*Data Set Name: aaaq.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | AAQ_1000 | Num | 8 | 2. | 2. | In the past 3 days, how much of the time did your asthma keep you from doing your usual activities at work, school, or at home? 0=None of the time, 1=A little of the time, 2=Some of the time, 3=Most of the time, 4=All of the time |
| 2 | AAQ_1010 | Num | 8 | 2. | 2. | During the past 3 days, how often have you had asthma symptoms? 0=Not at all, 1=Once per day, 2=2-3 times per day, 3=4-5 times per day, 4=6 or more times per day |
| 3 | AAQ_1020 | Num | 8 | 2. | 2. | During the past 3 days, how often have you used your rescue inhaler or nebulizer medication ? 0=Not at all, 1=Once per day, 2=2-3 times per day, 3=4-5 times per day, 4=6 or more times per day |
| 4 | AAQ_1030 | Num | 8 | 2. | 2. | During the past 3 days, how many total times did your asthma symptoms wake you up from sleep? 0=Not at all, 1=1 time in the last 3 days, 2=2-3 times in the last 3 days, 3=4-5 times in the last 3 days, 4=>=6 times in the last 3 days |
| 5 | AAQ_1040 | Num | 8 | 2. | 2. | How would you rate the amount of impairment you have experienced due to your asthma in the past 3 days? 0=No impairment, 1=Mild impairment, 2=Moderate impairment, 3=Severe impairment, 4=Very severe impairment |
| 6 | AAQ_1050 | Num | 8 | 2. | 2. | How stressed or frightened were you by your asthma symptoms in the past 3 days? 0=Not at all, 1=Mildly, 2=Moderately, 3=Severely, 4=Very severely |
| 7 | AAQ_1060 | Num | 8 | 2. | 2. | Why do you think your asthma was worse in the past 3 days compared to what is normal for you? 0=I have not been worse over the past 3 days. My asthma symptoms have been usual., 1=Common cold, 2=Allergies, 3=Pollution or chemical irritant, 4=Too little asth |
| 8 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 9 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 10 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: abp.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | ABP_1000 | Num | 8 | 2. | 2. | Are you currently retired? 1=Yes,0=No |
| 2 | ABP_1010 | Num | 8 | 2. | 2. | Are you retired because of asthma? 1=Yes,0=No |
| 3 | ABP_1020 | Num | 8 | 2. | 2. | Are you currently unemployed? 1=Yes,0=No |
| 4 | ABP_1030 | Num | 8 | 2. | 2. | Are you unemployed because of asthma? 1=Yes,0=No |
| 5 | ABP_1040 | Num | 8 | 2. | 2. | Do you get paid to do work? 1=Yes,0=No |
| 6 | ABP_1050 | Num | 8 | 2. | 2. | How much does your asthma bother you at your paid work? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 7 | ABP_1060 | Num | 8 | 2. | 2. | Overall, how much does your asthma bother you when you do jobs around the house? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery, 0=None of these really apply to me |
| 8 | ABP_1070 | Num | 8 | 2. | 2. | Overall, how much does your asthma bother your social life? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 9 | ABP_1080 | Num | 8 | 2. | 2. | Overall, how much does your asthma bother your personal life? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery, 0=None of these really apply to me |
| 10 | ABP_1090 | Num | 8 | 2. | 2. | Are you involved in leisure activities, such as: walking for pleasure, sports, exercise, travelling, taking vacations? 1=Yes,0=No |
| 11 | ABP_1100 | Num | 8 | 2. | 2. | When involved in leisure activities, how much does your asthma bother you? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 12 | ABP_1110 | Num | 8 | 2. | 2. | Would you say that you can't do some of these sorts of things because of asthma? 1=Yes,0=No |
| 13 | ABP_1120 | Num | 8 | 2. | 2. | How much does your asthma bother you when you sleep? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 14 | ABP_1130 | Num | 8 | 2. | 2. | How much does the cost of your asthma medicines bother you? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 15 | ABP_1140 | Num | 8 | 2. | 2. | Do you get free prescriptions? 1=Yes,0=No |
| 16 | ABP_1150 | Num | 8 | 2. | 2. | How much does the inconvenience or embarrassment of taking your asthma medicines bother you? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 17 | ABP_1160 | Num | 8 | 2. | 2. | How much do coughs and colds bother you? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery, 0=None of these really apply to me |
| 18 | ABP_1170 | Num | 8 | 2. | 2. | Feeling upset is also a bother.   Does your asthma make you feel anxious, depressed, tired, or helpless? 1=Yes,0=No |
| 19 | ABP_1180 | Num | 8 | 2. | 2. | Feeling upset is also a bother.   Does your asthma make you feel anxious, depressed, tired, or helpless? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |

| Num | Variable | Type | Len | Format | Informat | Label |
|-----|----------|------|-----|--------|----------|-------|
| 20 | ABP_1190 | Num | 8 | 2. | 2. | How much bother is the worry that you will have an asthma attack when visiting a new place? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 21 | ABP_1200 | Num | 8 | 2. | 2. | How much bother is the worry that you will catch a cold? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 22 | ABP_1210 | Num | 8 | 2. | 2. | How much bother is the worry that you will let others down? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 23 | ABP_1220 | Num | 8 | 2. | 2. | How much bother is the worry that your health may get worse in the future? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 24 | ABP_1230 | Num | 8 | 2. | 2. | How much bother is the worry that you won't be able to cope with an asthma attack? 0=No bother at all, 1=Minor irritation, 2=Slight bother, 3=Moderate bother, 4=A lot of bother, 5=Makes my life a misery |
| 25 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 26 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 27 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 28 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 29 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 30 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

*Data Set Name: act.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | ACT_1 | Num | 8 | 2. | 2. | In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home? 1=All of the time, 2=Most of the time, 3=Some of the time, 4=A little of the time, 5=None of the time |
| 2 | ACT_2 | Num | 8 | 2. | 2. | During the past 4 weeks, how often have your had shortness of breath? 1=All of the time, 2=Most of the time, 3=Some of the time, 4=A little of the time, 5=None of the time |
| 3 | ACT_3 | Num | 8 | 2. | 2. | During the past 4 weeks, how often did your asthma symptoms wake you up at night or earlier than usual in the morning? 1=All of the time, 2=Most of the time, 3=Some of the time, 4=A little of the time, 5=None of the time |
| 4 | ACT_4 | Num | 8 | 2. | 2. | During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication? 1=All of the time, 2=Most of the time, 3=Some of the time, 4=A little of the time, 5=None of the time |
| 5 | ACT_5 | Num | 8 | 2. | 2. | How would you rate your asthma control during the past 4 weeks? 1=All of the time, 2=Most of the time, 3=Some of the time, 4=A little of the time, 5=None of the time |
| 6 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 7 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 8 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 9 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 10 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 11 | 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. | Description of Adverse Event |
| 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_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 16 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 17 | ICD9LONG | Char | 200 | | | Long ICD-9 description |
| 18 | ICD9SHRT | Char | 35 | | | Short ICD-9 description |
| 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: asthma_hx_adult.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | AHA_1000 | Num | 8 | 3. | 3. | ASTHMA HISTORY1.Approximately how old were you when chest symptoms suggesting asthma first appeared? |
| 2 | AHA_1020 | Num | 8 | 2. | 2. | Did these symptoms appear immediately after or as a result of:1a. a respiratory infection such as a cold or pneumonia? 1=Yes, 0=No, 8=Don't Know |
| 3 | AHA_1030 | Num | 8 | 2. | 2. | an occupational or job change? 1=Yes, 0=No, 8=Don't Know |
| 4 | AHA_1040 | Num | 8 | 2. | 2. | a household move? 1=Yes, 0=No, 8=Don't Know |
| 5 | AHA_1050 | Num | 8 | 2. | 2. | a pregnancy? 1=Yes, 0=No, 8=Don't Know |
| 6 | AHA_1060 | Num | 8 | 2. | 2. | a hormonal change ? 1=Yes, 0=No, 8=Don't Know |
| 7 | AHA_1070 | Num | 8 | 3. | 3. | How old were you when a doctor first diagnosed you with asthma? |
| 8 | AHA_1090 | Num | 8 | 2. | 2. | Have any of your immediate blood relatives been told by a physician that they have asthma? 1=Yes, 0=No, 8=Don't Know |
| 9 | AHA_1100 | Num | 8 | 2. | 2. | Father   (1=Yes, 0=No, 8=Don't Know) |
| 10 | AHA_1110 | Num | 8 | 2. | 2. | Brother(s) or Sister(s)   (1=Yes, 0=No, 8=Don't Know, 9=N/A) |
| 11 | AHA_1120 | Num | 8 | 2. | 2. | Child(ren)   (1=Yes, 0=No, 8=Don't Know, 9=N/A) |
| 12 | AHA_1130 | Num | 8 | 2. | 2. | ASTHMA SYMPTOMS1.How do you categorize your asthma symptoms throughout the course of the year? 1=Relatively the same all year, 2=Vary by season |
| 13 | AHA_1140 | Num | 8 | 2. | 2. | Winter? 1=Yes,0=No |
| 14 | AHA_1150 | Num | 8 | 2. | 2. | Spring? 1=Yes,0=No |
| 15 | AHA_1160 | Num | 8 | 2. | 2. | Summer? 1=Yes,0=No |
| 16 | AHA_1170 | Num | 8 | 2. | 2. | Fall? 1=Yes,0=No |
| 17 | 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? |
| 18 | AHA_1190 | Num | 8 | 3. | 3. | Overnight hospitalizations have you had due to asthma? |
| 19 | AHA_1200 | Num | 8 | 3. | 3. | Courses of systemic corticosteroid therapy   for asthma have you taken? |
| 20 | AHA_1210 | Num | 8 | 4. | 4. | Days of work, school, or housework have you missed due to asthma? |
| 21 | 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? |
| 22 | AHA_1250 | Num | 8 | 2. | 2. | Have you ever been admitted to an intensive care unit for asthma? 1=Yes,0=No |
| 23 | AHA_1260 | Num | 8 | 3. | 3. | How many times have you been admitted to an intensive care unit for asthma? |
| 24 | AHA_1270 | Num | 8 | 2. | 2. | Have you ever had invasive mechanical ventilation? 1=Yes, 0=No, 8=Don't Know |
| 25 | AHA_1280 | Num | 8 | 2. | 2. | Have you ever had non-invasive mechanical ventilation? 1=Yes, 0=No, 8=Don't Know |
| 26 | AHA_1290 | Num | 8 | 2. | 2. | Do any of the following currently provoke your asthma? 1=Yes, 0=No, 8=Don't Know |
| 27 | AHA_1300 | Num | 8 | 2. | 2. | Menstrual cycle(If participant is male or a postmenopausal female, leave blank.) (1=Yes, 0=No, 8=Don't Know) |

