

**Data Set Name: aeclin.sas7bdat**

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJ_ID	Num	8			Public Subject ID
2	VNUM	Num	8			Visit Number
3	CAE_1020	Num	8	3.	3.	DESCRIPTION OF ADVERSE EVENT
4	CAE_1030	Char	6	\$6.	\$6.	ICD9 CODE
5	CAE_1040	Num	8			DATE STARTED
6	CAE_1050	Num	8			DATE STOPPED
7	CAE_1060	Num	8	YESF.	2.	ONGOING at current contact
8	CAE_1080	Num	8	CAE_1080F.	2.	Type
9	CAE_1090	Num	8	CAE_1090F.	2.	SEVERITY
10	CAE_1100	Num	8	YNF.	2.	Serious
11	CAE_1110	Num	8	CAE_1110F.	2.	LIKELIHOOD OF RELATIONSHIP TO STUDY DRUG
12	CAE_1120	Num	8	CAE_1120F.	2.	CHANGE IN STUDY MEDICATIONS
13	CAE_1130	Num	8	CAE_1130F.	2.	OUTCOME
14	CAE_1140	Num	8	CAE_1140F.	2.	TREATMENT REQUIRED
15	CAE_1150	Num	8	YESF.	2.	ONGOING at final contact

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

Num	Variable	Type	Len	Format	Informat	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.	2.	Who is completing the questionnaire?
5	AHX_1010	Num	8	AHX_1010TO1030F.	2.	On average, during the past MONTH, how often has the participant had a cough, wheeze, shortness of breath, or chest tightness?
6	AHX_1020	Num	8	AHX_1010TO1030F.	2.	On average, during the past MONTH, how often has the participant had cough, wheeze, shortness of breath, or chest tightness while exercising or playing?
7	AHX_1030	Num	8	AHX_1010TO1030F.	2.	On average, during the past MONTH, how often does asthma keep the participant from doing what he/she wants?
8	AHX_1040	Num	8	AHX_1040F.	2.	On average, during the past MONTH, how often was the participant awakened from sleep because of coughing, wheezing, shortness of breath, or chest tightness?
9	AHX_1050	Num	8	AHX_1050F.	2.	In general, during the past MONTH, how bothered was the participant by his/her asthma?
10	AHX_1060	Num	8	2.	2.	On average, during the past MONTH, how many days per week did days/week the participant use an albuterol inhaler or nebulizer?

**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	CMD_1000	Num	8		CODE
4	CMD_1010	Num	8		NAME OF MEDICATION
5	CMD_1020	Num	8		RELATED EVENT
6	CMD_1030	Num	8	NAF.	RELATED EVENT
7	CMD_1060	Num	8		START DATE
8	CMD_1090	Num	8		STOP DATE
9	CMD_1100	Num	8	YESF.	ONGOING AT CURRENT CONTACT
10	CMD_1110	Num	8	YESF.	ONGOING AT FINAL CONTACT

**Data Set Name: comply.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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_1000	Num	8	4.	4.	Number of scheduled inhalations
5	CMP_1010	Num	8	4.	4.	Total number of Used Doses
6	CMP_1020	Num	8	6.1	6.1	Percent adherence
7	CMP_1030	Num	8	4.	4.	Number of monitored days
8	CMP_1040	Num	8	4.	4.	Number of doses taken
9	CMP_1050	Num	8	6.1	6.1	% prescribed number of doses taken
10	CMP_1060	Num	8	4.	4.	Number of monitored days
11	CMP_1070	Num	8	4.	4.	Number of doses taken
12	CMP_1080	Num	8	6.1	6.1	% Prescribed number of doses taken
13	CMP_1090	Num	8	4.	4.	Number of scheduled capsules for Capsule Vial
14	CMP_1100	Num	8	4.	4.	Number of capsules dispensed in Capsule Vial
15	CMP_1110	Num	8	4.	4.	Number of capsules returned in Capsule Vial
16	CMP_1120	Num	8	4.	4.	Actual number of capsules taken
17	CMP_1130	Num	8	6.1	6.1	Percent adherence
18	CMP_1140	Num	8	4.	4.	Number of scheduled tablets for Tablet Vial
19	CMP_1150	Num	8	4.	4.	Number of tablets dispensed in Tablet Vial
20	CMP_1160	Num	8	4.	4.	Number of tablets returned in Tablet Vial
21	CMP_1170	Num	8	4.	4.	Actual number of tablets taken
22	CMP_1180	Num	8	6.1	6.1	Percent adherence
23	CMP_1190	Num	8	4.	4.	Number of scheduled inhalations
24	CMP_1200	Num	8	4.	4.	Number of unused inhalations
25	CMP_1210	Num	8	4.	4.	Number of used inhalations
26	CMP_1220	Num	8	6.1	6.1	Percent adherence

**Data Set Name: *contr\_ph.sas7bdat***

Num	Variable	Type	Len	Format	Informat	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_1100	Num	8	PHN_1100F.	2.	What type of phone call took place?
5	PHN_1110	Num	8	YNF.	2.	Since the last study visit, has there been any hospitalization for asthma?
6	PHN_1000	Num	8	YNF.	2.	Since the last study visit, has an oral or injectable corticosteroid been used for asthma, other than for Step Up through a CARE physician at a study visit?
7	PHN_1010	Num	8	YNF.	2.	If YES, was this corticosteroid course considered by the CARE physician to be consistent with poor control or an asthma exacerbation?
8	PHN_1020	Num	8	3.	3.	During how many nights has the participant woken up to use albuterol for asthma
9	PHN_1030	Num	8	YNF.	2.	Is Question #4 >= 2 nights?
10	PHN_1040	Num	8	3.	3.	On how many days has the participant had Diary Card Question answered 'YES'?
11	PHN_1050	Num	8	YNF.	2.	Is Question #6 > 6?
12	PHN_1090	Num	8	PHN_1090F.	2.	Is the participant controlled?

**Data Set Name: *contr\_ri.sas7bdat***

Num	Variable	Type	Len	Format	Informat	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	RUN_1000	Num	8	YNF.	2.	Since the last study visit has the participant required the use of an oral or injectable corticosteroid for asthma, other than for Step Up through a CARE physician at a study visit?
5	RUN_1010	Num	8	YNF.	2.	If YES, was this corticosteroid course considered by the CARE physician to be consistent with poor control or an asthma exacerbation?
6	RUN_1015	Num	8	3.	3.	Number of diary days with usable data in the past 14 days?
7	RUN_1020	Num	8	3.	3.	Number of nights with awakenings requiring albuterol in the past 14 days
8	RUN_1030	Num	8	YNF.	2.	Is Question #3a $\geq$ 2 nights?
9	RUN_1040	Num	8	3.	3.	Number of days with asthma signs or symptoms, albuterol use ,
10	RUN_1050	Num	8	YNF.	2.	Is Question #4a $>$ 6?
11	RUN_1060	Num	8	RUN_1060F.	2.	Is the participant controlled by the Diary Card? If any shaded box is selected, the participant is NOT controlled.
12	RUN_1070	Num	8	RUN_1070F.	2.	Is the participant's FEV1 value from today's spirometry measurement $\geq$ 80% of the participant's personal best FEV1 during the Run-In?
13	RUN_1080	Num	8	RUN_1080F.	2.	Is the participant controlled by physician consultation?
14	RUN_1090	Num	8	RUN_1090F.	2.	Is the participant controlled?
15	RUN_1095	Num	8	RUN_1095F.	2.	If YES, is Question #2 $\geq$ 11 days?
16	RUN_1100	Num	8	YNF.	2.	Is the participant uncontrolled on $>$ 1600 mcg budesonide salmeterol?
17	RUN_1110	Num	8	YNF.	2.	Is the participant controlled on 400 mcg budesonide + salmeterol?
18	RUN_1120	Num	8	YNF.	2.	If YES, has the participant completed the 4-week holding pattern?
19	RUN_1130	Num	8	YNF.	2.	Is the participant eligible?

**Data Set Name: control.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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	CNT_1000	Num	8	YNF.	2.	Since the last study visit has the participant required the use of an oral or injectable corticosteroid for asthma ?
5	CNT_1010	Num	8	3.	3.	In the past 2 weeks , on how many days has the participant had coughing or wheezing from asthma or used albuterol for asthma symptoms?
6	CNT_1020	Num	8	YNF.	2.	Is Question #2 > 6?
7	CNT_1030	Num	8	3.	3.	In the past 2 weeks , during how many nights has the participant woken up to use albuterol for asthma?
8	CNT_1040	Num	8	YNF.	2.	Is Question #3 >= 2?
9	CNT_1050	Num	8	CNT_1050F.	2.	Is the participant controlled by history?
10	CNT_1060	Num	8	CNT_1060F.	2.	Is the participant controlled according to the Diary Card?
11	CNT_1070	Num	8	YNF.	2.	If YES, Controlled by Diary Card, are there at least 11 days of usable diary data in the past 14 days since the last study visit ?
12	CNT_1080	Num	8	CNT_1080F.	2.	Is the participant controlled by physician consultation?
13	CNT_1090	Num	8	CNT_1090F.	2.	Is the participant controlled?
14	CNT_1100	Num	8	YNF.	2.	Is the participant's pre-bronchodilator FEV1 value >= 80% of the best pre-bronchodilator pre-randomization value?
15	CNT_1110	Num	8	CNT_1110F.	2.	Is the participant controlled by Diary Card and FEV1?

