment date)
4	CAP_1000	Num	8	1. Mite Mix CAP/FEIA test results (Au/L)
5	CAP_1010	Num	8	2. Roach Mix CAP/FEIA test results (Au/L)
6	CAP_1020	Num	8	3. Cat CAP/FEIA test results (Au/L)
7	CAP_1030	Num	8	4. Dog CAP/FEIA test results (Au/L)
8	CAP_1040	Num	8	5. Mold Mix CAP/FEIA test results (Au/L)
9	CAP_1050	Num	8	6. Grass Mix CAP/FEIA test results (Au/L)
10	CAP_1060	Num	8	7. Tree Mix CAP/FEIA test results (Au/L)
11	CAP_1070	Num	8	8. Weed Mix CAP/FEIA test results (Au/L)
12	CAP_1080	Num	8	9. Milk CAP/FEIA test results (Au/L)
13	CAP_1090	Num	8	10. Egg CAP/FEIA test results (Au/L)
14	CAP_1100	Num	8	11. Peanut CAP/FEIA test results (Au/L)
15	CAP_1110	Num	8	12. Other _____ CAP/FEIA test results (Au/L)
16	CAP_1120	Num	8	13. Other _____ CAP/FEIA test results (Au/L)

**Data Set Name: cmed\_as.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	CMD_1010	Num	8		Name of Medication
5	CMD_1000	Char	4		Med Code
6	CMD_1040	Num	8		Frequency
7	CMD_1060	Num	8		Med Start Date (number of days since enrollment date)
8	CMD_1090	Num	8		Med Stop Date (number of days since enrollment date)
9	CMD_1100	Num	8	YESF.	Flag: Ongoing at Data Entry

**Data Set Name: comply.sas7bdat**

Num	Variable	Type	Len	Label
1	SUBJ_ID	Num	8	Public Subject ID
2	VNUM	Num	8	Visit Number
3	VDATE	Num	8	Visit Date (number of days since enrollment date)
4	CMP_1120	Num	8	1a. Number of tablets dispensed in eDEM vial
5	CMP_1130	Num	8	1b. Number of tablets returned in eDEM vial
6	CMP_1140	Num	8	1c. Number of prescribed doses
7	CMP_1150	Num	8	1d. Actual number of tables taken (Question #1a - Question #1b)
8	CMP_1160	Num	8	1e. Percent compliance = (Question #1d / Question #1c) x 100
9	CMP_1000	Num	8	2a. Number of monitored days
10	CMP_1010	Num	8	2b. Number of doses taken
11	CMP_1020	Num	8	2c. % Prescribed number of doses taken
12	CMP_1021	Num	8	2d. Doses in time window/prescribed doses
13	CMP_1070	Num	8	3a. Number of scheduled inhalations since the last visit
14	CMP_1080	Num	8	3b. Dose counter number on the first Diskus
15	CMP_1090	Num	8	3c. Dose counter number on the second Diskus
16	CMP_1100	Num	8	3d. 120 - Question #3b - Question #3c
17	CMP_1110	Num	8	3e. Percent compliance = (Question #3d / Question #3a) x 100

**Data Set Name: diary.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	DIARYDT	Num	8		Diary Date (number of days since enrollment date)
5	DRY_1000	Num	8	YNF.	1. Awakened last night by asthma?
6	DRY_1010	Num	8		2. Time of AM Peak Flow
7	DRY_1020	Num	8		3. AM Peak Flow (liters/min)
8	DRY_1030	Num	8		3. FLAG: Circle the value if you have used your RESCUE inhaler in the last 2 hours.
9	DRY_1040	Num	8		4. Number of AM Study Diskus inhalations taken
10	DRY_1050	Num	8		5. Coordinator Completed: AM FEV1 (liters)
11	DRY_1060	Num	8		6. Time of PM Peak Flow
12	DRY_1070	Num	8		7. PM Peak Flow (liters/min)
13	DRY_1080	Num	8		7. FLAG: Circle the value if you have used your RESCUE inhaler in the last 2 hours.
14	DRY_1090	Num	8		8. Number of PM Study Diskus inhalations taken
15	DRY_1100	Num	8		9. Number of PM Study tablets taken
16	DRY_1110	Num	8		10. Coordinator Completed: PM FEV1 (liters)
17	DRY_1120	Num	8	SYMRATINGSCALEF.	11. Asthma Symptom: Coughing from asthma
18	DRY_1130	Num	8	SYMRATINGSCALEF.	12. Asthma Symptom: Wheezing
19	DRY_1140	Num	8		13. Rescue Inhaler: Before or after exercise
20	DRY_1150	Num	8		14. Rescue Inhaler: For asthma symptoms or low peak flow
21	DRY_1160	Num	8	YNF.	15. Absent from school or work for asthma?
22	DRY_1170	Num	8	YNF.	16. Contacted doctor for asthma?
23	DRY_1180	Num	8		17. FLAG: Parent/Legal Guardian initials

***Data Set Name: drug\_seq.sas7bdat***

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SUBJ_ID	Num	8	Public Subject ID
2	DRUG_SEQ	Char	10	Treatment sequence assigned to subject at randomization

**Data Set Name: elig1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	E1_1000	Num	8	YNF.	1. Has a parent/legal guardian appropriately signed and dated the informed consent?
5	E1_1010	Num	8		2. If YES, date form signed (number of days since enrollment date)
6	E1_1020	Num	8	YNF.	3. Has the participant appropriately signed and dated the assent form, or if the participant is less than 7 years old, has the participant given verbal assent?
7	E1_1030	Num	8		4. If YES, record the date verbal assent was given (number of days since enrollment date)
8	E1_1040	Num	8	YNF.	5. Is the participant 6 to <18 years old?
9	E1_1050	Num	8	YNF.	6. Has the participant smoked 11 or more cigarettes or any other substance in the past year?
10	E1_1060	Num	8	YNF.	7. Has the participant used smokeless tobacco products (chew, snuff) 11 or more times in the past year?
11	E1_1070	Num	8	YNF.	8. Has the participant ever had chicken pox or received the chicken pox vaccine?
12	E1_1080	Num	8	YNF.	9. Does the participant have a chronic or active lung disease other than asthma?
13	E1_1090	Num	8	YNF.	10. Does the participant have a significant medical illness other than asthma (e.g. thyroid disease, diabetes mellitus, Cushings's, Addison's, or hepatic disease)?
14	E1_1100	Num	8	YNF.	11. Does the participant have a history of cataracts, glaucoma, or other medical disorders (such as thrush that is difficult to treat) associated with an adverse effect to glucocorticoids?
15	E1_1110	Num	8	YNF.	12. Does the participant have concurrent medical problems other than asthma that are likely to require oral prednisone during the study?
16	E1_1120	Num	8	YNF.	13. During the past year, has the participant had 4 or more corticosteroid bursts for asthma exacerbations?
17	E1_1130	Num	8	YNF.	14. During the past year, has the participant been hospitalized 2 or more times for asthma?
18	E1_1140	Num	8	YNF.	15. Has the participant ever had an asthma exacerbation resulting in intubation and mechanical ventilation?
19	E1_1150	Num	8	YNF.	16. Has the participant ever had a seizure (during and asthma episode) that the physician thought was due to asthma?
20	E1_1160	Num	8	YNF.	17. Is the participant receiving allergy shots?
21	E1_1170	Num	8	YNF.	17a. If YES, has the dose been changed in the past 3 months?
22	E1_1180	Num	8	YNF.	18. Has the participant ever had an adverse reaction to fluticasone propionate, montelukast, or any of their ingredients?
23	E1_1190	Num	8	YNF.	19. Has the participant had a respiratory tract infection within the past 4 weeks?
24	E1_1200	Num	8	YNF.	20. Has the participant had a significant exacerbation of asthma within the past 4 weeks?
25	E1_1210	Num	8	YNF.	21. During the past 4 weeks, has the participant had a combination of asthma symptoms or bronchodilator use for relief for asthma symptoms or signs on an average of 3 or more days per week?
26	E1_1220	Num	8	YNF.	22a. Has the participant received any of the following treatments in the past 4 weeks? Oral inhaled corticosteroid treatment
27	E1_1230	Num	8	YNF.	22b. Has the participant received any of the following treatments in the past 4 weeks? Systemic corticosteroid treatment (oral or injectable)

Num	Variable	Type	Len	Format	Label
28	E1_1240	Num	8	YNF.	23. Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (EXCLDRUG) during the designated washout periods?
29	E1_1250	Num	8		24. Is the BMI of the participant > 35 kg/m <sup>2</sup> ?
30	E1_1260	Num	8	YNF.	24. Has the participant had her first period?
31	E1_1270	Num	8	YNF.	24a. Is the participant currently pregnant or nursing?
32	E1_1280	Num	8	YNF.	24b. Is the participant currently using an acceptable birth control method?
33	E1_1290	Num	8	YNF.	25. Does the participant's family have plans to move out of the area within the next 5 months?
34	E1_1300	Num	8	YNF.	26. Is there any other reason for which this participant should not be included in this study?
35	E1_1310	Num	8	YNF.	27. Is the participant eligible?
36	E1_1320	Num	8		Flag: Physician/CC signature
37	E1_1330	Num	8		Physician/CC signature Date (number of days since enrollment date)

**Data Set Name: elig2.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	E2_1000	Num	8	YNF.	1. Is the participant able to perform the required lung function procedures?
5	E2_1010	Num	8	YNF.	2. Is the participant able to perform reproducible spirometry?
6	E2_1020	Num	8	YNF.	3. Is the participant's pre-bronchodilator FEV1% predicted $\geq$ 70%? (Result of best effort)
7	E2_1030	Num	8		4. Is the participant able to demonstrate reversible airflow obstruction ( $\geq$ 12% improvement in FEV1 following the maximal bronchodilator testing procedure with albuterol MDI)?
8	E2_1040	Num	8	YNF.	4. Is the participant eligible?
9	E2_1050	Num	8		5. Personal best PEFr resulting from 3 acceptable blows on the AM1 device.
10	E2_1060	Num	8		Flag: Physician/CC signature
11	E2_1070	Num	8		Physician/CC signature Date (number of days since enrollment date)

