#### Data Set Name: act.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
4	ACT_1000	Num	8	ACT_1000F.	2.	In the past 4 wks, how much time did asthma keep you from getting as much done at work/school/home?
5	ACT_1010	Num	8	ACT_1010F.	2.	During the past 4 wks, how often have you had shortness of breath?
6	ACT_1020	Num	8	ACT_1020F.	2.	During the past 4 wks, how often did asthma symptoms wake you up?
7	ACT_1030	Num	8	ACT_1030F.	2.	During the past 4 wks, how often have you used your rescue inhaler or nebulizer medication?
8	ACT_1040	Num	8	ACT_1040F.	2.	How would you rate you asthma control during the past 4 wks?

## $\textit{Data Set Name: ae\_clin.sas7bdat}$

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 - Event count number
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.	Туре
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

## $\textit{Data Set Name: } c\_act.sas7bdat$

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
4	CAT_1000	Num	8	CAT_1000F.	How is your asthma today?
5	CAT_1010	Num	8	CAT_1010F.	How much of a problem is your asthma when you run, exercise, or play sports?
6	CAT_1020	Num	8	CAT_1020F.	Do you cough because of your asthma?
7	CAT_1030	Num	8	CAT_1030F.	Do you wake up during the night because of your asthma?
8	CAT_1040	Num	8	DAYMOF.	During the last 4 wks, on average, how many days per month did your child have daytime asthma symptoms?
9	CAT_1050	Num	8	DAYMOF.	During the last 4 wks, on average, how many days per month did your child wheeze during the day because of asthma?
10	CAT_1060	Num	8	DAYMOF.	During the last 4 wks, on average, how many days per month did your child wake up during the night because of asthma?

# Data Set Name: cap\_feia.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
4	CAP_1000	Num	8	7.2	7.2	Mite Mix CAP/FEIA test result
5	CAP_1010	Num	8	7.2	7.2	Roach Mix CAP/FEIA test result
6	CAP_1020	Num	8	7.2	7.2	Cat CAP/FEIA test result
7	CAP_1030	Num	8	7.2	7.2	Dog CAP/FEIA test result
8	CAP_1040	Num	8	7.2	7.2	Mold Mix CAP/FEIA test result
9	CAP_1050	Num	8	7.2	7.2	Grass Mix CAP/FEIA test result
10	CAP_1060	Num	8	7.2	7.2	Tree Mix CAP/FEIA test result
11	CAP_1070	Num	8	7.2	7.2	Weed Mix CAP/FEIA test result
12	CAP_1080	Num	8	7.2	7.2	Milk CAP/FEIA test result
13	CAP_1090	Num	8	7.2	7.2	Egg CAP/FEIA test result
14	CAP_1100	Num	8	7.2	7.2	Peanut CAP/FEIA test result
15	CAP_1110	Num	8	7.2	7.2	Other CAP/FEIA test result
16	CAP_1120	Num	8	7.2	7.2	Other CAP/FEIA test result

## $Data\ Set\ Name:\ cmed\_as.sas7bdat$

Num	Variable	Type	Len	Format	Label
1	SUBJ_ID	Num	8		Public Subject ID
2	VNUM	Num	8		Visit Number
3	CMD_1010	Num	8		Name of Medication - Medication count number
4	CMD_1000	Num	8		Code - link to DRUGCODE variable in MEDCODES dataset
5	CMD_1020	Num	8		Related Event number - link to CAE_1020 variable in AECLIN dataset
6	CMD_1030	Num	8	YESF.	Related Event - N/A
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
4	CMP_1000	Num	8	4.	4.	Diskus: number of scheduled inhalations
5	CMP_1010	Num	8	4.	4.	Diskus: total number of used doses
6	CMP_1020	Num	8	6.1	6.1	Diskus: percent adherence (CMP_1010/CMP_1000 x 100)
7	CMP_1030	Num	8	6.1	6.1	eDEM Monitor: % prescribed number of doses taken
8	CMP_1035	Num	8	6.1	6.1	eDEM Monitor: % days correct number of doses taken
9	CMP_1040	Num	8	4.	4.	Tablet count: number of scheduled tablets for tablet bottle
10	CMP_1050	Num	8	4.	4.	Tablet count: number of tablets dispensed in tablet bottle
11	CMP_1060	Num	8	4.	4.	Tablet count: number of tablets returned in tablet bottle
12	CMP_1070	Num	8	4.	4.	Tablet count: actual number of tablets taken (CMP_1050-CMP_1060)
13	CMP_1080	Num	8	6.1	6.1	Tablet count: percentage adherence (CMP_1070/CMP_1040) x 100)

## Data Set Name: contr\_ph.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
4	CPH_1000	Num	8	YNF.	Since the last study visit, has the participant been hospitalized for asthma?
5	CPH_1010	Num	8	YNF.	Since the last study visit, has an oral or injectable corticosteriod been used for asthma?
6	CPH_1030	Num	8	YNF.	Is the particpant eligible?
7	CPH_1040	Num	8	YNF.	Is the participant's asthma controlled according to the diary card?

## 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
4	DIARYDT	Num	8			Diary Date
5	DRY_1000	Num	8	YNF.	2.	Awakened at night to use albuterol for asthma?
6	DRY_1010	Num	8	5.	5.	Time of Wake Up Peak Flow
7	DRY_1020	Num	8	4.	4.	Wake Up Peak Flow (best of 3 tries)
8	DRY_1030	Num	8	YNF.	2.	Albuterol used in the two hours before Wake Up Peak Flow?
9	DRY_1040	Num	8	YNF.	2.	Number of study diskus inhalation(s) at Wake Up?
10	DRY_1050	Num	8	5.2	5.2	Coordinator Completed Wake Up FEV1 (liters)
11	DRY_1060	Num	8	5.	5.	Time of Bedtime Peak Flow
12	DRY_1070	Num	8	4.	4.	Bedtime Peak Flow (Best of 3 tries)
13	DRY_1080	Num	8	YNF.	2.	Albuterol used in the two hours before Bedtime Peak Flow?
14	DRY_1090	Num	8	YNF.	2.	Number of study diskus inhalation(s) at bedtime?
15	DRY_1110	Num	8	YNF.	2.	Study tablet taken at bedtime?
16	DRY_1120	Num	8	5.2	5.2	Coordinator Completed Bedtime FEV1 (liters)
17	DRY_1130	Num	8	SYMRATINGSCALEF.	2.	Rate your coughing from asthma during the past 24 hours
18	DRY_1140	Num	8	SYMRATINGSCALEF.	2.	Rate your wheezing during the past 24 hours
19	DRY_1150	Num	8	3.	3.	Num of puffs of albuterol taken before exercise in the past 24 hours
20	DRY_1160	Num	8	3.	3.	Num of puffs of albuterol taken for asthma sympotms or low peak flow in the past 24 hours
21	DRY_1180	Num	8	YNNAF.	2.	Absent from school or work for asthma symptoms?
22	DRY_1190	Num	8	YNF.	2.	Seen by a health care provider for asthma symptoms?