**Data Set Name: diary.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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	BEST	Num	8	4.	4.	BEST
6	DRY_1000	Num	8	YNF.	2.	Awakened at night to use albuterol for asthma?
7	DRY_1010	Num	8	5.	5.	Time of Wake Up Peak Flow
8	DRY_1020	Num	8	4.	4.	Wake Up Peak Flow
9	DRY_1030	Num	8	YNF.	2.	Albuterol used in the two hours before Wake Up Peak Flow?
10	DRY_1040	Num	8	YNF.	2.	One salmeterol inhalation taken at Wake Up?
11	DRY_1050	Num	8	YNF.	2.	budesonide inhalation taken at Wake Up?
12	DRY_1060	Num	8	5.2	5.2	Coordinator Completed Wake Up FEV1
13	DRY_1070	Num	8	5.	5.	Time of Bedtime Peak Flow
14	DRY_1080	Num	8	4.	4.	Bedtime Peak Flow
15	DRY_1090	Num	8	YNF.	2.	Albuterol used in the two hours before Bedtime Peak Flow?
16	DRY_1100	Num	8	YNF.	2.	One salmeterol inhalation taken at bedtime?
17	DRY_1110	Num	8	YNF.	2.	budesonide inhalation taken at bedtime?
18	DRY_1120	Num	8	YNF.	2.	Both study tablet and capsule taken at bedtime?
19	DRY_1130	Num	8	5.2	5.2	Coordinator Completed Bedtime FEV1
20	DRY_1140	Num	8	DRY_1140TO1150F.	2.	Rate your coughing from asthma during the past 24 hours.
21	DRY_1150	Num	8	DRY_1140TO1150F.	2.	Rate your wheezing during the past 24 hours.
22	DRY_1160	Num	8	3.	3.	Number of puffs of albuterol taken before exercise in the past 24 hours.
23	DRY_1170	Num	8	3.	3.	Number of puffs of albuterol taken for asthma symptoms or low peak flow in the past 24 hours.
24	DRY_1180	Num	8	YNNAF.	2.	Absent from school or work for asthma symptoms?
25	DRY_1190	Num	8	YNF.	2.	Contacted healthcare provider for asthma symptoms?



***Data Set Name: drugarms.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_ARM	Char	30	Treatment Arm

**Data Set Name: elig1.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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.	2.	Has the parent/legal guardian appropriately signed and dated the informed consent?
5	E1_1010	Num	8			If YES, record the date the form was signed
6	E1_1020	Num	8	YNF.	2.	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			If YES, record the date the assent was signed or verbally given
8	E1_1040	Num	8	YNF.	2.	Is the participant able to swallow the study capsules?
9	E1_1050	Num	8	YNDKF.	2.	Is the participant currently intolerant of or allergic to Serevent , Pulmicort , Singulair , know Zithromax or any of their ingredients?
10	E1_1060	Num	8	YNF.	2.	Is the participant able to take albuterol such as Proventil and Ventolin?
11	E1_1070	Num	8	YNF.	2.	Has the participant had her first period? If YES, please complete Questions #6a and #6b.
12	E1_1080	Num	8	YNF.	2.	Is the participant currently pregnant or nursing?
13	E1_1090	Num	8	YNF.	2.	Does the participant agree to avoid pregnancy during the study?
14	E1_1100	Num	8	YNF.	2.	Is the participant eligible? If any of the shaded boxes are selected, the participant is ineligible.
15	E1_1110	Num	8	YNF.	2.	Is the participant 6 to <18 years old?
16	E1_1120	Num	8	YNF.	2.	Is the participant's weight $\geq$ 25 kg ?
17	E1_1130	Num	8	YNF.	2.	Has the participant had physician-diagnosed asthma for at least one year?
18	E1_1140	Num	8	YNF.	2.	Has the participant been treated with an inhaled corticosteroid for the past 6 consecutive weeks?
19	E1_1150	Num	8	YNF.	2.	Has the participant smoked 11 or more cigarettes or any other substance in the past year?
20	E1_1160	Num	8	YNF.	2.	Has the participant used smokeless tobacco products 11 or more times in the past year?
21	E1_1170	Num	8	YNF.	2.	Has the participant ever had chicken pox or received the chicken pox vaccine?
22	E1_1180	Num	8	YNF.	2.	Has the participant been hospitalized for 4 or more wheezing illnesses within the past 12 months?
23	E1_1190	Num	8	YNF.	2.	Has the participant used an oral or systemic corticosteroid in the past 4 weeks?
24	E1_1200	Num	8	YNF.	2.	During the past year, has the participant had 5 or more courses of oral or systemic corticosteroids for asthma?
25	E1_1210	Num	8	YNF.	2.	Has the participant had an asthma exacerbation resulting in intubation and mechanical ventilation for asthma within the past year?
26	E1_1220	Num	8	YNF.	2.	Is the participant receiving allergy shots?
27	E1_1230	Num	8	YNF.	2.	If YES, has the dose been changed in the past 3 months?
28	E1_1240	Num	8	YNF.	2.	Does the participant have a history of severe sinusitis that required sinus surgery within the past 12 months?

Num	Variable	Type	Len	Format	Informat	Label
29	E1_1250	Num	8	YNF.	2.	Is the participant currently being treated with antibiotics for diagnosed sinus disease?
30	E1_1260	Num	8	YNF.	2.	Does the participant use maintenance oral or systemic antibiotics for treatment of an ongoing condition?
31	E1_1270	Num	8	YNF.	2.	Has the participant used macrolide antibiotics [erythromycin, Zithromax , Biaxin , Pediazole, Pediamycin, Ketek ] within the past 6 weeks?
32	E1_1280	Num	8	YNF.	2.	Does the participant have concurrent medical problems other than asthma that are likely to require a systemic corticosteroid during the study ?
33	E1_1290	Num	8	YNF.	2.	Does the participant have any active or chronic lung disease other than asthma?
34	E1_1300	Num	8	YNF.	2.	cardiac , liver, gastrointestinal, endocrine, seizures, immunodeficiency disorders, myasthenia gravis, active urinary tract obstruction]?
35	E1_1310	Num	8	YNF.	2.	Does the participant have a history of gastroesophageal reflux symptoms not controlled by standard medical therapy?
36	E1_1315	Num	8	YNF.	2.	Is the participant currently using digoxin, ergotamine, dihydroergotamine, triazolam, carbamazepine, cyclosporine, hexobarbital, phenytoin, or similar classes of medication?
37	E1_1320	Num	8	YNF.	2.	Has the participant used any of the drugs listed on the Exclusionary Drugs reference card during the designated washout period? Other Criteria
38	E1_1330	Num	8	YNF.	2.	Has the participant been involved in another investigational drug study within the past month?
39	E1_1340	Num	8	YNF.	2.	Does the participant's family have plans to move out of the area within the next 12 months?
40	E1_1350	Num	8	YNF.	2.	Is there any other reason for which this participant should not be included in this study? If YES, please describe: _____
41	E1_1360	Num	8	YNF.	2.	Is the participant eligible? If any of the shaded boxes are selected, the participant is ineligible.
42	E1_1370	Num	8	E1_1370F.	2.	Which inhaled corticosteroid was the participant taking most recently?
43	E1_1380	Num	8	E1_1390F.	5.	What was the most recent dose of inhaled corticosteroid? mcg/day
44	E1_1390	Num	8	E1_1390F.	2.	What is the pre-enrollment budesonide dose equivalent according to the Budesonide Equivalence Table ?
45	E1_1400	Num	8	3.	3.	On how many days during the past 2 weeks has the participant days had asthma signs or symptoms, albuterol use for symptoms or low peak flow, or peak flow values < 80% of personal best?
46	E1_1405	Num	8	YNF.	2.	Is Question #37 <= 6?
47	E1_1410	Num	8	3.	3.	On how many nights during the past 2 weeks has the participant nights had nighttime awakenings due to asthma?
48	E1_1420	Num	8	YNF.	2.	Is Question #39 < 2? Pulmonary Function Criteria
49	E1_1430	Num	8	E1_1430F.	2.	What is the participant's pre-bronchodilator FEV1 % predicted? If < 50%, skip to Question #43. The participant is ineligible.
50	E1_1440	Num	8	E1_1440F.	2.	Is the participant controlled by both symptom history and pulmonary function testing?
51	E1_1450	Num	8	YNF.	2.	If YES, Controlled, is the pre-enrollment budesonide dose equivalent 400 mcg/day?
52	E1_1460	Num	8	YNF.	2.	If NO, Uncontrolled, is the pre-enrollment budesonide dose equivalent > 1600 mcg/day?

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Informat</b>	<b>Label</b>
53	E1_1470	Num	8	YNF.	2.	Is the participant eligible? If any of the shaded boxes are selected, the participant is ineligible.
54	E1_1395	Num	8	YNF.	2.	Has the participant used an oral or systemic corticosteroid in the past 8 weeks?

**Data Set Name: elig2.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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.	2.	Has the participant received oral or systemic corticosteroid treatment for a reason other than asthma since the last study visit?
5	E2_1005	Num	8	YNF.	2.	Has the participant been able to swallow the oral study medications?
6	E2_1010	Num	8	3.	3.	Number of days since the last study visit days visit days)
7	E2_1020	Num	8	4.	4.	Number of complete measurements in the defined interval measurements
8	E2_1030	Num	8	6.1	6.1	Percent adherence = . % Medication use criteria
9	E2_1040	Num	8	E2_1040F.	2.	Categorize Question #5b.
10	E2_1050	Num	8	YNF.	2.	Visits 1a and 2 only: Has the participant shown evidence of adherence with the study capsules?
11	E2_1060	Num	8	YNF.	2.	Has the participant shown evidence of adherence with the Serevent <sup>®</sup> Diskus <sup>®</sup> ?
12	E2_1070	Num	8	YNF.	2.	Is there any other reason for which this participant should not be included in this study?
13	E2_1080	Num	8	YNF.	2.	Is the participant eligible?
14	E2_1003	Num	8	YNF.	2.	Has the participant used macrolide antibiotics [erythromycin, Zithromax , Biaxin , Pediazole, Pediamycin, Ketek ] since the last study visit?
15	E2_1075	Num	8	YNF.	2.	Visit 2 only, if no shaded boxes have been selected: Has the participant shown evidence of adherence with the Pulmicort Turbuhaler?

**Data Set Name: elig3.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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.	2.	Was the participant able to demonstrate reversible airflow obstruction at Visit 0 ?
5	E3_1010	Num	8	YNF.	2.	Is the participant ineligible for a methacholine challenge at this visit?
6	E3_1020	Num	8	YNF.	2.	If NO, is the participant's methacholine PC20 <= 12.5 mg/ml?
7	E3_1030	Num	8	YNF.	2.	If YES, was the participant able to demonstrate reversible airflow obstruction at the current visit? Clinic Use Only Visit 1 Reversal
8	E3_1040	Num	8	YNF.	2.	Is the participant eligible?