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 28 | AHA_1310 | Num | 8 | 2. | 2. | Aspirin or non-steroidal anti-inflammatory drugs (e.g., Aleve, Motrin) (1=Yes, 0=No, 8=Don't Know) |
| 29 | AHA_1320 | Num | 8 | 2. | 2. | Respiratory infections (e.g., colds)   (1=Yes, 0=No, 8=Don't Know) |
| 30 | AHA_1330 | Num | 8 | 2. | 2. | Irritants (e.g., pollution, odors, perfumes, chemicals, household cleaners) (1=Yes, 0=No, 8=Don't Know) |
| 31 | AHA_1340 | Num | 8 | 2. | 2. | Weather conditions (e.g., change in weather, humidity)   (1=Yes, 0=No, 8=Don't Know) |
| 32 | AHA_1350 | Num | 8 | 2. | 2. | Exposure to cold air   (1=Yes, 0=No, 8=Don't Know) |
| 33 | AHA_1360 | Num | 8 | 2. | 2. | Emotional factors (e.g., stress, laughing)   (1=Yes, 0=No, 8=Don't Know) |
| 34 | AHA_1370 | Num | 8 | 2. | 2. | Tobacco smoke   (1=Yes, 0=No, 8=Don't Know) |
| 35 | AHA_1380 | Num | 8 | 2. | 2. | Food additives/preservatives (e.g., MSG, sulfites)   (1=Yes, 0=No, 8=Don't Know) |
| 36 | AHA_1390 | Num | 8 | 2. | 2. | Allergies (e.g., dust, animals, pollens)    (1=Yes, 0=No, 8=Don't Know) |
| 37 | AHA_1400 | Num | 8 | 2. | 2. | Other (1=Yes,0=No) |
| 38 | AHA_1410 | Num | 8 | 2. | 2. | To which of the following did a doctor or other health practitioner say you were allergic? 1=Yes, 0=No, 8=Don't Know |
| 39 | AHA_1420 | Num | 8 | 2. | 2. | Foods   (1=Yes, 0=No, 8=Don't Know) |
| 40 | AHA_1430 | Num | 8 | 2. | 2. | Things you breathe in or are exposed to (e.g., dust, pollens, molds, animal fur, feathers, dander)   (1=Yes, 0=No, 8=Don't Know) |
| 41 | AHA_1440 | Num | 8 | 2. | 2. | Stinging insects such as bees or wasps (1=Yes, 0=No, 8=Don't Know) |
| 42 | AHA_1450 | Num | 8 | 2. | 2. | Latex   (1=Yes, 0=No, 8=Don't Know) |
| 43 | AHA_1460 | Num | 8 | 2. | 2. | Other   (1=Yes,0=No) |
| 44 | AHA_1470 | Num | 8 | 2. | 2. | Have you ever had eczema / atopic dermatitis ? 1=Yes, 0=No, 8=Don't Know |
| 45 | AHA_1500 | Num | 8 | 2. | 2. | If YES, was your eczema diagnosed by a doctor? 1=Yes,0=No |
| 46 | AHA_1570 | Num | 8 | 2. | 2. | Have any of your immediate blood relatives been told by a physician that they have allergies/eczema/hay fever? 1=Yes, 0=No, 8=Don't Know |
| 47 | AHA_1580 | Num | 8 | 2. | 2. | Father   (1=Yes, 0=No, 8=Don't Know, 9=N/A) |
| 48 | AHA_1590 | Num | 8 | 2. | 2. | Brother(s) or Sister(s)    (1=Yes, 0=No, 8=Don't Know, 9=N/A) |
| 49 | AHA_1600 | Num | 8 | 2. | 2. | Child(ren)   (1=Yes, 0=No, 8=Don't Know, 9=N/A) |
| 50 | AHA_1730 | Num | 8 | 2. | 2. | Did you grow up in a household where you were exposed to tobacco smoke? 1=Yes,0=No |
| 51 | AHA_1740 | Num | 8 | 2. | 2. | Do you currently smoke? 1=Yes,0=No |
| 52 | AHA_1750 | Num | 8 | 5.1 | 5.1 | Record smoking history in pack-years*. __ __ . __ pack-years |
| 53 | AHA_1760 | Num | 8 | 2. | 2. | Were you ever a smoker? 1=Yes,0=No |
| 54 | AHA_1770 | Num | 8 | 5.1 | 5.1 | Record smoking history in pack-years*. __ __ . __ pack-years |
| 55 | AHA_1780 | Num | 8 | 2. | 2. | Do you currently live in a household where you are exposed to tobacco smoke? 1=Yes,0=No |
| 56 | AHA_1790 | Num | 8 | 2. | 2. | Do you currently vape   or use a hookah ? 1=Yes,0=No |
| 57 | AHA_1800 | Num | 8 | 2. | 2. | How frequently do you vape or use a hookah? 1=Infrequently , 2=Occasionally , 3=Weekly , 4=Daily |

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 58 | AHA_1810 | Num | 8 | 2. | 2. | Do you currently vape (i.e., use nicotine or any other substances in an e-cigarette device) or use a hookah (waterpipe)?   If NO, skip to Q16.   How frequently do you vape or use a hookah?   If Infrequently or Occasionally, skip to Q17.   How many days a week |
| 59 | AHA_1820 | Num | 8 | 3. | 3. | Do you currently vape (i.e., use nicotine or any other substances in an e-cigarette device) or use a hookah (waterpipe)?   If NO, skip to Q16.   How frequently do you vape or use a hookah?   If Infrequently or Occasionally, skip to Q17.   How many times a day |
| 60 | AHA_1830 | Num | 8 | 3. | 3. | Do you currently vape (i.e., use nicotine or any other substances in an e-cigarette device) or use a hookah (waterpipe)?   If NO, skip to Q16.   How frequently do you vape or use a hookah?   If Infrequently or Occasionally, skip to Q17.   How many years have y |
| 61 | AHA_1840 | Num | 8 | 2. | 2. | Have you ever vaped or used a hookah in the past? 1=Yes,0=No |
| 62 | AHA_1850 | Num | 8 | 3. | 3. | Have you ever vaped or used a hookah in the past?   If NO, skip to Q17.   Approximately how many years did you vape or use a hookah?   (1-99 years) |
| 63 | AHA_1890 | Num | 8 | 2. | 2. | Do you currently live in a household where you are exposed to others vaping or using a hookah? 1=Yes,0=No |
| 64 | AHA_1900 | Num | 8 | 2. | 2. | Do you spend time in social settings   where you are exposed to others vaping or using a hookah? 1=Yes,0=No |
| 65 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 66 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 67 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 68 | DATE_VAPE | Num | 8 | | | When was the last time that you vaped or used a hookah? (number of days from Visit 1) |
| 69 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 70 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 71 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

*Data Set Name: asui.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | ASU_1000 | Num | 8 | 2. | 2. | How many days were you bothered by coughing during the past 2 weeks? 0=Not at all, 1=1-3 days, 2=4-7 days, 3=8-14 days |
| 2 | ASU_1010 | Num | 8 | 2. | 2. | On average, how severe was your coughing during the past 2 weeks? 1=Mild, 2=Moderate, 3=Severe |
| 3 | ASU_1020 | Num | 8 | 2. | 2. | How many days were you bothered by wheezing during the past 2 weeks? 0=Not at all, 1=1-3 days, 2=4-7 days, 3=8-14 days |
| 4 | ASU_1030 | Num | 8 | 2. | 2. | On average, how severe was your wheezing during the past 2 weeks? 1=Mild, 2=Moderate, 3=Severe |
| 5 | ASU_1040 | Num | 8 | 2. | 2. | How many days were you bothered by shortness of breath during the past 2 weeks? 0=Not at all, 1=1-3 days, 2=4-7 days, 3=8-14 days |
| 6 | ASU_1050 | Num | 8 | 2. | 2. | Over average, how severe was your shortness of breath during the past 2 weeks? 1=Mild, 2=Moderate, 3=Severe |
| 7 | ASU_1060 | Num | 8 | 2. | 2. | How many days were you awakened at night during the past 2 weeks? 0=Not at all, 1=1-3 days, 2=4-7 days, 3=8-14 days |
| 8 | ASU_1070 | Num | 8 | 2. | 2. | On average, how much of a problem was being awakened at night during the past 2 weeks? 1=Mild, 2=Moderate, 3=Severe |
| 9 | ASU_1080 | Num | 8 | 2. | 2. | How many days were you bothered by side effects of your asthma medication during the past 2 weeks? 0=Not at all, 1=1-3 days, 2=4-7 days, 3=8-14 days |
| 10 | ASU_1090 | Num | 8 | 2. | 2. | On average, how severe were the side effects of your asthma medication during the past 2 weeks? 1=Mild, 2=Moderate, 3=Severe |
| 11 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 12 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 13 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: baseline.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | BAS_1000 | Num | 8 | 4. | 4. | Participants baseline peak flow (PEF) value (0-999 L/M) First visit (Visit 0A, or Visit 1): PEF (FEF Max) from prebronchodilator (baseline) spirometry at first visit (convert to L/M) |
| 2 | BAS_1010 | Num | 8 | 3. | 3. | Participants baseline rescue use value (0-99 puffs/day) First visit (Visit 0A, or Visit 1): Self-reported average daily use of albuterol during the 14 days prior to first visit. |
| 3 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 4 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 5 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 6 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 7 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 8 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

*Data Set Name: bmi.sas7bdat*

| Num | Variable | Type | Len | Label |
|---|---|---|---|---|
| 1 | BMI | Num | 8 | body mass index computed from height and weight measured at Visit 1 |
| 2 | RAND_ID | Char | 6 | Randomized Master ID |
| 3 | ENROLL_TYPE | Char | 15 | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 4 | ENROLL_ORDER | Num | 8 | Enrollment Order Number |

