

Data Set Name: a_comply.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ACP_1000	Num	8	2.	2.	Has the participant used AVICA therapy since the last visit? 1=Yes,0=No
2	ACP_1010	Num	8	2.	2.	Did the parent/guardian complete and return the Parental AVICA Study Medication Diary? 1=Yes,0=No
3	ACP_1020	Num	8	2.	2.	Did the parent/guardian return the AVICA medication bottle? 1=Yes,0=No
4	ACP_1030	Char	4	\$4.	\$4.	Bottle Number
5	ACP_1040	Num	8	4.	4.	Bottle Weight (gm)
6	VDATE	Num	8			Number of days from Visit 1 to this visit
7	VNUM	Num	8			Visit Number
8	RAND_ID	Char	6			Randomized Master ID
9	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
10	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: a_diary.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ADR_1000	Num	8	3.	3.	Record Number (record_id)
2	ADR_1040	Num	8	3.	3.	Number Doses Given
3	ADR_1050	Num	8	2.	2.	Primary Reason for Use (1=fever, 2=discomfort/fussiness/irritability/pain, 3=other)
4	ADR_1060	Num	8	2.	2.	Cold/Flu Symptoms (1=Yes,0=No)
5	VDATE	Num	8			Number of days from Visit 1 to this visit
6	VNUM	Num	8			Visit Number
7	USEDATE	Num	8			Date of AVICA Medication Use (days from Visit 1)
8	RAND_ID	Char	6			Randomized Master ID
9	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
10	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: a_term.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ATR_1000	Num	8	2.	2.	Has the participant completed the AVICA study? 1=Yes,0=No
2	ATR_1010	Num	8	3.	3.	Primary reason the participant has withdrawn from the study.
3	VDATE	Num	8			Number of days from Visit 1 to this visit
4	VNUM	Num	8			Visit Number
5	RAND_ID	Char	6			Randomized Master ID
6	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
7	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: a_trtqx.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ATQ_1000	Num	8	2.	2.	Did your child use AVICA therapy? 1=Yes,0=No
2	ATQ_1010	Num	8	2.	2.	How well was your child's fever/pain controlled during the AVICA study? 1=Not at all, 2=Hardly at all, 3=Somewhat, 4=Fairly, 5=Very well
3	ATQ_1020	Num	8	2.	2.	Please check the box that most closely represents your feelings about which of the two treatments your child was receiving. 1=Acetaminophen, 2=Ibuprofen, 3=No idea
4	ATQ_1030	Num	8	2.	2.	In general, did your child have difficulty taking the drug? 1=Yes,0=No
5	ATQ_1040	Num	8	2.	2.	If your child had difficulty taking the drug, what was the primary reason for the difficulty? 1=Tasted bad, 2=Smelled bad, 3=Inconvenient, 4=Forgot / Too busy, 5=Doesn't like medicine, 6=Just didn't want to, 7=Side effects, 8=Other
6	ATQ_1050	Num	8	2.	2.	Prior to enrolling in the INFANT/AVICA study, which medication did you prefer to give to your child? 1=Acetaminophen, 2=Ibuprofen, 3=No preference
7	ATQ_1060	Num	8	2.	2.	In your opinion, which of the two treatments was the participant receiving? 1=Acetaminophen, 2=Ibuprofen, 3=No idea
8	VDATE	Num	8			Number of days from Visit 1 to this visit
9	VNUM	Num	8			Visit Number
10	RAND_ID	Char	6			Randomized Master ID
11	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
12	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: aeclin.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ICD9_CAT	Char	70			ICD-9 category
2	AEC_1000	Num	8	3.	3.	Adverse Event Number
3	AEC_1010	Char	6	\$6.	\$6.	ICD9 Code
4	AEC_1040	Num	8	2.	2.	Ongoing at current visit
5	AEC_1050	Num	8	2.	2.	Type (1=Intermitent; 2=Continuous)
6	AEC_1060	Num	8	2.	2.	Severity (1=Mild; 2=Moderate; 3=Severe)
7	AEC_1070	Num	8	2.	2.	Serious (0=No, 1=Yes)
8	AEC_1080	Num	8	2.	2.	Likelihood of Relationship to Study Drug(s) (1=None; 2=Unlikely (remote); 3=Possible; 4=Probable)
9	AEC_1090	Num	8	2.	2.	Change in Study Drugs (1=Unchanged; 2=Altered)
10	AEC_1100	Num	8	2.	2.	Outcome (1=Completely recovered; 2=Recovered, but with lasting effects; 3=Death)
11	AEC_1110	Num	8	2.	2.	Treatment Required (1=None; 2=Medication; 3=Hospitalization; 4=Other)
12	AEC_1120	Num	8	2.	2.	Ongoing at final visit
13	AEC_1020	Num	8			Date Started
14	AEC_1030	Num	8			Date Stopped
15	VNUM	Num	8			Visit Number
16	ICD9LONG	Char	200			Long ICD-9 description
17	ICD9SHRT	Char	35			Short ICD-9 description
18	RAND_ID	Char	6			Randomized Master ID
19	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
20	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: *astmahx.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	AHA_1000	Num	8	3.	3.	Approximately how old was the participant when chest symptoms suggesting asthma first appeared? YEARS
2	AHA_1010	Num	8	3.	3.	Approximately how old was the participant when chest symptoms suggesting asthma first appeared? MONTHS
3	AHA_1065	Num	8	2.	2.	Has a doctor diagnosed the participant with asthma? 1=Yes,0=No
4	AHA_1070	Num	8	3.	3.	If YES, how old was the participant when a doctor first diagnosed him/her with asthma? YEARS
5	AHA_1080	Num	8	3.	3.	If YES, how old was the participant when a doctor first diagnosed him/her with asthma? MONTHS
6	AHA_1090	Num	8	2.	2.	Have any of the participant's immediate blood relatives been told by a physician that they have asthma? Mother (1=Yes, 0=No, 8=Don't Know)
7	AHA_1100	Num	8	2.	2.	Have any of the participant's immediate blood relatives been told by a physician that they have asthma? Father (1=Yes, 0=No, 8=Don't Know)
8	AHA_1110	Num	8	2.	2.	Have any of the participant's immediate blood relatives been told by a physician that they have asthma? Brother(s) or Sister(s) (1=Yes, 0=No, 8=Don't Know, 9=N/A)
9	AHA_1130	Num	8	2.	2.	How do you categorize your asthma symptoms throughout the course of the year? 1=Relatively the same all year, 2=Vary by season
10	AHA_1140	Num	8	2.	2.	Do the participant's asthma symptoms worsen during the Winter? 1=Yes,0=No
11	AHA_1150	Num	8	2.	2.	Do the participant's asthma symptoms worsen during the Spring? 1=Yes,0=No
12	AHA_1160	Num	8	2.	2.	Do the participant's asthma symptoms worsen during the Summer? 1=Yes,0=No
13	AHA_1170	Num	8	2.	2.	Do the participant's asthma symptoms worsen during the Fall? 1=Yes,0=No
14	AHA_1180	Num	8	3.	3.	In the last 12 months, how many... 5a.Asthma episodes have you had that required emergency care or an unscheduled office visit?
15	AHA_1190	Num	8	3.	3.	In the last 12 months, how many Overnight hospitalizations has the participant had due to asthma?
16	AHA_1200	Num	8	3.	3.	In the last 12 months, how many Courses of systemic corticosteroid therapy for asthma has the participant taken?
17	AHA_1210	Num	8	4.	4.	In the last 12 months, how many Days of work, school/daycare, or housework has the participant missed due to asthma?
18	AHA_1220	Num	8	3.	3.	In the past 3 months, how many days of work, school, or housework have you missed due to asthma?
19	AHA_1230	Num	8	4.	4.	In the last 12 months, how many Days of work, school, or housework has the participant's parent/guardian or another caretaker missed because of the participant's asthma symptoms?
20	AHA_1240	Num	8	3.	3.	In the past 3 months, how many days of work, school, or housework has the participant's parent/guardian or another caretaker missed due to asthma?
21	AHA_1250	Num	8	2.	2.	Has the participant ever been admitted to an intensive care unit for asthma? 1=Yes,0=No

Num	Variable	Type	Len	Format	Informat	Label
22	AHA_1260	Num	8	3.	3.	How many times has the participant been admitted to an intensive care unit for asthma?
23	AHA_1270	Num	8	2.	2.	Has the participant ever had invasive mechanical ventilation? 1=Yes, 0=No, 8=Don't Know
24	AHA_1280	Num	8	2.	2.	Has the participant ever had non-invasive mechanical ventilation? 1=Yes, 0=No, 8=Don't Know
25	AHA_1290	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Exercise/Sports/Play (1=Yes, 0=No, 8=Don't Know)
26	AHA_1300	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Menstrual cycle(If participant is male or a postmenopausal female, leave blank.) (1=Yes, 0=No, 8=Don't Know)
27	AHA_1310	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Aspirin or non-steroidal anti-inflammatory drugs (e.g., Aleve, Motrin) (1=Yes, 0=No, 8=Don't Know)
28	AHA_1320	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Respiratory infections (e.g., colds) (1=Yes, 0=No, 8=Don't Know)
29	AHA_1330	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Irritants (e.g., pollution, odors, perfumes, chemicals, household cleaners) (1=Yes, 0=No, 8=Don't Know)
30	AHA_1340	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Weather conditions (e.g., change in weather, humidity) (1=Yes, 0=No, 8=Don't Know)
31	AHA_1350	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Exposure to cold air (1=Yes, 0=No, 8=Don't Know)
32	AHA_1360	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Emotional factors (e.g., stress, laughing) (1=Yes, 0=No, 8=Don't Know)
33	AHA_1370	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Tobacco smoke (1=Yes, 0=No, 8=Don't Know)
34	AHA_1380	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Food additives/preservatives (e.g., MSG, sulfites) (1=Yes, 0=No, 8=Don't Know)
35	AHA_1390	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Allergies (e.g., dust, animals, pollens) (1=Yes, 0=No, 8=Don't Know)
36	AHA_1400	Num	8	2.	2.	Do any of the following currently provoke the participant's asthma? Other (1=Yes,0=No)
37	AHA_1410	Num	8	2.	2.	To which of the following did a doctor or other health practitioner say the participant was allergic? Medicines (1=Yes, 0=No, 8=Don't Know)
38	AHA_1420	Num	8	2.	2.	To which of the following did a doctor or other health practitioner say the participant was allergic? Foods (1=Yes, 0=No, 8=Don't Know)
39	AHA_1430	Num	8	2.	2.	To which of the following did a doctor or other health practitioner say the participant was allergic? Things the participant breathes in or is exposed to (e.g., dust, pollens, molds, animal fur, feathers, dander) (1=Yes, 0=No, 8=Don't Know)
40	AHA_1440	Num	8	2.	2.	To which of the following did a doctor or other health practitioner say the participant was allergic? Stinging insects such as bees or wasps (1=Yes, 0=No, 8=Don't Know)
41	AHA_1450	Num	8	2.	2.	To which of the following did a doctor or other health practitioner say the participant was allergic? Latex (1=Yes, 0=No, 8=Don't Know)