**Data Set Name: elig3.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	E3_1000	Num	8	YNF.	1a. Has the study participant received any of the following treatments since the last study visit? Oral inhaled corticosteroid treatment
5	E3_1010	Num	8	YNF.	1b. Has the study participant received any of the following treatments since the last study visit? Systemic corticosteroid treatment (oral or injectable)
6	E3_1020	Num	8	YNF.	2. Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (EXCLDRUG) during the designated washout periods?
7	E3_1030	Num	8		3. Number of days since Visit 1, excluding today and the participant's Visit 1 date
8	E3_1040	Num	8		4a. Diary and peak flow compliance - Number of complete measurements in the defined interval
9	E3_1050	Num	8		4b. Diary and peak flow compliance - Percent compliance = (Question #4a / Question #3 x 5) x 100
10	E3_1060	Num	8	YNF.	4c. Diary and peak flow compliance - Is Question #4b >= 80%?
11	E3_1070	Num	8	YNF.	5. Is the participant eligible?
12	E3_1080	Num	8		6a. Albuterol use - Number of puffs of albuterol used for asthma symptoms or low peak flow (Question #14 on the Diary Card)
13	E3_1090	Num	8		6b. Albuterol use - Average number of puffs of albuterol per day used for asthma symptoms or low peak flow Average = (Question #6a / Question #3)
14	E3_1100	Num	8	YNF.	6c. Albuterol use - Is Question #6b > 8.0?
15	E3_1110	Num	8		7a. Night awakenings - Number of days in the defined interval with night awakenings due to asthma symptoms
16	E3_1120	Num	8		7b. Night awakenings - Average number of days per week with night awakenings due to asthma symptoms Average = (Question #7a / Question #3) x 7
17	E3_1130	Num	8	YNF.	7c. Night awakenings - Is Question #7b >= 2.0?
18	E3_1140	Num	8	YNF.	8a. Peak flow variability - Are there any usable peak flow variability measurements for this subject?
19	E3_1150	Num	8		8b. Peak flow variability - Average peak flow variability (see the Eligibility Calculator Report, or use the Peak Flow Variability Worksheet)
20	E3_1160	Num	8	YNF.	8c. Peak flow variability - Is Question #8b >= 30.0%?
21	E3_1170	Num	8	YNF.	9. Are the liver function tests for this participant within acceptable range?
22	E3_1171	Num	8	YNF.	10. Is the participant eligible?
23	E3_1172	Num	8	YNF.	11. Was the participant able to demonstrate reversible airflow obstruction (>= 12% improvement in FEV1 following the maximal bronchodilator testing procedure at Visit 1 with albuterol MDI)?
24	E3_1173	Num	8	YNF.	12. Is the participant's PC20 <= 12.5 mg/ml?
25	E3_1174	Num	8	YNF.	13. Is the participant eligible?
26	E3_1180	Num	8	YNF.	14. Does the parent/legal guardian believe that the participant and family will be able to comply with the study schedule and study requirements?
27	E3_1190	Num	8	YNF.	15. Is the participant able to coordinate the use of the Diskus?
28	E3_1200	Num	8	YNF.	16. Is the participant able to perform the required lung function procedures?
29	E3_1210	Num	8	YNF.	17. Is there any other reason for which this participant should not be included in this study?

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
30	E3_1220	Num	8	YNF.	18. Is the participant eligible?
31	E3_1260	Num	8		Flag: Physician/CC signature
32	E3_1270	Num	8		Physician/CC signature Date (number of days since enrollment date)

**Data Set Name: eno.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	ENO_1000	Num	8	YNF.	1. During the past 24 hours, has the child used sustained-release theophylline?
5	ENO_1010	Num	8	YNF.	2. During the past 12 hours, has the child used a long-acting bronchodilator (i.e., salmeterol)?
6	ENO_1020	Num	8	YNF.	3. During the past 4 hours, has the child used a short-acting bronchodilator?
7	ENO_1030	Num	8	YNF.	4. During the past 2 weeks, has the child had any respiratory infections, colds, or bronchitis?
8	ENO_1035	Num	8	YNF.	5. Has the child smoked cigarettes or any other substance in the past month?
9	ENO_1036	Num	8	YNF.	5a. If YES, has the child smoked within the past hour?
10	ENO_1040	Num	8	YNF.	6. Is there any other reason the child should not proceed with the exhaled nitric oxide procedure?
11	ENO_1045	Num	8	YNF.	7. Did the child eat or drink in the past hour?
12	ENO_1050	Num	8	YNF.	8. Is the child eligible to proceed with the exhaled nitric oxide procedure?
13	ENO_1060	Num	8		10. ENO Measurement #1 - Time
14	ENO_1070	Num	8		10. ENO Measurement #1 - Measured FENO
15	ENO_1080	Num	8		11. ENO Measurement #2 - Time
16	ENO_1090	Num	8		11. ENO Measurement #2 - Measured FENO
17	ENO_1100	Num	8		12. ENO Measurement #3 - Time
18	ENO_1110	Num	8		12. ENO Measurement #3 - Measured FENO
19	ENO_1120	Num	8		13. Average FENO
20	ENO_1130	Num	8		14. Average VNO

**Data Set Name: heq.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	HEQ_1000	Num	8	RESPONDENTF.	1. What is your relationship to the child?
5	HEQ_1010	Num	8	HEQ_1010F.	2. How long has the child lived in his/her current home?
6	HEQ_1020	Num	8	YNF.	3a. Are any of the following located on your property? - Barns
7	HEQ_1030	Num	8	YNF.	3b. Are any of the following located on your property? - Hay
8	HEQ_1040	Num	8	YNF.	3c. Are any of the following located on your property? - Woodsheds
9	HEQ_1050	Num	8	YNF.	3d. Are any of the following located on your property? - Firewood
10	HEQ_1060	Num	8	YNF.	3e. Are any of the following located on your property? - Chicken coops
11	HEQ_1070	Num	8	YNF.	3f. Are any of the following located on your property? - Horses
12	HEQ_1080	Num	8	HEQ_1080F.	4. Which best describes the child's current home?
13	HEQ_1090	Num	8		5. About how old is the child's current home? (years)
14	HEQ_1100	Num	8	YNF.	6. Does the child's home use a portable heater?
15	HEQ_1110	Num	8	YNF.	7. Does the child's home use a wood burning stove as a primary source of heat?
16	HEQ_1120	Num	8	YNF.	8. Does the child's home use a cooling system?
17	HEQ_1130	Num	8	HEQ_1130F.	9. Which type of cooling system is used in the child's home?
18	HEQ_1140	Num	8	YNF.	10a. Which rooms use a window unit? - Child's bedroom
19	HEQ_1150	Num	8	YNF.	10b. Which rooms use a window unit? - Other bedrooms
20	HEQ_1160	Num	8	YNF.	10c. Which rooms use a window unit? - Living or family room
21	HEQ_1170	Num	8	YNF.	10d. Which rooms use a window unit? - Kitchen
22	HEQ_1180	Num	8	YNF.	10e. Which rooms use a window unit? - Other
23	HEQ_1190	Num	8	YNDKF.	11. Does the child's home use a humidifier? (Include humidifier built into the heating system of the child's home)
24	HEQ_1200	Num	8	YNDKF.	12. Does the child's home use a de-humidifier? (Include de-humidifier built into the cooling system of the child's home)
25	HEQ_1210	Num	8	YNDKF.	13. Has there been water damage to the child's home, basement, or its contents during the past 12 months?
26	HEQ_1220	Num	8	YNDKF.	14. Has there been any mold or mildew, on any surfaces, inside the child's home in the past 12 months?
27	HEQ_1230	Num	8	YNF.	15a. Which room(s) have or have had mold or mildew? - Bathroom(s)
28	HEQ_1240	Num	8	YNF.	15b. Which room(s) have or have had mold or mildew? - Bedroom(s)
29	HEQ_1250	Num	8	YNF.	15c. Which room(s) have or have had mold or mildew? - Living or family room
30	HEQ_1260	Num	8	YNF.	15d. Which room(s) have or have had mold or mildew? - Kitchen
31	HEQ_1270	Num	8	YNF.	15e. Which room(s) have or have had mold or mildew? - Basement or attic
32	HEQ_1280	Num	8	YNF.	15f. Which room(s) have or have had mold or mildew? - Other
33	HEQ_1290	Num	8	YNF.	16. Do you ever see cockroaches in the child's home?
34	HEQ_1300	Num	8	YNF.	17a. In which room(s) have you seen cockroaches? - Bathroom(s)