*Data Set Name: change_meds.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | PAGE | Num | 8 | 3. | 3. | Page Number |
| 2 | CHG_1000 | Num | 8 | 2. | 2. | Reason for change in scheduled medications status (1=Adverse Event, 2=Other (specify)) |
| 3 | CHG_1010 | Num | 8 | 3. | 3. | Reason for change in scheduled medications status Related adverse event number (0-99) |
| 4 | CHG_1020 | Num | 8 | 2. | 2. | Current status of participants scheduled medications (1=Discontinued, 2=Resumed) |
| 5 | CHG_1030 | Num | 8 | | | Date change took effect |
| 6 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 7 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 8 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 9 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 10 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 11 | 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. | Name of Medication |
| 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_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 13 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 14 | GEN_NAME | Char | 100 | $100. | $100. | GEN_DRUG_NAME |
| 15 | CLASS | Char | 100 | $100. | $100. | 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: comply.sas7bdat

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | COM_1000 | Num | 8 | 4. | 4. | Diary and Peak Flow Compliance: Number of full days since the last visit (0-999 days) |
| 2 | COM_1010 | Num | 8 | 4. | 4. | Diary and Peak Flow Compliance: Number of days where AM and PM scheduled sessions are complete (AM and PM PEF and all diary questions for AM and PM answered) (0-999 days) |
| 3 | COM_1020 | Num | 8 | 6.1 | 6.1 | Diary and Peak Flow Compliance: Percent compliance If the compliance value in Q1c is less than 75Pct, re-emphasize the importance of completing scheduled diary assessments and peak flows. (0-150.0Pct) |
| 4 | COM_1030 | Num | 8 | 4. | 4. | Scheduled Respimat Compliance (Visits 2-9 only): Number of scheduled puffs since the last visit (0-999 puffs) |
| 5 | COM_1040 | Num | 8 | 4. | 4. | Scheduled Respimat Compliance (Visits 2-9 only): Number of remaining puffs on scheduled Respimat Reference all returned Respimats (0-999 puffs) |
| 6 | COM_1050 | Num | 8 | 4. | 4. | Scheduled Respimat Compliance (Visits 2-9 only): Number of puffs taken (60 x (# used Respimats)) - Q2b (0-999 puffs) |
| 7 | COM_1060 | Num | 8 | 6.1 | 6.1 | Scheduled Respimat Compliance (Visits 2-9 only): Percent compliance=Q2c/Q2a x 100 If the participant took less than 75Pct of the scheduled Respimat puffs, re-emphasize the importance of maintaining the daily dosing schedule. (0-150.0Pct) |
| 8 | COM_1070 | Num | 8 | 4. | 4. | Scheduled Twisthaler Compliance (Visits 4-9 only): Number of scheduled puffs since the last visit (0-999 puffs) |
| 9 | COM_1080 | Num | 8 | 4. | 4. | Scheduled Twisthaler Compliance (Visits 4-9 only): Number of remaining puffs reflected on scheduled Twisthaler counters Total the values reflected on all counters for all returned Twisthalers (i.e., out of their pouches). (0-999 puffs) |
| 10 | COM_1090 | Num | 8 | 4. | 4. | Scheduled Twisthaler Compliance (Visits 4-9 only): Number of puffs taken (60 x (# used Twisthalers)) - Q3b (0-999 puffs) |
| 11 | COM_1100 | Num | 8 | 6.1 | 6.1 | Scheduled Twisthaler Compliance (Visits 4-9 only): Percent compliance=Q3c/Q3a x 100 If the participant took less than 75Pct of the scheduled Twisthaler puffs, re-emphasize the importance of maintaining the daily dosing schedule. (0-150.0Pct) |
| 12 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 13 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 14 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: ctxqx.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | CTX_1000 | Num | 8 | 2. | 2. | 1=mometasone, 2=placebo |
| 2 | CTX_1010 | Num | 8 | 2. | 2. | Blinded Scheduled Twisthaler Contents - How sure are you about your answer in Q1? 1=Absolutely sure - I know what the Twisthaler/MDI contains, 2=Moderately sure, 3=Somewhat sure, 4=Not sure at all - purely a guess |
| 3 | CTX_1030 | Num | 8 | 2. | 2. | 1=tiotropium, 2=placebo |
| 4 | CTX_1040 | Num | 8 | 2. | 2. | Blinded Scheduled Respimat Contents - How sure are you about your answer in Q4? 1=Absolutely sure - I know what the Respimat capsules contain, 2=Moderately sure, 3=Somewhat sure, 4=Not sure at all - purely a guess |
| 5 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 6 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 7 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: elig0a.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | E0A_1000 | Num | 8 | 2. | 2. | Has the participant or parent/legal guardian signed the SIENA Informed Consent document? 1=Yes,0=No |
| 2 | E0A_1020 | Num | 8 | 2. | 2. | Ages 12-17 Only: Has the participant signed and dated the assent form or, if the participant is less than the local age of assent, has the participant given verbal assent? 1=Yes,0=No |
| 3 | E0A_1030 | Num | 8 | 2. | 2. | Has the participant used an inhaled corticosteroid in the past 6 weeks? 1=Yes,0=No |
| 4 | E0A_1040 | Num | 8 | 2. | 2. | Will the participant be 12 years of age, or older, as of Visit 1? 1=Yes,0=No |
| 5 | E0A_1043 | Num | 8 | 2. | 2. | Has the participant used an inhaled corticosteroid or combination inhaled corticosteroid/LABA in the past 3 weeks? 1=Yes,0=No |
| 6 | E0A_1045 | Num | 8 | 2. | 2. | If NO, has the participant used a leukotriene modifier in the past 3 weeks? 1=Yes,0=No |
| 7 | E0A_1050 | Num | 8 | 2. | 2. | Over the past 3 months, on average, how many days per week has the participant used inhaled corticosteroid therapy? |
| 8 | E0A_1060 | Num | 8 | 2. | 2. | Over the past 3 months, on average, how many days per week has the participant used inhaled corticosteroid therapy: < 5? 1=Yes,0=No |
| 9 | E0A_1070 | Num | 8 | 2. | 2. | Over the past 3 months, has the participant used greater than the equivalent of 80-240 mcg of inhaled beclomethasone daily? 1=Yes,0=No |
| 10 | E0A_1073 | Num | 8 | 2. | 2. | Over the past 3 months, on average, how many days per week has the participant used combination inhaled corticosteroid/LABA therapy? |
| 11 | E0A_1075 | Num | 8 | 2. | 2. | Over the past 3 months, on average, how many days per week has the participant used combination inhaled corticosteroid/LABA therapy, < 5 (1=Yes,0=No) |
| 12 | E0A_1080 | Num | 8 | 2. | 2. | Over the past 3 months, on average, how many days per week has the participant had daytime asthma symptoms? |
| 13 | E0A_1090 | Num | 8 | 2. | 2. | Over the past 3 months, on average, how many days per week has the participant had daytime asthma symptoms, <=2? 1=Yes,0=No |
| 14 | E0A_1100 | Num | 8 | 3. | 3. | Over the past 3 months, on average, how many nighttime awakenings per month has the participant had due to asthma symptoms? |
| 15 | E0A_1110 | Num | 8 | 2. | 2. | Over the past 3 months, on average, how many nighttime awakenings per month has the participant had due to asthma symptoms, <=2? 1=Yes,0=No |
| 16 | E0A_1120 | Num | 8 | 2. | 2. | Over the past 3 months, on average, how many days per week has the participant used his/her short acting betaagonist   for relief of symptoms? |
| 17 | E0A_1130 | Num | 8 | 2. | 2. | Over the past 3 months, on average, how many days per week has the participant used his/her short acting betaagonist   for relief of symptoms, < 2? 1=Yes,0=No |
| 18 | E0A_1140 | Num | 8 | 2. | 2. | Was the participants FEV1 Pct predicted > 80Pct? 1=Yes,0=No |
| 19 | E0A_1145 | Num | 8 | 2. | 2. | Was the participants FEV1 Pct predicted > 70Pct? 1=Yes,0=No |
| 20 | E0A_1150 | Num | 8 | 2. | 2. | Does the participant have current evidence of any of the conditions listed on the Exclusionary Medical Conditions for SIENA   reference card, or any chronic diseases that would prevent participation in the trial or put the participant at risk by participati |
| 21 | E0A_1160 | Num | 8 | 2. | 2. | Is the participant currently taking any medications listed on the Exclusionary Drugs for SIENA   reference card? 1=Yes,0=No |