Num	Variable	Type	Len	Format	Informat	Label
42	AHA_1460	Num	8	2.	2.	To which of the following did a doctor or other health practitioner say the participant was allergic? Other (1=Yes,0=No)
43	AHA_1470	Num	8	2.	2.	Has the participant ever had eczema / atopic dermatitis ? 1=Yes, 0=No, 8=Don't Know
44	AHA_1480	Num	8	3.	3.	At what age did the participant FIRST have eczema? YEARS
45	AHA_1490	Num	8	3.	3.	At what age did the participant FIRST have eczema? MONTHS
46	AHA_1500	Num	8	2.	2.	If YES, was your eczema diagnosed by a doctor? 1=Yes,0=No
47	AHA_1510	Num	8	2.	2.	During the past 12 months, how would you generally describe the participant's eczema? 1=None, 2=Mild, 3=Moderate, 4=Severe
48	AHA_1520	Num	8	2.	2.	Which parts of the participant's body were ever affected by eczema in the past 12 months? Head (1=Yes,0=No)
49	AHA_1530	Num	8	2.	2.	Which parts of the participant's body were ever affected by eczema in the past 12 months? Arms/Hands (1=Yes,0=No)
50	AHA_1540	Num	8	2.	2.	Which parts of the participant's body were ever affected by eczema in the past 12 months? Trunk (mid-section or torso) (1=Yes,0=No)
51	AHA_1550	Num	8	2.	2.	Which parts of the participant's body were ever affected by eczema in the past 12 months? Legs/Feet (1=Yes,0=No)
52	AHA_1560	Num	8	2.	2.	Which parts of the participant's body were ever affected by eczema in the past 12 months? Other (1=Yes,0=No)
53	AHA_1570	Num	8	2.	2.	Have any of the participant's immediate blood relatives been told by a physician that they have allergies/eczema/hay fever? Mother (1=Yes, 0=No, 8=Don't Know)
54	AHA_1580	Num	8	2.	2.	Have any of the participant's immediate blood relatives been told by a physician that they have allergies/eczema/hay fever? Father (1=Yes, 0=No, 8=Don't Know, 9=N/A)
55	AHA_1590	Num	8	2.	2.	Have any of the participant's immediate blood relatives been told by a physician that they have allergies/eczema/hay fever? Brother(s) or Sister(s) (1=Yes, 0=No, 8=Don't Know, 9=N/A)
56	AHA_1610	Num	8	2.	2.	Did the participants mother smoke tobacco or use a hookah while she was pregnant with the participant? 1=Yes, 0=No, 8=Dont Know
57	AHA_1620	Num	8	2.	2.	During which part(s) of the pregnancy did the participants mother smoke tobacco or use a hookah? First 3 months (1=Yes, 0=No, 8=Dont Know)
58	AHA_1630	Num	8	2.	2.	During which part(s) of the pregnancy did the participants mother smoke tobacco or use a hookah? Middle 3 months (1=Yes, 0=No, 8=Dont Know)
59	AHA_1640	Num	8	2.	2.	During which part(s) of the pregnancy did the participants mother smoke tobacco or use a hookah? Last 3 months (1=Yes, 0=No, 8=Dont Know)
60	AHA_1650	Num	8	2.	2.	Between the time the participant was born and when he/she turned 5 years of age, were there any tobacco smokers or users of a hookah in any household in which the participant spent time? 1=Yes, 0=No, 8=Dont Know
61	AHA_1660	Num	8	2.	2.	Did the participants mother smoke or use a hookah? 1=Yes, 0=No, 8=Dont Know
62	AHA_1670	Num	8	2.	2.	Did the participants father smoke or use a hookah? 1=Yes, 0=No, 8=Dont Know
63	AHA_1680	Num	8	2.	2.	Were there any other smokers or users of a hookah in the household? 1=Yes, 0=No, 8=Dont Know

Num	Variable	Type	Len	Format	Informat	Label
64	AHA_1690	Num	8	2.	2.	Are there any tobacco smokers or users of a hookah in any household in which the participant spends time? 1=Yes, 0=No, 8=Dont Know
65	AHA_1700	Num	8	2.	2.	Does the participants mother smoke or use a hookah? 1=Yes, 0=No, 8=Dont Know
66	AHA_1710	Num	8	2.	2.	Does the participants father smoke or use a hookah? 1=Yes, 0=No, 8=Dont Know
67	AHA_1720	Num	8	2.	2.	Are there any other smokers or users of a hookah in the household? 1=Yes, 0=No, 8=Dont Know
68	VDATE	Num	8			Number of days from Visit 1 to this visit
69	VNUM	Num	8			Visit Number
70	RAND_ID	Char	6			Randomized Master ID
71	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
72	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: cmed.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	CME_1040	Char	25			Code to identify a drug unit of measure; (Units)
2	CME_1050	Char	27			Code to identify how frequently a drug is taken or administered. (Frequency)
3	CME_1055	Char	40			Code to identify the route used to administer a drug. (Route)
4	CME_1000	Num	8	3.	3.	Medication Sequence Number
5	CME_1010	Num	8	7.	7.	This number corresponds to the ID number of the AHFS monograph. (Medication Code)
6	CME_1020	Num	8	3.	3.	Related Event
7	CME_1030	Num	8	9.2	9.2	Medication Dose
8	CME_1080	Num	8	2.	2.	Ongoing at current visit
9	CME_1090	Num	8	2.	2.	Ongoing at final visit
10	CME_1060	Num	8			Start Date
11	CME_1070	Num	8			Stop Date
12	VNUM	Num	8			Visit Number
13	GEN_NAME	Char	100	\$100.	\$100.	Generic Drug Name
14	CLASS_ID	Num	8	4.	4.	CLASS_ID
15	CLASS	Char	100	\$100.	\$100.	Drug Class Text
16	RAND_ID	Char	6			Randomized Master ID
17	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
18	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: cond_all.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PAL_1000	Num	8	2.	2.	Who is the respondent? 1=Self/Participant, 2=Parent/Guardian, 3=Other
2	PAL_1010	Num	8	2.	2.	Have you had any diseases, illnesses, conditions, or surgeries related to the following areas? Skin (1=Yes,0=No)
3	PAL_1020	Num	8	2.	2.	Have you ever had allergic rhinitis ? 1=Yes, 0=No, 9=Don't know
4	PAL_1030	Num	8	2.	2.	Have you ever had nasal polyps? 1=Yes, 0=No, 9=Don't know
5	PAL_1040	Num	8	2.	2.	Do you have chronic or recurrent sinusitis ? 1=Yes, 0=No, 9=Don't know
6	PAL_1050	Num	8	2.	2.	Have you ever been diagnosed with vocal cord dysfunction? 1=Yes, 0=No, 9=Don't know
7	PAL_1060	Num	8	2.	2.	Have you ever had other conditions related to the ear, nose, or throat? 1=Yes,0=No
8	PAL_1070	Num	8	2.	2.	Have you ever had pneumonia? 1=Yes, 0=No, 9=Don't know
9	PAL_1080	Num	8	2.	2.	If YES, were you diagnosed by chest x-ray? 1=Yes, 0=No, 9=Don't know
10	PAL_1090	Num	8	2.	2.	If YES, were you treated with antibiotics? 1=Yes, 0=No, 9=Don't know
11	PAL_1100	Num	8	2.	2.	Have you ever had bronchitis? 1=Yes, 0=No, 9=Don't know
12	PAL_1110	Num	8	2.	2.	Have you ever had other conditions related to the lungs ? 1=Yes, 0=No, 9=Don't know
13	PAL_1120	Num	8	2.	2.	Do you have gastroesophageal reflux disease ? 1=Yes, 0=No, 9=Don't know
14	PAL_1130	Num	8	2.	2.	Have you ever had other conditions related to the stomach or intestines? 1=Yes,0=No
15	PAL_1150	Num	8	2.	2.	Have you been diagnosed with sleep disordered breathing ? 1=Yes,0=No
16	PAL_1160	Num	8	2.	2.	If YES, are you being treated with CPAP or BiPAP? 1=Yes,0=No
17	PAL_1170	Num	8	2.	2.	Have you ever had other sleep disorders? 1=Yes,0=No
18	PAL_1180	Num	8	2.	2.	Have you ever had other conditions that have not been mentioned on this form? 1=Yes,0=No
19	VDATE	Num	8			Number of days from Visit 1 to this visit
20	VNUM	Num	8			Visit Number
21	RAND_ID	Char	6			Randomized Master ID
22	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
23	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: elig1.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	E1_1000	Num	8	2.	2.	Has the parent/legal guardian appropriately signed and dated the INFANT Informed Consent? 1=Yes,0=No
2	E1_1020	Num	8	2.	2.	Has the parent/legal guardian appropriately signed and dated the AVICA Informed Consent? 1=Yes,0=No
3	E1_1040	Num	8	2.	2.	Does the participant have an intolerance or allergy to fluticasone or montelukast? 1=Yes, 0=No, 8=Dont Know
4	E1_1050	Num	8	2.	2.	Does the participant have an intolerance or allergy to ibuprofen or acetaminophen? 1=Yes, 0=No, 8=Dont Know
5	E1_1060	Num	8	2.	2.	Does the participant have an intolerance or allergy to oral corticosteroids ? 1=Yes, 0=No, 8=Dont Know
6	E1_1070	Num	8	2.	2.	Is the participant able to take albuterol ? 1=Yes,0=No
7	E1_1080	Num	8	2.	2.	Is the participant 12 to 59 months old? 1=Yes,0=No
8	E1_1090	Num	8	2.	2.	Was the participant born before 35 weeks gestation? 1=Yes,0=No
9	E1_1100	Num	8	2.	2.	Does the parent report that the participant is up-to-date with immunizations? 1=Yes,0=No
10	E1_1110	Num	8	2.	2.	Has the participant ever had chicken pox or received one dose of the chicken pox vaccine? 1=Yes,0=No
11	E1_1120	Num	8	2.	2.	Is the participant receiving allergy shots? 1=Yes,0=No
12	E1_1130	Num	8	2.	2.	Is the participant receiving allergy shots? If YES, has the dose been changed in the past 3 months? 1=Yes,0=No
13	E1_1140	Num	8	2.	2.	Does the participant have any immunodeficiency disorders? 1=Yes,0=No
14	E1_1150	Num	8	2.	2.	Does the participant have uncontrolled gastroesophageal reflux? 1=Yes,0=No
15	E1_1160	Num	8	2.	2.	Does the participant have concurrent medical problems other than asthma that are likely to require oral or injectable corticosteroids during the study? 1=Yes,0=No
16	E1_1170	Num	8	2.	2.	Does the participant have a chronic or active lung disease other than asthma ? 1=Yes,0=No
17	E1_1180	Num	8	2.	2.	Does the participant have any co-morbid disorders associated with wheezing ? 1=Yes,0=No
18	E1_1190	Num	8	2.	2.	Does the participant have a chronic medical disorder that could interfere with drug metabolism/excretion ? 1=Yes,0=No
19	E1_1200	Num	8	2.	2.	Does the participant have a chronic medical disorder that may increase the risk of drug-related injury? 1=Yes,0=No
20	E1_1210	Num	8	2.	2.	Does the participant have significant developmental delay/failure to thrive ? 1=Yes,0=No
21	E1_1220	Num	8	2.	2.	Does the participant have a significant medical illness other than asthma ? 1=Yes,0=No
22	E1_1230	Num	8	3.	3.	During the past 6 months, how many oral or systemic corticosteroid courses has the participant had?
23	E1_1240	Num	8	2.	2.	During the past 6 months, has the participant had >=5 oral or systemic corticosteroid courses? 1=Yes,0=No