Num	Variable	Type	Len	Format	Label
35	HEQ_1310	Num	8	YNF.	17b. In which room(s) have you seen cockroaches? - Bedroom(s)
36	HEQ_1320	Num	8	YNF.	17c. In which room(s) have you seen cockroaches? - Living or family room
37	HEQ_1330	Num	8	YNF.	17d. In which room(s) have you seen cockroaches? - Kitchen
38	HEQ_1340	Num	8	YNF.	17e. In which room(s) have you seen cockroaches? - Basement or attic
39	HEQ_1350	Num	8	YNF.	17f. In which room(s) have you seen cockroaches? - Other
40	HEQ_1360	Num	8	YNF.	18. Does the child share his/her bedroom with another person?
41	HEQ_1370	Num	8		18a. If YES, how many others?
42	HEQ_1380	Num	8	HEQ_1380F.	19. What is the floor covering in the child's bedroom?
43	HEQ_1390	Num	8	HEQ_1390F.	19a. If SYNTHETIC OR WOOL CARPET, what type of padding is under the carpet in the child's bedroom?
44	HEQ_1400	Num	8	HEQ_1400F.	20. What type of mattress is on the child's bed?
45	HEQ_1410	Num	8		21. How old is the mattress used on the child's bed? (years)
46	HEQ_1420	Num	8	YNF.	22. Is the mattress completely enclosed in an allergy-proof, encasing cover?
47	HEQ_1430	Num	8	YNF.	23. Does the child's bed have a box spring?
48	HEQ_1440	Num	8	YNF.	24. Is the box spring completely enclosed in an allergy-proof, encasing cover?
49	HEQ_1450	Num	8	HEQ_1450F.	25. What type of pillow is used on the child's bed?
50	HEQ_1460	Num	8		26. How old is the pillow used on the child's bed? (years)
51	HEQ_1470	Num	8	YNF.	27. Is the pillow completely enclosed in an allergy-proof, encasing cover?
52	HEQ_1480	Num	8	YNF.	28. Are the child's bed covers or sheets washed in hot water at least 1 time per week?
53	HEQ_1490	Num	8	YNF.	29. Does your family have any animals?
54	HEQ_1500	Num	8		30a. Enter the number of animals that the family has. - Cat
55	HEQ_1510	Num	8		30b. Enter the number of animals that the family has. - Dog
56	HEQ_1520	Num	8		30c. Enter the number of animals that the family has. - Rabbit, guinea pig, hamster, gerbil, or mouse
57	HEQ_1530	Num	8		30d. Enter the number of animals that the family has. - Bird
58	HEQ_1540	Num	8		30e. Enter the number of animals that the family has. - Other
59	HEQ_1550	Num	8	YNF.	31. Are any pets allowed into the child's home?
60	HEQ_1560	Num	8	YNDKF.	32a. Which pets are allowed into the child's home? - Cat
61	HEQ_1570	Num	8	YNDKF.	32b. Which pets are allowed into the child's home? - Dog
62	HEQ_1580	Num	8	YNDKF.	32c. Which pets are allowed into the child's home? - Rabbit, guinea pig, hamster, gerbil, or mouse
63	HEQ_1590	Num	8	YNDKF.	32d. Which pets are allowed into the child's home? - Bird
64	HEQ_1600	Num	8	YNDKF.	32e. Which pets are allowed into the child's home? - Other
65	HEQ_1610	Num	8	YNDKF.	33a. Which pets are allowed into the child's bedroom? - Cat
66	HEQ_1620	Num	8	YNDKF.	33b. Which pets are allowed into the child's bedroom? - Dog
67	HEQ_1630	Num	8	YNDKF.	33c. Which pets are allowed into the child's bedroom? - Rabbit, guinea pig, hamster, gerbil, or mouse
68	HEQ_1640	Num	8	YNDKF.	33d. Which pets are allowed into the child's bedroom? - Bird
69	HEQ_1650	Num	8	YNDKF.	33e. Which pets are allowed into the child's bedroom? - Other

Num	Variable	Type	Len	Format	Label
70	HEQ_1660	Num	8	YNDKF.	34a. In general and on a regular basis, is the child exposed to any of the following animals for more than one hour each day? - Cat
71	HEQ_1670	Num	8	YNDKF.	34b. In general and on a regular basis, is the child exposed to any of the following animals for more than one hour each day? - Dog
72	HEQ_1680	Num	8	YNDKF.	34c. In general and on a regular basis, is the child exposed to any of the following animals for more than one hour each day? - Rabbit, guinea pig, hamster, gerbil, or mouse
73	HEQ_1690	Num	8	YNDKF.	34d. In general and on a regular basis, is the child exposed to any of the following animals for more than one hour each day? - Bird
74	HEQ_1700	Num	8	YNDKF.	34e. In general and on a regular basis, is the child exposed to any of the following animals for more than one hour each day? - Other

***Data Set Name: icd9.sas7bdat***

Num	Variable	Type	Len	Label
1	CODE	Char	12	ICD9 Code
2	DESC	Char	26	ICD9 Description

**Data Set Name: ios.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	IOS_1000	Num	8	YNF.	1. During the past 24 hours, has the participant used sustained-release theophylline?
5	IOS_1010	Num	8	YNF.	2. During the past 12 hours, has the participant used a long-acting bronchodilator (i.e., salmeterol)?
6	IOS_1020	Num	8	YNF.	3. During the past 4 hours, has the participant used a short-acting bronchodilator?
7	IOS_1030	Num	8	YNF.	4. During the past 2 weeks, has the participant had any respiratory infections, colds, or bronchitis?
8	IOS_1035	Num	8	YNF.	5. Is there any other reason the participant should not proceed with the pulmonary function testing?
9	IOS_1040	Num	8	YNF.	6. Is the participant eligible to proceed with the pulmonary function testing?
10	IOS_1050	Num	8		7. Standing height
11	IOS_1055	Num	8	YNF.	8. Did the participant refuse to perform the procedure?
12	IOS_1060	Num	8		9. Time IOS started
13	IOS_1080	Num	8		10a. Results of first effort - R5
14	IOS_1085	Num	8		10b. Results of first effort - R10
15	IOS_1090	Num	8		10c. Results of first effort - R15
16	IOS_1100	Num	8		10d. Results of first effort - R35
17	IOS_1110	Num	8		10e. Results of first effort - X5
18	IOS_1120	Num	8		10f. Results of first effort - Resonant Frequency
19	IOS_1130	Num	8		10g. Results of first effort - Area XA
20	IOS_1140	Num	8		14. Time bronchodilator given
21	IOS_1150	Num	8		15. Time postbronchodilator IOS started
22	IOS_1160	Num	8		16a. Results of first effort - R5
23	IOS_1165	Num	8		16b. Results of first effort - R10
24	IOS_1170	Num	8		16c. Results of first effort - R15
25	IOS_1180	Num	8		16d. Results of first effort - R35
26	IOS_1190	Num	8		16e. Results of first effort - X5
27	IOS_1200	Num	8		16f. Results of first effort - Resonant Frequency
28	IOS_1210	Num	8		16g. Results of first effort - Area XA
29	IOS_1220	Num	8	YNF.	19. In your judgement, was the participant's prebronchodilator technique acceptable?
30	IOS_1230	Num	8	YNF.	19a. If NO, why was it unacceptable? Coherence < 0.80 (for R10)
31	IOS_1240	Num	8	YNF.	19a. If NO, why was it unacceptable? Less than 3 good tests
32	IOS_1250	Num	8	YNF.	19a. If NO, why was it unacceptable? Inconsistent tidal breathing
33	IOS_1260	Num	8	YNF.	19a. If NO, why was it unacceptable? Participant refusal during test
34	IOS_1270	Num	8	YNF.	19a. If NO, why was it unacceptable? Other

Num	Variable	Type	Len	Format	Label
35	IOS_1280	Num	8	IOS_1600_1280F.	19b. If YES, grade the participant's technique.
36	IOS_1290	Num	8		11a. Results of second effort - R5
37	IOS_1295	Num	8		11b. Results of second effort - R10
38	IOS_1300	Num	8		11c. Results of second effort - R15
39	IOS_1310	Num	8		11d. Results of second effort - R35
40	IOS_1320	Num	8		11e. Results of second effort - X5
41	IOS_1330	Num	8		11f. Results of second effort - Resonant Frequency
42	IOS_1340	Num	8		11g. Results of second effort - Area XA
43	IOS_1350	Num	8		12a. Results of third effort - R5
44	IOS_1355	Num	8		12b. Results of third effort - R10
45	IOS_1360	Num	8		12c. Results of third effort - R15
46	IOS_1370	Num	8		12d. Results of third effort - R35
47	IOS_1380	Num	8		12e. Results of third effort - X5
48	IOS_1390	Num	8		12f. Results of third effort - Resonant Frequency
49	IOS_1400	Num	8		12g. Results of third effort - Area XA
50	IOS_1410	Num	8		17a. Results of second effort - R5
51	IOS_1415	Num	8		17b. Results of second effort - R10
52	IOS_1420	Num	8		17c. Results of second effort - R15
53	IOS_1430	Num	8		17d. Results of second effort - R35
54	IOS_1440	Num	8		17e. Results of second effort - X5
55	IOS_1450	Num	8		17f. Results of second effort - Resonant Frequency
56	IOS_1460	Num	8		17g. Results of second effort - Area XA
57	IOS_1470	Num	8		18a. Results of third effort - R5
58	IOS_1475	Num	8		18b. Results of third effort - R10
59	IOS_1480	Num	8		18c. Results of third effort - R15
60	IOS_1490	Num	8		18d. Results of third effort - R35
61	IOS_1500	Num	8		18e. Results of third effort - X5
62	IOS_1510	Num	8		18f. Results of third effort - Resonant Frequency
63	IOS_1520	Num	8		18g. Results of third effort - Area XA
64	IOS_1530	Num	8	YNF.	13. In your judgement, was the participant's prebronchodilator technique acceptable?
65	IOS_1540	Num	8	YNF.	13a. If NO, why was it unacceptable? Coherence < 0.80 (for R10)
66	IOS_1550	Num	8	YNF.	13a. If NO, why was it unacceptable? Poor repeatability (R10 values vary by more than 20%)
67	IOS_1560	Num	8	YNF.	13a. If NO, why was it unacceptable? Less than 3 good tests
68	IOS_1570	Num	8	YNF.	13a. If NO, why was it unacceptable? Inconsistent tidal breathing
69	IOS_1580	Num	8	YNF.	13a. If NO, why was it unacceptable? Participant refusal during test
70	IOS_1590	Num	8	YNF.	13a. If NO, why was it unacceptable? Other
71	IOS_1600	Num	8	IOS_1600_1280F.	13b. If YES, grade the participant's technique.

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
72	IOS_1235	Num	8	YNF.	19a. If NO, why was it unacceptable? Poor repeatability (R10 values vary by more than 20%)
73	IOS_1610	Num	8	IOS_1610F.	20. How was the participant positioned?
74	IOS_1620	Num	8	YNF.	21. Were the participant's cheeks held?
75	IOS_1630	Num	8	IOS_1630F.	21a. If YES, how were the participant's cheeks held?
76	IOS_1640	Num	8	YNF.	22. Were nose clips used?
77	IOS_1650	Num	8	IOS_1650F.	22a. If YES, how effective were the nose clips?
78	IOS_1660	Num	8	YNF.	22b. If NO, was the nose occluded?
79	IOS_1670	Num	8	IOS_1670F.	22bi. If YES, how was the nose occluded?
80	IOS_1680	Num	8	YNF.	23. Were there problems with the use of the standard mouthpiece?