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 22 | E0A_1170 | Num | 8 | 2. | 2. | Is the participant able to go off these medications for the required washout period prior to Visit 1 and for the duration of the study? 1=Yes,0=No |
| 23 | E0A_1180 | Num | 8 | 2. | 2. | Is the participant able to use the spirotel e-diary/PEF meter correctly, as evidenced by achieving a score of 13 on the spirotel Performance Checklist ? 1=Yes,0=No |
| 24 | E0A_1190 | Num | 8 | 2. | 2. | Is the participant eligible to proceed? 1=Yes,0=No |
| 25 | E0A_1010 | Num | 8 | | | Has the participant or parent/legal guardian signed the SIENA Informed Consent document? |
| 26 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 27 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 28 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 29 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 30 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 31 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: elig0b.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | E0B_1000 | Num | 8 | 4.1 | 4.1 | In the past month, on average, how many days per week has the participant had daytime symptoms? |
| 2 | E0B_1010 | Num | 8 | 2. | 2. | In the past month, on average, how many days per week has the participant had daytime symptoms, <=2? 1=Yes,0=No |
| 3 | E0B_1020 | Num | 8 | 5.1 | 5.1 | In the past month, on average, how many nighttime awakenings per month has the participant had due to asthma symptoms? |
| 4 | E0B_1030 | Num | 8 | 2. | 2. | In the past month, on average, how many nighttime awakenings per month has the participant had due to asthma symptoms,   <=2? 1=Yes,0=No |
| 5 | E0B_1040 | Num | 8 | 4.1 | 4.1 | In the past month, on average, how many days per week has the participant used his/her short acting beta-agonist   for relief of symptoms? |
| 6 | E0B_1050 | Num | 8 | 2. | 2. | In the past month, on average, how many days per week has the participant used his/her short acting beta-agonist   for relief of symptoms, < 2? 1=Yes,0=No |
| 7 | E0B_1060 | Num | 8 | 2. | 2. | Was the participants FEV1 Pct predicted > 80Pct? 1=Yes,0=No |
| 8 | E0B_1065 | Num | 8 | 2. | 2. | Was the participants FEV1 Pct predicted > 70Pct? 1=Yes,0=No |
| 9 | E0B_1070 | Num | 8 | 2. | 2. | Is there any new information that makes the participant ineligible according to the eligibility criteria? 1=Yes,0=No |
| 10 | E0B_1080 | Num | 8 | 2. | 2. | Is the participant eligible to proceed? 1=Yes,0=No |
| 11 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 12 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 13 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: elig1.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | E1_1000 | Num | 8 | 2. | 2. | Did the participant or parent/legal guardian sign the SIENA Informed Consent document? 1=Yes,0=No |
| 2 | E1_1020 | Num | 8 | 2. | 2. | Ages 12-17 Only: Has the participant signed and dated the assent form or, if the participant is less than the local age of assent, has the participant given verbal assent? 1=Yes,0=No |
| 3 | E1_1030 | Num | 8 | 2. | 2. | Is the participant 12 years of age, or older? 1=Yes,0=No |
| 4 | E1_1040 | Num | 8 | 2. | 2. | Does the participant plan to move away from the clinical site in the upcoming 11 months such that his/her ability to complete the study will be jeopardized? 1=Yes,0=No |
| 5 | E1_1050 | Num | 8 | 2. | 2. | Has the participant used investigative drugs and/or enrolled in an intervention trial in the past 30 days, or have plans to enroll in such a trial during the SIENA study? 1=Yes,0=No |
| 6 | E1_1060 | Num | 8 | 2. | 2. | Has the participant had a respiratory infection within the past 6 weeks? 1=Yes,0=No |
| 7 | E1_1065 | Num | 8 | 2. | 2. | Has the participant had a respiratory infection within the past 4 weeks? 1=Yes,0=No |
| 8 | E1_1070 | Num | 8 | 4.1 | 4.1 | During the past 4 weeks, on average, how many days per week has the participant had daytime asthma symptoms? |
| 9 | E1_1080 | Num | 8 | 2. | 2. | During the past 4 weeks, on average, how many days per week has the participant had daytime asthma symptoms  > 2? 1=Yes,0=No |
| 10 | E1_1090 | Num | 8 | 5.1 | 5.1 | During the past 4 weeks, how many nighttime awakenings due to asthma symptoms has the participant had? |
| 11 | E1_1100 | Num | 8 | 2. | 2. | During the past 4 weeks, how many nighttime awakenings due to asthma symptoms has the participant had,  > 2? 1=Yes,0=No |
| 12 | E1_1110 | Num | 8 | 4.1 | 4.1 | During the past 4 weeks, on average, how many days per week has the participant used his/her short-acting beta-agonist  for relief of symptoms? |
| 13 | E1_1120 | Num | 8 | 2. | 2. | During the past 4 weeks, on average, how many days per week has the participant used his/her short-acting beta-agonist  for relief of symptoms, > 2? 1=Yes,0=No |
| 14 | E1_1130 | Num | 8 | 2. | 2. | Is Q7a, Q8a, or Q9a checked YES? 1=Yes,0=No |
| 15 | E1_1140 | Num | 8 | 2. | 2. | Is the participant eligible to proceed? 1=Yes,0=No |
| 16 | E1_1010 | Num | 8 | | | Did the participant or parent/legal guardian sign the SIENA Informed Consent document? |
| 17 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 18 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 19 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: elig2.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | E2_1000 | Num | 8 | 2. | 2. | Does the participant have current evidence of any of the conditions listed on the Exclusionary Medical Conditions for SIENA reference card, or any chronic diseases that would prevent participation in the trial or put the participant at risk by participat |
| 2 | E2_1010 | Num | 8 | 2. | 2. | Does the participant have a history of bladder-neck obstruction, urinary retention, benign prostatic hyperplasia , or a clinically relevant urologic disorder that precludes study participation? 1=Yes,0=No |
| 3 | E2_1020 | Num | 8 | 2. | 2. | Does the participant have a history of narrow angle glaucoma? 1=Yes,0=No |
| 4 | E2_1030 | Num | 8 | 2. | 2. | Does the participant have a history of significant cardiovascular disorders or arrhythmias? 1=Yes,0=No |
| 5 | E2_1040 | Num | 8 | 2. | 2. | Has the participant taken any medications listed on the Exclusionary Drugs for SIENA reference card within the specified time periods? 1=Yes,0=No |
| 6 | E2_1050 | Num | 8 | 2. | 2. | Is the participant currently taking prescription or OTC medication other than those listed on the Allowed Medications reference card? 1=Yes,0=No |
| 7 | E2_1060 | Num | 8 | 2. | 2. | Based on input from the participant and the study physician, will the participant need to use intranasal steroids at any time during the study? 1=Yes,0=No |
| 8 | E2_1070 | Num | 8 | 2. | 2. | Is the participant willing to use a single intranasal steroid at a stable dose continuously for the duration of the study, starting at Visit 1? 1=Yes,0=No |
| 9 | E2_1080 | Num | 8 | 2. | 2. | Is the participant currently receiving allergen immunotherapy other than an established maintenance regimen implemented continuously for a minimum of 3 months? 1=Yes,0=No |
| 10 | E2_1090 | Num | 8 | 2. | 2. | Has the participant taken omalizumab within the past 3 months? 1=Yes,0=No |
| 11 | E2_1100 | Num | 8 | 2. | 2. | Has the participant used any smokeless tobacco products in the past year? 1=Yes,0=No |
| 12 | E2_1110 | Num | 8 | 2. | 2. | Has the participant smoked cigarettes, a pipe, cigar, marijuana, electronic cigarettes, or any other substance in the past year? 1=Yes,0=No |
| 13 | E2_1120 | Num | 8 | 2. | 2. | Ages 18+ Only: Does the participant have a smoking history of greater than 10 pack-years? 1=Yes,0=No |
| 14 | E2_1130 | Num | 8 | 2. | 2. | Ages 12-17 Only: Does the participant have a smoking history of greater than 5 pack-years? 1=Yes,0=No |
| 15 | E2_1140 | Num | 8 | 2. | 2. | Has the participant received a physician diagnosis of asthma at least 12 months ago? 1=Yes,0=No |
| 16 | E2_1145 | Num | 8 | 2. | 2. | Has the participant received a physician diagnosis of asthma at least 12 months ago or had a history consistent with asthma for the previous 12 months? 1=Yes,0=No |
| 17 | E2_1150 | Num | 8 | 2. | 2. | Has the participant experienced a life-threatening asthma exacerbation requiring treatment with intubation or mechanical ventilation in the past 5 years? 1=Yes,0=No |
| 18 | E2_1160 | Num | 8 | 2. | 2. | Has the participant had an asthma exacerbation requiring systemic corticosteroid treatment in the past 6 weeks? 1=Yes,0=No |
| 19 | E2_1170 | Num | 8 | 2. | 2. | Has the participant used an oral or inhaled corticosteroid, or leukotriene modifier in the past 6 weeks? 1=Yes,0=No |
| 20 | E2_1173 | Num | 8 | 2. | 2. | Has the participant used an oral corticosteroid in the past 6 weeks? 1=Yes,0=No |