**Data Set Name: elig4.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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	E4_1000	Num	8	YNF.	2.	Has the participant demonstrated control after Step Up on either 00 mcg or 1600 mcg budesonide daily dose according to today's pdated participant flowchart and today's P5_CONTROL_RUNIN uestion #8a?
5	E4_1010	Num	8	YNF.	2.	Has the participant demonstrated $\geq 75\%$ adherence with the diary ince the last study visit ?
6	E4_1020	Num	8	YNF.	2.	Were the participant's Visit 1 liver enzyme test results nd SGOT/AST) within normal range?
7	E4_1025	Num	8	YNF.	2.	Did the EKG show signs of significant abnormalities that would preclude continuation in the study?
8	E4_1027	Num	8			EKG Date
9	E4_1035	Num	8	YNF.	2.	Is the participant eligible? If any of the shaded boxes are selected, the participant is ineligible.
10	E4_1028	Num	8	YNF.	2.	Is the participant eligible? If any of the shaded boxes are selected, the participant is ineligible. If NO, please STOP HERE and complete the MARS Termination of Study Participation form.
11	E4_1090	Num	8	YNF.	2.	If NO, was the participant able to demonstrate either $\geq 12\%$ improvement in FEV1 following the post-bronchodilator testing procedure with 4 puffs albuterol OR methacholine PC20 $\leq 12.5$ mg/ml in another CARE study within the past year?
12	E4_1029	Num	8	YNF.	2.	Was the participant able to demonstrate either $\geq 12\%$ improvement in FEV1 following the post-bronchodilator testing procedure with 4 puffs albuterol at Visit 0 or 1 OR methacholine PC20 $\leq 12.5$ mg/ml at Visit 1?
13	E4_1030	Num	8	YNF.	2.	If NO, is the participant's methacholine PC20 $\leq 12.5$ mg/ml at the current visit?
14	E4_1070	Num	8	2.	2.	Physician/CC signature: _____
15	E4_1080	Num	8			Date: //

**Data Set Name: eno.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Informat</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	ENO_1000	Num	8	5.	5.	Time eNO started
5	ENO_1010	Num	8	6.1	6.1	ENO Measurement #1
6	ENO_1020	Num	8	6.1	6.1	ENO Measurement #2
7	ENO_1030	Num	8	6.1	6.1	ENO Measurement #3
8	ENO_1040	Num	8	6.1	6.1	Average FENO
9	ENO_1050	Num	8	6.1	6.1	Average VNO
10	ENO_1060	Num	8	ENO_1060F.	2.	Test Profile



**Data Set Name: eno\_chk.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	ENC_1000	Num	8	YNF.	Has the participant smoked cigarettes or any other substance in the past month?
5	ENC_1010	Num	8	YNF.	Has the participant smoked cigarettes or any other substance within the past hour?
6	ENC_1020	Num	8	YNF.	Is there any other reason the participant should not proceed with the exhaled nitric oxide procedure?
7	ENC_1030	Num	8	YNF.	Did the participant eat or drink in the past hour?
8	ENC_1040	Num	8	YNF.	Is the participant eligible to proceed with exhaled nitric oxide testing?

**Data Set Name: heq.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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	HEQ_1000F.	2.	Who is completing the questionnaire?
5	HEQ_1010	Num	8	YNF.	2.	Has the participant lived in his/her current house since birth?
6	HEQ_1020	Num	8	3.	3.	If NO, how long has the participant lived in years the current house?
7	HEQ_1030	Num	8	3.	3.	If NO, how long has the participant lived in months the current house?
8	HEQ_1040	Num	8	HEQ_1040F.	2.	Which best describes the participant's current house?
9	HEQ_1050	Num	8	4.	4.	How old is the participant's current house? years Enter '1' if less than a year.)
10	HEQ_1060	Num	8	YNF.	2.	Does the participant's house use a portable heater?
11	HEQ_1070	Num	8	YNF.	2.	Does the participant's house use a wood burning stove as a primary source of heat?
12	HEQ_1080	Num	8	YNDKF.	2.	Does the participant's house use an air conditioner?
13	HEQ_1090	Num	8	HEQ_1090F.	2.	Which type of air conditioner is used in the participant's house?
14	HEQ_1100	Num	8	YNF.	2.	Which type of air conditioner is used in the Participant's bedroom
15	HEQ_1110	Num	8	YNF.	2.	Which type of air conditioner is used in the Other bedrooms
16	HEQ_1120	Num	8	YNF.	2.	Which type of air conditioner is used in the Living or family room
17	HEQ_1130	Num	8	YNF.	2.	Which type of air conditioner is used in the Kitchen
18	HEQ_1140	Num	8	YNF.	2.	Which type of air conditioner is used in the Other
19	HEQ_1150	Num	8	YNDKF.	2.	Does the participant's house use an evaporative cooler
20	HEQ_1160	Num	8	HEQ_1160F.	2.	Which type of evaporative cooler is used in the participant's house?
21	HEQ_1170	Num	8	YNF.	2.	Which type of evaporative cooler is used in the Participant's bedroom
22	HEQ_1180	Num	8	YNF.	2.	Which type of evaporative cooler is used in the Other bedrooms
23	HEQ_1190	Num	8	YNF.	2.	Which type of evaporative cooler is used in the Living or family room
24	HEQ_1200	Num	8	YNF.	2.	Which type of evaporative cooler is used in the Kitchen
25	HEQ_1210	Num	8	YNF.	2.	Which type of evaporative cooler is used in the Other
26	HEQ_1220	Num	8	YNDKF.	2.	Does the participant's house use a humidifier?
27	HEQ_1230	Num	8	HEQ_1230F.	2.	Which type of humidifier is used in the participant's house?
28	HEQ_1260	Num	8	YNF.	2.	Which type of humidifier is used in the Participant's bedroom
29	HEQ_1270	Num	8	YNF.	2.	Which type of humidifier is used in the Other bedrooms
30	HEQ_1280	Num	8	YNF.	2.	Which type of humidifier is used in the Living or family room
31	HEQ_1290	Num	8	YNF.	2.	Which type of humidifier is used in the Kitchen
32	HEQ_1300	Num	8	YNF.	2.	Which type of humidifier is used in the Other
33	HEQ_1310	Num	8	YNDKF.	2.	Does the participant's house use a dehumidifier?
34	HEQ_1320	Num	8	HEQ_1320F.	2.	Which type of dehumidifier is used in the participant's house?
35	HEQ_1350	Num	8	YNF.	2.	Which type of dehumidifier is used in the Participant's bedroom
36	HEQ_1360	Num	8	YNF.	2.	Which type of dehumidifier is used in the Other bedrooms

Num	Variable	Type	Len	Format	Informat	Label
37	HEQ_1370	Num	8	YNF.	2.	Which type of dehumidifier is used in the Living or family room
38	HEQ_1380	Num	8	YNF.	2.	Which type of dehumidifier is used in the Kitchen
39	HEQ_1390	Num	8	YNF.	2.	Which type of dehumidifier is used in the Basement
40	HEQ_1400	Num	8	YNF.	2.	Which type of dehumidifier is used in the Other
41	HEQ_1410	Num	8	YNDKF.	2.	Has there been water damage to the participant's house
42	HEQ_1420	Num	8	YNDKF.	2.	Has there been any mold or mildew, on any surfaces, inside the participant's house in the past 12 months?
43	HEQ_1430	Num	8	YNF.	2.	Which rooms have or have had mold or mildew? Bathroom
44	HEQ_1440	Num	8	YNF.	2.	Which rooms have or have had mold or mildew? Basement or attic
45	HEQ_1450	Num	8	YNF.	2.	Which rooms have or have had mold or mildew? Kitchen
46	HEQ_1460	Num	8	YNF.	2.	Which rooms have or have had mold or mildew? Participant's bedroom
47	HEQ_1470	Num	8	YNF.	2.	Which rooms have or have had mold or mildew? Other bedrooms
48	HEQ_1480	Num	8	YNF.	2.	Which rooms have or have had mold or mildew? Living or family room
49	HEQ_1490	Num	8	YNF.	2.	Which rooms have or have had mold or mildew? Other
50	HEQ_1500	Num	8	YNF.	2.	Do you ever see cockroaches in the participant's house?
51	HEQ_1510	Num	8	YNF.	2.	In which room have you seen cockroaches? Kitchen
52	HEQ_1520	Num	8	YNF.	2.	In which room have you seen cockroaches? Basement or attic
53	HEQ_1530	Num	8	YNF.	2.	In which room have you seen cockroaches? Bathroom
54	HEQ_1540	Num	8	YNF.	2.	In which room have you seen cockroaches? Living or family room
55	HEQ_1550	Num	8	YNF.	2.	In which room have you seen cockroaches? Participant's bedroom
56	HEQ_1560	Num	8	YNF.	2.	In which room have you seen cockroaches? Other bedrooms
57	HEQ_1570	Num	8	YNF.	2.	In which room have you seen cockroaches? Garage
58	HEQ_1580	Num	8	YNF.	2.	In which room have you seen cockroaches? Other
59	HEQ_1590	Num	8	YNF.	2.	Does the participant share his/her bedroom with another person?
60	HEQ_1600	Num	8	3.	3.	If YES, how many others?
61	HEQ_1610	Num	8	HEQ_1610F.	2.	What is the floor covering in the participant's bedroom?
62	HEQ_1620	Num	8	HEQ_1620F.	2.	If carpeted, what type of padding is under the carpet in the participant's bedroom?
63	HEQ_1630	Num	8	HEQ_1630F.	2.	What type of mattress is on the participant's bed?
64	HEQ_1640	Num	8	UC99F.	3.	How old is the mattress used on the participant's bed? years
65	HEQ_1650	Num	8	YNF.	2.	Is the mattress completely enclosed in an allergy-proof, encasing cover?
66	HEQ_1660	Num	8	YNF.	2.	Does the participant's bed have a box spring?
67	HEQ_1670	Num	8	YNF.	2.	Is the box spring completely enclosed in an allergy-proof, encasing cover?
68	HEQ_1680	Num	8	HEQ_1680F.	2.	What type of pillow does the participant usually sleep with?
69	HEQ_1690	Num	8	UC99F.	3.	How old is the pillow the participant usually sleeps with in years?
70	HEQ_1700	Num	8	YNF.	2.	Is the pillow completely enclosed in an allergy-proof, encasing cover?
71	HEQ_1710	Num	8	3.	3.	How many times per month are the participant's bed covers or times sheets washed in hot water?
72	HEQ_1720	Num	8	YNF.	2.	Are any of the following located on your property or next to your property? Barns