Num	Variable	Type	Len	Format	Informat	Label
24	E1_1246	Num	8	2.	2.	Has the participant used an oral or systemic corticosteroid for any reason in the past 2 weeks? 1=Yes,0=No
25	E1_1250	Num	8	2.	2.	Does the participant have a primary medical caregiver whom the participant can contact for primary medical care? 1=Yes,0=No
26	E1_1260	Num	8	3.	3.	During the past 12 months, how many times has the participant been hospitalized for wheezing or respiratory illnesses?
27	E1_1270	Num	8	2.	2.	During the past 12 months, has the participant been hospitalized for wheezing or respiratory illnesses >=3 times? 1=Yes,0=No
28	E1_1280	Num	8	2.	2.	Has the participant ever had a near-fatal asthma exacerbation requiring intubation or assisted ventilation? 1=Yes,0=No
29	E1_1290	Num	8	2.	2.	Is the parent able to use the spirotel® e-diary correctly as evidenced by achieving a score of 4 on the spirotel® Performance Checklist ? 1=Yes,0=No
30	E1_1300	Num	8	2.	2.	Currently, or within the past month, has the participant been involved in another therapeutic drug trial? 1=Yes,0=No
31	E1_1310	Num	8	2.	2.	Does the participants family have plans to move out of the area before the end of the study? 1=Yes,0=No
32	E1_1320	Num	8	2.	2.	Is there any other reason for which this participant should not be included in this study? 1=Yes,0=No
33	E1_1330	Num	8	2.	2.	Is the participant eligible? 1=Yes,0=No
34	E1_1340	Num	8	2.	2.	During the past 4 weeks, has the participant been treated with a controller therapy? 1=Yes,0=No
35	E1_1350	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Advair (fluticasone- salmeterol) (1=Yes,0=No)
36	E1_1360	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Advair (fluticasone-salmeterol) (inhs/day)
37	E1_1370	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Symbicort (budesonide-fomoterol) (1=Yes)
38	E1_1380	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Symbicort (budesonide-fomoterol) (inhs/day)
39	E1_1390	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Dulera (mometasone-formoterol) (1=Yes)
40	E1_1400	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Dulera (mometasone-formoterol) (inhs/day)
41	E1_1410	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Beclomethasone HFA: 40 mcg/puff (1=Yes)
42	E1_1420	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Beclomethasone HFA: 40 mcg/puff (puffs/day)
43	E1_1430	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Beclomethasone HFA: 80 mcg/puff (1=Yes)
44	E1_1440	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Beclomethasone HFA: 80 mcg/puff (puffs/day)
45	E1_1450	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Budesonide Nebulizer 0.25mg suspension (1=Yes)
46	E1_1460	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Budesonide Nebulizer 0.25mg suspension (nebs/day)

Num	Variable	Type	Len	Format	Informat	Label
47	E1_1470	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Budesonide Nebulizer 0.5mg suspension (1=Yes)
48	E1_1480	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Budesonide Nebulizer 0.5mg suspension (nebs/day)
49	E1_1490	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Budesonide Nebulizer 1 mg suspension (1=Yes)
50	E1_1500	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Budesonide Nebulizer 1 mg suspension (nebs/day)
51	E1_1510	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Budesonide Flexhaler: 90 mcg/inh (1=Yes)
52	E1_1520	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Budesonide Flexhaler: 90 mcg/inh (inhs/day)
53	E1_1530	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Budesonide Flexhaler: 180 mcg/inh (1=Yes)
54	E1_1540	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Budesonide Flexhaler: 180 mcg/inh (inhs/day)
55	E1_1550	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Ciclesonide HFA: 80 mcg/puff (1=Yes)
56	E1_1560	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Ciclesonide HFA: 80 mcg/puff (puffs/day)
57	E1_1570	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Ciclesonide HFA: 160 mcg/puff (1=Yes)
58	E1_1580	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Ciclesonide HFA: 160 mcg/puff (puffs/day)
59	E1_1590	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Flunisolide HFA: 80 mcg/puff (1=Yes)
60	E1_1600	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Flunisolide HFA: 80 mcg/puff (puffs/day)
61	E1_1610	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone HFA: 44 mcg/puff (1=Yes)
62	E1_1620	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone HFA: 44 mcg/puff (puffs/day)
63	E1_1630	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone HFA: 110 mcg/puff (1=Yes)
64	E1_1640	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone HFA: 110 mcg/puff (puffs/day)
65	E1_1650	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone HFA: 220 mcg/puff (1=Yes)
66	E1_1660	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone HFA: 220 mcg/puff (puffs/day)
67	E1_1670	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone DPI: 50 mcg/inh (1=Yes)
68	E1_1680	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone DPI: 50 mcg/inh (inhs/day)
69	E1_1690	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone DPI: 100 mcg/inh (1=Yes)

Num	Variable	Type	Len	Format	Informat	Label
70	E1_1700	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone DPI: 100 mcg/inh (inhs/day)
71	E1_1710	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone DPI: 250 mcg/inh (1=Yes)
72	E1_1720	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Fluticasone DPI: 250 mcg/inh (inhs/day)
73	E1_1730	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Mometasone DPI: 110 mcg/inh (1=Yes)
74	E1_1740	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Mometasone DPI: 110 mcg/inh (inhs/day)
75	E1_1750	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Mometasone DPI: 220 mcg/inh (1=Yes)
76	E1_1760	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Mometasone DPI: 220 mcg/inh (inhs/day)
77	E1_1770	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Singulair 4 or 5 mg/tablet (1=Yes)
78	E1_1780	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Singulair 4 or 5 mg/tablet (tablets/day)
79	E1_1790	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Singulair 4 mg/packet (1=Yes)
80	E1_1800	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Singulair 4 mg/packet (packet/day)
81	E1_1810	Num	8	2.	2.	Which controller therapies was the participant taking during the last 4 weeks, Triamcinolone MDI: 75 mcg/puff (1=Yes)
82	E1_1820	Num	8	3.	3.	Which controller therapies was the participant taking during the last 4 weeks, Triamcinolone MDI: 75 mcg/puff (puffs/day)
83	E1_1830	Num	8	2.	2.	Is the participant taking more than 1 controller therapy and the second controller therapy is not a LTRA? 1=Yes,0=No
84	E1_1840	Num	8	2.	2.	Are any of the doses greater than the limit? 1=Yes,0=No
85	E1_1010	Num	8			Date the INFANT Informed Consent form was signed (days from Visit 1)
86	E1_1030	Num	8			Date the AVICA Informed Consent form was signed (days from Visit 1)
87	VDATE	Num	8			Number of days from Visit 1 to this visit
88	VNUM	Num	8			Visit Number
89	RAND_ID	Char	6			Randomized Master ID
90	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
91	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: elig2.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	E2_1000	Num	8	2.	2.	Is the participant currently taking BOTH ICS and LTRA? 1=Yes,0=No
2	E2_1010	Num	8	2.	2.	LTRA for reasons other than asthma? 1=Yes,0=No
3	E2_1020	Num	8	2.	2.	Can LTRA be discontinued? 1=Yes,0=No
4	E2_1030	Num	8	2.	2.	How many months has the participant been treated with a daily controller therapy during the past 6 months?
5	E2_1040	Num	8	2.	2.	Has the participant been treated with a daily controller therapy >3 months during the past 6 months? 1=Yes,0=No
6	E2_1050	Num	8	2.	2.	Did the participant have any asthma symptoms while taking ICS or LTRA? 1=Yes,0=No
7	E2_1060	Num	8	3.	3.	During the past 12 months, how many wheezing episodes has the participant had ?
8	E2_1070	Num	8	2.	2.	During the past 12 months, has the participant had >=4 wheezing episodes? 1=Yes,0=No
9	E2_1080	Num	8	3.	3.	During the past 12 months, how many asthma exacerbations requiring systemic corticosteroids has the participant had?
10	E2_1090	Num	8	2.	2.	During the past 12 months, has the participant had >=2 asthma exacerbations requiring oral/systemic corticosteroids? 1=Yes,0=No
11	E2_1100	Num	8	3.	3.	During the past 4 weeks, how many days has the participant had daytime asthma symptoms?
12	E2_1110	Num	8	2.	2.	During the past 4 weeks, has the participant had daytime asthma symptoms >8 days? 1=Yes,0=No
13	E2_1120	Num	8	3.	3.	During the past 4 weeks, how many nighttime awakenings has the participant had?
14	E2_1130	Num	8	2.	2.	During the past 4 weeks, has the participant had >1 nighttime awakening? 1=Yes,0=No
15	E2_1140	Num	8	2.	2.	If the participant had >=4 wheezing episodes or >=2 asthma exacerbations requiring oral/systemic corticosteroids during the past 12 months, is the participant taking ICS or LTRA on a daily basis? 1=Yes,0=No
16	E2_1150	Num	8	2.	2.	If the participant had daytime asthma symptoms >8 days or >1 nighttime awakening during the past 4 weeks, did the symptoms appear after the ICS or LTRA was discontinued? 1=Yes,0=No
17	E2_1160	Num	8	2.	2.	If the symptoms appeared after the ICS or LTRA was discontinued, is the participant taking ICS or LTRA on a daily basis (not intermittently) (1=Yes,0=No)
18	E2_1170	Num	8	2.	2.	Is there any other reason for which this participant should not be included in this study? 1=Yes,0=No
19	E2_1180	Num	8	2.	2.	Is the participant eligible? 1=Yes,0=No
20	E2_1190	Num	8	2.	2.	During the Run-In period, what LTRA will this participant be using? 1=Placebo LTRA, 2=Active LTRA
21	E2_1200	Num	8	2.	2.	During the Run-In period, what ICS will this participant be using? 1=Placebo ICS, 2=Active ICS
22	VDATE	Num	8			Number of days from Visit 1 to this visit
23	VNUM	Num	8			Visit Number