**Data Set Name: jun\_acq.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	JUN_1000	Num	8	JUN_1000F.	1. Who is the respondent?
5	JUN_1010	Num	8	JUN_1010F.	2. On average, during the past week, how often were you awakened by your asthma during the night?
6	JUN_1020	Num	8	JUN_1020F.	3. On average, during the past week, how bad were your asthma symptoms when you woke up in the morning?
7	JUN_1030	Num	8	JUN_1030F.	4. In general, during the past week, how limited were you in your activities because of your asthma?
8	JUN_1040	Num	8	JUN_1040F.	5. In general, during the past week, how much shortness of breath did you experience because of your asthma?
9	JUN_1050	Num	8	JUN_1050F.	6. In general, during the past week, how much of the time did you wheeze?
10	JUN_1060	Num	8	JUN_1060F.	7. On average, during the past week, how many puffs of short-acting bronchodilator (e.g. Ventolin) have you used each day?
11	JUN_1110	Num	8	YNF.	8. Were pre-bronchodilator FEV1 and FEB1% predicted measures completed...?
12	JUN_1130	Num	8		Respondent Initials Date (number of days since enrollment date)

**Data Set Name: lab.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	LAB_1000	Num	8	LAB_1000F.	1. Pregnancy test results
5	LAB_1020	Num	8		Participant's Initials Date (number of days since enrollment date)
6	LAB_1030	Num	8		2. BLOOD TESTS - SGPT/ALT
7	LAB_1040	Num	8		3. BLOOD TESTS - SGOT/AST
8	LAB_1050	Num	8		4. BLOOD TESTS - Total Bilirubin
9	LAB_1060	Num	8		5. BLOOD TESTS - Total WBC
10	LAB_1070	Num	8		6. BLOOD TESTS - Eosinophils
11	LAB_1075	Num	8		7. BLOOD TESTS - Hematocrit

**Data Set Name: mataq.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	MAT_1000	Num	8	MAT_1000F.	1. Who is the respondent?
5	MAT_1010	Num	8	MAT_1010_1050F.	2a. Since the last study visit, how many days did the participant: Have wheezing or difficulty breathing when playing or exercising?
6	MAT_1020	Num	8	MAT_1010_1050F.	2b. Since the last study visit, how many days did the participant: Have wheezing during the day when not playing or exercising?
7	MAT_1030	Num	8	MAT_1010_1050F.	2c. Since the last study visit, how many days did the participant: Wake up at night with wheezing or difficult breathing?
8	MAT_1040	Num	8	MAT_1010_1050F.	2d. Since the last study visit, how many days did the participant: Miss days of school or work because of his/her asthma?
9	MAT_1050	Num	8	MAT_1010_1050F.	2e. Since the last study visit, how many days did the participant: Miss any daily activities (for example, playing or exercising, going to a friend's house, or any family activity) because of his/her asthma?
10	MAT_1060	Num	8	YNUF.	3a. Do you believe: The participant's asthma was well controlled since the last study visit?
11	MAT_1070	Num	8	YNUF.	3b. Do you believe: The participant is able to take the study medicine(s) as directed?
12	MAT_1080	Num	8	YNUF.	3c. Do you believe: The study medicine(s) the participant takes are useful for controlling asthma?
13	MAT_1090	Num	8	MAT_1090F.	4. Since the last study visit, on days the participant used albuterol for quick relief, how many puffs a day did he or she usually take?
14	MAT_1100	Num	8	MAT_1100F.	5. Since the last study visit, what was the greatest number of puffs of albuterol in one day the participant used for quick relief from asthma symptoms?
15	MAT_1110	Num	8	MAT_1110F.	6. Since the last study visit, what was the greatest number of nebulizer treatments with albuterol the participant used in one day for quick relief from asthma symptoms?
16	MAT_1130	Num	8		Respondent Initials Date (number of days since enrollment date)

**Data Set Name: maxbd.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	MAX_1000	Num	8	YNF.	1. During the past 2 weeks, has the child had any respiratory infections, colds, or bronchitis?
5	MAX_1010	Num	8	YNF.	2. During the past 48 hours, has the child used any oral decongestants or cold remedies?
6	MAX_1020	Num	8	YNF.	3. During the past 4 hours, has the child consumed caffeine?
7	MAX_1030	Num	8	YNF.	4. During the past 8 hours, has the child used medications with caffeine?
8	MAX_1040	Num	8	YNF.	5. During the past 12 hours, has the child used a long-acting inhaled beta-agonist (e.g. Serevent, formoterol)?
9	MAX_1050	Num	8	YNF.	6. During the past 24 hours, has the child used sustained-release theophylline?
10	MAX_1060	Num	8	YNF.	7. During the past 4 hours, has the child used a short-acting bronchodilator?
11	MAX_1070	Num	8	YNF.	8. Is there any other reason the child should not proceed with the pulmonary function testing?
12	MAX_1080	Num	8	YNF.	9. Is the child eligible to proceed with the pulmonary function testing?
13	MAX_1090	Num	8		10. Standing height (barefoot or thin socks)
14	MAX_1100	Num	8		11. Time spirometry started
15	MAX_1110	Num	8		12a. Results of best effort: FVC
16	MAX_1120	Num	8		12b. Results of best effort: FEV1
17	MAX_1130	Num	8		12c. Results of best effort: FEV1 (% predicted)
18	MAX_1140	Num	8		12d. Results of best effort: FEV1/FVC
19	MAX_1150	Num	8		12e. Results of best effort: FEF25-75
20	MAX_1160	Num	8		12f. Results of best effort: FEF50
21	MAX_1170	Num	8		12g. Results of best effort: FEF75
22	MAX_1180	Num	8		12h. Results of best effort: Peak flow from best effort
23	MAX_1190	Num	8		12i. Results of best effort: FET
24	MAX_1200	Num	8		12j. Results of best effort: FET (Peak Flow)
25	MAX_1210	Num	8		12k. Results of best effort: V backextrapolation ex
26	MAX_1220	Num	8		12l. Results of best effort: V backextrapolation % FVC
27	MAX_1230	Num	8		12m. Results of best effort: ATS Accepted
28	MAX_1240	Num	8		12n. Results of best effort: ATS Error Code
29	MAX_1250	Num	8		13. Time albuterol administered
30	MAX_1260	Num	8		14a. Child's FEV1 after 4 puffs of albuterol: Time spirometry started
31	MAX_1270	Num	8		14b. Child's FEV1 after 4 puffs of albuterol: FEV1
32	MAX_1280	Num	8		14c. Child's FEV1 after 4 puffs of albuterol: FEV1 (% predicted)
33	MAX_1290	Num	8		15. Time albuterol administered
34	MAX_1300	Num	8		16a. Child's FEV1 after additional 2 puffs of albuterol: Time spirometry started

Num	Variable	Type	Len	Format	Label
35	MAX_1310	Num	8		16b. Child's FEV1 after additional 2 puffs of albuterol: FEV1
36	MAX_1320	Num	8		16c. Child's FEV1 after additional 2 puffs of albuterol: FEV1 (% predicted)
37	MAX_1330	Num	8		16d. Child's FEV1 after additional 2 puffs of albuterol: Percent difference in FEV1 ((Question #16b - Question #14b) / (Question #14b)) x 100
38	MAX_1340	Num	8	YNF.	16e. Child's FEV1 after additional 2 puffs of albuterol: Is the percent difference in Question #16d <= 5.0%?
39	MAX_1350	Num	8		17. Time albuterol administered
40	MAX_1360	Num	8		18a. Child's FEV1 after last 2 puffs of albuterol: Time spirometry started
41	MAX_1370	Num	8		18b. Child's FEV1 after last 2 puffs of albuterol: FEV1
42	MAX_1380	Num	8		18c. Child's FEV1 after last 2 puffs of albuterol: FEV1 (% predicted)
43	MAX_1390	Num	8	YNF.	19. In your judgement, was the child's technique acceptable?
44	MAX_1400	Num	8	YNF.	19a. If NO, why was it unacceptable? Inadequate inspiratory effort
45	MAX_1410	Num	8	YNF.	19a. If NO, why was it unacceptable? Inadequate expiratory effort
46	MAX_1420	Num	8	YNF.	19a. If NO, why was it unacceptable? Inadequate duration of expiration
47	MAX_1430	Num	8	YNF.	19a. If NO, why was it unacceptable? Cough during procedure
48	MAX_1440	Num	8	YNF.	19a. If NO, why was it unacceptable? Other (specify)
49	MAX_1450	Num	8	MAX_1450F.	19b. If YES, grade the child's technique.