Num	Variable	Type	Len	Format	Informat	Label
73	HEQ_1730	Num	8	YNF.	2.	Are any of the following located on your property or next to your property? Hay
74	HEQ_1740	Num	8	YNF.	2.	Are any of the following located on your property or next to your property? Woodsheds
75	HEQ_1750	Num	8	YNF.	2.	Are any of the following located on your property or next to your property? Firewood
76	HEQ_1760	Num	8	YNF.	2.	Are any of the following located on your property or next to your property? Chicken coops
77	HEQ_1770	Num	8	YNF.	2.	Are any of the following located on your property or next to your property? Corral
78	HEQ_1780	Num	8	YNF.	2.	Does your family have any animals?
79	HEQ_1790	Num	8	3.	3.	Enter the number of animals that the family has. Cat
80	HEQ_1800	Num	8	3.	3.	Enter the number of animals that the family has. Dog
81	HEQ_1810	Num	8	3.	3.	Enter the number of animals that the family has. Rabbit, guinea pig, hamster, gerbil, or mouse
82	HEQ_1820	Num	8	3.	3.	Enter the number of animals that the family has. Bird
83	HEQ_1830	Num	8	3.	3.	Enter the number of animals that the family has. Other
84	HEQ_1840	Num	8	YNF.	2.	Are there any animals in the participant's house?
85	HEQ_1850	Num	8	YNF.	2.	Which animals are in the participant's house? Cat
86	HEQ_1860	Num	8	YNF.	2.	Which animals are in the participant's house? Dog
87	HEQ_1870	Num	8	YNF.	2.	Which animals are in the participant's house? Rabbit, guinea pig, hamster, gerbil, or mouse
88	HEQ_1880	Num	8	YNF.	2.	Which animals are in the participant's house? Bird
89	HEQ_1890	Num	8	YNF.	2.	Which animals are in the participant's house? Other
90	HEQ_1900	Num	8	YNF.	2.	Which animals are in the participant's bedroom? Cat
91	HEQ_1910	Num	8	YNF.	2.	Which animals are in the participant's bedroom? Dog
92	HEQ_1920	Num	8	YNF.	2.	Which animals are in the participant's bedroom? Rabbit, guinea pig, hamster, gerbil, or mouse
93	HEQ_1930	Num	8	YNF.	2.	Which animals are in the participant's bedroom? Bird
94	HEQ_1940	Num	8	YNF.	2.	Which animals are in the participant's bedroom? Other
95	HEQ_1950	Num	8	YNF.	2.	In general, and on a regular basis, is the participant exposed to any of the following animals? Cat
96	HEQ_1960	Num	8	YNF.	2.	In general, and on a regular basis, is the participant exposed to any of the following animals? Dog
97	HEQ_1970	Num	8	YNF.	2.	In general, and on a regular basis, is the participant exposed to any of the following animals? Rabbit, guinea pig, hamster, gerbil, or mouse
98	HEQ_1980	Num	8	YNF.	2.	In general, and on a regular basis, is the participant exposed to any of the following animals? Bird
99	HEQ_1990	Num	8	YNF.	2.	In general, and on a regular basis, is the participant exposed to any of the following animals? Farm animals
100	HEQ_2000	Num	8	YNF.	2.	In general, and on a regular basis, is the participant exposed to any of the following animals? Other

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

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

**Data Set Name: ige.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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	IGE_1000	Num	8	YNF.	2.	Was the IgE result obtained?
5	IGE_1010	Num	8	IGE_1010F.	2.	If NO, why was the result not obtained?
6	IGE_1020	Num	8	8.1	8.1	IGE Exact value
7	IGE_1030	Num	8	4.1	4.1	IGE Lower limit of detection

**Data Set Name: ios\_pre.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	IPR_1010	Num	8		Time IOS started
5	IPR_1020	Num	8		first effort R5 . kPa/l/s
6	IPR_1030	Num	8		first effort R10 . kPa/l/s
7	IPR_1040	Num	8		first effort R15 . kPa/l/s
8	IPR_1050	Num	8		first effort R35 . kPa/l/s
9	IPR_1060	Num	8		first effort X5 . kPa/l/s
10	IPR_1070	Num	8		first effort Resonant Frequency . Hz
11	IPR_1080	Num	8		first effort Area XA . kPa/l
12	IPR_1090	Num	8		second effort R5 . kPa/l/s
13	IPR_1100	Num	8		second effort R10 . kPa/l/s
14	IPR_1110	Num	8		second effort R15 . kPa/l/s
15	IPR_1120	Num	8		second effort R35 . kPa/l/s
16	IPR_1130	Num	8		second effort X5 . kPa/l/s
17	IPR_1140	Num	8		second effort Resonant Frequency . Hz
18	IPR_1150	Num	8		second effort Area XA . kPa/l
19	IPR_1160	Num	8		third effort R5 . kPa/l/s
20	IPR_1170	Num	8		third effort R10 . kPa/l/s
21	IPR_1180	Num	8		third effort R15 . kPa/l/s
22	IPR_1190	Num	8		third effort R35 . kPa/l/s
23	IPR_1200	Num	8		third effort X5 . kPa/l/s
24	IPR_1210	Num	8		third effort Resonant Frequency . Hz
25	IPR_1220	Num	8		third effort Area XA . kPa/l
26	IPR_1230	Num	8	YNF.	In your judgement, was the participant's pre-bronchodilator technique acceptable?
27	IPR_1240	Num	8	YNF.	If NO, why was it unacceptable Coherence < 0.80
28	IPR_1250	Num	8	YNF.	If NO, why was it unacceptable Poor repeatability
29	IPR_1260	Num	8	YNF.	If NO, why was it unacceptable Fewer than 3 good tests
30	IPR_1270	Num	8	YNF.	If NO, why was it unacceptable Inconsistent tidal breathing
31	IPR_1280	Num	8	YNF.	If NO, why was it unacceptable Participant refusal during test
32	IPR_1290	Num	8	YNF.	If NO, why was it unacceptable Other
33	IPR_1300	Num	8	IPR_1300F.	If YES, grade the participant's technique
34	IPR_1310	Num	8	IPR_1310F.	How was the participant positioned?
35	IPR_1320	Num	8	YNF.	Were the participant's cheeks held?
36	IPR_1330	Num	8	IPR_1330F.	If YES, how were the participant's cheeks held?

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
37	IPR_1340	Num	8	YNF.	Were nose clips used?
38	IPR_1350	Num	8	IPR_1350F.	If YES, how effective were the nose clips?
39	IPR_1360	Num	8	YNF.	If NO, was the nose occluded?
40	IPR_1370	Num	8	IPR_1370F.	If YES, how was the nose occluded?



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

Num	Variable	Type	Len	Format	Informat	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.	2.	Who is completing the questionnaire?
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.	2.	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.	2.	In general, during the past week, how limited were you in your activities because of your asthma?
8	JUN_1040	Num	8	JUN_1040F.	2.	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.	2.	In general, during the past week, how much of the time did you wheeze?
10	JUN_1060	Num	8	JUN_1060F.	2.	On average, during the past week, how many puffs of short-acting bronchodilator have you used each day?
11	JUN_1070	Num	8	JUN_1070F.	2.	Were pre-bronchodilator FEV1 and FEV1 % predicted measures

**Data Set Name: lab.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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.	2.	Pregnancy test results
5	LAB_1020	Num	8			Pregnancy test results Date
6	LAB_1030	Num	8	4.	4.	SGPT/ALT
7	LAB_1040	Num	8	4.	4.	SGOT/AST
8	LAB_1060	Num	8	6.	6.	Total WBC
9	LAB_1070	Num	8	5.1	5.1	Eosinophils
10	LAB_1080	Num	8	YNF.	2.	Was blood obtained for the serum save?
11	LAB_1090	Num	8	YNF.	2.	Was blood obtained for superantigen analysis?
12	LAB_1100	Num	8	YNF.	2.	Was a urine sample collected for cotinine measurement?
13	LAB_1110	Num	8	YNF.	2.	Was a nasal washing completed and a sample collected?
14	LAB_1120	Num	8	YNF.	2.	Was a nasal swab collected for antibiotic resistance?
15	LAB_1130	Num	8	YNF.	2.	Was a nasal swab collected for a superantigen culture?

**Data Set Name: med.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Informat</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.	2.	What type of visit is this?
5	MED_1010	Num	8	MED_1010F.	2.	What is the budesonide dose prescribed at this visit?
6	MED_1050	Num	8	2.	2.	Coordinator Signature
7	MED_1060	Num	8			Coordinator Date

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

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	DRUGCODE	Num	8	Drug Code
2	CATEGORY	Char	200	Drug Category Description
3	BRAND_NM	Char	200	Brand Name Description
4	GENER_NM	Char	200	Generic Name Description

**Data Set Name: medhx.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.	What is your relationship to the child?
5	MHX_1010	Num	8		How old was the participant when chest symptoms suggesting asthma first began (years)?
6	MHX_1020	Num	8		How old was the participant when chest symptoms suggesting asthma first began (months)?
7	MHX_1030	Num	8	YNF.	Has a physician diagnosed the participant with asthma?
8	MHX_1040	Num	8		If YES, how old was the participant when a doctor first said he or she had asthma (years)?
9	MHX_1050	Num	8		If YES, how old was the participant when a doctor first said he or she had asthma (months)?
10	MHX_1060	Num	8	YNF.	Has the participant ever been hospitalized overnight for asthma?
11	MHX_1070	Num	8		During the past 12 months, how many times has the participant been hospitalized overnight for asthma?
12	MHX_1080	Num	8	YNF.	Has the participant ever been admitted to an intensive care unit for asthma?
13	MHX_1090	Num	8		During the past 12 months, how many times has the participant been admitted to an intensive care unit for asthma?
14	MHX_1100	Num	8		During the past 12 months, how many: Times has the participant been seen in an emergency department for asthma?
15	MHX_1110	Num	8		During the past 12 months, how many: Times has the participant been seen at a doctor's office for worsening of asthma symptoms?
16	MHX_1120	Num	8		Days of work or school did the participant miss because of asthma symptoms? (Enter '999' if not applicable.)
17	MHX_1130	Num	8		Days of work did you or another caretaker miss because of days the participant's asthma symptoms?
18	MHX_1140	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Exposure to house dust?
19	MHX_1150	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Exposure to animals?
20	MHX_1160	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Exposure to spring and fall pollens?
21	MHX_1170	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Exposure to damp, musty area?
22	MHX_1180	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Exposure to tobacco smoke?
23	MHX_1190	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Exposure to a change in the weather?
24	MHX_1200	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Respiratory infections?
25	MHX_1210	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Exposure to chemicals?
26	MHX_1220	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Food?
27	MHX_1230	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Exposure to cold air?
28	MHX_1240	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Exercise/play?
29	MHX_1250	Num	8	MHX_1140TO1250F.	Is the participant's asthma provoked by: Emotional factors?
30	MHX_1260	Num	8	YNF.	Has the participant ever had hay fever?