Num	Variable	Type	Len	Format	Informat	Label
24	RAND_ID	Char	6			Randomized Master ID
25	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
26	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: elig3.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	E3_1000	Num	8	3.	3.	During the past 4 weeks, how many days has the participant had daytime asthma symptoms?
2	E3_1010	Num	8	2.	2.	During the past 4 weeks, how many days has the participant had daytime asthma symptoms, Q1 > 8? 1=Yes,0=No
3	E3_1020	Num	8	3.	3.	During the past 4 weeks, how many nighttime awakenings has the participant had?
4	E3_1030	Num	8	2.	2.	During the past 4 weeks, how many nighttime awakenings has the participant had, >=1? 1=Yes,0=No
5	E3_1040	Num	8	3.	3.	During the past 12 months, how many wheezing episodes has the participant had ?
6	E3_1050	Num	8	2.	2.	During the past 12 months, how many wheezing episodes has the participant had , >=4? 1=Yes,0=No
7	E3_1060	Num	8	3.	3.	During the past 6 months, how many asthma exacerbations requiring systemic corticosteroids has the participant had?
8	E3_1070	Num	8	2.	2.	During the past 6 months, how many asthma exacerbations requiring systemic corticosteroids has the participant had, >=2? 1=Yes,0=No
9	E3_1080	Num	8	2.	2.	Are any of the starred responses selected? 1=Yes,0=No
10	E3_1090	Num	8	2.	2.	Is there any other reason for which this participant should not be included in this study? 1=Yes,0=No
11	E3_1100	Num	8	2.	2.	Is the participant eligible? 1=Yes,0=No
12	VDATE	Num	8			Number of days from Visit 1 to this visit
13	VNUM	Num	8			Visit Number
14	RAND_ID	Char	6			Randomized Master ID
15	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
16	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: elig4.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	E4_1000	Num	8	2.	2.	Did the participant have any exacerbations requiring systemic corticosteroids? 1=Yes,0=No
2	E4_1010	Num	8	2.	2.	Was participant hospitalized? 1=Yes,0=No
3	E4_1020	Num	8	2.	2.	Did the participant take any medication for asthma other than albuterol? 1=Yes,0=No
4	E4_1030	Num	8	2.	2.	Did the participant develop any new medical conditions? 1=Yes,0=No
5	E4_1040	Num	8	6.1	6.1	According to the spirotel® INFANT Eligibility Report: Percent compliance for Diary Completion
6	E4_1050	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Is the compliance for Diary Completion >=75Pct? 1=Yes,0=No
7	E4_1060	Num	8	6.1	6.1	According to the spirotel® INFANT Eligibility Report: Percent compliance for Brown Daily Inhaler
8	E4_1070	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Is the compliance for Brown Daily Inhaler >=75Pct? 1=Yes,0=No
9	E4_1080	Num	8	6.1	6.1	According to the spirotel® INFANT Eligibility Report: Percent compliance for Oral Study Medication
10	E4_1090	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Is the compliance for Oral Study Medication >=75Pct? 1=Yes,0=No
11	E4_1100	Num	8	4.1	4.1	According to the spirotel® INFANT Eligibility Report: Average number of days per week with daytime asthma symptoms.
12	E4_1110	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Did the participant have daily daytime asthma symptoms 7 days per week ? 1=Yes,0=No
13	E4_1120	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Did the participant have daytime asthma symptoms more than 2 days per week ? 1=Yes,0=No
14	E4_1130	Num	8	3.	3.	According to the spirotel® INFANT Eligibility Report: Number of nighttime awakenings from asthma
15	E4_1140	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Did the participant have > 1 nighttime awakening from asthma ? 1=Yes,0=No
16	E4_1150	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Did the participant have 1 nighttime awakening from asthma (Q8=1) (1=Yes,0=No)
17	E4_1160	Num	8	2.	2.	According to P4_ELIG2 or P4_ELIG3 Q3a , did the participant have 4 or more wheezing episodes in the 12 months prior to enrollment? 1=Yes,0=No
18	E4_1170	Num	8	2.	2.	According to P4_ELIG1 Q21, did the participant have 2 or more exacerbations requiring systemic corticosteroids in the 6 months prior to enrollment? 1=Yes,0=No
19	E4_1180	Num	8	2.	2.	Are any of the starred responses selected? 1=Yes,0=No
20	E4_1190	Num	8	2.	2.	Is there any other reason for which this participant should not be included in this study? 1=Yes,0=No
21	E4_1200	Num	8	2.	2.	Is the participant eligible? 1=Yes,0=No
22	VDATE	Num	8			Number of days from Visit 1 to this visit
23	VNUM	Num	8			Visit Number
24	RAND_ID	Char	6			Randomized Master ID

Num	Variable	Type	Len	Format	Informat	Label
25	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
26	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: elig5.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	E5_1000	Num	8	2.	2.	Did the participant have any exacerbations requiring systemic corticosteroids? 1=Yes,0=No
2	E5_1010	Num	8	2.	2.	If the participant had any exacerbations requiring systemic corticosteroids, was the participant hospitalized? 1=Yes,0=No
3	E5_1020	Num	8	2.	2.	Did the participant take any additional medication for asthma , including an increase in medication dose or frequency? 1=Yes,0=No
4	E5_1030	Num	8	2.	2.	Did the participant develop any new medical conditions? 1=Yes,0=No
5	E5_1040	Num	8	6.1	6.1	According to the spirotel® INFANT Eligibility Report: Percent compliance for Diary Completion
6	E5_1050	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Is the compliance for Diary Completion >=75Pct? 1=Yes,0=No
7	E5_1060	Num	8	6.1	6.1	According to the spirotel® INFANT Eligibility Report: Percent compliance for Brown Daily Inhaler
8	E5_1070	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Is the compliance for Brown Daily Inhaler >=75Pct? 1=Yes,0=No
9	E5_1080	Num	8	6.1	6.1	According to the spirotel® INFANT Eligibility Report: Percent compliance for Oral Study Medication
10	E5_1090	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Is the compliance for Oral Study Medication >=75Pct? 1=Yes,0=No
11	E5_1100	Num	8	4.1	4.1	According to the spirotel® INFANT Eligibility Report: Average number of days per week with daytime asthma symptoms.
12	E5_1110	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Did the participant have daytime asthma symptoms >2 days per week? 1=Yes,0=No
13	E5_1120	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Did the participant have daytime asthma symptoms 7 days per week? 1=Yes,0=No
14	E5_1130	Num	8	3.	3.	According to the spirotel® INFANT Eligibility Report: Number of nighttime awakenings from asthma
15	E5_1140	Num	8	2.	2.	According to the spirotel® INFANT Eligibility Report: Did the participant have > 1 nighttime awakening from asthma? 1=Yes,0=No
16	E5_1150	Num	8	2.	2.	Is there any other reason for which this participant should not be included in this study? 1=Yes,0=No
17	E5_1160	Num	8	2.	2.	Is the participant eligible? 1=Yes,0=No
18	VDATE	Num	8			Number of days from Visit 1 to this visit
19	VNUM	Num	8			Visit Number
20	RAND_ID	Char	6			Randomized Master ID
21	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
22	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: heq.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	HEQ_1000	Num	8	2.	2.	Who is the respondent? 1=Self/Participant, 2=Parent/Guardian, 3=Other
2	HEQ_1010	Num	8	3.	3.	How long have you lived in the current house? (Estimate if uncertain.) (1010) years
3	HEQ_1020	Num	8	3.	3.	How long have you lived in the current house? (Estimate if uncertain.)(1020) months
4	HEQ_1030	Num	8	2.	2.	Does your house use a wood burning stove as a primary source of heat? 1=Yes, 0=No, 8=Don't Know
5	HEQ_1040	Num	8	2.	2.	Does your house use an air conditioner? 1=Yes, 0=No, 8=Don't Know
6	HEQ_1050	Num	8	2.	2.	Does your house use an evaporative cooler ? 1=Yes, 0=No, 8=Don't Know
7	HEQ_1060	Num	8	2.	2.	Does your house use a humidifier? 1=Yes, 0=No, 8=Don't Know
8	HEQ_1070	Num	8	2.	2.	Does your house use a dehumidifier? 1=Yes, 0=No, 8=Don't Know
9	HEQ_1080	Num	8	2.	2.	Has there been water damage to your house, basement, or its contents during the past 12 months? 1=Yes, 0=No, 8=Don't Know
10	HEQ_1090	Num	8	2.	2.	Has there been any mold or mildew, on any surfaces, inside your house in the past 12 months? 1=Yes, 0=No, 8=Don't Know
11	HEQ_1100	Num	8	2.	2.	Which rooms have or have had mold or mildew?10a.Bathroom(s) (1 = Yes, 0 = No)
12	HEQ_1110	Num	8	2.	2.	Which rooms have or have had mold or mildew?10b.Basement or attic (1 = Yes, 0 = No)
13	HEQ_1120	Num	8	2.	2.	Which rooms have or have had mold or mildew? 10c.Kitchen (1 = Yes, 0 = No)
14	HEQ_1130	Num	8	2.	2.	Which rooms have or have had mold or mildew? 10d.Your bedroom (1 = Yes, 0 = No)
15	HEQ_1140	Num	8	2.	2.	Which rooms have or have had mold or mildew? 10e.Other bedrooms (1 = Yes, 0 = No)
16	HEQ_1150	Num	8	2.	2.	Which rooms have or have had mold or mildew? 10f.Living or family room (1 = Yes, 0 = No)
17	HEQ_1160	Num	8	2.	2.	Which rooms have or have had mold or mildew? 10g.Other (1 = Yes, 0 = No)
18	HEQ_1170	Num	8	2.	2.	Do you ever see cockroaches in your house? 1=Yes,0=No
19	HEQ_1180	Num	8	2.	2.	In which room(s) have you seen cockroaches?12a.Kitchen (1 = Yes, 0 = No)
20	HEQ_1190	Num	8	2.	2.	In which room(s) have you seen cockroaches? 12b.Basement or attic (1 = Yes, 0 = No)
21	HEQ_1200	Num	8	2.	2.	In which room(s) have you seen cockroaches? 12c.Bathroom(s) (1 = Yes, 0 = No)
22	HEQ_1210	Num	8	2.	2.	In which room(s) have you seen cockroaches? 12d.Living or family room (1 = Yes, 0 = No)
23	HEQ_1220	Num	8	2.	2.	In which room(s) have you seen cockroaches? 12e.Your bedroom (1 = Yes, 0 = No)
24	HEQ_1230	Num	8	2.	2.	In which room(s) have you seen cockroaches? 12f.Other bedrooms (1 = Yes, 0 = No)