N	um	Variable	Type	Len	Label
	1	SUBJ_ID	Num	8	Public Subject ID
	2	DRUG_SEQ	Char	30	Treatment sequence assigned to subject at randomization

## 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
4	E1_1000	Num	8	YNF.	2.	Has the parent/guardian appropriately signed and dated the consent?
5	E1_1010	Num	8			If yes, date 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, given verbal assent?
7	E1_1030	Num	8			If yes, date of assent
8	E1_1040	Num	8	YNF.	2.	Has the participant consented to a genotype evaluation?
9	E1_1050	Num	8			If yes, date signed
10	E1_1055	Num	8	YNF.	2.	Will the participant be using Spanish translated materials while enrolled in the TREXA Study?
11	E1_1060	Num	8	YNF.	2.	Is the participant able to chew or swallow (whichever is applicable) the study tablets?
12	E1_1070	Num	8	YNDKF.	2.	Is the participant currently intolerant of or allergic to ICS (fluticasone), LTRA (montelukast), LABA (salmetrol) or any of their ingredients?
13	E1_1080	Num	8	YNF.	2.	Is the participant able to take albuterol (such as Proventil and Ventolin), or is the participant able to take xopenex?
14	E1_1090	Num	8	YNF.	2.	Has the participant had her first period?
15	E1_1100	Num	8	YNF.	2.	Is the participant currently pregnant or nursing?
16	E1_1110	Num	8	YNF.	2.	Does the participant agree to avoid pregnancy during the study?
17	E1_1120	Num	8	YNF.	2.	Is the participant eligible?
18	E1_1130	Num	8	YNF.	2.	Is the participant 6 to < 18 years old?
19	E1_1140	Num	8	YNF.	2.	Has the participant smoked 11 or more cigarettes or any other substance in the past year?
20	E1_1150	Num	8	YNF.	2.	Has the participant used smokeless tobacco products (chew, snuff) 11 or more times in the past year?
21	E1_1160	Num	8	YNF.	2.	Has the participant ever had chicken pox or received the chicken pox vaccine?
22	E1_1170	Num	8	YNF.	2.	Is the participant receiving allergy shots?
23	E1_1180	Num	8	YNF.	2.	If YES, has the dose been changed in the past 3 months?
24	E1_1190	Num	8	YNF.	2.	During the past year, has the participant had 6 or more courses of oral or systemic corticosteriods for asthma?
25	E1_1200	Num	8	YNF.	2.	Has the participant been hospitalized more than 3 times for asthma during the past year?
26	E1_1210	Num	8	YNF.	2.	Has the participant had an asthma exacerbation resulting in intubation, mechanical ventilation or resulting in a hypoxic seizure within the past 5 years?
27	E1_1220	Num	8	YNF.	2.	Has the participant had a significant asthma exacerbation requiring corticosteriods within the past 2 weeks?
28	E1_1230	Num	8	YNF.	2.	Has the participant used an oral, injectable or systemic corticosteroid for any reason in the past 2 weeks?

Num	Variable	Type	Len	Format	Informat	Label
29	E1_1240	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?
30	E1_1250	Num	8	YNF.	2.	Does the participant have any active or chronic lung disease other than asthma?
31	E1_1260	Num	8	YNF.	2.	Does the participant have a significant medical illness other than asthma?
32	E1_1270	Num	8	YNF.	2.	Does the participant have a history of gastroesophageal reflux symptoms not controlled by standard medical therapy?
33	E1_1280	Num	8	YNF.	2.	Does the participant have a history of cataracts, glaucoma, or any other medical disorder associated with an adverse effect to corticosteroids?
34	E1_1290	Num	8	YNF.	2.	During the past 2 weeks, has the participant used any medications known to significantly interact with corticosteroid disposition?
35	E1_1300	Num	8	YNF.	2.	Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (P7_EXCLDRUG) during the designated washout periods?
36	E1_1310	Num	8	YNF.	2.	Has the participant been involved in another investigational drug study within the past month (except for the CARE Network TREXA trial)?
37	E1_1320	Num	8	YNF.	2.	Does the participant's family have plans to move out of the area within the next 12 months?
38	E1_1330	Num	8	YNF.	2.	Is there any other reason for which this participant should not be included in this study?
39	E1_1340	Num	8	YNF.	2.	Is the participant eligible?

## 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	
4	E2_1000	Num	8	YNF.	2.	Has the participant been treated with a controller therapy for at least 4 v to visit 1?	veeks prior
5	E2_1050	Num	8	4.	4.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	QVAR
6	E2_1060	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: QVAR N/A	
7	E2_1090	Num	8	5.	5.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	Pulmicort
8	E2_1100	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Pulmicort N/A	
9	E2_1105	Num	8	4.	4.	Quantity of controller therapy participant took during the last 4 weeks: Symbicort mcg/day	
10	E2_1106	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Symbicort N/A	
11	E2_1110	Num	8	5.	5.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	Aerobid
12	E2_1120	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Aerobid N/A	
13	E2_1130	Num	8	4.	4.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	Flovent
14	E2_1140	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Flovent N/A	
15	E2_1170	Num	8	5.	5.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	Azmacort
16	E2_1180	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Azmacort N/A	
17	E2_1190	Num	8	4.	4.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	Singulair
18	E2_1200	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Singulair N/A	
19	E2_1210	Num	8	4.	4.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	Accolate
20	E2_1220	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Accolate N/A	
21	E2_1230	Num	8	5.	5.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	Uniphyl
22	E2_1240	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Uniphyl N/A	
23	E2_1250	Num	8	4.	4.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	Intal
24	E2_1260	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Intal N/A	
25	E2_1270	Num	8	4.	4.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	Serevent
26	E2_1280	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Serevent N/A	
27	E2_1310	Num	8	4.	4.	Quantity of controller therapy participant took during the last 4 weeks: mcg/day	Advair
28	E2_1320	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Advair N/A	

Num	Variable	Type	Len	Format	Informat	Lahel		
29	E2_1330	Num	8		4.	Quantity of controller therapy participant took during the last 4 weeks: Asmanex mcg/day		
30	E2_1340	Num	8	NAF.	2.	Controller therapy NOT APPLICABLE: Asmanex N/A		
31	E2_1350	Num	8	E2_1350F.	2.	Classify the participant as		
32	E2_1360	Num	8	3.	3.	In the last 2 weeks, on how many days has the participant had coughing or wheezing from asthma or used albuterol for asthma symptoms?		
33	E2_1370	Num	8	YNF.	2.	Is E2_1360 > 4?		
34	E2_1380	Num	8	3.	3.	In the last 2 weeks, during how many nights has the participant woken up to use albuterol for asthma?		
35	E2_1390	Num	8	YNF.	2.	Is E2_1380 > 1?		
36	E2_1400	Num	8	YNF.	2.	Is the participant uncontrolled?		
37	E2_1410	Num	8	YNF.	2.	Is the participant eligible?		
38	E2_1420	Num	8	3.	3.	In the last 2 weeks, on how many days has the participant had coughing or wheezing from asthma or used albuterol for asthma symptoms?		
39	E2_1430	Num	8	YNF.	2.	Is E2_1420 > 4?		
40	E2_1440	Num	8	3.	3.	In the last 2 weeks, during how many nights has the participant woken up to use albuterol for asthma?		
41	E2_1450	Num	8	YNF.	2.	Is E2_1440 > 1?		
42	E2_1460	Num	8	YNF.	2.	Is the participant uncontrolled?		
43	E2_1470	Num	8	YNF.	2.	Is the participant eligible?		
44	E2_1480	Num	8	3.	3.	In the last 2 weeks, on how many days has the participant had coughing or wheezing from asthma or used albuterol for asthma symptoms?		
45	E2_1490	Num	8	YNF.	2.	Is E2_1480 > 4?		
46	E2_1500	Num	8	3.	3.	In the last 2 weeks, during how many nights has the participant woken up to use albuterol for asthma?		
47	E2_1510	Num	8	YNF.	2.	Is E2_1500 > 1?		
48	E2_1520	Num	8	YNF.	2.	Is the participant uncontrolled?		