Num	Variable	Type	Len	Format	Label
31	MHX_1270	Num	8		At what age did the participant FIRST have hay fever? (years)
32	MHX_1280	Num	8		At what age did the participant FIRST have hay fever? (months)
33	MHX_1290	Num	8	YNF.	Has the participant ever seen a doctor or other health practitioner because of hay fever?
34	MHX_1300	Num	8	MHX_1300F.	During the past 12 months, how would you generally describe the participant's hay fever?
35	MHX_1310	Num	8	YNF.	Has the participant ever had atopic dermatitis (eczema)?
36	MHX_1320	Num	8		At what age did the participant FIRST have atopic dermatitis (eczema) (years)?
37	MHX_1330	Num	8		At what age did the participant FIRST have atopic dermatitis (eczema) (months)?
38	MHX_1340	Num	8	YNF.	Has the participant ever seen a doctor or other health practitioner because of atopic dermatitis (eczema)?
39	MHX_1350	Num	8	MHX_1350F.	During the past 12 months, how would you generally describe the participant's atopic dermatitis (eczema)?
40	MHX_1360	Num	8	YNF.	Which parts of the participant's body were ever affected by eczema in the past 12 months? :Head
41	MHX_1370	Num	8	YNF.	Which parts of the participant's body were ever affected by eczema in the past 12 months? :Arms/Hands
42	MHX_1380	Num	8	YNF.	Which parts of the participant's body were ever affected by eczema in the past 12 months? :Trunk (mid-section or torso)
43	MHX_1390	Num	8	YNF.	Which parts of the participant's body were ever affected by eczema in the past 12 months? :Legs/Feet
44	MHX_1400	Num	8	YNF.	Which parts of the participant's body were ever affected by eczema in the past 12 months? :Other _____
45	MHX_1410	Num	8	YNF.	To which of the following did a doctor or other health practitioner say the participant was allergic?: Medicines
46	MHX_1420	Num	8	YNF.	To which of the following did a doctor or other health practitioner say the participant was allergic?: Foods
47	MHX_1430	Num	8	YNF.	To which of the following did a doctor or other health practitioner say the participant was allergic?: Things you breathe in or inhale (e.g., dust, pollens, molds, animal fur, or dander)
48	MHX_1440	Num	8	YNF.	To which of the following did a doctor or other health practitioner say the participant was allergic?: Stinging insects such as bees or wasps
49	MHX_1450	Num	8	MHX_1450F.	During the past 12 months, how many months did the participant use antihistamines and/or decongestants to treat nose, eye, and sinus symptoms (prescription or over the counter)?
50	MHX_1460	Num	8		During the past 12 months, how many months did the participant use a steroid nasal spray, beclomethasone, budesonide, flunisolide to treat nose, eye, or sinus symptoms? (Enter '00' if none.)
51	MHX_1470	Num	8		During the past 12 months, how many times have you contacted or visited a doctor because of problems with the participant's nose, eyes, or sinuses? (Enter '00' if none.)
52	MHX_1480	Num	8		During the past 12 months, how many times has the participant had a sinus infection that required treatment with antibiotics? (Enter '00' if none.)

Num	Variable	Type	Len	Format	Label
53	MHX_1490	Num	8		During the past 12 months, how many times has the participant had a sinus infection that required treatment with steroids by mouth or by injection (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone, Solumedrol)? (Enter '00' if none.)
54	MHX_1500	Num	8		During the past 12 months, how many times has the participant had pneumonia?
55	MHX_1510	Num	8		Has the participant ever had sinus surgery for sinusitis or polyps?
56	MHX_1520	Num	8	YDNF.	During the past 12 months, how would you describe any symptoms that have affected the participant's nose, eyes, or sinuses?
57	MHX_1530	Num	8	YNDKF.	Has a doctor ever said that the [BIOLOGICAL] father of the participant had: Asthma?
58	MHX_1540	Num	8	YNDKF.	Has a doctor ever said that the [BIOLOGICAL] father of the participant had: Hay fever, eczema, or other atopic disorder?
59	MHX_1550	Num	8	YNDKF.	Has a doctor ever said that the [BIOLOGICAL] father of the participant had: Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis?
60	MHX_1560	Num	8	YNDKF.	Has a doctor ever said that the [BIOLOGICAL] mother of the participant had: Asthma?
61	MHX_1570	Num	8	YNDKF.	Has a doctor ever said that the [BIOLOGICAL] mother of the participant had: Hay fever, eczema, or other atopic disorder?
62	MHX_1580	Num	8	YNDKF.	Has a doctor ever said that the [BIOLOGICAL] mother of the participant had: Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis?
63	MHX_1590	Num	8	YNDKF.	Does the participant have any [BIOLOGICAL] siblings?
64	MHX_1600	Num	8	YNDKF.	Has a doctor ever said that any [BIOLOGICAL] sibling of the participant had: Asthma?
65	MHX_1610	Num	8	YNDKF.	Has a doctor ever said that any [BIOLOGICAL] sibling of the participant had: Hay fever, eczema, or other atopic disorder?
66	MHX_1620	Num	8	YNDKF.	Has a doctor ever said that any [BIOLOGICAL] sibling of the participant had: Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis?
67	MHX_1630	Num	8	YNDKF.	Did the participant's mother smoke while she was pregnant with the participant?
68	MHX_1640	Num	8	YNDKF.	During which part(s) of the pregnancy did the participant's mother smoke? First 3 months
69	MHX_1650	Num	8	YNDKF.	During which part(s) of the pregnancy did the participant's mother smoke? Middle 3 months
70	MHX_1660	Num	8	YNDKF.	During which part(s) of the pregnancy did the participant's mother smoke? Last 3 months
71	MHX_1670	Num	8	YNDKF.	Between the time the participant was born and he/she turned 5 years of age:Did the participant's mother (or stepmother or female guardian) smoke?
72	MHX_1680	Num	8	YNDKF.	Between the time the participant was born and he/she turned 5 years of age:Did the participant's father (or stepfather or male guardian) smoke?
73	MHX_1690	Num	8	YNDKF.	Between the time the participant was born and he/she turned 5 years of age:Were there any other smokers in the household? (Include visitors, such as grandparents or baby-sitters, who visited at least once weekly.)
74	MHX_1700	Num	8	YNDKF.	At the present time:Does the participant's mother (or stepmother or female guardian) smoke?

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
75	MHX_1710	Num	8	YNDKF.	At the present time:Does the participant's father (or stepfather or male guardian) smoke?
76	MHX_1720	Num	8	YNDKF.	At the present time:Are there any other smokers in the household? (Include visitors, such as grandparents or baby-sitters, who visited at least once weekly.)



**Data Set Name: metha.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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.	2.	Was baseline (pre-diluent) spirometry completed?
5	MTH_1010	Num	8			Earliest expiration date of all 10 methacholine solutions
6	MTH_1020	Num	8	5.2	5.2	Solution 0 (diluent) FEV1
7	MTH_1030	Num	8	5.2	5.2	Solution 0 (diluent) FVC
8	MTH_1040	Num	8	5.2	5.2	Solution 0 (diluent 2) FEV1
9	MTH_1050	Num	8	5.2	5.2	Solution 0 (diluent 2) FVC
10	MTH_1060	Num	8	5.2	5.2	Solution 1 (0.098 mg/ml) FEV1
11	MTH_1070	Num	8	5.2	5.2	Solution 1 (0.098 mg/ml) FVC
12	MTH_1080	Num	8	5.2	5.2	Solution 2 (0.195 mg/ml) FEV1
13	MTH_1090	Num	8	5.2	5.2	Solution 2 (0.195 mg/ml) FVC
14	MTH_1100	Num	8	5.2	5.2	Solution 3 (0.391 mg/ml) FEV1
15	MTH_1110	Num	8	5.2	5.2	Solution 3 (0.391 mg/ml) FVC
16	MTH_1120	Num	8	5.2	5.2	Solution 4 (0.781 mg/ml) FEV1
17	MTH_1130	Num	8	5.2	5.2	Solution 4 (0.781 mg/ml) FVC
18	MTH_1140	Num	8	5.2	5.2	Solution 5 (1.563 mg/ml) FEV1
19	MTH_1150	Num	8	5.2	5.2	Solution 5 (1.563 mg/ml) FVC
20	MTH_1160	Num	8	5.2	5.2	Solution 6 (3.125 mg/ml) FEV1
21	MTH_1170	Num	8	5.2	5.2	Solution 6 (3.125 mg/ml) FVC
22	MTH_1180	Num	8	5.2	5.2	Solution 7 (6.25 mg/ml) FEV1
23	MTH_1190	Num	8	5.2	5.2	Solution 7 (6.25 mg/ml) FVC
24	MTH_1200	Num	8	5.2	5.2	Solution 8 (12.5 mg/ml) FEV1
25	MTH_1210	Num	8	5.2	5.2	Solution 8 (12.5 mg/ml) FVC
26	MTH_1220	Num	8	5.2	5.2	Solution 9 (25 mg/ml) FEV1
27	MTH_1230	Num	8	5.2	5.2	Solution 9 (25 mg/ml) FVC
28	MTH_1240	Num	8	YNF.	2.	Did the participant drop >= 20% of the post-diluent (Solution 0) FEV1 value?
29	MTH_1250	Num	8	7.3	7.3	If YES, record PC20
30	MTH_1260	Num	8	YNF.	2.	If NO, was the methacholine challenge stopped for safety
31	MTH_1270	Num	8	5.	5.	Time methacholine challenge was completed (based on 24-hour clock)
32	MTH_1280	Num	8	5.	5.	Time albuterol administered (based on 24-hour clock) (All participants must receive the standard reversal.)
33	MTH_1300	Num	8	5.2	5.2	Participant's FEV1 after standard reversal (2 puffs albuterol with Aerochamber) from methacholine challenge
34	MTH_1310	Num	8	5.	5.	Time of FEV1 in Question #7a (based on 24-hour clock)

Num	Variable	Type	Len	Format	Informat	Label
35	MTH_1320	Num	8	YNF.	2.	Was the FEV1 from Question #7a $\geq$ the Methacholine Reversal Reference Value in the gray box on page 1 of this form?