Num	Variable	Type	Len	Format	Informat	Label
25	HEQ_1240	Num	8	2.	2.	In which room(s) have you seen cockroaches? 12g.Garage (1 = Yes, 0 = No)
26	HEQ_1250	Num	8	2.	2.	In which room(s) have you seen cockroaches? 12h.Other (1 = Yes, 0 = No)
27	HEQ_1260	Num	8	2.	2.	Do you ever see rodents or rodent droppings in your house? 1=Yes,0=No
28	HEQ_1270	Num	8	2.	2.	14.In which room(s) have you seen rodents or rodent droppings? 14a. Kitchen (1 = Yes, 0 = No)
29	HEQ_1280	Num	8	2.	2.	14.In which room(s) have you seen rodents or rodent droppings? 14b. Basement or attic (1 = Yes, 0 = No)
30	HEQ_1290	Num	8	2.	2.	14.In which room(s) have you seen rodents or rodent droppings? 14c. Bathroom(s) (1 = Yes, 0 = No)
31	HEQ_1300	Num	8	2.	2.	14.In which room(s) have you seen rodents or rodent droppings?14d. Living or family room (1 = Yes, 0 = No)
32	HEQ_1310	Num	8	2.	2.	14.In which room(s) have you seen rodents or rodent droppings? 14e. Your bedroom(1 = Yes, 0 = No)
33	HEQ_1320	Num	8	2.	2.	14.In which room(s) have you seen rodents or rodent droppings? 14f. Other bedrooms (1 = Yes, 0 = No)
34	HEQ_1330	Num	8	2.	2.	14.In which room(s) have you seen rodents or rodent droppings? 14g. Garage (1 = Yes, 0 = No)
35	HEQ_1340	Num	8	2.	2.	14.In which room(s) have you seen rodents or rodent droppings? 14h. Other (1 = Yes, 0 = No)
36	HEQ_1350	Num	8	2.	2.	15.Are any of the following located on your property or next to your property? 15a. Barns(1 = Yes, 0 = No)
37	HEQ_1360	Num	8	2.	2.	15.Are any of the following located on your property or next to your property?15b. Hay(1 = Yes, 0 = No)
38	HEQ_1370	Num	8	2.	2.	15.Are any of the following located on your property or next to your property? 15c. Woodsheds(1 = Yes, 0 = No)
39	HEQ_1380	Num	8	2.	2.	15.Are any of the following located on your property or next to your property? 15d. Firewood(1 = Yes, 0 = No)
40	HEQ_1390	Num	8	2.	2.	15.Are any of the following located on your property or next to your property?15e. Chicken coops (1 = Yes, 0 = No)
41	HEQ_1400	Num	8	2.	2.	15.Are any of the following located on your property or next to your property? 15f. Corral (1 = Yes, 0 = No)
42	HEQ_1410	Num	8	2.	2.	CHARACTERISTICS OF THE PARTICIPANT'S BEDROOM16.What is the floor covering in your bedroom? 1=Rug/carpet, 2=Vinyl tile or linoleum, 3=Wood, 4=Ceramic tile, 5=Other , 9=Don't know
43	HEQ_1420	Num	8	2.	2.	What type of mattress is on your bed? 1=None, 2=Inner spring mattress, 3=Foam mattress, 4=Waterbed, 5=Air mattress, 6=Other , 9=Don't know
44	HEQ_1430	Num	8	2.	2.	Is the mattress completely enclosed in an allergy-proof, encasing cover? 1=Yes,0=No
45	HEQ_1440	Num	8	2.	2.	Does your bed have a box spring? 1=Yes,0=No
46	HEQ_1450	Num	8	2.	2.	Is the box spring completely enclosed in an allergy-proof, encasing cover? 1=Yes,0=No
47	HEQ_1460	Num	8	2.	2.	What type of pillow do you usually sleep with? 1=None, 2=Feather/down, 3=Foam/Dacron/synthetic, 5=Other , 9=Don't know
48	HEQ_1470	Num	8	2.	2.	Is the pillow completely enclosed in an allergy-proof, encasing cover? 1=Yes,0=No

Num	Variable	Type	Len	Format	Informat	Label
49	HEQ_1480	Num	8	2.	2.	Does your household have any pets? 1=Yes,0=No
50	HEQ_1490	Num	8	3.	3.	Enter the number of pets that the household has. (Enter '00' if none. If none to Q24a - Q24d, skip to the next question.)24a.Cat
51	HEQ_1500	Num	8	2.	2.	Cat (1=Indoor, 2=Outdoor, 3=Both)
52	HEQ_1510	Num	8	3.	3.	Enter the number of pets that the household has. Dog
53	HEQ_1520	Num	8	2.	2.	Dog(1=Indoor, 2=Outdoor, 3=Both)
54	HEQ_1530	Num	8	3.	3.	Enter the number of pets that the household has 24c.Rabbit, guinea pig, hamster, gerbil, or mouse
55	HEQ_1540	Num	8	2.	2.	Rabbit, guinea pig, hamster, gerbil, or mouse (1=Indoor, 2=Outdoor, 3=Both)
56	HEQ_1550	Num	8	3.	3.	Enter the number of pets that the household has 24d.Bird
57	HEQ_1560	Num	8	2.	2.	Bird (1=Indoor, 2=Outdoor, 3=Both)
58	HEQ_1570	Num	8	2.	2.	In general, and on a regular basis, are you exposed to any of the following animals? 25a.Cat(1 = Yes, 0 = No)
59	HEQ_1580	Num	8	2.	2.	In general, and on a regular basis, are you exposed to any of the following animals? 25b.Dog(1 = Yes, 0 = No)
60	HEQ_1590	Num	8	2.	2.	In general, and on a regular basis, are you exposed to any of the following animals? 25c.Rabbit, guinea pig, hamster, gerbil, or mouse(1 = Yes, 0 = No)
61	HEQ_1600	Num	8	2.	2.	In general, and on a regular basis, are you exposed to any of the following animals? 25d.Bird (1 = Yes, 0 = No)
62	HEQ_1610	Num	8	2.	2.	In general, and on a regular basis, are you exposed to any of the following animals? 25e.Farm animals (1 = Yes, 0 = No)
63	HEQ_1620	Num	8	2.	2.	In general, and on a regular basis, are you exposed to any of the following animals? 25f.Other (1 = Yes, 0 = No)
64	HEQ_1630	Num	8	2.	2.	DAY CARE26.Did the participant attend day care during the 1st year of life? 1=Yes,0=No
65	HEQ_1640	Num	8	3.	3.	If the participant attended day care during the 1st year of life, at what age did the day care attendance begin? Months
66	HEQ_1650	Num	8	2.	2.	Does the participant currently attend day care? 1=Yes,0=No
67	HEQ_1660	Num	8	2.	2.	Is the day care (1=In home day care, 2=Nonresidential, 3=Mixed)
68	HEQ_1670	Num	8	3.	3.	How many children are in the participant's day care room?
69	HEQ_1680	Num	8	3.	3.	How many hours per day is the participant at day care?
70	HEQ_1690	Num	8	2.	2.	How many days per week is the participant at day care?
71	HEQ_1700	Num	8	3.	3.	How many months per year is the participant at day care?
72	VDATE	Num	8			Number of days from Visit 1 to this visit
73	VNUM	Num	8			Visit Number
74	RAND_ID	Char	6			Randomized Master ID
75	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
76	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: *i_comply.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	ICP_1000	Num	8	4.	4.	Information for Q1 - Q7 is obtained from the spiroteI® Participant Compliance Report (P4_COMPLY_RPT). Number of full days since the last visit
2	ICP_1010	Num	8	4.	4.	Diary Completion Number of days where PM scheduled session is complete
3	ICP_1020	Num	8	6.1	6.1	Diary Completion Percent compliance
4	ICP_1030	Num	8	4.	4.	Brown Daily Inhaler: Number of puffs that were taken from the brown daily inhaler
5	ICP_1040	Num	8	6.1	6.1	Brown Daily Inhaler: Percent compliance
6	ICP_1050	Num	8	4.	4.	Oral Medication: Number of days where oral study medication was taken
7	ICP_1060	Num	8	6.1	6.1	Oral Medication; Percent compliance
8	VDATE	Num	8			Number of days from Visit 1 to this visit
9	VNUM	Num	8			Visit Number
10	RAND_ID	Char	6			Randomized Master ID
11	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
12	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: *i_fail.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	IFL_1000	Num	8	2.	2.	Has the participant required 4 courses of prednisolone since randomization? 1=Yes,0=No
2	IFL_1010	Num	8	2.	2.	Has the participant been hospitalized for more than 24 hours due to an asthma exacerbation? 1=Yes,0=No
3	IFL_1020	Num	8	2.	2.	Has the participant moved forward to the next treatment arm due to recurrent exacerbations two times during the course of the study? 1=Yes,0=No
4	IFL_1030	Num	8	2.	2.	Is the participant a study failure? 1=Yes,0=No
5	IFL_1040	Num	8			Date INFANT study failure occurred.
6	VDATE	Num	8			Number of days from Visit 1 to this visit
7	VNUM	Num	8			Visit Number
8	RAND_ID	Char	6			Randomized Master ID
9	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
10	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: *i_term.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	ITR_1000	Num	8	2.	2.	Has the participant completed the INFANTstudy? 1=Yes,0=No
2	ITR_1010	Num	8	3.	3.	Primary reason the participant has withdrawn from the study.
3	VDATE	Num	8			Number of days from Visit 1 to this visit
4	VNUM	Num	8			Visit Number
5	RAND_ID	Char	6			Randomized Master ID
6	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
7	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: *i_trtqx.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	ITQ_1000	Num	8	2.	2.	During this treatment period, how well did you think the study medications received during the INFANT study controlled the participants asthma symptoms? 1=Not at all, 2=Hardly at all, 3=Somewhat, 4=Fairly, 5=Very well
2	ITQ_1010	Num	8	2.	2.	Please check the box that most closely represents your feelings about the brown Daily Inhaler. 1=Definitely placebo, 2=Probably placebo, 3=I dont know, but my guess would be:, 4=Probably active drug, 5=Definitely active drug
3	ITQ_1020	Num	8	2.	2.	Please check the box that most closely represents your feelings about the brown Daily Inhaler. I dont know, but my guess would be: (1=Placebo, 2=Active drug)
4	ITQ_1030	Num	8	2.	2.	During this treatment period, what best describes how the participant took the brown Daily Inhaler? 1=More regularly at the beginning, 2=More regularly at the end, 3=The same throughout the study
5	ITQ_1040	Num	8	2.	2.	Did the participant object to taking the brown Daily Inhaler? 1=Yes,0=No
6	ITQ_1050	Num	8	2.	2.	If YES, what was the primary reason the participant didnt like taking the brown Daily Inhaler? 1=Tasted bad, 2=Smelled bad, 3=Inconvenient, 4=Forgot / Too busy, 5=Doesnt like medicine, 6=Just didnt want to, 7=Side effects, 8=Other
7	ITQ_1060	Num	8	2.	2.	Please check the box that most closely represents your feelings about the white Rescue Inhaler. 1=Definitely placebo, 2=Probably placebo, 3=I dont know, but my guess would be:, 4=Probably active drug, 5=Definitely active drug
8	ITQ_1070	Num	8	2.	2.	Please check the box that most closely represents your feelings about the white Rescue Inhaler. I dont know, but my guess would be: (1=Placebo, 2=Active drug)
9	ITQ_1080	Num	8	2.	2.	During this treatment period, what best describes how the participant took the white Rescue Inhaler? 1=More regularly at the beginning, 2=More regularly at the end, 3=The same throughout the study
10	ITQ_1090	Num	8	2.	2.	Did the participant object to taking the white Rescue Inhaler? 1=Yes,0=No
11	ITQ_1100	Num	8	2.	2.	Did the participant object to taking the white Rescue Inhaler? 1=Tasted bad, 2=Smelled bad, 3=Inconvenient, 4=Forgot / Too busy, 5=Doesnt like medicine, 6=Just didnt want to, 7=Side effects, 8=Other
12	ITQ_1110	Num	8	2.	2.	Before participation in the INFANT study, how often did the participant use a spacer to take inhaler medications? 1=Always, 2=Sometimes, 3=Occasionally, 4=Never, 5=Not applicable-inhaler medications not used before INFANT
13	ITQ_1120	Num	8	2.	2.	Please rate the difficulty of using 2 rescue inhalers during the INFANT study. 1=Easy, 2=Okay, 3=Inconvenient, 4=Hard, 5=Not applicable
14	ITQ_1130	Num	8	2.	2.	Please check the box that most closely represents your feelings about the study tablets/granules. 1=Definitely placebo, 2=Probably placebo, 3=I dont know, but my guess would be:, 4=Probably active drug, 5=Definitely active drug
15	ITQ_1140	Num	8	2.	2.	Please check the box that most closely represents your feelings about the study tablets/granules. I dont know, but my guess would be: (1=Placebo, 2=Active drug)