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 21 | E2_1175 | Num | 8 | 2. | 2. | Has the participant used an inhaled corticosteroid or leukotriene modifier in the past 3 weeks? 1=Yes,0=No |
| 22 | E2_1180 | Num | 8 | 2. | 2. | Is the participant potentially able to bear children? 1=Yes, 0=No, 9=N/A |
| 23 | E2_1190 | Num | 8 | 2. | 2. | Is the participant currently pregnant or lactating? 1=Yes,0=No |
| 24 | E2_1200 | Num | 8 | 2. | 2. | Does the participant agree to use one of the approved methods indicated on the Birth Control Methods   reference card for the duration of the study? 1=Yes,0=No |
| 25 | E2_1210 | Num | 8 | 2. | 2. | Is the participant eligible to proceed? 1=Yes,0=No |
| 26 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 27 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 28 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 29 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 30 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 31 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: elig3.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | E3_1000 | Num | 8 | 2. | 2. | Was the participants prebronchodilator FEV1 >=70Pct predicted? 1=Yes,0=No |
| 2 | E3_1010 | Num | 8 | 2. | 2. | Did the participants FEV1 improve >=12Pct and >=200 ml in response to four puffs of albuterol? 1=Yes,0=No |
| 3 | E3_1020 | Num | 8 | 2. | 2. | Does the participant have valid source documentation within the past 6 months for an overread AsthmaNet methacholine challenge   with a PC20 <=16 mg/ml? 1=Yes,0=No |
| 4 | E3_1030 | Num | 8 | 6.2 | 6.2 | Did the participants FEV1 improve >=12Pct and >=200 ml in response to four puffs of albuterol? |
| 5 | E3_1070 | Num | 8 | 2. | 2. | Was the participants methacholine PC20 <=16 mg/ml? 1=Yes,0=No |
| 6 | E3_1080 | Num | 8 | 2. | 2. | Is the participant able to use the spirotel e-diary/PEF meter correctly, as evidenced by achieving a score of 13 on the Spirotel Performance Checklist ? 1=Yes, 0=No, 9=N/A |
| 7 | E3_1090 | Num | 8 | 2. | 2. | Has the participant used the Twisthaler previously? 1=Yes,0=No |
| 8 | E3_1100 | Num | 8 | 2. | 2. | Is the participant able to use a Twisthaler properly, as evidenced by achieving a score of 12 on the Twisthaler Inhalation Technique Checklist ? 1=Yes,0=No |
| 9 | E3_1110 | Num | 8 | 2. | 2. | Is the participant able to use a metered dose inhaler properly, as evidenced by achieving a score of 11 on the MDI Inhalation Technique Checklist   ? 1=Yes,0=No |
| 10 | E3_1120 | Num | 8 | 2. | 2. | Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation? 1=Yes,0=No |
| 11 | E3_1130 | Num | 8 | 2. | 2. | Is the participant eligible to proceed? 1=Yes,0=No |
| 12 | E3_1040 | Num | 8 | | | Does the participant have valid source documentation within the past 6 months for an overread AsthmaNet methacholine challenge   with a PC20 <=16 mg/ml? |
| 13 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 14 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 15 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: elig4.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | E4_1000 | Num | 8 | 2. | 2. | Since Visit 1, has the participant experienced a treatment failure event as defined in the protocol? 1=Yes,0=No |
| 2 | E4_1010 | Num | 8 | 2. | 2. | Has the participant experienced two or more treatment failures? 1=Yes,0=No |
| 3 | E4_1020 | Num | 8 | 2. | 2. | Since Visit 1, has the participant experienced one or more asthma exacerbations as defined in the protocol? 1=Yes,0=No |
| 4 | E4_1030 | Num | 8 | 2. | 2. | Since Visit 1, has the participant taken any medications listed on the Exclusionary Drugs for SIENA   reference card? 1=Yes,0=No |
| 5 | E4_1050 | Num | 8 | 2. | 2. | Is there any new information that makes the participant ineligible according to the eligibility criteria? 1=Yes,0=No |
| 6 | E4_1060 | Num | 8 | 2. | 2. | Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation? 1=Yes,0=No |
| 7 | E4_1070 | Num | 8 | 2. | 2. | Is the participant eligible to proceed? 1=Yes,0=No |
| 8 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 9 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 10 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: elig5.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | E5_1000 | Num | 8 | 2. | 2. | Did the participant provide two acceptable sputum induction samples during the run-in? 1=Yes,0=No |
| 2 | E5_1010 | Num | 8 | 2. | 2. | Since Visit 1, has the participant experienced a treatment failure event as defined in the protocol? 1=Yes,0=No |
| 3 | E5_1020 | Num | 8 | 2. | 2. | Has the participant experienced two or more treatment failures? 1=Yes,0=No |
| 4 | E5_1030 | Num | 8 | 2. | 2. | Did the participant complete Asmanex220 mcg treatment at least 6 weeks ago? 1=Yes,0=No |
| 5 | E5_1035 | Num | 8 | 2. | 2. | Has the participant experienced two or more treatment failures? 1=Yes,0=No |
| 6 | E5_1040 | Num | 8 | 2. | 2. | Since Visit 1, has the participant experienced one or more asthma exacerbations as defined in the protocol? 1=Yes,0=No |
| 7 | E5_1050 | Num | 8 | 2. | 2. | Since Visit 1, has the participant taken any medications listed on the Exclusionary Drugs for SIENA reference card? 1=Yes,0=No |
| 8 | E5_1060 | Num | 8 | 2. | 2. | Has the participant experienced a respiratory tract infection in the past 6 weeks? 1=Yes,0=No |
| 9 | E5_1065 | Num | 8 | 2. | 2. | Has the participant experienced a respiratory tract infection in the past 4 weeks? 1=Yes,0=No |
| 10 | E5_1070 | Num | 8 | 2. | 2. | According to the Spirotel SIENA Eligibility Report: Did the participant report daytime asthma symptoms daily during the run-in? 1=Yes,0=No |
| 11 | E5_1080 | Num | 8 | 2. | 2. | According to the Spirotel SIENA Eligibility Report: Did the participant report night-time awakenings due to asthma symptoms more than once per week during the run-in? 1=Yes,0=No |
| 12 | E5_1085 | Num | 8 | 2. | 2. | According to the Spirotel SIENA Eligibility Report: Did the participant report night-time awakenings due to asthma symptoms more than twice per week during the run-in? 1=Yes,0=No |
| 13 | E5_1090 | Num | 8 | 2. | 2. | According to the Spirotel SIENA Eligibility Report: Did the participant report daily albuterol use for asthma symptom control during the run-in? 1=Yes,0=No |
| 14 | E5_1100 | Num | 8 | 2. | 2. | According to the Spirotel SIENA Eligibility Report: Did the participant record at least 75Pct of AM and PM peak flow measurements and symptoms on his or her spirotel during the run-in? 1=Yes,0=No |
| 15 | E5_1110 | Num | 8 | 2. | 2. | Did the participant take at least 75Pct of the required puffs from his or her Respimat during the run-in? 1=Yes,0=No |
| 16 | E5_1120 | Num | 8 | 2. | 2. | Was the participants prebronchodilator FEV1 >=70Pct predicted? 1=Yes,0=No |
| 17 | E5_1130 | Num | 8 | 2. | 2. | Has the participant used the Respimat previously? 1=Yes,0=No |
| 18 | E5_1140 | Num | 8 | 2. | 2. | Is the participant able to use a Respimat inhaler properly, as evidenced by achieving a score of 15 on the Respimat Inhalation Technique Checklist? 1=Yes,0=No |
| 19 | E5_1150 | Num | 8 | 2. | 2. | Does the participant wish to withdraw consent from the study? 1=Yes,0=No |
| 20 | E5_1160 | Num | 8 | 2. | 2. | Is there any new information that makes the participant ineligible according to the eligibility criteria? 1=Yes,0=No |

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 21 | E5_1170 | Num | 8 | 2. | 2. | Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation? 1=Yes,0=No |
| 22 | E5_1180 | Num | 8 | 2. | 2. | Is the participant eligible to proceed? 1=Yes,0=No |
| 23 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 24 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 25 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 26 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 27 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 28 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: eno.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|-----|----------|------|-----|--------|----------|-------|
| 1 | ENO_1000 | Num | 8 | 2. | 2. | Has QC procedure been performed on the NIOX MINO today? 1=Yes,0=No |
| 2 | ENO_1010 | Num | 8 | 2. | 2. | Did the participant eat or drink within the past hour? 1=Yes,0=No |
| 3 | ENO_1020 | Num | 8 | 2. | 2. | Did the participant take part in strenuous activity/exercise within the past hour? 1=Yes,0=No |
| 4 | ENO_1040 | Char | 4 | $4. | $4. | Time eNO started (based on a 24-hour clock) (0000-2359) |
| 5 | ENO_1050 | Char | 3 | $3. | $3. | ENO Measurement |
| 6 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 7 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 8 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 9 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 10 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 11 | 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 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 65 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 66 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 67 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 68 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 69 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