**Data Set Name: metha\_ad.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	MAD_1000	Num	8	YNF.	Was additional treatment used in the first hour?
5	MAD_1010	Num	8	YNF.	Additional albuterol by MDI
6	MAD_1020	Num	8	MAD_1020F.	Number of additional puffs of albuterol administered
7	MAD_1030	Num	8	YNF.	Nebulized beta-agonist
8	MAD_1040	Num	8	YNF.	Subcutaneous epinephrine
9	MAD_1050	Num	8	YNF.	Implementation of clinic emergency protocol or algorithm
10	MAD_1060	Num	8	YNF.	Other
11	MAD_1070	Num	8		FEV1
12	MAD_1080	Num	8		Time of FEV1 in Question #2a
13	MAD_1090	Num	8	YNF.	Was the FEV1 from Question #2a > the Methacholine
14	MAD_1100	Num	8	YNF.	Was additional treatment used after one hour?
15	MAD_1110	Num	8	YNF.	Additional albuterol by MDI
16	MAD_1120	Num	8	MAD_1120F.	Number of additional puffs of albuterol administered
17	MAD_1130	Num	8	YNF.	Nebulized beta-agonist
18	MAD_1140	Num	8	YNF.	Subcutaneous epinephrine
19	MAD_1150	Num	8	YNF.	Implementation of clinic emergency protocol or algorithm
20	MAD_1160	Num	8	YNF.	Treatment in the emergency room
21	MAD_1170	Num	8	YNF.	Overnight hospitalization
22	MAD_1180	Num	8	YNF.	Other
23	MAD_1190	Num	8		FEV1
24	MAD_1200	Num	8		Time of FEV1 in Question #4a
25	MAD_1210	Num	8	YNF.	Was the FEV1 from Question #4a > the Methacholine
26	MAD_1310	Num	8		Physician/CC Signature:
27	MAD_1320	Num	8		Date:

**Data Set Name: metha\_ch.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	MCH_1000	Num	8	YNF.	During the past 4 weeks, has the participant had any respiratory infections, colds, or bronchitis ?
5	MCH_1010	Num	8	YNF.	Has it been less than 4 weeks since the participant last took an oral or injectable steroid ?
6	MCH_1020	Num	8	YNF.	During the past 4 weeks, has the participant had any other severe acute illness?
7	MCH_1030	Num	8	YNF.	If YES, has the participant received permission from the supervising physician to proceed with the methacholine challenge testing?
8	MCH_1040	Num	8	YNF.	Is the participant currently having an acute asthma attack?
9	MCH_1050	Num	8	YNF.	Has the participant used any asthma medication other than study medication in the past month?
10	MCH_1060	Num	8		Inhaled Corticosteroid
11	MCH_1070	Num	8		Inhaled Corticosteroid date
12	MCH_1080	Num	8		Cromolyn/nedocromil
13	MCH_1090	Num	8		Cromolyn/nedocromil date
14	MCH_1100	Num	8		Leukotriene receptor antagonists
15	MCH_1110	Num	8		Leukotriene receptor antagonists date
16	MCH_1120	Num	8		Long-acting beta-agonist
17	MCH_1130	Num	8		Long-acting beta-agonist date
18	MCH_1140	Num	8	YNF.	Does the participant have a baseline FEV1 less than 70% of predicted FEV1?
19	MCH_1150	Num	8	MCH_1150F.	Pregnancy test results 1 Positive
20	MCH_1160	Num	8	YNF.	Is there any other reason you should not proceed with the methacholine challenge?
21	MCH_1170	Num	8	YNF.	Is the participant eligible to proceed with the diluent
22	MCH_1180	Num	8	YNF.	Was the Methacholine Challenge started?
23	MCH_1190	Num	8	MCH_1190F.	If NO, indicate the primary reason

**Data Set Name: pacqlq.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	PCQ_1000	Num	8	PCQ_1000F.	What is your relationship to the child?
5	PCQ_1010	Num	8	PCQ_1010TO1130F.	Did you feel helpless or frightened when your child experienced cough, wheeze, or breathlessness?
6	PCQ_1020	Num	8	PCQ_1010TO1130F.	Did your family need to change plans because of your child's asthma?
7	PCQ_1030	Num	8	PCQ_1010TO1130F.	Did you feel frustrated or impatient because your child was irritable due to asthma?
8	PCQ_1040	Num	8	PCQ_1010TO1130F.	Did your child's asthma interfere with your job or work around the house?
9	PCQ_1050	Num	8	PCQ_1010TO1130F.	Did you feel upset because of your child's cough, wheeze, or breathlessness?
10	PCQ_1060	Num	8	PCQ_1010TO1130F.	Did you have sleepless nights because of your child's asthma?
11	PCQ_1070	Num	8	PCQ_1010TO1130F.	Were you bothered because your child's asthma interfered with family relationships?
12	PCQ_1080	Num	8	PCQ_1010TO1130F.	Were you awakened during the night because of your child's asthma?
13	PCQ_1090	Num	8	PCQ_1010TO1130F.	Did you feel angry that your child has asthma?
14	PCQ_1100	Num	8	PCQ_1010TO1130F.	About your child's performance of normal daily activities?
15	PCQ_1110	Num	8	PCQ_1010TO1130F.	About your child's asthma medications and side effects?
16	PCQ_1120	Num	8	PCQ_1010TO1130F.	About being over-protective of your child?
17	PCQ_1130	Num	8	PCQ_1010TO1130F.	About your child being able to lead a normal life?

**Data Set Name: paqlqs.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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	QLQ_1000	Num	8	QLQ_BOTHERED.	2.	PHYSICAL ACTIVITIES (such as running, swimming, sports, walking uphill/upstairs and bicycling)?
5	QLQ_1010	Num	8	QLQ_BOTHERED.	2.	BEING WITH ANIMALS (such as playing with pets and looking after animals)?
6	QLQ_1020	Num	8	QLQ_BOTHERED.	2.	ACTIVITIES WITH FAMILY AND FRIENDS
7	QLQ_1030	Num	8	QLQ_BOTHERED.	2.	COUGHING
8	QLQ_1040	Num	8	QLQ_TIME.	2.	Feel FRUSTRATED because of your asthma?
9	QLQ_1050	Num	8	QLQ_TIME.	2.	Feel TIRED because of your asthma?
10	QLQ_1060	Num	8	QLQ_TIME.	2.	Feel WORRIED, CONCERNED OR TROUBLED because of your asthma?
11	QLQ_1070	Num	8	QLQ_BOTHERED.	2.	ASTHMA ATTACKS?
12	QLQ_1080	Num	8	QLQ_TIME.	2.	Feel ANGRY because of asthma?
13	QLQ_1090	Num	8	QLQ_BOTHERED.	2.	WHEEZING?
14	QLQ_1100	Num	8	QLQ_TIME.	2.	Feel IRRITABLE (cranky/grouchy) because of your asthma?
15	QLQ_1110	Num	8	QLQ_BOTHERED.	2.	TIGHTNESS IN YOUR CHEST?
16	QLQ_1120	Num	8	QLQ_TIME.	2.	Feel DIFFERENT OR LEFT OUT because of your asthma?
17	QLQ_1130	Num	8	QLQ_BOTHERED.	2.	SHORTNESS OF BREATH?
18	QLQ_1140	Num	8	QLQ_TIME.	2.	Feel FRUSTRATED BECAUSE YOU COULDN'T KEEP UP WITH OTHERS?
19	QLQ_1150	Num	8	QLQ_TIME.	2.	WAKE UP DURING THE NIGHT because of your asthma?
20	QLQ_1160	Num	8	QLQ_TIME.	2.	Feel UNCOMFORTABLE because of your asthma?
21	QLQ_1170	Num	8	QLQ_TIME.	2.	Feel OUT OF BREATH because of your asthma?
22	QLQ_1180	Num	8	QLQ_TIME.	2.	Feel YOU COULDN'T KEEP UP WITH OTHERS because of your asthma?
23	QLQ_1190	Num	8	QLQ_TIME.	2.	Have trouble SLEEPING AT NIGHT because of asthma?
24	QLQ_1200	Num	8	QLQ_TIME.	2.	Feel FRIGHTENED BY AN ASTHMA ATTACK?
25	QLQ_1210	Num	8	QLQ_BOTHERED.	2.	How much were you bothered by your asthma during these activities?
26	QLQ_1220	Num	8	QLQ_TIME.	2.	Have difficulty taking a DEEP BREATH?

**Data Set Name: *pefr.sas7bdat***

Num	Variable	Type	Len	Format	Informat	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	PFR_1000	Num	8	4.	4.	Reference Value determined at previous visit
5	PFR_1010	Num	8	4.	4.	Highest Peak Flow from Pool
6	PFR_1020	Num	8	4.	4.	2nd highest Peak Flow from Pool
7	PFR_1030	Num	8	4.	4.	3rd highest Peak Flow from Pool
8	PFR_1040	Num	8	YNF.	2.	Is the highest Peak Flow from the Pool equal to the participant's Reference Value from the last visit
9	PFR_1050	Num	8	5.2	5.2	Question #3/Question #2
10	PFR_1060	Num	8	YNF.	2.	Is Question #6 greater than 0.9?
11	PFR_1070	Num	8	5.2	5.2	Question #4/Question #3
12	PFR_1080	Num	8	YNF.	2.	Is Question #8 greater than 0.9?
13	PFR_1090	Num	8	4.	4.	Reference Value