Num	Variable	Type	Len	Format	Informat	Label
16	ITQ_1150	Num	8	2.	2.	During this treatment period, what best describes how the participant took the oral study medication? 1=More regularly at the beginning, 2=More regularly at the end, 3=The same throughout the study
17	ITQ_1160	Num	8	2.	2.	Did the participant object to taking the oral study medication? 1=Yes,0=No
18	ITQ_1170	Num	8	2.	2.	Did the participant object to taking the oral study medication? 1=Tasted bad, 2=Smelled bad, 3=Inconvenient, 4=Forgot / Too busy, 5=Doesnt like medicine, 6=Just didnt want to, 7=Side effects, 8=Other
19	ITQ_1180	Num	8	2.	2.	In your opinion, what was contained in the brown Daily Inhaler for this participant? 1=Inhaled corticosteroid, 2=Placebo, 3=No idea
20	ITQ_1190	Num	8	2.	2.	In your opinion, what was contained in the white Rescue Inhaler for this participant? 1=Inhaled corticosteroid, 2=Placebo, 3=No idea
21	ITQ_1200	Num	8	2.	2.	In your opinion, what was contained in the oral study medication for this participant? 1=LTRA, 2=Placebo, 3=No idea
22	VDATE	Num	8			Number of days from Visit 1 to this visit
23	VNUM	Num	8			Visit Number
24	RAND_ID	Char	6			Randomized Master ID
25	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
26	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: *i_txfail.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	ITX_1000	Num	8	2.	2.	Has the participant received his/her second course of an oral/systemic corticosteroid for an asthma exacerbation within any of the three treatment periods ? 1=Yes,0=No
2	ITX_1010	Num	8			Date treatment arm failure occurred
3	VDATE	Num	8			Number of days from Visit 1 to this visit
4	VNUM	Num	8			Visit Number
5	RAND_ID	Char	6			Randomized Master ID
6	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
7	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: immuno.sas7bdat

Num	Variable	Type	Len	Label
1	COLL_DT	Num	8	Collect Date
2	IGE	Num	8	IgE level in peripheral blood (kU/L)
3	CAT	Num	8	Sensitized to Cat allergen
4	DOG	Num	8	Sensitized to Dog allergen
5	COCKRCH1	Num	8	Sensitized to Cockroach allergen
6	MITE1	Num	8	Sensitized to Mite 1 allergen
7	MITE2	Num	8	Sensitized to Mite 2 allergen
8	EGG_WH1	Num	8	Sensitized to Egg White allergen
9	RAT	Num	8	Sensitized to Rat allergen
10	RAGWEED	Num	8	Sensitized to Ragweed allergen
11	MILK1	Num	8	Sensitized to Milk allergen
12	MOUSE	Num	8	Sensitized to Mouse allergen
13	PEANUT1	Num	8	Sensitized to Peanut allergen
14	WEED	Num	8	Sensitized to Weed allergen
15	TREE1	Num	8	Sensitized to Tree 1 allergen
16	TREE2	Num	8	Sensitized to Tree 2 allergen
17	MOLD	Num	8	Sensitized to Mold allergen
18	GRASS	Num	8	Sensitized to Grass allergen
19	RAND_ID	Char	6	Randomized Master ID
20	ENROLL_TYPE	Char	15	Enrollment Type (Screen Fail, Randomized, Healthy Control)
21	ENROLL_ORDER	Num	8	Enrollment Order Number