## 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	
4	E3_1000	Num	8	YNF.	2.	Is the participant's pre-bronchodialator FEV1 % predicted >= 60%?	
5	E3_1010	Num	8	YNF.	2.	Is the participant able to perform reproducibe Spirometry according to ATS criteria?	
6	E3_1020	Num	8	YNF.	2.	Did the participant reverse >= 12% following bronchodilator administration (4 puffs)?	
7	E3_1025	Num	8	4.	4.	AM1 PERF (pre-bronchodilator Peak Flow value obtained from AM1 device)?	
8	E3_1030	Num	8	YNF.	2.	Is the participant eligible?	
9	E3_1040	Num	8	4.	4.	Calculate Predicted PERF (calculated from Excel Spreadsheet)	
10	E3_1050	Num	8	4.	4.	E3_1040 x 0.08	
11	E3_1060	Num	8	4.	4.	Larger of E3_1025 and E3_1050	

## 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			
4	E4_1110	Num	8	YNF.	2.	Since the last study visit or phone contact, has the participant had an asthma exacerbation requiring corticosteroids?			
5	E4_1000	Num	8	YNF.	2.	Has the participant's asthma been controlled since visit 1?			
6	E4_1010	Num	8	3.	3.	Number of days since the last study visit (include PM from visit 1 and AM from current visit to equal a whole day)			
7	E4_1020	Num	8	4.	4.	Number of complete measurements in the defined interval (measurements that count toward adherence include nighttime awakenings, AM and PM peak flow measures, coughing and wheezing symptoms, and rescue albuterol use)			
8	E4_1030	Num	8	6.1	6.1	Percent adherence = E4_1020 / (E4_1010 x 6) x 100			
9	E4_1040	Num	8	PERCENT75F.	2.	Categorize E4_1030			
10	E4_1050	Num	8	PERCENT75F.	2.	What is the participant's level of adherence with the study Diskus?			
11	E4_1060	Num	8	PERCENT75F.	2.	What is the participant's level of adherence with the study tablets (both manual count and eDEM)?			
12	E4_1065	Num	8	PERCENT75F.	2.	What is the participant's level of adherence of days with the correct number of doses taken?			
13	E4_1067	Num	8	YNNAF.	2.	Did the participant reverse >= 12% following brochodilator administration (4 puffs)?			
14	E4_1070	Num	8	YNF.	2.	Is there any other reason for which this participant should not be included in this study?			
15	E4_1080	Num	8	YNF.	2.	Is the participant eligible?			
16	E4_1100	Num	8			Date			

## Data Set Name: elig5.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	
4	E5_1260	Num	8	YNF.	2.	Since the last study visit or phone contact, has the participant had an asthma exacerbation requiring corticosteroids?	
5	E5_1010	Num	8	YNF.	2.	Is the participant being randomized less than 2 weeks after enrollemnt (Participant myst be in Run-In at least 7 days)?	
6	E5_1020	Num	8	3.	3.	Diary Completion: Number of days since the last study visit (include PM from previous visit and AM from current visit to equal a whole day)	
7	E5_1030	Num	8	4.	4.	Diary Completion: Number of complete measurements in the defined interval (measurements that count toward adherence include nighttime awakenings, AM and PM peak flow measures, coughing and wheezing symptoms, and rescue albuterol use)	
8	E5_1040	Num	8	6.1	6.1	Diary Completion: Percent adherence = E5_1030 / (E5_1020 x 6) x 100	
9	E5_1050	Num	8	YNF.	2.	Diary Completion: Is the percent adherence >= 75%?	
10	E5_1060	Num	8	YNF.	2.	Medication Use: Has the participant shown evidence of adherence (>=75%) with the study tablets (both manual count and eDEM)?	
11	E5_1065	Num	8	YNF.	2.	Medication Use: Has the participant shown evidence of adherence (>=75%) with the percent of days with the correct number of doses taken?	
12	E5_1070	Num	8	YNF.	2.	Medication Use: Has the participant shown evidence of adherence (>=75%) with the study Diskus?	
13	E5_1080	Num	8	3.	3.	Diary Completion: Number of days since the last study visit (include PM from previous visit and AM from current visit to equal a whole day)	
14	E5_1090	Num	8	4.	4.	Diary Completion: Number of complete measurements in the defined interval (measurements that count toward adherence include nighttime awakenings, AM and PM peak flow measures, coughing and wheezing symptoms, and rescue albuterol use)	
15	E5_1100	Num	8	6.1	6.1	Diary Completion: Percent adherence = E5_1090 / (E5_1080 x 6) x 100	
16	E5_1110	Num	8	YNF.	2.	Diary Completion: Is the percent adherence >= 90%?	
17	E5_1120	Num	8	YNF.	2.	Medication Use: Has the participant shown evidence of adherence (>=90%) with the study tablets (both manual count and eDEM)?	
18	E5_1130	Num	8	YNF.	2.	Medication Use: Has the participant shown evidence of adherence (>=90%) with the study Diskus?	
19	E5_1135	Num	8	YNF.	2.	Medication Use: Has the participant shown evidence of adherence (>=90%) with the percent of days with the correct number of doses taken?	
20	E5_1140	Num	8	YNF.	2.	Has the participant's asthma been controlled since visit 1?	
21	E5_1150	Num	8	YNF.	2.	Is the participant eligible?	
22	E5_1155	Num	8	YNF.	2.	Does the participant have source documentation of methacholine PC20<=12.5 mg/ml in another CARE study within the past 2 years or source documentation of >=12% improvement in FEV1 following post-pronchodilator testing procedure with a maximum of 4 puffs alb	
23	E5_1160	Num	8	YNF.	2.	Was the participant able to demonstrate >=12% improvement in FEV1 following the post-bronchodilator testing procedure with 4 puffs of albuterol at visit 1 or 2?	

Num	Variable	Type	Len	Format	Informat	Label	
24	E5_1165	Num	8	YNF.	2.	Can the Methacholine Challenge be performed (participant's pre-bronchodilator FEV1 % predicted >==70% and participant has not had a cold in the past 2 weeks)?	
25	E5_1170	Num	8	YNF.	2.	Is the participant's methacholine PC20<= 12.5 mg/ml?	
26	E5_1175	Num	8	YNF.	2.	Was the participant able to demonstrate >=12% improvement in FEV1 following the post-bronchodilator testing procedure with 4 puffs albuterol at the current visit?	
27	E5_1177	Num	8		Rescheduled visit 2A (date)		
28	E5_1180	Num	8	YNF.	2.	Can the Methacholine Challenge be performed (participant's pre-bronchodilator FEV1 % predicted >=70% and participant has not had a cold in the past 2 weeks)?	
29	E5_1185	Num	8	YNF.	2.	Is the participant's methacholine PC20<= 12.5 mg/ml?	
30	E5_1190	Num	8	YNF.	2.	Is there any other reason for which this participant should not be included in this study?	
31	E5_1200	Num	8	YNF.	2.	Is the participant eligible?	
32	E5_1250	Num	8			Date	