**Data Set Name: med.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	MED_1000	Num	8	MED_1000F.	1. What type of visit is this?
5	MED_1040	Num	8		Flag: Coordinator signature
6	MED_1050	Num	8		Coordinator signature Date (number of days since enrollment date)

***Data Set Name: medcodes.sas7bdat***

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	CATEGORY	Char	50	Drug Category Description
2	BRAND_NM	Char	48	Brand Name Description
3	GENER_NM	Char	50	Generic Name Description
4	DRUGCODE	Num	8	Drug Code

**Data Set Name: medhx2.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	MHX_1000	Num	8	MHX_1000F.	1. What is your relationship to the child?
5	MHX_1015	Num	8	MHX_1015F.	3a. What is the child's ethnic background?
6	RACE_BLACK	Num	8	YNF.	RACE: Black/African American
7	RACE_WHITE	Num	8	YNF.	RACE: White
8	MHX_1030	Num	8	MHX_1030F.	4. What is the child's gender?
9	MHX_1040	Num	8	YNF.	5. Has a doctor or other health practitioner ever said that the child has heart disease?
10	MHX_1050	Num	8	YNF.	6. During the past 12 months, did the child have any illnesses other than asthma (do not count minor colds or allergies)?
11	MHX_1060	Num	8	YNF.	7. During the past 12 months, has the child had any asthma symptoms?
12	MHX_1061	Num	8	YNF.	7ai. If YES, what were the child's symptoms: Wheezing
13	MHX_1062	Num	8	YNF.	7aii. If YES, what were the child's symptoms: Coughing
14	MHX_1063	Num	8	YNF.	7aiii. If YES, what were the child's symptoms: Shortness of breath
15	MHX_1064	Num	8	YNF.	7aiv. If YES, what were the child's symptoms: Chest tightness
16	MHX_1065	Num	8	YNF.	7av. If YES, what were the child's symptoms: Other
17	MHX_1070	Num	8	YNF.	8a. During the past 12 months, has the child had: Pneumonia
18	MHX_1080	Num	8	YNF.	8b. During the past 12 months, has the child had: Sinusitis
19	MHX_1160	Num	8	YNF.	9. During the past 12 months has the child had any chronic symptoms that affected his/her nose, eyes, or sinuses?
20	MHX_1170	Num	8	MHX_1170_1290F.	9a. During the past 12 months, how would you generally describe these chronic symptoms?
21	MHX_1180	Num	8	MHX_1180TO1190F.	10. During the past 12 months, how frequently has the child used antihistamines and/or decongestants to treat nose, eye, and sinus symptoms (prescription or over the counter)?
22	MHX_1190	Num	8	MHX_1180TO1190F.	11. During the past 12 months, how frequently has the child used nasal steroids to treat nose, and sinus symptoms?
23	MHX_1200	Num	8		12. During the past 12 months, how many times have you contacted or visited a doctor because of problems with the child's nose, eyes, or sinuses?
24	MHX_1210	Num	8		13. During the past 12 months, how many times has the child had a sinus infection that required treatment with antibiotics?
25	MHX_1220	Num	8		14. During the past 12 months, how many times has the child had a sinus infection that required treatment with an oral steroid?
26	MHX_1230	Num	8	YNF.	15. Has the child ever had sinus surgery?
27	MHX_1240	Num	8	YNF.	16. Has the child ever been diagnosed with eczema (atopic dermatitis) by a physician?
28	MHX_1250	Num	8	YNF.	17a. Which parts of the child's body were ever affected by eczema? Head
29	MHX_1260	Num	8	YNF.	17b. Which parts of the child's body were ever affected by eczema? Arms/Hands

Num	Variable	Type	Len	Format	Label
30	MHX_1270	Num	8	YNF.	17c. Which parts of the child's body were ever affected by eczema? Trunk (mid-section or torso)
31	MHX_1280	Num	8	YNF.	17d. Which parts of the child's body were ever affected by eczema? Legs/Feet
32	MHX_1285	Num	8	YNF.	17e. Which parts of the child's body were ever affected by eczema? Other
33	MHX_1290	Num	8	MHX_1170_1290F.	18. How would you describe your child's worst case of eczema?
34	MHX_1300	Num	8	YNDKF.	19a. Has a doctor ever said that the [BIOLOGICAL] father of the child had: Asthma
35	MHX_1310	Num	8	YNDKF.	19b. Has a doctor ever said that the [BIOLOGICAL] father of the child had: Hay fever, eczema, or other atopic disorder?
36	MHX_1320	Num	8	YNDKF.	19c. Has a doctor ever said that the [BIOLOGICAL] father of the child had: Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis?
37	MHX_1330	Num	8	YNDKF.	20a. Has a doctor ever said that the [BIOLOGICAL] mother of the child had: Asthma
38	MHX_1340	Num	8	YNDKF.	20b. Has a doctor ever said that the [BIOLOGICAL] mother of the child had: Hay fever, eczema, or other atopic disorder?
39	MHX_1350	Num	8	YNDKF.	20c. Has a doctor ever said that the [BIOLOGICAL] mother of the child had: Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis?
40	MHX_1360	Num	8	YNF.	21. Does the child have a [BIOLOGICAL] sibling? (Include half siblings)
41	MHX_1370	Num	8	YNDKF.	22a. Has a doctor ever said that the [BIOLOGICAL] sibling of the child had: Asthma (Include half siblings)
42	MHX_1380	Num	8	YNDKF.	22b. Has a doctor ever said that the [BIOLOGICAL] sibling of the child had: Hay fever, eczema, or other atopic disorder? (Include half siblings)
43	MHX_1390	Num	8	YNDKF.	22c. Has a doctor ever said that the [BIOLOGICAL] sibling of the child had: Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis? (Include half siblings)
44	MHX_1400	Num	8	YNDKF.	23. Did the child's mother smoke while she was pregnant with this child?
45	MHX_1410	Num	8	YNDKF.	24a. During which part(s) of the pregnancy did the child's mother smoke? - First 3 months
46	MHX_1420	Num	8	YNDKF.	24b. During which part(s) of the pregnancy did the child's mother smoke? - Middle 3 months
47	MHX_1430	Num	8	YNDKF.	24c. During which part(s) of the pregnancy did the child's mother smoke? - Last 3 months
48	MHX_1440	Num	8	YNDKF.	25a. Between the time the child was born and he/she turned two years old, did the child's mother (or stepmother or female guardian) smoke?
49	MHX_1450	Num	8	YNDKF.	25b. Between the time the child was born and he/she turned two years old, did the child's father (or stepfather or male guardian) smoke?
50	MHX_1460	Num	8	YNDKF.	25c. Between the time the child was born and he/she turned two years old, were there any other smokers in the household? (Include visitors, such as grandparents or babysitters, who visited at least weekly)
51	MHX_1470	Num	8	YNDKF.	26a. Since the child turned two years old and until the present time OR until the start of first grade, did the child's mother (or stepmother or female guardian) smoke?

Num	Variable	Type	Len	Format	Label
52	MHX_1480	Num	8	YNDKF.	26b. Since the child turned two years old and until the present time OR until the start of first grade, did the child's father (or stepfather or male guardian)?
53	MHX_1490	Num	8	YNDKF.	26c. Since the child turned two years old and until the present time OR until the start of first grade, were there any other smokers in the household? (Incl. visitors, such as grandparents or babysitters, who visited at least weekly)
54	AGE	Num	8		
55	RACE_OTHER	Num	8	YNF.	RACE: American Indian/Alaskan Native, Asian, or Native Hawai'ian/Other Pacific Islander

**Data Set Name: metha.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	MTH_1000	Num	8	YNF.	1. During the past 4 weeks, has the child had any respiratory infections (i.e., upper respiratory infection, cold, or bronchitis)?
5	MTH_1010	Num	8	YNF.	2. Has it been less than 4 weeks since the child last took an oral steroid (i.e., prednisolone, prednisone)?
6	MTH_1020	Num	8	YNF.	3. During the past 4 weeks, has the child had any other severe acute illness?
7	MTH_1030	Num	8	YNF.	3. If YES, has the child received permission from the supervising physician to proceed with the methacholine challenge testing?
8	MTH_1040	Num	8	YNF.	4. Is the child currently having an acute asthma attack?
9	MTH_1050	Num	8	YNF.	5. During the past 24 hours, has the child used sustained-release theophylline?
10	MTH_1060	Num	8	YNF.	6. During the past 12 hours, has the child used a long-acting bronchodilator (i.e., salmeterol)?
11	MTH_1070	Num	8	YNF.	7. During the past 4 hours, has the child used a short-acting bronchodilator?
12	MTH_1080	Num	8	YNF.	8. During the past 4 hours, has the child had any caffeine (i.e., chocolate, cola drinks, caffeinated coffee or tea, or medication with caffeine)?
13	MTH_1090	Num	8	YNF.	9. Is the child using any anti-inflammatories?
14	MTH_1100	Num	8		9a. Inhaled corticosteroid
15	MTH_1110	Num	8		9a. Inhaled corticosteroid - Date (number of days since enrollment date)
16	MTH_1120	Num	8		9a. Cromolyn/nedocromil
17	MTH_1130	Num	8		9a. Cromolyn/nedocromil - Date (number of days since enrollment date)
18	MTH_1140	Num	8		9a. Leukotriene receptor antagonists
19	MTH_1150	Num	8		9a. Leukotriene receptor antagonists - Date (number of days since enrollment date)
20	MTH_1160	Num	8	YNF.	10. Does the child have a baseline (pre-diluent) FEV1 less than 70% of predicted FEV1?
21	MTH_1170	Num	8	YNF.	11. Is there any other reason you should not proceed with the methacholine challenge?
22	MTH_1180	Num	8	YNF.	12. Is the child eligible to proceed with the diluent (solution #0) pulmonary function testing for the methacholine challenge?
23	MTH_1190	Num	8		13. Standing height (barefoot or thin socks) - cm
24	MTH_1210	Num	8	YNF.	14. Was baseline (pre-diluent) spirometry completed?
25	MTH_1280	Num	8		15. Earliest expiration date of all 10 methacholine solutions (number of days since enrollment date)
26	MTH_1290	Num	8		16a. FVC/FEV1 for serial challenges Solution 0 (diluent) - FEV1
27	MTH_1300	Num	8		16a. FVC/FEV1 for serial challenges Solution 0 (diluent) - FVC
28	MTH_1310	Num	8		16b. FVC/FEV1 for serial challenges Solution 1 (0.098 mg/ml) - FEV1
29	MTH_1320	Num	8		16b. FVC/FEV1 for serial challenges Solution 1 (0.098 mg/ml) - FVC
30	MTH_1330	Num	8		16c. FVC/FEV1 for serial challenges Solution 2 (0.195 mg/ml) - FEV1
31	MTH_1340	Num	8		16c. FVC/FEV1 for serial challenges Solution 2 (0.195 mg/ml) - FVC
32	MTH_1350	Num	8		16d. FVC/FEV1 for serial challenges Solution 3 (0.391 mg/ml) - FEV1