*Data Set Name: household_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 (1=No High School diploma/GED, 2=High Schol grad, 3=Technical training, 4=Some college, no degree, 5=Assoc degree, 6=Bachelor degree, 7=Masters degree/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 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 6 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 7 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: ige.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | IGE | Char | 14 | $14. | $14. | Total IgE |
| 2 | RE1 | Char | 14 | $14. | $14. | Cat (E1) |
| 3 | RE5 | Char | 14 | $14. | $14. | Dog (E5) |
| 4 | RE72 | Char | 14 | $14. | $14. | Mouse (E72) |
| 5 | RE74 | Char | 14 | $14. | $14. | Rat (E74) |
| 6 | RMX1 | Char | 14 | $14. | $14. | Mold mix (MX1) |
| 7 | RI6 | Char | 14 | $14. | $14. | Cockroach, German (I6) |
| 8 | RGX2 | Char | 14 | $14. | $14. | Grass mix (GX2) |
| 9 | RTX4 | Char | 14 | $14. | $14. | Tree mix (TX4) |
| 10 | RTX6 | Char | 14 | $14. | $14. | Tree mix (TX6) |
| 11 | RWX1 | Char | 14 | $14. | $14. | Weed mix (WX1) |
| 12 | RW3 | Char | 14 | $14. | $14. | Weed (W3) |
| 13 | RD2 | Char | 14 | $14. | $14. | Mite (D2) |
| 14 | RD1 | Char | 14 | $14. | $14. | Mite (D1) |
| 15 | N_ALLERGENPOS | Num | 8 | | | Number or allergen specific (Cat, Dog, Mouse, etc) that were either POS or greater than 0.35 |
| 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: lab.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | LAB_1000 | Num | 8 | 5. | 5. | CBC with differential cell count: Eosinophils (absolute count) (0-9999/uL) |
| 2 | LAB_1010 | Num | 8 | 6.1 | 6.1 | CBC with differential cell count: WBC (0-999.9 K/uL) |
| 3 | LAB_1020 | Num | 8 | 5.1 | 5.1 | CBC with differential cell count: Differential Lymphocytes (0-99.9Pct) |
| 4 | LAB_1030 | Num | 8 | 5.1 | 5.1 | CBC with differential cell count: Differential Monocytes (0-99.9Pct) |
| 5 | LAB_1040 | Num | 8 | 5.1 | 5.1 | CBC with differential cell count: Differential Basophils (0-99.9Pct) |
| 6 | LAB_1050 | Num | 8 | 5.1 | 5.1 | CBC with differential cell count: Differential Neutrophils (0-99.9Pct) |
| 7 | LAB_1060 | Num | 8 | 5.1 | 5.1 | CBC with differential cell count: Differential Eosinophils (0-99.9Pct) |
| 8 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 9 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 10 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: lexam_ped.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | PLE_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 | PLE_1010 | Num | 8 | 3. | 3. | PARENTAL HEIGHT - First study visit only or until both are completed1.Biological mother's height (complete height or check unknown) __ __ inches |
| 3 | PLE_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 | PLE_1030 | Num | 8 | 2. | 2. | Biological father's height (complete height or check unknown) __ feet |
| 5 | PLE_1040 | Num | 8 | 3. | 3. | Biological father's height (complete height or check unknown) __ __ inches |
| 6 | PLE_1050 | Num | 8 | 2. | 2. | Biological father's height (complete height or check unknown) (9=Don't Know) |
| 7 | PLE_1060 | Num | 8 | 2. | 2. | PARTICIPANT MEASUREMENTS - Complete at all applicable study visits3. What type of height measurement was obtained? 1=Standing height, 2=Length |
| 8 | PLE_1070 | Num | 8 | 6.1 | 6.1 | First measurement __ __ __ . __ cm |
| 9 | PLE_1080 | Num | 8 | 6.1 | 6.1 | Second measurement __ __ __ . __ cm |
| 10 | PLE_1090 | Num | 8 | 6.1 | 6.1 | Third measurement __ __ __ . __ cm |
| 11 | PLE_1100 | Num | 8 | 6.1 | 6.1 | Average height or length measurement __ __ __ . __ cm |
| 12 | PLE_1110 | Num | 8 | 2. | 2. | In your judgment, was the participant's height or length measurement acceptable? 1=Yes,0=No |
| 13 | PLE_1130 | Num | 8 | 6.1 | 6.1 | Weight (shoes off, light clothing) __ __ __ . __ kg |
| 14 | PLE_1140 | Num | 8 | 2. | 2. | ORAL CANDIDIASIS5.Does the participant have evidence of oral candidiasis? 1=Yes,0=No |
| 15 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 16 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 17 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: metha.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | MTH_1000 | Num | 8 | 5.2 | 5.2 | Post Diluent FEV1 |
| 2 | MTH_1010 | Num | 8 | 2. | 2. | Did the participant drop     20Pct at the diluent stage? 1=Yes,0=No |
| 3 | MTH_1020 | Num | 8 | 8.4 | 8.4 | Last concentration of methacholine administered __ __ . __ __ __ __ mg/ml |
| 4 | MTH_1030 | Num | 8 | 5.2 | 5.2 | FEV1 after last concentration of methacholine administered |
| 5 | MTH_1040 | Num | 8 | 2. | 2. | Did the participant achieve a PC20? 1=Yes,0=No |
| 6 | MTH_1050 | Num | 8 | 6.2 | 6.2 | PC20 __ __ . __ __ mg/ml |
| 7 | MTH_1060 | Char | 4 | $4. | $4. | Time methacholine challenge ended (based on 24-hour clock) |
| 8 | MTH_1070 | Num | 8 | 5.2 | 5.2 | FEV1 |
| 9 | MTH_1080 | Char | 4 | $4. | $4. | Time of FEV1 in Q7a (based on 24-hour clock) |
| 10 | MTH_1090 | Num | 8 | 2. | 2. | Was the FEV1 from Q7a     the methacholine reversal reference value   in the gray box above? 1=Yes,0=No |
| 11 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 12 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 13 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: metha_add_trt.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | MAD_1000 | Num | 8 | 2. | 2. | Was an additional treatment used in the first hour? 1=Yes,0=No |
| 2 | MAD_1010 | Num | 8 | 2. | 2. | Additional albuterol by MDI (1=Yes,0=No) |
| 3 | MAD_1020 | Num | 8 | 2. | 2. | Number of additional puffs of albuterol administered (1=2, 2=4, 3=>4) |
| 4 | MAD_1030 | Num | 8 | 2. | 2. | Nebulized Beta-agonist    (1=Yes,0=No) |
| 5 | MAD_1040 | Num | 8 | 2. | 2. | Subcutaneous epinephrine    (1=Yes,0=No) |
| 6 | MAD_1050 | Num | 8 | 2. | 2. | Implementation of clinic emergency protocol or algorithm (1=Yes,0=No) |
| 7 | MAD_1060 | Num | 8 | 2. | 2. | Other   (1=Yes,0=No) |
| 8 | MAD_1070 | Num | 8 | 5.2 | 5.2 | Participant's FEV1 after additional treatment within first hour.2a.FEV1 |
| 9 | MAD_1090 | Char | 4 | $4. | $4. | Time of FEV1 in Q2a (based on 24-hour clock) |
| 10 | MAD_1100 | Num | 8 | 2. | 2. | Was the FEV1 from Q2a >the methacholine reversal reference value   in the gray box on the Methacholine Challenge Testing   form? 1=Yes,0=No |
| 11 | MAD_1110 | Num | 8 | 2. | 2. | Was additional treatment used after one hour? 1=Yes,0=No |
| 12 | MAD_1120 | Num | 8 | 2. | 2. | Additional albuterol by MDI (1=Yes,0=No) |
| 13 | MAD_1130 | Num | 8 | 2. | 2. | Number of additional puffs of albuterol administered (1=2, 2=4, 3=>4) |
| 14 | MAD_1140 | Num | 8 | 2. | 2. | Nebulized Beta-agonist   (1=Yes,0=No) |
| 15 | MAD_1150 | Num | 8 | 2. | 2. | Subcutaneous epinephrine     (1=Yes,0=No) |
| 16 | MAD_1160 | Num | 8 | 2. | 2. | Implementation of clinic emergency protocol or algorithm   (1=Yes,0=No) |
| 17 | MAD_1170 | Num | 8 | 2. | 2. | Treatment in the emergency room   (1=Yes,0=No) |
| 18 | MAD_1180 | Num | 8 | 2. | 2. | Overnight hospitalization (1=Yes,0=No) |
| 19 | MAD_1190 | Num | 8 | 2. | 2. | Other (1=Yes,0=No) |
| 20 | MAD_1200 | Num | 8 | 5.2 | 5.2 | Participant's final FEV1 after methacholine challenge4a.FEV1 |
| 21 | MAD_1220 | Char | 4 | $4. | $4. | Time of FEV1 in Q4a (based on 24-hour clock) |
| 22 | MAD_1230 | Num | 8 | 2. | 2. | Was the FEV1 from Q4a ? 1=Yes,0=No |
| 23 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 24 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 25 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 26 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 27 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 28 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: methachk_adult.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | MCA_1000 | Num | 8 | 2. | 2. | Exclusions and Confounders1.Has the participant had any severe acute illness in the past 4 weeks? 1=Yes,0=No |
| 2 | MCA_1010 | Num | 8 | 2. | 2. | If YES, has the participant received permission from the supervising physician to proceed with the methacholine challenge testing? 1=Yes,0=No |
| 3 | MCA_1050 | Num | 8 | 2. | 2. | Has the participant used an oral or injectable steroid   in the last 4 weeks? 1=Yes,0=No |
| 4 | MCA_1060 | Num | 8 | 2. | 2. | Does the participant have a baseline   FEV1 less than 55Pct of predicted or less than 1.0 L? 1=Yes,0=No |
| 5 | MCA_1070 | Num | 8 | 2. | 2. | Pregnancy test results:   (Check N/A if the participant is male, or is female and is post-menopausal, had a hysterectomy or tubal ligation.) (1=Positive, 0=Negative, 9=N/A) |
| 6 | MCA_1080 | Num | 8 | 2. | 2. | Is the participant's systolic blood pressure > 200 mm Hg or diastolic blood pressure > 100 mm Hg? 1=Yes,0=No |
| 7 | MCA_1100 | Num | 8 | 2. | 2. | Is there any other reason the participant should not proceed with the methacholine challenge testing? 1=Yes,0=No |
| 8 | MCA_1110 | Num | 8 | 2. | 2. | Is the participant eligible to proceed with the diluent   pulmonary function testing for the methacholine challenge? 1=Yes,0=No |
| 9 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 10 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 11 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 12 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 13 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 14 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## Data Set Name: methachk_ped.sas7bdat

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | MCP_1000 | Num | 8 | 2. | 2. | Exclusions and Confounders:   1.Has the participant had any severe acute illness in the past 4 weeks? 1=Yes,0=No |
| 2 | MCP_1010 | Num | 8 | 2. | 2. | If YES, has the participant received permission from the supervising physician to proceed with the methacholine challenge testing? 1=Yes,0=No |
| 3 | MCP_1030 | Num | 8 | 2. | 2. | During the past 4 weeks, has the participant had any respiratory infections, colds, or bronchitis ? 1=Yes,0=No |
| 4 | MCP_1040 | Num | 8 | 2. | 2. | If YES, during the past 2 weeks, has the participant had any respiratory infections, colds, or bronchitis ? 1=Yes,0=No |
| 5 | MCP_1050 | Num | 8 | 2. | 2. | Has the participant used an oral or injectable steroid   in the last 4 weeks? 1=Yes,0=No |
| 6 | MCP_1060 | Num | 8 | 2. | 2. | Does the participant have a baseline   FEV1 less than 70Pct of predicted? 1=Yes,0=No |
| 7 | MCP_1070 | Num | 8 | 2. | 2. | Pregnancy test results(Check N/A if the participant is male, or is female and has not started menses.)(1=Positive, 0=Negative, 9=N/A) |
| 8 | MCP_1080 | Num | 8 | 2. | 2. | If participant's age is ? 1=Yes,0=No |
| 9 | MCP_1090 | Num | 8 | 2. | 2. | If participant's age is < 12 years: Is the participant's systolic blood pressure > 180 mm Hg or diastolic blood pressure > 90 mm Hg? 1=Yes,0=No |
| 10 | MCP_1100 | Num | 8 | 2. | 2. | Is there any other reason the participant should not proceed with the methacholine challenge testing? 1=Yes,0=No |
| 11 | MCP_1110 | Num | 8 | 2. | 2. | Is the participant eligible to proceed with the diluent   pulmonary function testing for the methacholine challenge? 1=Yes,0=No |
| 12 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 13 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 14 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: palb4_spiro.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | PA4_1000 | Char | 4 | $4. | $4. | Time albuterol administered (based on 24-hour clock) |
| 2 | PA4_1010 | Char | 4 | $4. | $4. | Time post-albuterol spirometry started (based on 24-hour clock) |
| 3 | PA4_1020 | Num | 8 | 5.2 | 5.2 | Highest FVC |
| 4 | PA4_1030 | Num | 8 | 5.2 | 5.2 | Highest FEV1 |
| 5 | PA4_1040 | Num | 8 | 4. | 4. | Highest FEV1 (Pct predicted) |
| 6 | PA4_1050 | Num | 8 | 6.2 | 6.2 | FEF Max |
| 7 | PA4_1060 | Num | 8 | 5.2 | 5.2 | FEF25-75 |
| 8 | PA4_1070 | Num | 8 | 2. | 2. | In your judgment, was the subject's spirometry technique acceptable? 1=Yes,0=No |
| 9 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 10 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 11 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 12 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 13 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 14 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## Data Set Name: parttxqx.sas7bdat