Data Set Name: lab.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	LAB_1000	Num	8	2.	2.	Were you able to collect a blood sample from the participant today? 1=Yes,0=No
2	LAB_1010	Num	8	6.	6.	Total WBC (cu.mm)
3	LAB_1020	Num	8	5.1	5.1	Eosinophils (Pct)
4	LAB_1030	Num	8	2.	2.	Were you able to collect a sample for allergen-specific IgE, total IgE and ECP? 1=Yes,0=No
5	LAB_1040	Num	8	2.	2.	Were you able to collect a sample for genetic analysis? 1=Yes,0=No
6	LAB_1050	Num	8	2.	2.	Were you able to collect a sample for metabolomics and proteomics? 1=Yes,0=No
7	LAB_1060	Num	8	2.	2.	Were you able to collect a sample for glutathione and metabolites? 1=Yes,0=No
8	LAB_1070	Num	8	2.	2.	Were you able to collect a urine sample from the participant today? 1=Yes,0=No
9	LAB_1080	Num	8	2.	2.	Were you able to collect a nasal sample from the participant today? 1=Yes,0=No
10	LAB_1090	Num	8	2.	2.	Which nasal sample collection technique was used? 1=Nasal Blow, 2=Nasal Swab
11	VDATE	Num	8			Number of days from Visit 1 to this visit
12	VNUM	Num	8			Visit Number
13	RAND_ID	Char	6			Randomized Master ID
14	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
15	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: *lexam.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	LX_1000	Num	8	2.	2.	PARENTAL HEIGHT - First study visit only or until both are completed 1.Biological mother's height (complete height or check unknown) __ feet
2	LX_1010	Num	8	3.	3.	PARENTAL HEIGHT - First study visit only or until both are completed 1.Biological mother's height (complete height or check unknown) __ __ inches
3	LX_1020	Num	8	2.	2.	PARENTAL HEIGHT - First study visit only or until both are completed 1.Biological mother's height (complete height or check unknown) (9=Don't Know)
4	LX_1030	Num	8	2.	2.	Biological father's height (complete height or check unknown) __ feet
5	LX_1040	Num	8	3.	3.	Biological father's height (complete height or check unknown) __ __ inches
6	LX_1050	Num	8	2.	2.	Biological father's height (complete height or check unknown) (9=Don't Know)
7	LX_1060	Num	8	2.	2.	PARTICIPANT MEASUREMENTS - Complete at all applicable study visits 3. What type of height measurement was obtained? 1=Standing height, 2=Length
8	LX_1070	Num	8	6.1	6.1	Participant height/length, First measurement __ __ __ . __ cm
9	LX_1080	Num	8	6.1	6.1	Participant height/length, Second measurement __ __ __ . __ cm
10	LX_1090	Num	8	6.1	6.1	Participant height/length, Third measurement __ __ __ . __ cm
11	LX_1100	Num	8	6.1	6.1	Average height or length measurement __ __ __ . __ cm
12	LX_1110	Num	8	2.	2.	In your judgment, was the participant's height or length measurement acceptable? 1=Yes,0=No
13	LX_1130	Num	8	6.1	6.1	Weight (shoes off, light clothing) __ __ __ . __ kg
14	LX_1140	Num	8	2.	2.	ORAL CANDIDIASIS5.Does the participant have evidence of oral candidiasis? 1=Yes,0=No
15	VDATE	Num	8			Number of days from Visit 1 to this visit
16	VNUM	Num	8			Visit Number
17	RAND_ID	Char	6			Randomized Master ID
18	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
19	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: phone.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PHN_1000	Num	8	2.	2.	Since the last visit or phone contact, has your child been to a doctor for breathing problems? 1=Yes,0=No
2	PHN_1010	Num	8	3.	3.	Since the last visit or phone contact, how many times has your child been to a doctor for breathing problems?
3	PHN_1020	Num	8	2.	2.	Since the last visit or phone contact, has your child been to an ER/urgent care facility for breathing problems? 1=Yes,0=No
4	PHN_1030	Num	8	2.	2.	Since the last visit or phone contact, has your child been hospitalized for breathing problems? 1=Yes,0=No
5	PHN_1040	Num	8	2.	2.	During the past 2 weeks, did your child have wheezing or cough? 1=Yes,0=No
6	PHN_1050	Num	8	3.	3.	During the past 2 weeks, how many days did your child have wheezing or cough?
7	PHN_1060	Num	8	2.	2.	During the past 2 weeks, did your child have wheezing or cough >5 days? 1=Yes,0=No
8	PHN_1070	Num	8	2.	2.	During the past 2 weeks, did your child awaken from sleep due to asthma symptoms? 1=Yes,0=No
9	PHN_1080	Num	8	3.	3.	During the past 2 weeks, how many nights did your child awaken from sleep due to asthma symptoms?
10	PHN_1090	Num	8	2.	2.	During the past 2 weeks, did your child awaken from sleep due to asthma symptoms >1 night? 1=Yes,0=No
11	PHN_1100	Num	8	2.	2.	During the past 2 weeks, did your child take any albuterol ? 1=Yes,0=No
12	PHN_1110	Num	8	3.	3.	During the past 2 weeks, how many days did your child take albuterol?
13	PHN_1120	Num	8	2.	2.	Has your child been using the white Rescue inhaler each time the red Albuterol inhaler is used? 1=Yes,0=No
14	PHN_1130	Num	8	2.	2.	Have you been completing the spirotel® Diary daily? 1=Yes,0=No
15	PHN_1140	Num	8	2.	2.	Has your child been using the brown Daily inhaler every morning and evening? 1=Yes,0=No
16	PHN_1150	Num	8	2.	2.	Has your child been taking the oral study medication once daily? 1=Yes,0=No
17	PHN_1160	Num	8	2.	2.	Since the last visit or phone contact, has your child used AVICA medication? 1=Yes,0=No
18	PHN_1170	Num	8	2.	2.	Since the last visit or phone contact, has your child used prednisolone? 1=Yes,0=No
19	PHN_1180	Num	8	2.	2.	How many times was prednisolone used since starting the current treatment sequence (since visits 2, 4, 6)?
20	VDATE	Num	8			Number of days from Visit 1 to this visit
21	VNUM	Num	8			Visit Number
22	RAND_ID	Char	6			Randomized Master ID
23	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
24	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: pred.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PR_1010	Num	8	2.	2.	Why was the prednisolone course prescribed?
2	PR_1020	Num	8	2.	2.	Is the start of this prednisolone course on the same day as Visit 4 or 6? 1=Yes,0=No
3	PR_1030	Num	8	2.	2.	Is this the second prednisolone course within a treatment sequence ? 1=Yes,0=No
4	PR_1000	Num	8			Start date of prednisolone
5	VDATE	Num	8			Number of days from Visit 1 to this visit
6	VNUM	Num	8			Visit Number
7	RAND_ID	Char	6			Randomized Master ID
8	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
9	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: priortrt.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PTR_1000	Num	8	2.	2.	Who is the respondent? 1=Self/Participant, 2=Parent/Guardian, 3=Other
2	PTR_1010	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Short-acting Inhaled Beta-Agonists by Inhaler (1=Yes, 0=No, 9=Don't Know)
3	PTR_1050	Num	8	4.	4.	Average weekly puffs of Short-acting Inhaled Beta-Agonists in the past month (Enter '000' if none used) weekly puffs
4	PTR_1060	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Rescue treatment via a Nebulizer Machine (1=Yes, 0=No, 9=Don't Know)
5	PTR_1100	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Long-acting Inhaled Beta-Agonists (1=Yes, 0=No, 9=Don't Know)
6	PTR_1140	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Oral Beta-Agonists (1=Yes, 0=No, 9=Don't Know)
7	PTR_1180	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Oral Theophylline (1=Yes, 0=No, 9=Don't Know)
8	PTR_1220	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Inhaled Anticholinergic by Inhaler (1=Yes, 0=No, 9=Don't Know)
9	PTR_1260	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Leukotriene Antagonist / 5LO Inhibitors (1=Yes, 0=No, 9=Don't Know)
10	PTR_1300	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? IgE Blocker (1=Yes, 0=No, 9=Don't Know)
11	PTR_1340	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Oral Steroids FOR ASTHMA (1=Yes, 0=No, 9=Don't Know)
12	PTR_1380	Num	8	2.	2.	If YES, in the past 12 months, how many courses of steroids by mouth have you taken FOR ASTHMA? 1=1 course, 2=2 courses, 3=3 courses, 4=4 courses, 5=5 courses, 6=More than 5 courses
13	PTR_1390	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Injectable Steroids FOR ASTHMA (1=Yes, 0=No, 9=Don't Know)
14	PTR_1430	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Steroids by Inhaler (1=Yes, 0=No, 9=Don't Know)
15	PTR_1470	Num	8	4.	4.	Indicate most recent type of inhaled steroid taken (refer to PRIOR_TRT_CARD reference card) code
16	PTR_1480	Num	8	3.	3.	Indicate number of daily puffs Steroids by Inhaler used during the past 12 months
17	PTR_1490	Num	8	3.	3.	Indicate the total number of months that you used the inhaled steroid out of the past 12 months months
18	PTR_1500	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Steroids by Nebulizer (1=Yes, 0=No, 9=Don't Know)

Num	Variable	Type	Len	Format	Informat	Label
19	PTR_1540	Num	8	3.	3.	Indicate number of daily treatments Steroids by Nebulizer used during the past 12 months
20	PTR_1550	Num	8	3.	3.	Indicate the total number of months that you used the nebulized steroid out of the past 12 months months
21	PTR_1560	Num	8	2.	2.	During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES? Long-Acting Beta-Agonist and Inhaled Steroid Combination Medications (1=Yes, 0=No, 9=Don't Know)
22	PTR_1600	Num	8	5.	5.	Indicate most recent type of combination medication taken (refer to PRIOR_TRT_CARD reference card) code
23	PTR_1610	Num	8	3.	3.	Indicate number of daily puffs Long-Acting Beta-Agonist and Inhaled Steroid Combination Medications used during the past 12 months
24	PTR_1620	Num	8	3.	3.	Indicate the total number of months that you used the combination medication out of the past 12 months months
25	PTR_1630	Num	8	2.	2.	During the past 12 months were the following nasal treatments used FOR ALLERGIES? Nasal Steroids (1=Yes, 0=No, 9=Don't Know)
26	PTR_1670	Num	8	2.	2.	During the past 12 months were the following nasal treatments used FOR ALLERGIES? Non-steroidal Anti-allergic Nasal Medications (1=Yes, 0=No, 9=Don't Know)
27	PTR_1710	Num	8	2.	2.	During the past 12 months were the following general allergy treatments used? Anti-allergic Oral Medications (1=Yes, 0=No, 9=Don't Know)
28	PTR_1750	Num	8	2.	2.	During the past 12 months were the following skin treatments used FOR ECZEMA OR ALLERGIES? Topical Steroids - Prescription (1=Yes, 0=No, 9=Don't Know)
29	PTR_1790	Num	8	2.	2.	During the past 12 months were the following skin treatments used FOR ECZEMA OR ALLERGIES? Topical Steroids - OTC (1=Yes, 0=No, 9=Don't Know)
30	PTR_1830	Num	8	2.	2.	During the past 12 months were there any OTHER medications used FOR ASTHMA OR ALLERGIES?
31	PTR_1870	Num	8	2.	2.	During the past 12 months were the following treatments used for conditions OTHER THAN ASTHMA? Oral Steroids (1=Yes, 0=No, 9=Don't Know)
32	PTR_1910	Num	8	2.	2.	During the past 12 months were the following treatments used for conditions OTHER THAN ASTHMA? Injectable Steroids (1=Yes, 0=No, 9=Don't Know)
33	VDATE	Num	8			Number of days from Visit 1 to this visit
34	VNUM	Num	8			Visit Number
35	DATE_Q02	Num	8			Short-acting Inhaled Beta-Agonists by Inhaler (e.g., albuterol, Primatene Mist, Maxair, ProAir, Proventil, Ventolin, Xopenex) Date
36	DATE_Q03	Num	8			Rescue treatment via a Nebulizer Machine (e.g., albuterol, ipratropium, Combivent, Xopenex, levalbuterol) Date
37	DATE_Q04	Num	8			Long-acting Inhaled Beta-Agonists (e.g., Serevent, Foradil, salmeterol, formoterol) Do not consider combination medications. Date
38	DATE_Q05	Num	8			Oral Beta-Agonists (e.g., albuterol, Brethine, Bricanyl, metaproterenol, Proventil, Ventolin, Repetabs, Volmax) Date
39	DATE_Q06	Num	8			Oral Theophylline (short-acting or sustained release) (e.g., Aminophylline, Slo-Phyllin, Slo-bid, Theo-Dur, Uniphyll) Date
40	DATE_Q07	Num	8			Inhaled Anticholinergic by Inhaler (e.g., Atrovent, Combivent, Spiriva) Date