#### Data Set Name: eno.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	
4	ENO_1000	Num	8	5.	5.	Time eNO started (based on 12-hour clock)	
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
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 in 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 pas hour?
8	ENC_1040	Num	8	YNF.	Is the participant eligible to proceed with the 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		
4	HEQ_1000	Num	8	RESPONDENTF.	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 the current house? (years)		
7	HEQ_1030	Num	8	3.	3.	If NO, how long has the participant lived in the current house? (months)		
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? (Estimate if uncertain. 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 rooms use a window unit? Participant's bedroom		
15	HEQ_1110	Num	8	YNF.	2.	Which rooms use a window unit? Other bedrooms		
16	HEQ_1120	Num	8	YNF.	2.	Which rooms use a window unit? Living or family room		
17	HEQ_1130	Num	8	YNF.	2.	Which rooms use a window unit? Kitchen		
18	HEQ_1140	Num	8	YNF.	2.	Which rooms use a window unit? Other		
19	HEQ_1150	Num	8	YNDKF.	2.	Does the participant's house use an evaporative cooler (swamp 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 rooms use a window unit? Participant's bedroom		
22	HEQ_1180	Num	8	YNF.	2.	Which rooms use a window unit? Other bedrooms		
23	HEQ_1190	Num	8	YNF.	2.	Which rooms use a window unit? Living or family room		
24	HEQ_1200	Num	8	YNF.	2.	Which rooms use a window unit? Kitchen		
25	HEQ_1210	Num	8	YNF.	2.	Which rooms use a window unit? Other		
26	HEQ_1220	Num	8	YNDKF.	2.	Does the participant's house use a humidifier? (Include humidifier built into the heating system of the participant's house.)		
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 rooms use a humidifier? Participant's bedroom		
29	HEQ_1270	Num	8	YNF. 2.		Which rooms use a humidifier? Other bedrooms		
30	HEQ_1280	Num	8	YNF.	2.	Which rooms use a humidifier? Living or family room		
31	HEQ_1290	Num	8	YNF.	2.	Which rooms use a humidifier? Kitchen		
32	HEQ_1300	Num	8	YNF.	2.	Which rooms use a humidifier? Other		
33	HEQ_1310	Num	8	YNDKF.	2.	Does the participant's house use a dehumidifier? (Include dehumidifier built into the cooling system of the participant's house.)		
34	HEQ_1320	Num	8	HEQ_1320F.	2.	Which type of dehumidifier is used in the participant's house?		

Num	Variable	Type	Len	Format 1	Informat	Label		
35	HEQ_1350	Num	8	YNF. 2	2.	Which rooms use a dehumidifier? Participant's bedroom		
36	HEQ_1360	Num	8	YNF. 2	2.	Which rooms use a dehumidifier? Other bedrooms		
37	HEQ_1370	Num	8	YNF. 2	2.	Which rooms use a dehumidifier? Living or family room		
38	HEQ_1380	Num	8	YNF. 2	2.	Which rooms use a dehumidifier? Kitchen		
39	HEQ_1390	Num	8	YNF. 2	2.	Which rooms use a dehumidifier? Basement		
40	HEQ_1400	Num	8	YNF. 2	2.	Which rooms use a dehumidifier? Other		
41	HEQ_1410	Num	8	YNDKF. 2	2.	Has there been water damage to the participant's house, basement, or its contents during the past 12 months?		
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(s)		
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	2.	Do you ever see cockroaches in the participant's house?		
51	HEQ_1510	Num	8	YNF.	2.	In which room(s) have you seen cockroaches? Kitchen		
52	HEQ_1520	Num	8	YNF.	2.	In which room(s) have you seen cockroaches? Basement or attic		
53	HEQ_1530	Num	8	YNF. 2	2.	In which room(s) have you seen cockroaches? Bathroom(s)		
54	HEQ_1540	Num	8	YNF.	2.	In which room(s) have you seen cockroaches? Living or family room		
55	HEQ_1550	Num	8	YNF.	2.	In which room(s) have you seen cockroaches? Participant's bedroom		
56	HEQ_1560	Num	8	YNF.	2.	In which room(s) have you seen cockroaches? Other bedrooms		
57	HEQ_1570	Num	8	YNF.	2.	In which room(s) have you seen cockroaches? Garage		
58	HEQ_1580	Num	8	YNF.	2.	In which room(s) 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	2.	What is the floor covering in the participant's bedroom?		
62	HEQ_1620	Num	8	HEQ_1620F. 2	2.	If carpeted, what type of padding is under the carpet in the participant's bedroom?		
63	HEQ_1630	Num	8	HEQ_1630F. 2	2.	What type of mattress is on the participant's bed?		
64	HEQ_1640	Num	8	3.	3.	How old is the mattress used on the participant's bed? (years) (Estimate or enter '99' if uncertain. Enter '1' if less than a year.)		
65	HEQ_1650	Num	8	YNF. 2	2.	Is the mattress completely enclosed in an allergy-proof, encasing cover?		
66	HEQ_1660	Num	8	YNF. 2	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	2.	What type of pillow does the participant usually sleep with?		
69	HEQ_1690	Num	8	3.	3.	How old is the pillow the participant usually sleeps with? (years) (Estimate or enter '99' if uncertain. Enter '1' if less than a year.)		

Num	Variable	Type	Len	Format	Informat	Label		
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 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		
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 cats that the family has. (Enter '00' if none)		
80	HEQ_1800	Num	8	3.	3.	Enter the number of dogs that the family has. (Enter '00' if none)		
81	HEQ_1810	Num	8	3.	3.	Enter the number of robbits, guinea pigs, hamsters, gerbils, or mice that the family has. (Enter '00' if none)		
82	HEQ_1820	Num	8	3.	3.	Enter the number of birds that the family has. (Enter '00' if none)		
83	HEQ_1830	Num	8	3.	3.	Enter the number of other animals that the family has. (Enter '00' if none)		
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		

Num	Variable	Type	Len	Format	Informat	Label
99	HEQ_1990	Num	8	YNF.		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 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			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
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: Complete the exact value, or if the IgE value is below the limit of detection, complete the limit of detection; exact value
7	IGE_1030	Num	8	4.1	4.1	IgE: Complete the exact value, or if the IgE value is below the limit of detection, complete the limit of detection; 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
4	IPR_1010	Num	8		Time IOS started (based on a 24-hour clock)
5	IPR_1020	Num	8		Results of first effort: R5 (kPa/I/s)
6	IPR_1030	Num	8		Results of first effort: R10 (kPa/I/s)
7	IPR_1040	Num	8		Results of first effort: R15 (kPa/I/s)
8	IPR_1050	Num	8		Results of first effort: R35 (kPa/I/s)
9	IPR_1060	Num	8		Results of first effort: X5 (kPa/I/s)
10	IPR_1070	Num	8		Results of first effort: Resonant Frequency (Hz)
11	IPR_1080	Num	8		Results of first effort: Area Xa (kPA/l)
12	IPR_1090	Num	8		Results of second effort: R5 (kPa/I/s)
13	IPR_1100	Num	8		Results of second effort: R10 (kPa/I/s)
14	IPR_1110	Num	8		Results of second effort: R15 (kPa/I/s)
15	IPR_1120	Num	8		Results of second effort: R35 (kPa/I/s)
16	IPR_1130	Num	8		Results of second effort: X5 (kPa/I/s)
17	IPR_1140	Num	8		Results of second effort: Resonant Frequency (Hz)
18	IPR_1150	Num	8		Results of second effort: Area Xa (kPA/l)
19	IPR_1160	Num	8		Results of third effort: R5 (kPa/I/s)
20	IPR_1170	Num	8		Results of third effort: R10 (kPa/I/s)
21	IPR_1180	Num	8		Results of third effort: R15 (kPa/I/s)
22	IPR_1190	Num	8		Results of third effort: R35 (kPa/I/s)
23	IPR_1200	Num	8		Results of thrid effort: X5 (kPa/I/s)
24	IPR_1210	Num	8		Results of third effort: Resonant Frequency (Hz)
25	IPR_1220	Num	8		Results of 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, was it unacceptable for coherence < 0.80 (for R10)?
28	IPR_1250	Num	8	YNF.	If no, was it unacceptable for poor repeatability (R10 values vary by more than 20%)?
29	IPR_1260	Num	8	YNF.	If no, was it unacceptable for fewer than 3 good tests?
30	IPR_1270	Num	8	YNF.	If no, was it unacceptable for inconsistent tidal breathing?
31	IPR_1280	Num	8	YNF.	If no, was it unacceptable for participant refusal during test?
32	IPR_1290	Num	8	YNF.	If no, was it unacceptable for 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?