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | PTX_1000 | Num | 8 | 2. | 2. | Who is the respondent? 1=Self/Participant, 2=Parent/Guardian, 3=Other |
| 2 | PTX_1010 | Num | 8 | 2. | 2. | Please check the box next to the treatment that you believe you received over the past 12 weeks. 1=mometasone, 2=placebo |
| 3 | PTX_1020 | Num | 8 | 2. | 2. | Blinded Scheduled Twisthaler Contents: How sure are you about your answer to Question 2? 1=Absolutely sure -   I know what the MDI contains, 2=Moderately sure, 3=Somewhat sure, 4=Not sure at all - purely a guess |
| 4 | PTX_1030 | Num | 8 | 2. | 2. | Please comment with respect to any observations you made that helped you make your choice in Question 2 . 1=I have no comments, 2=I noticed the following: |
| 5 | PTX_1040 | Num | 8 | 2. | 2. | Please check the box next to the treatment that you believe you received over the past 12 weeks. 1=tiotropium, 2=placebo |
| 6 | PTX_1050 | Num | 8 | 2. | 2. | How sure are you about your answer to Question 5? 1=Absolutely sure - I know what the Respimat capsules contain, 2=Moderately sure, 3=Somewhat sure, 4=Not sure at all - purely a guess |
| 7 | PTX_1060 | Num | 8 | 2. | 2. | 1=I have no comments, 2=I noticed the following: |
| 8 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 9 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 10 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: periostin.sas7bdat*

| Num | Variable | Type | Len | Label |
|---|---|---|---|---|
| 1 | VNUM | Num | 8 | Visit Number (numeric) |
| 2 | PERIOSTIN | Num | 8 | Level of periostin in peripheral blood (ng/ml) |
| 3 | VDATE | Num | 8 | Number of days from Visit 1 to this visit |
| 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: pipra4_spiro.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | PI4_1000 | Char | 4 | $4. | $4. | Time ipratropium administered (based on 24-hour clock) (0000-2359) |
| 2 | PI4_1010 | Char | 4 | $4. | $4. | Time post-ipratropium spirometry started (based on 24-hour clock) (0000-2359) |
| 3 | PI4_1020 | Num | 8 | 5.2 | 5.2 | Highest FVC (0-9.99 L) |
| 4 | PI4_1030 | Num | 8 | 5.2 | 5.2 | Highest FEV1 (0-9.99 L) |
| 5 | PI4_1040 | Num | 8 | 4. | 4. | Highest FEV1 (Pct predicted) (0-999 Pct predicted) |
| 6 | PI4_1050 | Num | 8 | 6.2 | 6.2 | FEF Max (0-99.99 L/S) |
| 7 | PI4_1060 | Num | 8 | 5.2 | 5.2 | FEF25-75 (0-9.99 L/S) |
| 8 | PI4_1070 | Num | 8 | 2. | 2. | In your judgment, was the participants spirometry technique acceptable? 1=Yes,0=No |
| 9 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 10 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 11 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 12 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 13 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 14 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: preg_test.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | PRG_1000 | Num | 8 | 2. | 2. | Is the participant unable to bear children due to any of the following reasons? 1=Yes,0=No |
| 2 | PRG_1010 | Num | 8 | 2. | 2. | Post-menopausal (at least one year since last menses) (1=Yes,0=No) |
| 3 | PRG_1020 | Num | 8 | 2. | 2. | Hysterectomy    (1=Yes,0=No) |
| 4 | PRG_1030 | Num | 8 | 2. | 2. | Tubal ligation(1=Yes,0=No) |
| 5 | PRG_1040 | Num | 8 | 2. | 2. | Pregnancy test results   (1=Positive, 0=Negative) |
| 6 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 7 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 8 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 9 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 10 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 11 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## Data Set Name: prior_cond_adult.sas7bdat

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | PAD_1000 | Num | 8 | 2. | 2. | Have you had any diseases, illnesses, conditions, or surgeries related Blood, Lymph, or Immune Systems? 1=Yes,0=No |
| 2 | PAD_1010 | Num | 8 | 2. | 2. | Eyes(1=Yes,0=No) |
| 3 | PAD_1020 | Num | 8 | 2. | 2. | Breasts (1=Yes,0=No) |
| 4 | PAD_1030 | Num | 8 | 2. | 2. | Endocrine Systems (1=Yes,0=No) |
| 5 | PAD_1040 | Num | 8 | 2. | 2. | Heart and Blood Vessels   (1=Yes,0=No) |
| 6 | PAD_1050 | Num | 8 | 2. | 2. | Liver or Pancreas (1=Yes,0=No) |
| 7 | PAD_1060 | Num | 8 | 2. | 2. | Kidneys or Urinary Tract System   (1=Yes,0=No) |
| 8 | PAD_1070 | Num | 8 | 2. | 2. | Reproductive System (1=Yes,0=No) |
| 9 | PAD_1080 | Num | 8 | 2. | 2. | Muscles or Bones (1=Yes,0=No) |
| 10 | PAD_1090 | Num | 8 | 2. | 2. | Nervous System (1=Yes,0=No) |
| 11 | PAD_1100 | Num | 8 | 2. | 2. | Psychiatric(1=Yes,0=No) |
| 12 | PAD_1110 | Num | 8 | 2. | 2. | Drug Allergies (1=Yes,0=No) |
| 13 | PAD_1120 | Num | 8 | 2. | 2. | Other (1=Yes,0=No) |
| 14 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 15 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 16 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: prior_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. | 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 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 20 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 21 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: prior_trt.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. | Short-acting Inhaled Beta-Agonists by Inhaler (e.g., albuterol, Primatene Mist, Maxair, ProAir, Proventil, Ventolin, Xopenex)   (1=Yes, 0=No, 9=Don't Know) |
| 3 | PTR_1050 | Num | 8 | 4. | 4. | If YES, indicate average weekly puffs in the past month (Enter '000' if none used) weekly puffs |
| 4 | PTR_1060 | Num | 8 | 2. | 2. | Rescue treatment via a Nebulizer Machine (e.g., albuterol, ipratropium, Combivent, Xopenex, levalbuterol)   (1=Yes, 0=No, 9=Don't Know) |
| 5 | PTR_1100 | Num | 8 | 2. | 2. | Long-acting Inhaled Beta-Agonists (e.g., Serevent, Foradil, salmeterol, formoterol) Do not consider combination medications. (1=Yes, 0=No, 9=Don't Know) |
| 6 | PTR_1140 | Num | 8 | 2. | 2. | Oral Beta-Agonists (e.g., albuterol, Brethine, Bricanyl, metaproterenol, Proventil, Ventolin, Repetabs, Volmax)   (1=Yes, 0=No, 9=Don't Know) |
| 7 | PTR_1180 | Num | 8 | 2. | 2. | Oral Theophylline (short-acting or sustained release)(e.g., Aminophylline, Slo-Phyllin, Slo-bid, Theo-Dur, Uniphyl)        (1=Yes, 0=No, 9=Don't Know) |
| 8 | PTR_1220 | Num | 8 | 2. | 2. | Inhaled Anticholinergic by Inhaler (e.g., Atrovent, Combivent, Spiriva)   (1=Yes, 0=No, 9=Don't Know) |
| 9 | PTR_1260 | Num | 8 | 2. | 2. | Leukotriene Antagonist / 5LO Inhibitors (e.g., Accolate, Zyflo, Singulair) (1=Yes, 0=No, 9=Don't Know) |
| 10 | PTR_1300 | Num | 8 | 2. | 2. | IgE Blocker (e.g., Xolair)     (1=Yes, 0=No, 9=Don't Know) |
| 11 | PTR_1340 | Num | 8 | 2. | 2. | Oral Steroids FOR ASTHMA (e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron,   dexamethasone)          (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. | Injectable Steroids FOR ASTHMA (e.g., Medrol, Solumedrol, Decadron, dexamethasone, triamcinolone, Kenalog, hydrocortisone IV)       (1=Yes, 0=No, 9=Don't Know) |
| 14 | PTR_1430 | Num | 8 | 2. | 2. | Steroids by Inhaler (e.g., Asmanex Twisthaler, QVAR, Flovent, Pulmicort Flexhaler)       (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 used daily puffs |
| 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. | Steroids by Nebulizer (e.g., Pulmicort Respules, budesonide) (1=Yes, 0=No, 9=Don't Know) |
| 19 | PTR_1535 | Num | 8 | 3. | 3. | Steroids by Nebulizer (e.g., Pulmicort Respules, budesonide). If YES, complete Q13a - Q13c. Indicate most recent type of nebulized steroid taken (refer to PRIOR_TRT_CARD reference card) |
| 20 | PTR_1540 | Num | 8 | 3. | 3. | Indicate number of daily treatments used daily treatments |
| 21 | 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 |

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 22 | PTR_1560 | Num | 8 | 2. | 2. | Long-Acting Beta-Agonist and Inhaled Steroid Combination Medications (e.g., Advair Diskus, Symbicort MDI, Dulera MDI)     (1=Yes, 0=No, 9=Don't Know) |
| 23 | PTR_1600 | Num | 8 | 5. | 5. | Indicate most recent type of combination medication taken (refer to PRIOR_TRT_CARD reference card) code |
| 24 | PTR_1610 | Num | 8 | 3. | 3. | Indicate number of daily puffs used daily puffs |
| 25 | 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 |
| 26 | PTR_1630 | Num | 8 | 2. | 2. | Nasal Steroids (e.g., Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Omnaris, Rhinocort, Nasonex)       (1=Yes, 0=No, 9=Don't Know) |
| 27 | PTR_1670 | Num | 8 | 2. | 2. | Non-steroidal Anti-allergic Nasal Medications (e.g., Nasalcrom, Astelin, Astepro, ipratropium)    (1=Yes, 0=No, 9=Don't Know) |
| 28 | PTR_1710 | Num | 8 | 2. | 2. | Anti-allergic Oral Medications (e.g., fexofenadine, loratadine, cetirizine, chlorpheniramine) (1=Yes, 0=No, 9=Don't Know) |
| 29 | PTR_1750 | Num | 8 | 2. | 2. | Topical Steroids - Prescription (e.g., Synalar, Lidex, Dermacin, Fluocinonide) (1=Yes, 0=No, 9=Don't Know) |
| 30 | PTR_1790 | Num | 8 | 2. | 2. | Topical Steroids - OTC (e.g., Hydrocortisone - multiple strengths and products) (1=Yes, 0=No, 9=Don't Know) |
| 31 | PTR_1830 | Num | 8 | 2. | 2. | Other Medication FOR ASTHMA OR ALLERGIES (1=Yes, 0=No, 9=Don't Know) |
| 32 | PTR_1870 | Num | 8 | 2. | 2. | Oral Steroids for Conditions Other Than Asthma (e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron, dexamethasone) (1=Yes, 0=No, 9=Don't Know) |
| 33 | PTR_1910 | Num | 8 | 2. | 2. | Injectable Steroids for Conditions Other Than Asthma (e.g., Medrol, Solumedrol, Decadron, dexamethasone,   triamcinolone, Kenalog, hydrocortisone IV)    (1=Yes, 0=No, 9=Don't Know) |
| 34 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 35 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 36 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 37 | DATE_Q02 | Num | 8 | | | Short-acting Inhaled Beta-Agonists by Inhaler (e.g., albuterol, Primatene Mist, Maxair, ProAir, Proventil, Ventolin, Xopenex) Date |
| 38 | DATE_Q03 | Num | 8 | | | Rescue treatment via a Nebulizer Machine (e.g., albuterol, ipratropium, Combivent, Xopenex, levalbuterol) Date |
| 39 | DATE_Q04 | Num | 8 | | | Long-acting Inhaled Beta-Agonists (e.g., Serevent, Foradil, salmeterol, formoterol) Do not consider combination medications. Date |
| 40 | DATE_Q05 | Num | 8 | | | Oral Beta-Agonists (e.g., albuterol, Brethine, Bricanyl, metaproterenol, Proventil, Ventolin, Repetabs, Volmax) Date |
| 41 | DATE_Q07 | Num | 8 | | | Inhaled Anticholinergic by Inhaler (e.g., Atrovent, Combivent, Spiriva) Date |
| 42 | DATE_Q08 | Num | 8 | | | Leukotriene Antagonist / 5LO Inhibitors (e.g., Accolate, Zyflo, Singulair) Date |
| 43 | DATE_Q09 | Num | 8 | | | IgE Blocker (e.g., Xolair) Date |
| 44 | DATE_Q10 | Num | 8 | | | Oral Steroids FOR ASTHMA (e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron, dexamethasone) Date |
| 45 | DATE_Q11 | Num | 8 | | | Injectable Steroids FOR ASTHMA (e.g., Medrol, Solumedrol, Decadron, dexamethasone, triamcinolone, Kenalog, hydrocortisone IV) Date |