Num	Variable	Type	Len	Format	Label
33	MTH_1360	Num	8		16d. FVC/FEV1 for serial challenges Solution 3 (0.391 mg/ml) - FVC
34	MTH_1370	Num	8		16e. FVC/FEV1 for serial challenges Solution 4 (0.781 mg/ml) - FEV1
35	MTH_1380	Num	8		16e. FVC/FEV1 for serial challenges Solution 4 (0.781 mg/ml) - FVC
36	MTH_1390	Num	8		16f. FVC/FEV1 for serial challenges Solution 5 (1.563 mg/ml) - FEV1
37	MTH_1400	Num	8		16f. FVC/FEV1 for serial challenges Solution 5 (1.563 mg/ml) - FVC
38	MTH_1410	Num	8		16g. FVC/FEV1 for serial challenges Solution 6 (3.125 mg/ml) - FEV1
39	MTH_1420	Num	8		16g. FVC/FEV1 for serial challenges Solution 6 (3.125 mg/ml) - FVC
40	MTH_1430	Num	8		16h. FVC/FEV1 for serial challenges Solution 7 (6.25 mg/ml) - FEV1
41	MTH_1440	Num	8		16h. FVC/FEV1 for serial challenges Solution 7 (6.25 mg/ml) - FVC
42	MTH_1450	Num	8		16i. FVC/FEV1 for serial challenges Solution 8 (12.5 mg/ml) - FEV1
43	MTH_1460	Num	8		16i. FVC/FEV1 for serial challenges Solution 8 (12.5 mg/ml) - FVC
44	MTH_1470	Num	8		16j. FVC/FEV1 for serial challenges Solution 9 (25 mg/ml) - FEV1
45	MTH_1480	Num	8		16j. FVC/FEV1 for serial challenges Solution 9 (25 mg/ml) - FVC
46	MTH_1490	Num	8		17. PC20
47	MTH_1500	Num	8		17a. Time methacholine challenge was completed (based on 24-hour clock)
48	MTH_1510	Num	8		18a. FEV1
49	MTH_1530	Num	8		18b. Time of FEV1 in Question #18a (based on 24-hour clock)
50	MTH_1540	Num	8	YNF.	18c. Was the FEV1 from Question #18a $\geq$ the Methacholine Reversal Reference Value in the gray box on page 2 of this form?
51	MTH_1550	Num	8	YNF.	19. Was additional treatment used in the first hour?
52	MTH_1560	Num	8	YNF.	19a. Additional albuterol by MDI
53	MTH_1570	Num	8	NUMPUFFF.	19ai. Number of additional puffs of albuterol administered
54	MTH_1580	Num	8	YNF.	19b. Nebulized beta-agonist
55	MTH_1590	Num	8	YNF.	19c. Subcutaneous epinephrine
56	MTH_1600	Num	8	YNF.	19d. Implementation of clinic emergency protocol or algorithm
57	MTH_1610	Num	8	YNF.	19e. Other
58	MTH_1620	Num	8		20a. FEV1
59	MTH_1640	Num	8		20b. Time of FEV1 in Question #20a (based on 24-hour clock)
60	MTH_1650	Num	8	YNF.	20c. Was the FEV1 from Question #20a $\geq$ the Methacholine Reversal Reference Value in the gray box on page 2 of this form?
61	MTH_1660	Num	8	YNF.	21. Was additional treatment used after one hour?
62	MTH_1670	Num	8	YNF.	21a. Additional albuterol by MDI
63	MTH_1680	Num	8	NUMPUFFF.	21ai. Number of additional puffs of albuterol administered
64	MTH_1690	Num	8	YNF.	21b. Nebulized beta-agonist
65	MTH_1700	Num	8	YNF.	21c. Subcutaneous epinephrine
66	MTH_1710	Num	8	YNF.	21d. Implementation of clinic emergency protocol or algorithm
67	MTH_1720	Num	8	YNF.	21e. Treatment in the emergency room
68	MTH_1730	Num	8	YNF.	21f. Overnight hospitalization
69	MTH_1740	Num	8	YNF.	21g. Other

Num	Variable	Type	Len	Format	Label
70	MTH_1750	Num	8		22a. FEV1
71	MTH_1770	Num	8		22b. Time of FEV1 in Question #22a (based on 24-hour clock)
72	MTH_1780	Num	8	YNF.	22c. Was the FEV1 from Question #22a $\geq$ the Methacholine Reversal Reference Value in the gray box on page 2 of this form?
73	MTH_1790	Num	8		Flag: Physician/CC signature
74	MTH_1800	Num	8		Physician/CC signature Date (number of days since enrollment date)

**Data Set Name: phone.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	PHN_1000	Num	8		1. How many nights did the participant wake up because of asthma?
5	PHN_1010	Num	8		2. On how many days was the participant's AM peak flow in the red zone?
6	PHN_1020	Num	8		3. On how many days was the participant's PM peak flow in the red zone?
7	PHN_1030	Num	8		4. On how many days did the participant rate his/her coughing from asthma as 3 (severe)?
8	PHN_1040	Num	8		5. On how many days did the participant rate his/her wheezing as 3 (severe)?
9	PHN_1050	Num	8		6. On how many days did the participant take 9 or more puffs from the Rescue inhaler for asthma signs or low peak flow?
10	PHN_1060	Num	8	YNF.	7. Since the last study visit, not counting hospitalizations, did the participant have an unscheduled doctor or health care provider visit because of acute asthma?
11	PHN_1070	Num	8		7a. If YES, how many visits?
12	PHN_1080	Num	8	YNF.	8. Since the last study visit, has the participant been hospitalized for asthma?
13	PHN_1090	Num	8	YNF.	9. Do you have any questions that I can help to answer?

**Data Set Name: phy\_exam.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	PX_1000	Num	8	YNF.	1. Was the Harpenden stadiometer calibrated, per CARE MOP, immediately prior to the visit?
5	PX_1010	Num	8		2. Time measurements started (based on 24-hour clock)
6	PX_1020	Num	8		3a. Standing height (barefoot or thin socks) First - measurement (cm)
7	PX_1030	Num	8		3b. Standing height (barefoot or thin socks) Second - measurement (cm)
8	PX_1040	Num	8		3c. Standing height (barefoot or thin socks) Third - measurement (cm)
9	PX_1041	Num	8		3d. Standing height (barefoot or thin socks) Average height measurement (cm)
10	PX_1050	Num	8		4. Weight (shoes off, light clothing) (kg)
11	PX_1045	Num	8	YNF.	3e. In your judgement, was the subject's height measurement acceptable?
12	PX_1060	Num	8	YNF.	5. Resting blood pressure - systolic (mm Hg)
13	PX_1070	Num	8		5. Resting blood pressure - diastolic (mm Hg)
14	PX_1080	Num	8	YNF.	6. Is chest auscultation clear?
15	PX_1090	Num	8	YNF.	6a. Slight expiratory wheeze
16	PX_1100	Num	8	YNF.	6b. Loud expiratory wheeze
17	PX_1110	Num	8	YNF.	6c. Inspiratory and expiratory wheezes
18	PX_1120	Num	8	YNF.	6d. Acute respiratory distress
19	PX_1130	Num	8	YNF.	6e. Rales and/or rhonchi
20	PX_1140	Num	8	YNF.	6f. Crackles
21	PX_1150	Num	8	YNF.	6g. Other
22	PX_1155	Num	8	YNF.	7. Does the subject have evidence of oral candidiasis?
23	PX_1160	Num	8		8. In the past month, has the child had any symptoms affecting his/her nose, eyes, or sinuses?
24	PX_1170	Num	8	PX_1170F.	8a. In general, how would you describe the child's symptoms?
25	PX_1180	Num	8	PX_1180_1190F.	9. How frequently has the child used antihistamines and/or decongestants to treat the nose, eye, and sinus symptoms (prescription or over the counter)?
26	PX_1190	Num	8	PX_1180_1190F.	10. How frequently has the child used nasal steroids to treat the nose, eye, and sinus symptoms?
27	PX_1200	Num	8		11. MALE TANNER STAGING - Genital stage (range 1-5)
28	PX_1210	Num	8		12. MALE TANNER STAGING - Testicular volume (smallest of right and left) (cc)
29	PX_1220	Num	8		13. MALE TANNER STAGING - Pubic hair stage (range 1-5)
30	PX_1230	Num	8		14. FEMALE TANNER STAGING - Breast stage (range 1-5)
31	PX_1240	Num	8		15. FEMALE TANNER STAGING - Pubic hair stage (range 1-5)
32	PX_1250	Num	8	YNF.	16. FEMALE TANNER STAGING - Has menarche occurred?
33	PX_1260	Num	8		17. FEMALE TANNER STAGING - What was the child's age at menarche?
34	PX_1270	Num	8		Flag: Physician/CC signature

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
35	PX_1280	Num	8		Physician/CC signature Date (number of days since enrollment date)

**Data Set Name: priormed.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	PRM_1000	Num	8	YNF.	2. In the past 12 months, has the participant used any asthma medication(s) other than albuterol (Proventil, Ventolin)?
5	PRM_1010	Num	8		3a. In the past 12 months, for how many months has the participant used the following medications: Salmeterol (Serevent) or formoterol (Foradil)
6	PRM_1020	Num	8		3b. In the past 12 months, for how many months has the participant used the following medications: Inhaled or nebulized corticosteroids [beclomethasone (Beclivent, Vanceril, QVAR), budesonide (Pulmicort), flunisolide (Aerobid), etc.]
7	PRM_1030	Num	8		3c. In the past 12 months, for how many months has the participant used the following medications: Montelukast (Singulair)
8	PRM_1040	Num	8		3d. In the past 12 months, for how many months has the participant used the following medications: Zafirlukast (Accolate)
9	PRM_1050	Num	8		3e. In the past 12 months, for how many months has the participant used the following medications: Theophylline (Slo-bid, Theo-dur, Slo-Phyllin)
10	PRM_1060	Num	8		3f. In the past 12 months, for how many months has the participant used the following medications: Advair
11	PRM_1065	Num	8		3g. In the past 12 months, for how many months has the participant used the following medications: Cromolyn/Nedocromil
12	PRM_1070	Num	8		3h. In the past 12 months, for how many months has the participant used the following medications: Other
13	PRM_1080	Num	8		3i. In the past 12 months, for how many months has the participant used the following medications: Other
14	PRM_1090	Num	8	PRM_1090F.	4. In the past 12 months, how many courses of prednisolone (Prelone) or prednisone has the participant taken?
15	PRM_1100	Num	8	PRM_1100F.	1. Who is the respondent?