Num	Variable	Type	Len	Format	Label
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: 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
4	LAB_1000	Num	8	LAB_1000F.	2.	Pregnancy test results
5	LAB_1030	Num	8	6.	6.	Total WBC
6	LAB_1040	Num	8	5.1	5.1	Eosinophils
7	LAB_1050	Num	8	YNF.	2.	Was blood obtained for the serum save?
8	LAB_1060	Num	8	YNF.	2.	Was urine obtained for the urine save?

#### Data Set Name: med.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
4	MED_1000	Num	8	MED_1000F.	2.	What type of visit is this?
5	MED_1050	Num	8			Date
6	MED_1055	Num	8	6.1	6.1	Reference Peak Flow % predicted from Excel Spreadsheet at Visit 2A (does not change during study)
7	MED_1060	Num	8	4.	4.	Reference Peak Flow (L/min)

#### Data Set Name: medcodes.sas7bdat

Num	Variable	Type	Len	Label
1	DRUGCODE	Num	8	Drug Code
2	CATEGORY	Char	200	Drug Category
3	BRAND_NM	Char	200	Brand name
4	GENER_NM	Char	200	Generic name

#### 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
4	MHX_1000	Num	8	RESPONDENTF.	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 sympotms 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? (Enter '00' if none.)
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? (Enter '00' if none.)
14	MHX_1100	Num	8		In the past 12 months: times has the participant been seen in an emergency department for asthma?
15	MHX_1110	Num	8		In the past 12 months: times has the participant been seen at a doctor's office for worsening of asthma symptoms?
16	MHX_1120	Num	8		In the past 12 months: 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 the participant's asthma symptoms? (Enter '999' if not applicable.)
18	MHX_1140	Num	8	ASTHMAF.	Is the participant's asthma provoked by exposure to house dust?
19	MHX_1150	Num	8	ASTHMAF.	Is the participant's asthma provoked by exposure to animals?
20	MHX_1160	Num	8	ASTHMAF.	Is the participant's asthma provoked by exposure to spring and fall pollens?
21	MHX_1170	Num	8	ASTHMAF.	Is the participant's asthma provoked by exposure to damp, musty area?
22	MHX_1180	Num	8	ASTHMAF.	Is the participant's asthma provoked by exposure to tobacco smoke?
23	MHX_1190	Num	8	ASTHMAF.	Is the participant's asthma provoked by exposure to a change in the weather?
24	MHX_1200	Num	8	ASTHMAF.	Is the participant's asthma provoked by respiratory infections?
25	MHX_1210	Num	8	ASTHMAF.	Is the participant's asthma provoked by exposure to chemicals?
26	MHX_1220	Num	8	ASTHMAF.	Is the participant's asthma provoked by food?
27	MHX_1230	Num	8	ASTHMAF.	Is the participant's asthma provoked by exposure to cold air?
28	MHX_1240	Num	8	ASTHMAF.	Is the participant's asthma provoked by exercise/play?
29	MHX_1250	Num	8	ASTHMAF.	Is the participant's asthma provoked by emotional factors?

Num	Variable	Type	Len	Format	Label
30	MHX_1260	Num	8	YNF.	Has the participant ever had hay fever? (i.e., itchy eyes, runny nose, or sneezing recurring over several weeks in a particular season)
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	SYMPTONSF.	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	SYMPTONSF.	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.	Did a doctor or other health practitioner say the participant was allergic to medications?
46	MHX_1420	Num	8	YNF.	Did a doctor or other health practitioner say the participant was allergic to food(s)?
47	MHX_1430	Num	8	YNF.	Did a doctor or other health practitioner say the participant was allergic to things you breath in or inhale?
48	MHX_1440	Num	8	YNF.	Did a doctor or other health practitioner say the participant was allergic to stinging insects such as bees or wasps?
49	MHX_1450	Num	8	SYMPTONSF.	During the past 12 months, how would you describe any symptoms that have affected the participant's nose, eyes, or sinuses?
50	MHX_1460	Num	8		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)? (Enter '00' if none.)
51	MHX_1470	Num	8		During the past 12 months, how many months did the participant use a steroid nasal spray to treat nose, eye, or sinus symptoms? (Enter '00' if none.)
52	MHX_1480	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.)
53	MHX_1490	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.)
54	MHX_1500	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? (Enter '00' if none.)
55	MHX_1510	Num	8		During the past 12 months, how many times has the participant had pneumonia?

Num	Variable	Type	Len	Format	Label
56	MHX_1520	Num	8	YNF.	Has the participant ever had sinus surgery for sinusitis or polyps?
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? (Include half 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?
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	
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 (L)	
7	MTH_1030	Num	8	5.2	5.2	Solution 0 (diluent) FVC (L)	
8	MTH_1040	Num	8	5.2	5.2	Solution 0 (diluent 2) FEV1 (L)	
9	MTH_1050	Num	8	5.2	5.2	Solution 0 (diluent 2) FVC (L)	
10	MTH_1060	Num	8	5.2	5.2	Solution 1 (0.098 mg/ml) FEV1 (L)	
11	MTH_1070	Num	8	5.2	5.2	Solution 1 (0.098 mg/ml) FVC (L)	
12	MTH_1080	Num	8	5.2	5.2	Solution 2 (0.195 mg/ml) FEV1 (L)	
13	MTH_1090	Num	8	5.2	5.2	Solution 2 (0.195 mg/ml) FVC (L)	
14	MTH_1100	Num	8	5.2	5.2	Solution 3 (0.391 mg/ml) FEV1 (L)	
15	MTH_1110	Num	8	5.2	5.2	Solution 3 (0.391 mg/ml) FVC (L)	
16	MTH_1120	Num	8	5.2	5.2	Solution 4 (0.781 mg/ml) FEV1 (L)	
17	MTH_1130	Num	8	5.2	5.2	Solution 4 (0.781 mg/ml) FVC (L)	
18	MTH_1140	Num	8	5.2	5.2	Solution 5 (1.563 mg/ml) FEV1 (L)	
19	MTH_1150	Num	8	5.2	5.2	Solution 5 (1.563 mg/ml) FVC (L)	
20	MTH_1160	Num	8	5.2	5.2	Solution 6 (3.125 mg/ml) FEV1 (L)	
21	MTH_1170	Num	8	5.2	5.2	Solution 6 (3.125 mg/ml) FVC (L)	
22	MTH_1180	Num	8	5.2	5.2	Solution 7 (6.25 mg/ml) FEV1 (L)	
23	MTH_1190	Num	8	5.2	5.2	Solution 7 (6.25 mg/ml) FVC (L)	
24	MTH_1200	Num	8	5.2	5.2	Solution 8 (12.5 mg/ml) FEV1 (L)	
25	MTH_1210	Num	8	5.2	5.2	Solution 8 (12.5 mg/ml) FVC (L)	
26	MTH_1220	Num	8	5.2	5.2	Solution 9 (25 mg/ml) FEV1 (L)	
27	MTH_1230	Num	8	5.2	5.2	Solution 9 (25 mg/ml) FVC (L)	
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 reasons?	
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)	
33	MTH_1300	Num	8	5.2	5.2	Participant's FEV1 after standard reversal (2 puffs albuterol with Aerochamber) from methacholine challenge (L)	
34	MTH_1310	Num	8	5.	5.	Time of FEV1 from MTH_1300 (based on 24-hour clock)	
35	MTH_1320	Num	8	YNF.	2.	Was the FEV1 from MTH_1300 >= the Methacholine Reversal Reference Value in the gray box on page 1 of this form?	