**Data Set Name: pft\_chk.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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	PFT_1000	Num	8	YNF.	2.	During the past 48 hours, has the participant used any oral decongestants or cold remedies?
5	PFT_1010	Num	8	YNF.	2.	During the past 4 hours, has the participant consumed caffeine?
6	PFT_1020	Num	8	YNF.	2.	During the past 8 hours, has the participant used medications with caffeine?
7	PFT_1030	Num	8	YNF.	2.	During the past 2 weeks, has the participant had any respiratory infections, colds, or bronchitis?
8	PFT_1040	Num	8	YNDKF.	2.	During the past 24 hours, has the participant taken the study medication?
9	PFT_1050	Num	8	YESF.	2.	Tablet/Capsule
10	PFT_1055	Num	8	3.	3.	Tablet/Capsule Hours
11	PFT_1060	Num	8	YESF.	2.	Diskus
12	PFT_1065	Num	8	3.	3.	Diskus Hours
13	PFT_1070	Num	8	YESF.	2.	MDI
14	PFT_1075	Num	8	3.	3.	MDI Hours
15	PFT_1080	Num	8	YESF.	2.	Nebulizer
16	PFT_1085	Num	8	3.	3.	Nebulizer Hours
17	PFT_1090	Num	8	YESF.	2.	Other
18	PFT_1095	Num	8	3.	3.	Other Hours
19	PFT_1100	Num	8	YNF.	2.	During the past 24 hours, has the participant used sustained-release theophylline?
20	PFT_1110	Num	8	YNF.	2.	During the past 12 hours, has the participant used a long-acting bronchodilator?
21	PFT_1120	Num	8	YNF.	2.	During the past 4 hours, has the participant used a short-acting bronchodilator?
22	PFT_1130	Num	8	YNF.	2.	Is there any other reason the participant should not proceed with pulmonary function testing?
23	PFT_1140	Num	8	YNF.	2.	Is the participant eligible to proceed with pulmonary function testing?
24	PFT_1150	Num	8	6.1	6.1	Standing height (barefoot or thin socks):
25	PFT_1160	Num	8	YNNAF.	2.	Exhaled Nitric Oxide Testing
26	PFT_1170	Num	8	PFT_1170F.	2.	Exhaled Nitric Oxide Testing If NO, indicate the reason
27	PFT_1200	Num	8	YNNAF.	2.	Pre-Bronchodilator IOS Testing
28	PFT_1210	Num	8	PFT_1210F.	2.	Pre-Bronchodilator IOS Testing If NO, indicate the reason
29	PFT_1220	Num	8	YNNAF.	2.	Post-Bronchodilator IOS Testing
30	PFT_1230	Num	8	PFT_1230F.	2.	Post-Bronchodilator IOS Testing If NO, indicate the reason
31	PFT_1240	Num	8	YNNAF.	2.	Pre-Bronchodilator Spirometry
32	PFT_1250	Num	8	PFT_1250F.	2.	Pre-Bronchodilator Spirometry If NO, indicate the reason
33	PFT_1260	Num	8	YNNAF.	2.	Post-Bronchodilator Spirometry
34	PFT_1270	Num	8	PFT_1270F.	2.	Post-Bronchodilator Spirometry If NO, indicate the reason



<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Informat</b>	<b>Label</b>
35	PFT_1280	Num	8	YNNAF.	2.	Maximal Bronchodilator Testing
36	PFT_1290	Num	8	PFT_1290F.	2.	Maximal Bronchodilator Testing If NO, indicate the reason
37	PFT_1300	Num	8	YNNAF.	2.	Methacholine Challenge Testing
38	PFT_1310	Num	8	PFT_1310F.	2.	Methacholine Challenge Testing If NO, indicate the reason

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

Num	Variable	Type	Len	Format	Informat	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	PHY_1000	Num	8	5.	5.	Time measurements started (based on a 24-hour clock)
5	PHY_1010	Num	8	6.1	6.1	Standing height (barefoot or thin socks)
6	PHY_1020	Num	8	6.1	6.1	Standing height First measurement
7	PHY_1030	Num	8	6.1	6.1	Standing height Second measurement
8	PHY_1040	Num	8	6.1	6.1	Standing height Third measurement
9	PHY_1050	Num	8	YNF.	2.	Average height measurement
10	PHY_1060	Num	8	6.1	6.1	In your judgement, was the participant's height measurement acceptable?
11	PHY_1070	Num	8	YNF.	2.	Weight (shoes off, light clothing)
12	PHY_1080	Num	8	YNF.	2.	Slight expiratory wheeze
13	PHY_1090	Num	8	YNF.	2.	Loud expiratory wheeze
14	PHY_1100	Num	8	YNF.	2.	Inspiratory and expiratory wheeze
15	PHY_1110	Num	8	YNF.	2.	Rales
16	PHY_1120	Num	8	YNF.	2.	Rhonchi
17	PHY_1130	Num	8	YNF.	2.	Crackles
18	PHY_1140	Num	8	YNF.	2.	Other_____
19	PHY_1150	Num	8	YNF.	2.	Does the participant have evidence of oral candidiasis?
20	PHY_1160	Num	8	PHY_1160TO1170F.	2.	In general, how would you describe the participant's nasal symptoms?
21	PHY_1170	Num	8	PHY_1160TO1170F.	2.	In general, how would you describe the participant's eczema?

**Data Set Name: priormed.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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	PRM_1000F.	2.	Who is the respondent?
5	PRM_1010	Num	8	YNF.	2.	In the past 12 months, has the participant used any asthma medication(s) other than albuterol
6	PRM_1020	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Salmeterol (Serevent) or formoterol (Foradil)
7	PRM_1030	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Inhaled or nebulized corticosteroids
8	PRM_1040	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Leukotriene Modifiers [montelukast (Singulair), zafirlukast (Accolate)]
9	PRM_1050	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Theophylline (Slo-bid, Theo-dur, Slo-Phyllin)
10	PRM_1060	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Advair/Symbicort
11	PRM_1070	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Cromolyn/Nedocromil (Intal, Tilade)
12	PRM_1080	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Other:
13	PRM_1090	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Other:
14	PRM_1100	Num	8	PRM_1100F.	2.	In the past 12 months, how many courses of steroids by mouth or injection has the participant taken for asthma?

**Data Set Name: registry.sas7bdat**

Num	Variable	Type	Len	Format	Informat	Label
1	SUBJ_ID	Num	8			Public Subject ID
2	REG_1000	Num	8	YNF.	2.	Did the parent/legal guardian sign and date a CARE Protocol
3	REG_1020	Num	8	YNF.	2.	If YES, did the participant sign and date a CARE Protocol Informed Assent and HIPAA Authorization form?
4	REG_1050	Num	8	REG_1050F.	2.	Participant's gender
5	REG_1060	Num	8	REG_1060F.	2.	Participant's ethnic background
6	REG_1070	Num	8	YNF.	2.	American Indian or Alaskan Native
7	REG_1090	Num	8	YNF.	2.	Black or African American
8	REG_1100	Num	8	YNF.	2.	White
9	REG_1120	Num	8	REG_1120F.	2.	Participant's primary racial identification
10	REG_1015	Num	8	YNF.	2.	Is participant assent required for the protocol in Question #1?
11	AGE	Num	8			Difference between the enrollment date and the birthdate
12	REG_OTHER	Num	8			Other Race(Asian, Native Hawaiian or Other Pacific Islander)

**Data Set Name: s5.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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	S_1000	Num	8	S_1000TO1030F.	2.	Blocked up or stuffy nose
5	S_1010	Num	8	S_1000TO1030F.	2.	Headaches or face pain
6	S_1020	Num	8	S_1000TO1030F.	2.	Coughing during the day
7	S_1030	Num	8	S_1000TO1030F.	2.	Coughing at night
8	S_1040	Num	8	S_1040F.	2.	During the last few days, what has been the color of the mucus from your child's nose?

**Data Set Name: serious.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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			Date of Adverse Event
5	SER_1010	Char	6	\$6.	\$6.	Description of Adverse Event . Describe: _____
6	SER_1020	Num	8	YNF.	2.	Is the participant currently taking study drug? If NO, proceed to Question #6.
7	SER_1030	Num	8	4.	4.	Time interval between the last administration of the study drug and the Adverse Event
8	SER_1040	Num	8	YNF.	2.	What was the unit of time for the interval in Question #4?
9	SER_1050	Num	8	YNF.	2.	Fatal event
10	SER_1060	Num	8	YNF.	2.	Life-threatening event
11	SER_1070	Num	8	YNF.	2.	Inpatient hospitalization required If NO, proceed to Question #6d.
12	SER_1080	Num	8			Admission date
13	SER_1090	Num	8			Discharge date
14	SER_1100	Num	8	YNF.	2.	Disabling or incapacitating
15	SER_1110	Num	8	YNF.	2.	Overdose
16	SER_1120	Num	8	YNF.	2.	Cancer
17	SER_1130	Num	8	YNF.	2.	Congenital anomaly
18	SER_1140	Num	8	YNF.	2.	Serious laboratory abnormality with clinical symptoms
19	SER_1150	Num	8	YNF.	2.	Height failure
20	SER_1160	Num	8	YNDKF.	2.	Pregnancy
21	SER_1170	Num	8	YNF.	2.	Other _____
22	SER_1180	Num	8	YNF.	2.	Toxicity of study drug
23	SER_1190	Num	8	YNF.	2.	Withdraw of study drug
24	SER_1200	Num	8	YNF.	2.	Concurrent medication
25	SER_1210	Num	8	YNF.	2.	Other condition or event

**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_1000	Num	8	YNF.	Has the participant had a previous skin test using CARE procedures within the approved time limit?
5	SKN_1010	Num	8		Date of previous skin test // Month Day Year
6	SKN_1030	Num	8	YNF.	Has the participant used any of the medications, listed in the skin test section of the CARE MOP within the exclusionary periods?
7	SKN_1040	Num	8	YNF.	If YES, STOP HERE, reschedule the skin testing procedure. Has the participant ever had a severe systemic reaction to allergy skin testing?
8	SKN_1050	Num	8	YNF.	Has the participant ever had an anaphylactic reaction to egg?
9	SKN_1060	Num	8	YNF.	Has the participant ever had an anaphylactic reaction to peanut?
10	SKN_1070	Num	8	YNF.	Has the participant ever had an anaphylactic reaction to milk?
11	SKN_1080	Num	8		Time test sites pricked (based on a 24-hour clock)
12	SKN_1090	Num	8		Time test sites evaluated (based on a 24-hour clock)
13	SKN_1100	Num	8		((Histamine: Largest Wheal) + (Histamine: Perpendicular Wheal))/2 mm
14	SKN_1110	Num	8	YNF.	Is SKN_1100 < 3mm?
15	SKN_1120	Num	8		((Saline: Largest Wheal) + (Saline: Perpendicular Wheal))/2 mm
16	SKN_1130	Num	8		SKN_1100 - SKN_1120
17	SKN_1140	Num	8	YNF.	Is SKN_1130 < 3 mm?
18	SKN_1150	Num	8		SKN_1120 + 3 mm
19	SKN_1160	Num	8	YNF.	Histamine (A1) Was there a reaction?
20	SKN_1170	Num	8		Histamine (A1) Largest Wheal Diameter:
21	SKN_1180	Num	8		Histamine (A1) Perpendicular Wheal Diameter:
22	SKN_1190	Num	8	YNF.	Mite Mix (A2) Was there a reaction?
23	SKN_1200	Num	8		Mite Mix (A2) Largest Wheal Diameter:
24	SKN_1210	Num	8		Mite Mix (A2) Perpendicular Wheal Diameter:
25	SKN_1220	Num	8	YNF.	Roach Mix (A3) Was there a reaction?
26	SKN_1230	Num	8		Roach Mix (A3) Largest Wheal Diameter:
27	SKN_1240	Num	8		Roach Mix (A3) Perpendicular Wheal Diameter:
28	SKN_1250	Num	8	YNF.	Cat (A4) Was there a reaction?
29	SKN_1260	Num	8		Cat (A4) Largest Wheal Diameter:
30	SKN_1270	Num	8		Cat (A4) Perpendicular Wheal Diameter:
31	SKN_1280	Num	8	YNF.	Dog (A5) Was there a reaction?
32	SKN_1290	Num	8		Dog (A5) Largest Wheal Diameter:
33	SKN_1300	Num	8		Dog (A5) Perpendicular Wheal Diameter:
34	SKN_1310	Num	8	YNF.	Mold Mix (A6) Was there a reaction?