**Data Set Name: serious.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	SER_1000	Num	8		1. Date of Adverse Event (number of days since enrollment date)
5	SER_1010	Char	6		2. Description of Adverse Event (ICD9 Code)
6	SER_1020	Num	8		3. Time interval between the last administration of the study drug and the Adverse Event.
7	SER_1030	Num	8	SER_1030F.	4. What was the unit of time for the above interval?
8	SER_1040	Num	8	YNF.	5a. Why was the event serious? - Fatal event
9	SER_1050	Num	8	YNF.	5b. Why was the event serious? - Life-threatening event
10	SER_1060	Num	8	YNF.	5c. Why was the event serious? - Inpatient hospitalization required
11	SER_1070	Num	8		5c1. Admission date (number of days since enrollment date)
12	SER_1080	Num	8		5c2. Discharge date (number of days since enrollment date)
13	SER_1090	Num	8	YNF.	5d. Why was the event serious? - Hospitalization prolonged
14	SER_1100	Num	8	YNF.	5e. Why was the event serious? - Disabling or incapacitating
15	SER_1110	Num	8	YNF.	5f. Why was the event serious? - Overdose
16	SER_1120	Num	8	YNF.	5g. Why was the event serious? - Cancer
17	SER_1130	Num	8	YNF.	5h. Why was the event serious? - Congenital anomaly
18	SER_1140	Num	8	YNF.	5i. Why was the event serious? - Serious laboratory abnormality with clinical symptoms
19	SER_1145	Num	8	YNF.	5j. Why was the event serious? - Height failure
20	SER_1150	Num	8	YNF.	5l. Why was the event serious? - Other
21	SER_1147	Num	8	YNNAF.	5k. Why was the event serious? - Pregnancy
22	SER_1160	Num	8	YNF.	6a. What, in your opinion, caused the event? - Toxicity of study drug(s)
23	SER_1170	Num	8	YNF.	6b. What, in your opinion, caused the event? - Withdrawal of study drug(s)
24	SER_1180	Num	8	YNF.	6c. What, in your opinion, caused the event? - Concurrent medication
25	SER_1190	Num	8	YNF.	6d. What, in your opinion, caused the event? - Concurrent disorder
26	SER_1200	Num	8	YNF.	6e. What, in your opinion, caused the event? - Other event

**Data Set Name: sexam.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	SX_1000	Num	8	YNF.	1. Was the Harpenden stadiometer calibrated, per CARE MOP, immediately prior to the visit?
5	SX_1010	Num	8		2. Time measurements started (based on 24-hour clock)
6	SX_1020	Num	8		3a. Standing height (barefoot or thin socks) - First measurement (cm)
7	SX_1030	Num	8		3b. Standing height (barefoot or thin socks) - Second measurement (cm)
8	SX_1040	Num	8		3c. Standing height (barefoot or thin socks) - Third measurement (cm)
9	SX_1041	Num	8		3d. Standing height (barefoot or thin socks) - Average height measurement (cm)
10	SX_1045	Num	8	YNF.	3e. In your judgement, was the subject's height measurement acceptable?
11	SX_1050	Num	8		4. Weight (shoes off, light clothing) (kg)
12	SX_1060	Num	8	YNF.	5. Is chest auscultation clear?
13	SX_1070	Num	8	YNF.	5a. Slight expiratory wheeze
14	SX_1080	Num	8	YNF.	5b. Loud expiratory wheeze
15	SX_1090	Num	8	YNF.	5c. Inspiratory and expiratory wheezes
16	SX_1100	Num	8	YNF.	5d. Acute respiratory distress
17	SX_1110	Num	8	YNF.	5e. Rales and/or rhonchi
18	SX_1120	Num	8	YNF.	5f. Crackles
19	SX_1130	Num	8	YNF.	5g. Other
20	SX_1135	Num	8	YNF.	6. Does the subject have evidence of oral candidiasis?
21	SX_1140	Num	8	YNF.	7. Does the child currently have any symptoms that affect his/her nose, eyes, or sinuses?
22	SX_1150	Num	8	SX_1150_1260F.	8. In general, how would you describe the child's symptoms?
23	SX_1160	Num	8	SX_1160_1170F.	9. Since the last clinic visit, how frequently has the child used antihistamines and/or decongestants to treat nose, eye, and sinus symptoms (prescription or over the counter)?
24	SX_1170	Num	8	SX_1160_1170F.	10. Since the last clinic visit, how frequently has the child used nasal steroids to treat nose, eye, and sinus symptoms?
25	SX_1180	Num	8		11. Since the last clinic visit, how many times have you contacted or visited a doctor because of problems with the child's nose, eyes, or sinuses?
26	SX_1190	Num	8		12. Since the last clinic visit, how many times has the child had a sinus infection that required treatment with antibiotics?
27	SX_1200	Num	8		13. Since the last clinic visit, how many times has the child had a sinus infection that required treatment with an oral steroid?
28	SX_1210	Num	8	YNF.	14. Does the child currently have any eczema?
29	SX_1220	Num	8	YNF.	15a. Which parts of the child's body are affected by eczema? Head
30	SX_1230	Num	8	YNF.	15b. Which parts of the child's body are affected by eczema? Arms/Hands
31	SX_1240	Num	8	YNF.	15c. Which parts of the child's body are affected by eczema? Trunk (mid-section or torso)

Num	Variable	Type	Len	Format	Label
32	SX_1250	Num	8	YNF.	15d. Which parts of the child's body are affected by eczema? Legs/Feet
33	SX_1255	Num	8	YNF.	15e. Which parts of the child's body are affected by eczema? Other
34	SX_1260	Num	8	SX_1150_1260F.	16. In general, how would you describe the child's eczema?
35	SX_1270	Num	8		Flag: Physician/CC signature
36	SX_1280	Num	8		Physician/CC signature Date (number of days since enrollment date)
37	SX_1300	Num	8	YNF.	Ask the respondent: Has the child experienced any new medical conditions since the last clinic visit?

**Data Set Name: skin.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	SKN_2000	Num	8	YNF.	1. Has the subject had a previous skin test using CARE procedures within the approved time limit?
5	SKN_2010	Num	8		1. Date of previous skin test (number of days since enrollment date)
6	SKN_1000	Num	8	YNF.	2. Has the child used any of the medications, listed in the skin test section of the CARE MOP, within the exclusionary periods?
7	SKN_1010	Num	8	YNF.	3. Has the child ever had a severe systemic reaction to allergy skin testing?
8	SKN_1020	Num	8	YNF.	4. Has the child ever had an anaphylactic reaction to egg?
9	SKN_1030	Num	8	YNF.	5. Has the child ever had an anaphylactic reaction to peanut?
10	SKN_1040	Num	8	YNF.	6. Has the child ever had an anaphylactic reaction to milk?
11	SKN_1050	Num	8		Time test sites pricked (based on 24-hour clock)
12	SKN_1060	Num	8		Time test sites evaluated (based on 24-hour clock)
13	SKN_1070	Num	8	YNF.	8. Saline (A8) - Was there a reaction?
14	SKN_1080	Num	8		8. Saline (A8) - Largest Wheal Diameter (mm)
15	SKN_1090	Num	8		8. Saline (A8) - Perpindicular Wheal Diameter (mm)
16	SKN_1100	Num	8	YNF.	2. Mite Mix (A2) - Was there a reaction?
17	SKN_1110	Num	8		2. Mite Mix (A2) - Largest Wheal Diameter (mm)
18	SKN_1120	Num	8		2. Mite Mix (A2) - Perpindicular Wheal Diameter (mm)
19	SKN_1130	Num	8	YNF.	3. Roach Mix (A3) - Was there a reaction?
20	SKN_1140	Num	8		3. Roach Mix (A3) - Largest Wheal Diameter (mm)
21	SKN_1150	Num	8		3. Roach Mix (A3) - Perpindicular Wheal Diameter (mm)
22	SKN_1160	Num	8	YNF.	4. Cat (A4) - Was there a reaction?
23	SKN_1170	Num	8		4. Cat (A4) - Largest Wheal Diameter (mm)
24	SKN_1180	Num	8		4. Cat (A4) - Perpindicular Wheal Diameter (mm)
25	SKN_1190	Num	8	YNF.	5. Dog (A5) - Was there a reaction?
26	SKN_1200	Num	8		5. Dog (A5) - Largest Wheal Diameter (mm)
27	SKN_1210	Num	8		5. Dog (A5) - Perpindicular Wheal Diameter (mm)
28	SKN_1220	Num	8	YNF.	6. Mold Mix (A6) - Was there a reaction?
29	SKN_1230	Num	8		6. Mold Mix (A6) - Largest Wheal Diameter (mm)
30	SKN_1240	Num	8		6. Mold Mix (A6) - Perpindicular Wheal Diameter (mm)
31	SKN_1250	Num	8	YNF.	7. Grass Mix (A7) - Was there a reaction?
32	SKN_1260	Num	8		7. Grass Mix (A7) - Largest Wheal Diameter (mm)
33	SKN_1270	Num	8		7. Grass Mix (A7) - Perpindicular Wheal Diameter (mm)
34	SKN_1280	Num	8	YNF.	9. Tree Mix (B1) - Was there a reaction?
35	SKN_1290	Num	8		9. Tree Mix (B1) - Largest Wheal Diameter (mm)