## ${\it Data \ Set \ Name: metha\_ad.sas7bdat}$

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
4	MAD_1000	Num	8	YNF.	Was additional treatment used in the first hour?
5	MAD_1010	Num	8	YNF.	First hour: Additional albuterol by MDI
6	MAD_1020	Num	8	NUMPUFFF.	NumberFirst hour: of additional puffs of albuterol administered
7	MAD_1030	Num	8	YNF.	First hour: Nebulized beta-agonist
8	MAD_1040	Num	8	YNF.	First hour: Subcutaneous epinephrine
9	MAD_1050	Num	8	YNF.	First hour: Implementation of clinic emergency protocol or algorithm
10	MAD_1060	Num	8	YNF.	First hour: Other
11	MAD_1070	Num	8		Participant's FEV1 after additional treatment within first hour (L)
12	MAD_1080	Num	8		Time of FEV1 in MAD_1070 (based on 24-hour clock)
13	MAD_1090	Num	8	YNF.	Was the FEV1 from MAD_1070 >= the Methacholine Reversal Reference Value in the gray box on the Methacholine Challenge Testing (METHA) form?
14	MAD_1100	Num	8	YNF.	Was additional treatment used after one hour?
15	MAD_1110	Num	8	YNF.	After first hour: Additional albuterol by MDI
16	MAD_1120	Num	8	NUMPUFFF.	After first hour: Number of additional puffs of albuterol administered
17	MAD_1130	Num	8	YNF.	After first hour: Nebulized beta-agonist
18	MAD_1140	Num	8	YNF.	After first hour: Subcutaneous epinephrine
19	MAD_1150	Num	8	YNF.	After first hour: Implementation of clinic emergency protocol or algorithm
20	MAD_1160	Num	8	YNF.	After first hour: Treatment in the emergency room
21	MAD_1170	Num	8	YNF.	After first hour: Overnight hospitalization
22	MAD_1180	Num	8	YNF.	After first hour: Other
23	MAD_1190	Num	8		Participant's final FEV1 after additional treatment (L)
24	MAD_1200	Num	8		Time of FEV1 in MAD_1190 (based on 24-hour clock)
25	MAD_1210	Num	8	YNF.	Was the FEV1 from MAD_1190 >= the Methacholine Reversal Reference Value in the gray box on the Methacholine Challenge Testing (METHA) form?
26	MAD_1320	Num	8		Date signed

## ${\it Data \ Set \ Name: metha\_ch.sas7bdat}$

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
4	MCH_1000	Num	8	YNF.	During the past 4 weeks, has the participant had any respiratory infections, colds, or bronchitis?
5	MCH_1005	Num	8	YNF.	If yes, during the past 2 weeks, has the participant had any respiratory infections, cold, or bronchitis?
6	MCH_1010	Num	8	YNF.	Has it been less than 4 weeks since the participant last took an oral or injectable steroid?
7	MCH_1020	Num	8	YNF.	During the past 4 weeks, has the participant had any other severe acute illness?
8	MCH_1030	Num	8	YNF.	If YES, has the participant received permission from the supervising physician to proceed with the methacholine challenge testing?
9	MCH_1040	Num	8	YNF.	Is the participant currently having an acute asthma attack?
10	MCH_1050	Num	8	YNF.	Has the participant used any asthma medication other than study medication(s) in the past month?
11	MCH_1060	Num	8	YESF.	If YES, class: Inhaled Corticosteroid
12	MCH_1070	Num	8		If YES, date last used Inhaled Corticosteroid
13	MCH_1080	Num	8	YESF.	If YES, class: Cromolyn/nedocromil
14	MCH_1090	Num	8		If YES, date last used Cromolyn/nedocromil
15	MCH_1100	Num	8	YESF.	If YES, class: Leukotriene receptor antagonists
16	MCH_1110	Num	8		If YES, date last used Leukotriene receptor antagonists
17	MCH_1120	Num	8	YESF.	If YES, class: Long-acting beta-agonist
18	MCH_1130	Num	8		If YES, date last used Long-acting beta-agonist
19	MCH_1140	Num	8	YNF.	Does the participant have a baseline (pre-diluent) FEV1 less than 70% of predicted FEV1?
20	MCH_1150	Num	8	MCH_1150F.	Pregnancy test results (Check N/A if the participant is male, or is female and has not started menses.)
21	MCH_1160	Num	8	YNF.	Is there any other reason you should not proceed with the methacholine challenge?
22	MCH_1170	Num	8	YNF.	Is the participant eligible to proceed with the diluent (Solution #0) pulmonary function testing for the Methacholine Challenge?
23	MCH_1180	Num	8	YNF.	Was the Methacholine Challenge started?
24	MCH_1190	Num	8	MCH_1190F.	If NO, indicate the primary reason

# 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
4	QLQ_1000	Num	8	BOTHEREDF.	2.	HOW BOTHERED HAVE YOU BEEN DURING THE LAST WEEK DOING: Physical Activities
5	QLQ_1010	Num	8	BOTHEREDF.	2.	HOW BOTHERED HAVE YOU BEEN DURING THE LAST WEEK DOING: Being with animals
6	QLQ_1020	Num	8	BOTHEREDF.	2.	HOW BOTHERED HAVE YOU BEEN DURING THE LAST WEEK DOING: Activities with family and friends
7	QLQ_1030	Num	8	BOTHEREDF.	2.	HOW BOTHERED HAVE YOU BEEN DURING THE LAST WEEK DOING: Coughing
8	QLQ_1040	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel frustrated because of your asthma?
9	QLQ_1050	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel tired because of your asthma?
10	QLQ_1060	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel worried, concerned or troubled because of your asthma?
11	QLQ_1070	Num	8	BOTHEREDF.	2.	HOW BOTHERED HAVE YOU BEEN DURING THE LAST WEEK BY: Asthma attacks?
12	QLQ_1080	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel angry because of your asthma?
13	QLQ_1090	Num	8	BOTHEREDF.	2.	HOW BOTHERED HAVE YOU BEEN DURING THE LAST WEEK BY: Wheezing?
14	QLQ_1100	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel irritable because of your asthma?
15	QLQ_1110	Num	8	BOTHEREDF.	2.	HOW BOTHERED HAVE YOU BEEN DURING THE LAST WEEK BY: Tightness in your chest?
16	QLQ_1120	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel different or left out because of your asthma?
17	QLQ_1130	Num	8	BOTHEREDF.	2.	HOW BOTHERED HAVE YOU BEEN DURING THE LAST WEEK BY: Shortness of breath?
18	QLQ_1140	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel FRUSTRATED BECAUSE YOU COULDN'T KEEP UP WITH OTHERS?
19	QLQ_1150	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: WAKE UP DURING THE NIGHT because of your asthma?
20	QLQ_1160	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel UNCOMFORTABLE because of your asthma?
21	QLQ_1170	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel OUT OF BREATH because of your asthma?
22	QLQ_1180	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel YOU COULDN'T KEEP UP WITH OTHERS because of your asthma?
23	QLQ_1190	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Have trouble SLEEPING AT NIGHT because of asthma?