Num	Variable	Type	Len	Format	Label
35	SKN_1320	Num	8		Mold Mix (A6) Largest Wheal Diameter:
36	SKN_1330	Num	8		Mold Mix (A6) Perpendicular Wheal Diameter:
37	SKN_1340	Num	8	YNF.	Grass Mix (A7) Was there a reaction?
38	SKN_1350	Num	8		Grass Mix (A7) Largest Wheal Diameter:
39	SKN_1360	Num	8		Grass Mix (A7) Perpendicular Wheal Diameter:
40	SKN_1370	Num	8	YNF.	Saline (A8) Was there a reaction?
41	SKN_1380	Num	8		Saline (A8) Largest Wheal Diameter:
42	SKN_1390	Num	8		Saline (A8) Perpendicular Wheal Diameter:
43	SKN_1400	Num	8	YNF.	Tree Mix (B1) Was there a reaction?
44	SKN_1410	Num	8		Tree Mix (B1) Largest Wheal Diameter:
45	SKN_1420	Num	8		Tree Mix (B1) Perpendicular Wheal Diameter:
46	SKN_1430	Num	8	YNF.	Weed Mix (B2) Was there a reaction?
47	SKN_1440	Num	8		Weed Mix (B2) Largest Wheal Diameter:
48	SKN_1450	Num	8		Weed Mix (B2) Perpendicular Wheal Diameter:
49	SKN_1460	Num	8	YNF.	Milk (B3) Was there a reaction?
50	SKN_1470	Num	8		Milk (B3) Largest Wheal Diameter:
51	SKN_1480	Num	8		Milk (B3) Perpendicular Wheal Diameter:
52	SKN_1490	Num	8	YNF.	Egg (B4) Was there a reaction?
53	SKN_1500	Num	8		Egg (B4) Largest Wheal Diameter:
54	SKN_1510	Num	8		Egg (B4) Perpendicular Wheal Diameter:
55	SKN_1520	Num	8	YNF.	Peanut (B5) Was there a reaction?
56	SKN_1530	Num	8		Peanut (B5) Largest Wheal Diameter:
57	SKN_1540	Num	8		Peanut (B5) Perpendicular Wheal Diameter:
58	SKN_1550	Num	8	YNF.	Other _____ (B6) Was there a reaction?
59	SKN_1560	Num	8		Other _____ (B6) Largest Wheal Diameter:
60	SKN_1570	Num	8		Other _____ (B6) Perpendicular Wheal Diameter:
61	SKN_1580	Num	8	YNF.	Other _____ (B7) Was there a reaction?
62	SKN_1590	Num	8		Other _____ (B7) Largest Wheal Diameter:
63	SKN_1600	Num	8		Other _____ (B7) Perpendicular Wheal Diameter:
64	SKN_1610	Num	8	YNF.	Other _____ (B8) Was there a reaction?
65	SKN_1620	Num	8		Other _____ (B8) Largest Wheal Diameter:
66	SKN_1630	Num	8		Other _____ (B8) Perpendicular Wheal Diameter:



**Data Set Name: sn\_5.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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	SN_1000	Num	8	SN_1000TO1040F.	2.	SINUS INFECTION: Nasal discharge, bad breath, daytime cough, post-nasal drip, headache, facial pain or head banging. How often was this a problem for your child during the past 4 weeks?
5	SN_1010	Num	8	SN_1000TO1040F.	2.	NASAL OBSTRUCTION: Stuffy or blocked nose, nasal congestion, reduced sense of smell, trouble breathing with mouth closed. How often was this a problem for your child during the past 4 weeks?
6	SN_1020	Num	8	SN_1000TO1040F.	2.	ALLERGY SYMPTOMS: Sneezing, itchy nose/eyes, need to rub nose/eyes, or watery eyes. How often was this a problem for your child during the past 4 weeks?
7	SN_1030	Num	8	SN_1000TO1040F.	2.	EMOTIONAL DISTRESS: Irritable, frustrated, sad, restless, or trouble sleeping. How often was this a problem for your child during the past 4 weeks because of nose or sinus illness?
8	SN_1040	Num	8	SN_1000TO1040F.	2.	ACTIVITY LIMITATIONS: Missed school/daycare, lost time with family/friends, unable to do projects. How often was this a problem for your child during the past 4 weeks because of nose or sinus illness?
9	SN_1050	Num	8	3.	3.	Overall, how would you rate your child's quality of life as a result of nose or sinus problems?

**Data Set Name: *spiro\_po.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	SPO_1000	Num	8		Time bronchodilator given
5	SPO_1010	Num	8		Time post-bronchodilator spirometry started 24-hour clock)
6	SPO_1020	Num	8		FVC . L
7	SPO_1030	Num	8		FEV1 . L
8	SPO_1040	Num	8		FEV1 % predicted
9	SPO_1050	Num	8		FEV1 / FVC %
10	SPO_1060	Num	8		FEF25-75 . liters/sec
11	SPO_1140	Num	8		ATS Accepted .
12	SPO_1150	Num	8		ATS Error Code .
13	SPO_1160	Num	8	YNF.	In your judgement, was the participant's post-bronchodilator technique acceptable?
14	SPO_1170	Num	8	YNF.	Inadequate start of test, no rapid onset of expiration, large back extrapolation
15	SPO_1180	Num	8	YNF.	Unacceptable peak flow
16	SPO_1190	Num	8	YNF.	Unacceptable FET
17	SPO_1200	Num	8	YNF.	Cough/Glottic closure during maneuver
18	SPO_1210	Num	8	YNF.	Abrupt ending, sharp drop, or cessation in flow
19	SPO_1220	Num	8	YNF.	Other
20	SPO_1230	Num	8	SPO_1230F.	If YES, grade the participant's technique

**Data Set Name: *spiro\_pr.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_1010	Num	8		Time spirometry started
5	SPR_1020	Num	8		FVC . L
6	SPR_1030	Num	8		FEV1 . L
7	SPR_1040	Num	8		FEV1 % predicted
8	SPR_1050	Num	8		FEV1 / FVC %
9	SPR_1060	Num	8		FEF25-75 . liters/sec
10	SPR_1070	Num	8		FEF50 . liters/sec
11	SPR_1080	Num	8		FEF75 . liters/sec
12	SPR_1090	Num	8		PEF . liters/sec
13	SPR_1100	Num	8		FET . sec
14	SPR_1110	Num	8		FET PEF . sec
15	SPR_1120	Num	8		V backextrapolation ex . liters
16	SPR_1130	Num	8		V backextrapolation % FVC . %
17	SPR_1140	Num	8		ATS Accepted .
18	SPR_1150	Num	8		ATS Error Code .
19	SPR_1160	Num	8	YNF.	In your judgement, was the participant's pre-bronchodilator
20	SPR_1170	Num	8	YNF.	Inadequate start of test, no rapid onset of expiration,
21	SPR_1180	Num	8	YNF.	Unacceptable peak flow
22	SPR_1190	Num	8	YNF.	Unacceptable FET
23	SPR_1200	Num	8	YNF.	Cough/Glottic closure during maneuver
24	SPR_1210	Num	8	YNF.	Abrupt ending, sharp drop, or cessation in flow
25	SPR_1220	Num	8	YNF.	Other
26	SPR_1230	Num	8	SPO_1230F.	If YES, grade the participant's technique

**Data Set Name: term.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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_1000	Num	8	YNF.	2.	Has the participant completed the study?
5	TRM_1020	Num	8	YNF.	2.	Has the participant been deemed ineligible prior to randomization?
6	TRM_1030	Num	8	TRM_1030F.	3.	If YES, indicate the primary reason.
7	TRM_1040	Num	8	YNF.	2.	Has the participant been withdrawn from the study due to pregnancy?
8	TRM_1070	Num	8	YNF.	2.	Has the participant been assigned treatment failure status?
9	TRM_1080	Num	8	YNF.	2.	Has the participant been lost to follow up?
10	TRM_1090	Num	8	YNF.	2.	Has the participant experienced a serious adverse event?
11	TRM_1100	Num	8	YNF.	2.	Did a physician initiate the termination of study participation?
12	TRM_1110	Num	8	YNF.	2.	Is there any other reason why the participant is being terminated from the study?
13	TRM_1120	Num	8	TRM_1120F.	3.	If YES, indicate the primary reason.
14	TRM_1130	Num	8	2.	2.	Clinic Coordinator's Signature
15	TRM_1140	Num	8			Clinic Coordinator's Signature Date: //
16	TRM_1150	Num	8	2.	2.	Principal Investigator's Signature
17	TRM_1160	Num	8			Principal Investigator's Signature Date

**Data Set Name: trtfail.sas7bdat**

Num	Variable	Type	Len	Format	Informat	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.	2.	Has the participant met the criteria for inadequate control?
5	TXF_1010	Num	8	YNF.	2.	Has the participant been hospitalized for asthma?
6	TXF_1020	Num	8	YNF.	2.	Has the participant had a hypoxic seizure due to asthma?
7	TXF_1030	Num	8	YNF.	2.	Has the participant required intubation for asthma?
8	TXF_1040	Num	8	YNF.	2.	Has the participant received, or will he/she receive a course of an oral/systemic corticosteroid for an asthma exacerbation?
9	TXF_1045	Num	8			What was the start date of the oral/systemic corticosteroid? //
10	TXF_1050	Num	8	TXF_1050F.	2.	Why was the course prescribed?
11	TXF_1060	Num	8	YNF.	2.	Is the participant a treatment failure? If any of the shaded boxes are selected, the participant is a treatment failure.
12	TXF_1070	Num	8			Date treatment failure occurred //
13	TXF_1080	Num	8	2.	2.	Physician/CC signature: _____
14	TXF_1090	Num	8			Physician/CC signature Date: //