Num	Variable	Type	Len	Format	Label
36	SKN_1300	Num	8		9. Tree Mix (B1) - Perpindicular Wheal Diameter (mm)
37	SKN_1310	Num	8	YNF.	10. Weed Mix (B2) - Was there a reaction?
38	SKN_1320	Num	8		10. Weed Mix (B2) - Largest Wheal Diameter (mm)
39	SKN_1330	Num	8		10. Weed Mix (B2) - Perpindicular Wheal Diameter (mm)
40	SKN_1340	Num	8	YNF.	11. Milk (B3) - Was there a reaction?
41	SKN_1350	Num	8		11. Milk (B3) - Largest Wheal Diameter (mm)
42	SKN_1360	Num	8		11. Milk (B3) - Perpindicular Wheal Diameter (mm)
43	SKN_1370	Num	8	YNF.	12. Egg (B4) - Was there a reaction?
44	SKN_1380	Num	8		12. Egg (B4) - Largest Wheal Diameter (mm)
45	SKN_1390	Num	8		12. Egg (B4) - Perpindicular Wheal Diameter (mm)
46	SKN_1400	Num	8	YNF.	13. Peanut (B5) - Was there a reaction?
47	SKN_1410	Num	8		13. Peanut (B5) - Largest Wheal Diameter (mm)
48	SKN_1420	Num	8		13. Peanut (B5) - Perpindicular Wheal Diameter (mm)
49	SKN_1430	Num	8	YNF.	15. Other (B7) - Was there a reaction?
50	SKN_1440	Num	8		15. Other (B7) - Largest Wheal Diameter (mm)
51	SKN_1450	Num	8		15. Other (B7) - Perpindicular Wheal Diameter (mm)
52	SKN_1460	Num	8	YNF.	14. Other (B6) - Was there a reaction?
53	SKN_1470	Num	8		14. Other (B6) - Largest Wheal Diameter (mm)
54	SKN_1480	Num	8		14. Other (B6) - Perpindicular Wheal Diameter (mm)
55	SKN_1490	Num	8	YNF.	1. Histamine (A1) - Was there a reaction?
56	SKN_1500	Num	8		1. Histamine (A1) - Largest Wheal Diameter (mm)
57	SKN_1510	Num	8		1. Histamine (A1) - Perpindicular Wheal Diameter (mm)
58	SKN_1520	Num	8	YNF.	16. Other (B8) - Was there a reaction?
59	SKN_1530	Num	8		16. Other (B8) - Largest Wheal Diameter (mm)
60	SKN_1540	Num	8		16. Other (B8) - Perpindicular Wheal Diameter (mm)

**Data Set Name: spiro.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	SPR_1000	Num	8	YNF.	1. During the past 24 hours, has the participant used sustained-release theophylline?
5	SPR_1010	Num	8	YNF.	2. During the past 12 hours, has the participant used a long-acting bronchodilator (i.e., salmeterol)?
6	SPR_1020	Num	8	YNF.	3. During the past 4 hours, has the participant used a short-acting bronchodilator?
7	SPR_1030	Num	8	YNF.	4. During the past 2 weeks, has the participant had any respiratory infections, colds, or bronchitis?
8	SPR_1035	Num	8	YNF.	5. Is there any other reason the participant should not proceed with the pulmonary function testing?
9	SPR_1040	Num	8	YNF.	6. Is the participant eligible to proceed with the pulmonary function testing?
10	SPR_1055	Num	8	YNF.	8. Did the participant refuse to perform the procedure?
11	SPR_1060	Num	8		9. Time spirometry started (based on 24-hour clock)
12	SPR_1080	Num	8		10a. Results of best effort - FVC
13	SPR_1090	Num	8		10b. Results of best effort - FEV1
14	SPR_1100	Num	8		10c. Results of best effort - FEV1 (% predicted)
15	SPR_1110	Num	8		10d. Results of best effort - FEV1/FVC
16	SPR_1120	Num	8		10e. Results of best effort - FEF25-75
17	SPR_1130	Num	8		10f. Results of best effort - FEF50
18	SPR_1140	Num	8		10g. Results of best effort - FEF75
19	SPR_1150	Num	8		10h. Results of best effort - PEF (best effort)
20	SPR_1151	Num	8		10i. Results of best effort - FET
21	SPR_1152	Num	8		10j. Results of best effort - FET PEF
22	SPR_1153	Num	8		10k. Results of best effort - V backextrapolation ex
23	SPR_1154	Num	8		10l. Results of best effort - V backextrapolation % FVC
24	SPR_1155	Num	8		10m. Results of best effort - ATS Accepted
25	SPR_1156	Num	8		10n. Results of best effort - ATS Error Code
26	SPR_1290	Num	8	YNF.	11. In your judgement, was the participant's prebronchodilator technique acceptable?
27	SPR_1300	Num	8	YNF.	11a. If NO, why was it unacceptable? Inadequate inspiratory effort
28	SPR_1310	Num	8	YNF.	11a. If NO, why was it unacceptable? Inadequate expiratory effort
29	SPR_1320	Num	8	YNF.	11a. If NO, why was it unacceptable? Inadequate duration of expiration
30	SPR_1330	Num	8	YNF.	11a. If NO, why was it unacceptable? Cough during procedure
31	SPR_1335	Num	8	YNF.	11a. If NO, why was it unacceptable? Participant refusal during test
32	SPR_1340	Num	8	YNF.	11a. If NO, why was it unacceptable? Other
33	SPR_1350	Num	8	SPR_1350_1280F.	11b. If YES, grade the participant's technique.
34	SPR_1260	Num	8	YNF.	15. In your judgement, was the participant's postbronchodilator technique acceptable?

Num	Variable	Type	Len	Format	Label
35	SPR_1170	Num	8		13. Time postbronchodilator spirometry started (based on 24-hour clock)
36	SPR_1180	Num	8		14a. Results of best effort - FVC
37	SPR_1190	Num	8		14b. Results of best effort - FEV1
38	SPR_1200	Num	8		14c. Results of best effort - FEV1 (% predicted)
39	SPR_1210	Num	8		14d. Results of best effort - FEV1/FVC
40	SPR_1220	Num	8		14e. Results of best effort - FEF25-75
41	SPR_1230	Num	8		14f. Results of best effort - FEF50
42	SPR_1240	Num	8		14g. Results of best effort - FEF75
43	SPR_1250	Num	8		14h. Results of best effort - PEF (best effort)
44	SPR_1251	Num	8		14i. Results of best effort - FET
45	SPR_1252	Num	8		14j. Results of best effort - FET PEF
46	SPR_1253	Num	8		14k. Results of best effort - V backextrapolation ex
47	SPR_1254	Num	8		14l. Results of best effort - V backextrapolation % FVC
48	SPR_1255	Num	8		14m. Results of best effort - ATS Accepted
49	SPR_1256	Num	8		14n. Results of best effort - ATS Error Code
50	SPR_1270	Num	8	YNF.	15a. If NO, why was it unacceptable? Inadequate inspiratory effort
51	SPR_1271	Num	8	YNF.	15a. If NO, why was it unacceptable? Inadequate expiratory effort
52	SPR_1272	Num	8	YNF.	15a. If NO, why was it unacceptable? Inadequate duration of expiration
53	SPR_1273	Num	8	YNF.	15a. If NO, why was it unacceptable? Cough during procedure
54	SPR_1275	Num	8	YNF.	15a. If NO, why was it unacceptable? Participant refusal during test
55	SPR_1274	Num	8	YNF.	15a. If NO, why was it unacceptable? Other
56	SPR_1280	Num	8	SPR_1350_1280F.	15b. If YES, grade the participant's technique.

**Data Set Name: term.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	TRM_1010	Num	8	YNF.	1. Has the participant completed the study?
5	TRM_1020	Num	8	YNF.	2. Has the participant been deemed ineligible during the assessment/characterization period?
6	TRM_1030	Num	8	YNNAF.	3. Has the participant been withdrawn from the study due to pregnancy?
7	TRM_1050	Num	8		Participant's Initials Date (number of days since enrollment date)
8	TRM_1060	Num	8	YNF.	4. Has the participant been assigned treatment failure status?
9	TRM_1070	Num	8	YNF.	5. Is there any other reason why the participant is being terminated from the study?
10	TRM_1080	Num	8	TRM_1080F.	5. If YES, indicate the primary reason.
11	TRM_1090	Num	8	YNF.	6. Has the participant been lost to follow up?
12	TRM_1100	Num	8	YNF.	7. Has the participant experienced a serious adverse event (i.e., an adverse event resulting in death or hospitalization, etc.)?
13	TRM_1110	Num	8	YNF.	8. Did a physician initiate the termination of study participation?
14	TRM_1120	Num	8		Flag: Clinic Coordinator's Signature
15	TRM_1130	Num	8		Date of Clinic Coordinator's Signature (number of days since enrollment date)
16	TRM_1140	Num	8		Flag: Principal Investigator's Signature
17	TRM_1150	Num	8		Date of Principal Investigator's Signature (number of days since enrollment date)

**Data Set Name: trtfail.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	VDATE	Num	8		Visit Date (number of days since enrollment date)
4	TXF_1000	Num	8	YNF.	1. Has the participant required emergency department treatment for asthma?
5	TXF_1010	Num	8	YNF.	2. Has the participant been hospitalized for asthma?
6	TXF_1020	Num	8	YNF.	3. Has the participant had a hypoxic seizure due to asthma?
7	TXF_1030	Num	8	YNF.	4. Has the participant required intubation for asthma?
8	TXF_1040	Num	8	YNF.	5a. Has the participant received any of the following non-study medications? Systemic (oral, IV, IM, SC) corticosteroids
9	TXF_1050	Num	8	YNF.	5b. Has the participant received any of the following non-study medications? Inhaled oral corticosteroids
10	TXF_1060	Num	8	YNF.	5c. Has the participant received any of the following non-study medications? Salmeterol
11	TXF_1070	Num	8	YNF.	5d. Has the participant received any of the following non-study medications? Theophylline
12	TXF_1080	Num	8	YNF.	5e. Has the participant received any of the following non-study medications? Leukotriene modifier (Accolate (zafirlukast), Singulair (montelukast), Zileutin (zyflo))
13	TXF_1090	Num	8	YNF.	6. Is the participant a treatment failure?
14	TXF_1100	Num	8		7. Date treatment failure occurred (number of days since enrollment date)
15	TXF_1110	Num	8		Flag: Physician/CC signature
16	TXF_1120	Num	8		Date of Physician/CC signature (number of days since enrollment date)