Num	Variable	Type	Len	Format	Informat	Label
41	DATE_Q08	Num	8			Leukotriene Antagonist / 5LO Inhibitors (e.g., Accolate, Zflo, Singulair) Date
42	DATE_Q09	Num	8			IgE Blocker (e.g., Xolair) Date
43	DATE_Q10	Num	8			Oral Steroids FOR ASTHMA (e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron, dexamethasone) Date
44	DATE_Q11	Num	8			Injectable Steroids FOR ASTHMA (e.g., Medrol, Solumedrol, Decadron, dexamethasone, triamcinolone, Kenalog, hydrocortisone IV) Date
45	DATE_Q12	Num	8			Steroids by Inhaler (e.g., Asmanex Twisthaler, QVAR, Flovent, Pulmicort Flexhaler) Date
46	DATE_Q13	Num	8			Steroids by Nebulizer (e.g., Pulmicort Respules, budesonide) Date
47	DATE_Q14	Num	8			Long-Acting Beta-Agonist and Inhaled Steroid Combination Medications (e.g., Advair Diskus, Symbicort MDI, Dulera MDI) Date
48	DATE_Q15	Num	8			Nasal Steroids (e.g., Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Omnaris, Rhinocort, Nasonex) Date
49	DATE_Q16	Num	8			Non-steroidal Anti-allergic Nasal Medications (e.g., Nasalcrom, Astelin, Astepro, ipratropium) Date
50	DATE_Q17	Num	8			Anti-allergic Oral Medications (e.g., fexofenadine, loratadine, cetirizine, chlorpheniramine) Date
51	DATE_Q18	Num	8			Topical Steroids - Prescription (e.g., Synalar, Lidex, Dermacin, Fluocinonide) Date
52	DATE_Q19	Num	8			Topical Steroids - OTC (e.g., Hydrocortisone - multiple strengths and products) Date
53	DATE_Q20	Num	8			Other Medication FOR ASTHMA OR ALLERGIES Date
54	DATE_Q21	Num	8			Oral Steroids for Conditions Other Than Asthma (e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron, dexamethasone) Date
55	DATE_Q22	Num	8			Injectable Steroids for Conditions Other Than Asthma (e.g., Medrol, Solumedrol, Decadron, dexamethasone, triamcinolone, Kenalog, hydrocortisone IV) Date
56	RAND_ID	Char	6			Randomized Master ID
57	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
58	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: regimen.sas7bdat

Num	Variable	Type	Len	Label
1	AVI_REG	Char	25	AVICA Regimen
2	INF_REG	Char	25	INFANT regimen – treatments listed in order assigned
3	RAND_ID	Char	6	Randomized Master ID
4	ENROLL_TYPE	Char	15	Enrollment Type (Screen Fail, Randomized, Healthy Control)
5	ENROLL_ORDER	Num	8	Enrollment Order Number

Data Set Name: registry.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	REG_1080	Num	8	2.	2.	Sex (1=Male, 2=Female)
2	REG_1150	Num	8	3.	3.	Primary Racial Identification for Spirometry (1=Amer Indian or Alaskan Native, 2=Asian or Pacific Islander, 3=Black, 4=White, 5=Hispanic or Latino, 6=Other)
3	AGE	Num	8			Age at Visit 1
4	RAND_ID	Char	6			Randomized Master ID
5	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
6	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: sei.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SEL_1000	Num	8	2.	2.	Who is the respondent? 1=Self/Participant, 2=Parent/Guardian, 3=Other (specify
2	SEL_1010	Num	8	3.	3.	Highest education of any household member (0=No High School diploma, 1=GED, 2=High Schol grad, 3=Technical training, 4=Some college, no degree, 5=Assoc degree, 6=Bachelor degree, 7=Masters degree, 8=MD/PhD/JD/PharmD, 9=Decline to answer, 10=Don't know)
3	SEL_1020	Num	8	3.	3.	Category best describes the combined annual income, before taxes, of all members of your household for the last year. (1=Less than \$25,000, 2=\$25,000 - \$49,999, 3=\$50,000 - \$99,999, 4=\$100,000 or more, 9=Decline to answer, 10= Don't know)
4	SEL_1030	Num	8	3.	3.	How many people are supported by this income reported in Q3?
5	VDATE	Num	8			Number of days from Visit 1 to this visit
6	VNUM	Num	8			Visit Number
7	RAND_ID	Char	6			Randomized Master ID
8	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
9	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: serious.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SER_1010	Char	6	\$6.	\$6.	Description of Adverse Event (ICD9 Code)
2	SER_1020	Num	8	2.	2.	Is the participant currently taking study drug? 1=Yes,0=No
3	SER_1030	Num	8	4.	4.	Time interval between the last administration of the study drug and the Adverse Event
4	SER_1040	Num	8	2.	2.	What was the unit of time for the interval between the last administration of the study drug and the Adverse Event? 1=Second, 2=Minute, 3=Hour, 4=Day
5	SER_1050	Num	8	2.	2.	Why was the event serious? Fatal event (1=Yes,0=No)
6	SER_1060	Num	8	2.	2.	Why was the event serious? Life-threatening event (1=Yes,0=No)
7	SER_1070	Num	8	2.	2.	Why was the event serious? Inpatient hospitalization required (1=Yes,0=No)
8	SER_1100	Num	8	2.	2.	Why was the event serious? Hospitalization prolonged (1=Yes,0=No)
9	SER_1110	Num	8	2.	2.	Why was the event serious? Disabling or incapacitating (1=Yes,0=No)
10	SER_1120	Num	8	2.	2.	Why was the event serious? Overdose (1=Yes,0=No)
11	SER_1130	Num	8	2.	2.	Why was the event serious? Cancer (1=Yes,0=No)
12	SER_1140	Num	8	2.	2.	Why was the event serious? Congenital anomaly (1=Yes,0=No)
13	SER_1150	Num	8	2.	2.	Why was the event serious? Serious laboratory abnormality with clinical symptoms (1=Yes,0=No)
14	SER_1160	Num	8	2.	2.	Why was the event serious? Height failure (per protocol MOP) (1=Yes,0=No)
15	SER_1170	Num	8	2.	2.	Why was the event serious? Pregnancy (1=Yes,0=No,9=N/A)
16	SER_1180	Num	8	2.	2.	Why was the event serious? Other (1=Yes,0=No)
17	SER_1190	Num	8	2.	2.	What in your opinion caused the event? Toxicity of study drug(s) (1=Yes,0=No)
18	SER_1200	Num	8	2.	2.	What in your opinion caused the event? Withdrawal of study drug(s) (1=Yes,0=No)
19	SER_1210	Num	8	2.	2.	What in your opinion caused the event? Concurrent medication (1=Yes,0=No)
20	SER_1220	Num	8	2.	2.	What in your opinion caused the event? Other condition or event (1=Yes,0=No)
21	SER_1240	Num	8	2.	2.	Was the event expected or unexpected? 1=Expected, 2=Unexpected
22	SER_1250	Num	8	2.	2.	Was the event possibly, probably, or definitely related to study participation? 1=Yes,0=No
23	SER_1000	Num	8			Date of Adverse Event
24	SER_1080	Num	8			Admission date
25	SER_1090	Num	8			Discharge date
26	VDATE	Num	8			Number of days from Visit 1 to this visit
27	VNUM	Num	8			Visit Number
28	RAND_ID	Char	6			Randomized Master ID
29	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)

Num	Variable	Type	Len	Format	Informat	Label
30	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: sexam.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SX_1060	Num	8	2.	2.	What type of height measurement was obtained? 1=Standing height, 2=Length
2	SX_1070	Num	8	6.1	6.1	Participant height/length, First measurement ____ . __ cm
3	SX_1080	Num	8	6.1	6.1	Participant height/length, Second measurement ____ . __ cm
4	SX_1090	Num	8	6.1	6.1	Participant height/length, Third measurement ____ . __ cm
5	SX_1100	Num	8	6.1	6.1	Average height or length measurement ____ . __ cm
6	SX_1110	Num	8	2.	2.	In your judgment, was the participant's height or length measurement acceptable? 1=Yes,0=No
7	SX_1130	Num	8	6.1	6.1	Weight (shoes off, light clothing) ____ . __ kg
8	SX_1140	Num	8	2.	2.	Does the participant have evidence of oral candidiasis? 1=Yes,0=No
9	VDATE	Num	8			Number of days from Visit 1 to this visit
10	VNUM	Num	8			Visit Number
11	RAND_ID	Char	6			Randomized Master ID
12	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
13	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: spirotel.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SPR_10	Num	8	2.	2.	Did your child have any asthma symptoms today, (0=No, 3=Yes)
2	SPR_11	Num	8	2.	2.	Did your child awaken at night with difficulty breathing, 0=No, 3=Yes
3	SPR_12	Num	8	2.	2.	How severe was your childs cough today, (0=Absent, 1=Mild, 2=Moderate, 3=Severe)
4	SPR_13	Num	8	2.	2.	How severe was your childs wheezing today, (0=Absent, 1=Mild, 2=Moderate, 3=Severe)
5	SPR_14	Num	8	2.	2.	How severe was your childs trouble breathing today, (0=Absent, 1=Mild, 2=Moderate, 3=Severe)
6	SPR_15	Num	8	2.	2.	How much did your childs asthma symptoms interfere with your childs activities today, (0=Absent, 1=Mild, 2=Moderate, 3=Severe)
7	SPR_16	Num	8	3.	3.	Number of puffs from your red Albuterol Inhaler taken for asthma symptoms in the past 24 hours
8	SPR_17	Num	8	3.	3.	Number of puffs from your white Rescue Inhaler taken for asthma symptoms in the past 24 hours
9	SPR_18	Num	8	2.	2.	Number of inhalations taken from your brown daily inhaler in the past 24 hours
10	SPR_19	Num	8	2.	2.	Oral study medication taken at bedtime?
11	VDATE	Num	8			Number of days from Visit 1 to this visit
12	VNUM	Num	8			Visit Number
13	DDATE	Num	8			Diary date
14	DTIME	Num	8	TIME8.2		Diary time
15	RAND_ID	Char	6			Randomized Master ID
16	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
17	ENROLL_ORDER	Num	8			Enrollment Order Number

Data Set Name: termr.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	TRR_1000	Num	8	3.	3.	Indicate the primary reason the participant has withdrawn from the study? 1=inability to demonstrate adherence with spirotel, 2=inability to demonstrate adherence with study medications, 3=too few asthma symptoms during Run-In, 4=too many asthma symptoms d
2	VDATE	Num	8			Number of days from Visit 1 to this visit
3	VNUM	Num	8			Visit Number
4	RAND_ID	Char	6			Randomized Master ID
5	ENROLL_TYPE	Char	15			Enrollment Type (Screen Fail, Randomized, Healthy Control)
6	ENROLL_ORDER	Num	8			Enrollment Order Number