Num	Variable	Type	Len	Format	Informat	Label
24	QLQ_1200	Num	8	OFTENF.	2.	IN GENERAL, HOW OFTEN DURING THE LAST WEEK DID YOU: Feel FRIGHTENED BY AN ASTHMA ATTACK?
25	QLQ_1210	Num	8	BOTHEREDF.	2.	Thinking about all the activities you did in the past week: How much were you bothered by your asthma during these activities?
26	QLQ_1220	Num	8	OFTENF.	2.	In general, how often during the last week did you 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
4	PF_1000	Num	8	4.	4.	Reference Value determined at previous visit (l/min)
5	PF_1010	Num	8	4.	4.	Highest Peak Flow from Pool (l/min)
6	PF_1020	Num	8	4.	4.	2nd highest Peak Flow from Pool (l/min)
7	PF_1030	Num	8	4.	4.	3rd highest Peak Flow from Pool (l/min)
8	PF_1040	Num	8	YNF.	2.	Is the highest Peak Flow from the Pool (PF_1010) equal to the participant's Reference Value from the last visit (PF_1000)?
9	PF_1050	Num	8	5.2	5.2	PF_1020 / PF_1010
10	PF_1060	Num	8	YNF.	2.	Is PF_1050 greater than 0.9?
11	PF_1070	Num	8	5.2	5.2	PF_1030 / PF_1020
12	PF_1080	Num	8	YNF.	2.	Is PF_1070 greater than 0.9?
13	PF_1090	Num	8	4.	4.	Reference Value

# Data Set Name: pft\_chk.sas7bdat

Num	Variable	Туре	Len	Format	Informat	Label
1	SUBJ_ID	Num	8			Public Subject ID
2	VNUM	Num	8			Visit Number
3	VDATE	Num	8			Visit 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	YNNAF.	2.	During the past 24 hours, has the participant taken the study medication?
9	PFT_1050	Num	8	YESF.	2.	Delivery Device: Tablet/Capsule
10	PFT_1055	Num	8	3.	3.	Hours Since Last Dose - Tablet/Capsule
11	PFT_1060	Num	8	YESF.	2.	Delivery Device: Diskus
12	PFT_1065	Num	8	3.	3.	Hours Since Last Dose - Diskus
13	PFT_1070	Num	8	YESF.	2.	Delivery Device: MDI
14	PFT_1075	Num	8	3.	3.	Hours Since Last Dose - MDI
15	PFT_1080	Num	8	YESF.	2.	Delivery Device: Nebulizer
16	PFT_1085	Num	8	3.	3.	Hours Since Last Dose - Nebulizer
17	PFT_1090	Num	8	YESF.	2.	Delivery Device: Other
18	PFT_1095	Num	8	3.	3.	Hours Since Last Dose - Other
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) (cm)
25	PFT_1160	Num	8	YNNAF.	2.	Was Exhaled Nitric Oxide Testing performed?
26	PFT_1170	Num	8	PROCFAILF.	2.	If NO, indicate the reason
27	PFT_1200	Num	8	YNNAF.	2.	Was Pre-Bronchodilator IOS Testing performed?
28	PFT_1210	Num	8	PROCFAILF.	2.	If NO, indicate the reason
29	PFT_1220	Num	8	YNNAF.	2.	Was Post-Bronchodilator IOS Testing performed?
30	PFT_1230	Num	8	PROCFAILF.	2.	If NO, indicate the reason
31	PFT_1240	Num	8	YNNAF.	2.	Was Pre-Bronchodilator Spirometry performed?
32	PFT_1250	Num	8	PROCFAILF.	2.	If NO, indicate the reason
33	PFT_1260	Num	8	YNNAF.	2.	Was Post-Bronchodilator Spirometry performed?
34	PFT_1270	Num	8	PROCFAILF.	2.	If NO, indicate the reason

Num	Variable	Type	Len	Format	Informat	Label
35	PFT_1280	Num	8	YNNAF.	2.	Was Maximal Bronchodilator Testing performed?
36	PFT_1290	Num	8	PROCFAILF.	2.	If NO, indicate the reason
37	PFT_1300	Num	8	YNNAF.	2.	Was Methacholine Challenge Testing performed?
38	PFT_1310	Num	8	PROCFAILF.	2.	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
4	PHY_1000	Num	8	5.	5.	Time measurements started (based on 24-hour clock)
5	PHY_1010	Num	8	6.1	6.1	Standing height (barefoot or thin socks) - first measurement (cm)
6	PHY_1020	Num	8	6.1	6.1	Standing height (barefoot or thin socks) - second measurement (cm)
7	PHY_1030	Num	8	6.1	6.1	Standing height (barefoot or thin socks) - third measurement (cm)
8	PHY_1040	Num	8	6.1	6.1	Standing height (barefoot or thin socks) - average measurement (cm)
9	PHY_1050	Num	8	YNF.	2.	In your judgement, was the participant's height measurement acceptable?
10	PHY_1060	Num	8	6.1	6.1	Weight (shoes off, light clothing) (kg)
11	PHY_1070	Num	8	YNF.	2.	Is chest auscultation clear?
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	SYMPTONSF.	2.	In general, how would you describe the participant's nasal symptoms?
21	PHY_1170	Num	8	SYMPTONSF.	2.	In general, how would you describe the participant's eczema?

# Data Set Name: pred.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
4	PRD_1000	Num	8		Start date of prednisone
5	PRD_1010	Num	8	PRD_1010F.	Why was the prednisone course prescribed?
6	PRD_1015	Num	8		Total Amount of Prednisone
7	PRD_1020	Num	8	YNF.	Is the end of this prednisone course within 7 days of the start of the next treatment sequence?
8	PRD_1030	Num	8	YNF.	Is this the second prednisone course within a treatment sequence or a single prednisone course that is 8 or more days long?

# 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	PRM_1000	Num	8	RESPONDENTF.	2.	Who is the respondent?
4	PRM_1010	Num	8	YNF.	2.	In the past 12 months, has the participant used any asthma medication(s) other than albuterol?
5	PRM_1020	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Salmeterol (Serevent) or formoterol (Foradil) ? (Enter '00' if none.)
6	PRM_1030	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Inhaled or nebulized corticosteroids? (Enter '00' if none.)
7	PRM_1040	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Leukotriene Modifiers? (Enter '00' if none.)
8	PRM_1050	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Theophylline? (Enter '00' if none.)
9	PRM_1060	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Advair/Symbicort? (Enter '00' if none.)
10	PRM_1070	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Cromolyn/Nedocromil? (Enter '00' if none.)
11	PRM_1080	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Other? (Enter '00' if none.)
12	PRM_1090	Num	8	3.	3.	In the past 12 months, for how many months has the participant used Other? (Enter '00' if none.)
13	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.	Q1000
3	REG_1050	Num	8	GENDERF.	2.	Participant's gender
4	REG_1060	Num	8	ETHNICF.	2.	Participant's ethnic background
5	REG_1070	Num	8	YNF.	2.	Participant's racial background: American Indian or Alaskan Native
6	REG_1090	Num	8	YNF.	2.	Participant's racial background: Black or African American
7	REG_1100	Num	8	YNF.	2.	Participant's racial background: White
8	REG_1120	Num	8	PRIMARY_RACE.	2.	Participant's primary racial identification
9	AGE	Num	8			Participant's Age
10	WHITE	Num	8	YNF.		
11	BLACK	Num	8	YNF.		
12	HAWAIIAN	Num	8	YNF.		
13	ASIAN	Num	8	YNF.		
14	AMER_IND	Num	8	YNF.		
15	HISPANIC	Num	8	ETHNICF.		
16	REG_OTHER	Num	8			Participant's racial background: Other

