

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: lte4.sas7bdat

Num	Variable	Type	Len	Format	Label
1	RAND_ID	Char	6		Randomized Master ID
2	CREATININE	Num	8	BEST.	Urine Creatinine (mg/ml)
3	LTE4	Num	8		Urine LTE4 (pg/ml)
4	LTE4_CREAT_RATIO	Num	8		Urine LTE4-Creatinine Ratio (pg LTE4/mg Creatinine)

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	SEI_1000	Num	8	2.	2.	Who is the respondent? 1=Self/Participant, 2=Parent/Guardian, 3=Other (specify)
2	SEI_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	SEI_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	SEI_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