### 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
4	SER_1000	Num	8			Date of Adverse Event
5	SER_1010	Char	6	\$6.	\$6.	Description of Adverse Event (ICD9 Code)
6	SER_1020	Num	8	YNF.	2.	Is the participant currently taking study drug?
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	SER_1040F.	2.	What was the unit of time for the interval in SER_1030?
9	SER_1050	Num	8	YNF.	2.	Reason the event was serious: Fatal event
10	SER_1060	Num	8	YNF.	2.	Reason the event was serious: Life-threatening event
11	SER_1070	Num	8	YNF.	2.	Reason the event was serious: Inpatient hospitalization required
12	SER_1080	Num	8			Admission date
13	SER_1090	Num	8			Discharge date
14	SER_1100	Num	8	YNF.	2.	Reason the event was serious: Disabling or incapacitating
15	SER_1110	Num	8	YNF.	2.	Reason the event was serious: Overdose
16	SER_1120	Num	8	YNF.	2.	Reason the event was serious: Cancer
17	SER_1130	Num	8	YNF.	2.	Reason the event was serious: Congenital anomaly
18	SER_1140	Num	8	YNF.	2.	Reason the event was serious: Serious laboratory abnormality with clinical symptoms
19	SER_1150	Num	8	YNF.	2.	Reason the event was serious: Height failure
20	SER_1160	Num	8	YNNAF.	2.	Reason the event was serious: Pregnancy
21	SER_1170	Num	8	YNF.	2.	Reason the event was serious: Other
22	SER_1180	Num	8	YNF.	2.	Did Toxicity of study drug(s) cause the event?
23	SER_1190	Num	8	YNF.	2.	Did Withdraw of study drug(s) cause the event?
24	SER_1200	Num	8	YNF.	2.	Did Concurrent medication cause the event?
25	SER_1210	Num	8	YNF.	2.	Did Other condition or event cause the 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
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
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.	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 24-hour clock)
12	SKN_1090	Num	8		Time test sites evaluated (based on 24-hour clock)
13	SKN_1100	Num	8		{(Histamine: Largest Wheal) + (Histamine: Perpendicular Wheal)}/2
14	SKN_1110	Num	8	YNF.	Is SKN_1100 < 3mm?
15	SKN_1120	Num	8		{(Saline: Largest Wheal) + (Saline: Perpendicular Wheal)}/2
16	SKN_1130	Num	8		SKN_1100 - SKN_1120 =
17	SKN_1140	Num	8	YNF.	Is SKN_1130 < 3mm?
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 (mm)
21	SKN_1180	Num	8		Histamine (A1): Perpendicular Wheal Diameter (mm)
22	SKN_1190	Num	8	YNF.	Mite Mix (A2): Was there a reaction?
23	SKN_1200	Num	8		Mite Mix (A2): Largest Wheal Diameter (mm)
24	SKN_1210	Num	8		Mite Mix (A2): Perpendicular Wheal Diameter (mm)
25	SKN_1220	Num	8	YNF.	Roach Mix (A3): Was there a reaction?
26	SKN_1230	Num	8		Roach Mix (A3): Largest Wheal Diameter (mm)
27	SKN_1240	Num	8		Roach Mix (A3): Perpendicular Wheal Diameter (mm)
28	SKN_1250	Num	8	YNF.	Cat (A4): Was there a reaction?
29	SKN_1260	Num	8		Cat (A4): Largest Wheal Diameter (mm)
30	SKN_1270	Num	8		Cat (A4): Perpendicular Wheal Diameter (mm)
31	SKN_1280	Num	8	YNF.	Dog (A5): Was there a reaction?
32	SKN_1290	Num	8		Dog (A5): Largest Wheal Diameter (mm)
33	SKN_1300	Num	8		Dog (A5): Perpendicular Wheal Diameter (mm)
34	SKN_1310	Num	8	YNF.	Mold Mix (A6): Was there a reaction?
35	SKN_1320	Num	8		Mold Mix (A6): Largest Wheal Diameter (mm)

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

## 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
4	SPO_1000	Num	8		Time bronchodilator given (based on 24-hour clock)
5	SPO_1010	Num	8		Time post-bronchodilator spirometry started (based on 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.	If NO why: Inadequate start of test, no rapid onset of expiration, large back extrapolation
15	SPO_1180	Num	8	YNF.	If NO why: Unacceptable peak flow (low, rounded, not clearly determined)
16	SPO_1190	Num	8	YNF.	If NO why: Unacceptable FET
17	SPO_1200	Num	8	YNF.	If NO why: Cough/Glottic closure during maneuver
18	SPO_1210	Num	8	YNF.	If NO why: Abrupt ending, sharp drop, or cessation in flow
19	SPO_1220	Num	8	YNF.	If NO why: 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
4	SPR_1010	Num	8		Time spirometry started (based on 24-hour clock)
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 (best effort) (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 technique acceptable?
20	SPR_1170	Num	8	YNF.	If NO why: Inadequate start of test, no rapid onset of expiration, large back extrapolation
21	SPR_1180	Num	8	YNF.	If NO why: Unacceptable peak flow (low, rounded, not clearly determined)
22	SPR_1190	Num	8	YNF.	If NO why: Unacceptable FET
23	SPR_1200	Num	8	YNF.	If NO why: Cough/Glottic closure during maneuver
24	SPR_1210	Num	8	YNF.	If NO why: Abrupt ending, sharp drop, or cessation in flow
25	SPR_1220	Num	8	YNF.	If NO why: Other
26	SPR_1230	Num	8	SPR_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
4	TRM_1000	Num	8	YNF.	2.	Has the participant completed the study?
5	TRM_1010	Num	8	TRM_1010F.	3.	Indicate the primary reason why the participant is being terminated from the study after randomization.
6	TRM_1030	Num	8	YESF.	2.	Clinic Coordinator's signed
7	TRM_1040	Num	8			Date Clinic Coordinator signed
8	TRM_1050	Num	8	YESF.	2.	Principal Investigator's signed
9	TRM_1060	Num	8			Date Principal Investigator signed

### Data Set Name: termr.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
4	TMR_1010	Num	8	TMR_1010F.	Indicate the primary reason for ineligibility during the Run-In.
5	TMR_1030	Num	8	YESF.	Clinic Coordinator's signed
6	TMR_1040	Num	8		Date Clinic Coordinator signed
7	TMR_1050	Num	8	YESF.	Principal Investigator's signed
8	TMR_1060	Num	8		Date Principal Investigator signed

# 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
4	TXF_1000	Num	8	YNF.	2.	Has the participant been hospitalized for asthma?
5	TXF_1010	Num	8	YNF.	2.	Has the participant received his/her second course of an oral/systemic corticosteroid for an asthma exacerbation within any of the 3 treatment periods or a single prednisone course that is 8 or more days long?
6	TXF_1020	Num	8	YNF.	2.	Is the participant a treatment failure?
7	TXF_1030	Num	8			Date treatment failure occurred
8	TXF_1040	Num	8	YESF.	2.	Physician/CC signed
9	TXF_1050	Num	8			Date signed