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 46 | DATE_Q12 | Num | 8 | | | Steroids by Inhaler (e.g., Asmanex Twisthaler, QVAR, Flovent, Pulmicort Flexhaler) Date |
| 47 | DATE_Q13 | Num | 8 | | | Steroids by Nebulizer (e.g., Pulmicort Respules, budesonide) Date |
| 48 | DATE_Q14 | Num | 8 | | | Long-Acting Beta-Agonist and Inhaled Steroid Combination Medications (e.g., Advair Diskus, Symbicort MDI, Dulera MDI) Date |
| 49 | DATE_Q15 | Num | 8 | | | Nasal Steroids (e.g., Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Omnaris, Rhinocort, Nasonex) Date |
| 50 | DATE_Q16 | Num | 8 | | | Non-steroidal Anti-allergic Nasal Medications (e.g., Nasalcrom, Astelin, Astepro, ipratropium) Date |
| 51 | DATE_Q17 | Num | 8 | | | Anti-allergic Oral Medications (e.g., fexofenadine, loratadine, cetirizine, chlorpheniramine) Date |
| 52 | DATE_Q18 | Num | 8 | | | Topical Steroids - Prescription (e.g., Synalar, Lidex, Dermacin, Fluocinonide) Date |
| 53 | DATE_Q19 | Num | 8 | | | Topical Steroids - OTC (e.g., Hydrocortisone - multiple strengths and products) Date |
| 54 | DATE_Q20 | Num | 8 | | | Other Medication FOR ASTHMA OR ALLERGIES Date |
| 55 | DATE_Q21 | Num | 8 | | | Oral Steroids for Conditions Other Than Asthma (e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron, dexamethasone) Date |
| 56 | DATE_Q22 | Num | 8 | | | Injectable Steroids for Conditions Other Than Asthma (e.g., Medrol, Solumedrol, Decadron, dexamethasone, triamcinolone, Kenalog, hydrocortisone IV) Date |
| 57 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 58 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 59 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

*Data Set Name: pss_10.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | P10_1000 | Num | 8 | 2. | 2. | In the last month, how often have you been upset because of something that happened unexpectedly? 0=Never, 1=Almost never, 2=Sometimes, 3=Fairly often, 4=Very often |
| 2 | P10_1010 | Num | 8 | 2. | 2. | In the last month, how often have you felt that you were unable to control the important things in your life? 0=Never, 1=Almost never, 2=Sometimes, 3=Fairly often, 4=Very often |
| 3 | P10_1020 | Num | 8 | 2. | 2. | In the last month, how often have you felt nervous and stressed? 0=Never, 1=Almost never, 2=Sometimes, 3=Fairly often, 4=Very often |
| 4 | P10_1030 | Num | 8 | 2. | 2. | In the last month, how often have you felt confident about being able to handle your personal problems? 0=Never, 1=Almost never, 2=Sometimes, 3=Fairly often, 4=Very often |
| 5 | P10_1040 | Num | 8 | 2. | 2. | In the last month, how often have you felt that things were going your way? 0=Never, 1=Almost never, 2=Sometimes, 3=Fairly often, 4=Very often |
| 6 | P10_1050 | Num | 8 | 2. | 2. | In the last month, how often have you found that you could not cope with all the things that you had to do? 0=Never, 1=Almost never, 2=Sometimes, 3=Fairly often, 4=Very often |
| 7 | P10_1060 | Num | 8 | 2. | 2. | In the last month, how often have you been able to control irritations in your life? 0=Never, 1=Almost never, 2=Sometimes, 3=Fairly often, 4=Very often |
| 8 | P10_1070 | Num | 8 | 2. | 2. | In the last month, how often have you felt that you were on top of things? 0=Never, 1=Almost never, 2=Sometimes, 3=Fairly often, 4=Very often |
| 9 | P10_1080 | Num | 8 | 2. | 2. | In the last month, how often have you been angered because of things that happened that were outside of your control? 0=Never, 1=Almost never, 2=Sometimes, 3=Fairly often, 4=Very often |
| 10 | P10_1090 | Num | 8 | 2. | 2. | In the last month, how often have you felt that your difficulties were piling up so high that you could not overcome them? 0=Never, 1=Almost never, 2=Sometimes, 3=Fairly often, 4=Very often |
| 11 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 12 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 13 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: pulmonarychk.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | PCH_1000 | Num | 8 | 2. | 2. | Have you consumed caffeine in the past 4 hours? 1=Yes,0=No |
| 2 | PCH_1010 | Num | 8 | 2. | 2. | Have you used medications with caffeine in the past 4 hours? 1=Yes,0=No |
| 3 | PCH_1020 | Num | 8 | 2. | 2. | Have you used any weight loss medications in the past 4 hours? 1=Yes,0=No |
| 4 | PCH_1030 | Num | 8 | 2. | 2. | Have you consumed any food containing alcohol or beverages containing alcohol in the past 4 hours? 1=Yes,0=No |
| 5 | PCH_1040 | Num | 8 | 2. | 2. | Have you used a rescue intermediate-acting inhaled betaagonist in the past 6 hours? 1=Yes,0=No |
| 6 | PCH_1050 | Num | 8 | 2. | 2. | Have you used a short-acting anticholinergic in the past 6 hours? 1=Yes,0=No |
| 7 | PCH_1060 | Num | 8 | 2. | 2. | Have you used any ophthalmic antihistamines in the past 6 hours? 1=Yes,0=No |
| 8 | PCH_1070 | Num | 8 | 2. | 2. | Have you used any nasal antihistamines in the past 6 hours? 1=Yes,0=No |
| 9 | PCH_1080 | Num | 8 | 2. | 2. | Have you used any nasal decongestants in the past 6 hours? 1=Yes,0=No |
| 10 | PCH_1090 | Num | 8 | 2. | 2. | Have you used any oral antihistamines in the past 48 hours? 1=Yes,0=No |
| 11 | PCH_1100 | Num | 8 | 2. | 2. | Have you used any oral decongestants or cold remedies in the past 48 hours? 1=Yes,0=No |
| 12 | PCH_1110 | Num | 8 | 2. | 2. | Have you used any smokeless tobacco products today? 1=Yes,0=No |
| 13 | PCH_1120 | Num | 8 | 2. | 2. | At this time, is your asthma worse because of recent exposure to triggers? 1=Yes,0=No |
| 14 | PCH_1130 | Num | 8 | 2. | 2. | Is there any other reason you should not proceed with spirometry testing? 1=Yes,0=No |
| 15 | PCH_1140 | Num | 8 | 2. | 2. | Is the participant eligible to proceed with the spirometry testing? 1=Yes,0=No |
| 16 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 17 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 18 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: rand_iaql_12.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | IAQ_1000 | Num | 8 | 2. | 2. | In the past 4 weeks, I worried about the long-term effects of asthma on my health (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 2 | IAQ_1010 | Num | 8 | 2. | 2. | In the past 4 weeks, I had to worry about asthma triggers (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 3 | IAQ_1020 | Num | 8 | 2. | 2. | In the past 4 weeks, my asthma was on my mind (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 4 | IAQ_1030 | Num | 8 | 2. | 2. | In the past 4 weeks, it was hard to get a good nights sleep because of my asthma (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 5 | IAQ_1040 | Num | 8 | 2. | 2. | In the past 4 weeks, I felt like I couldnt enjoy life because of my asthma (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 6 | IAQ_1050 | Num | 8 | 2. | 2. | In the past 4 weeks, I felt that asthma was controlling my life (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 7 | IAQ_1060 | Num | 8 | 2. | 2. | In the past 4 weeks, I felt frustrated that I couldnt make plans in advance because of my asthma (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 8 | IAQ_1070 | Num | 8 | 2. | 2. | In the past 4 weeks, because of my asthma, everyday activities were a struggle (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 9 | IAQ_1080 | Num | 8 | 2. | 2. | In the past 4 weeks, asthma placed stress on my relationships with family, friends, significant others, or co-workers (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 10 | IAQ_1090 | Num | 8 | 2. | 2. | In the past 4 weeks, because of my asthma, I felt frustrated that I have to do things differently than people who dont have asthma (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 11 | IAQ_1100 | Num | 8 | 2. | 2. | In the past 4 weeks, I felt like I missed out on doing things with others because of my asthma (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 12 | IAQ_1110 | Num | 8 | 2. | 2. | In the past 4 weeks, because of my asthma, I had to do a lot of planning to make sure I always had an inhaler ready (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much) |
| 13 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 14 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 15 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: regimen.sas7bdat*

| Num | Variable | Type | Len | Label |
|---|---|---|---|---|
| 1 | REGIMEN_PERIOD_1 | Char | 10 | Randomized treatment assignment period 1: (Mometasone, Tiotropium or Placebo) |
| 2 | REGIMEN_PERIOD_2 | Char | 10 | Randomized treatment assignment period 2: (Mometasone, Tiotropium or Placebo) |
| 3 | REGIMEN_PERIOD_3 | Char | 10 | Randomized treatment assignment period 3: (Mometasone, Tiotropium or Placebo) |
| 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: 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 | | | Participant's 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: 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 in Question #4? 1=Second, 2=Minute, 3=Hour, 4=Day |
| 5 | SER_1050 | Num | 8 | 2. | 2. | Fatal event      (1=Yes,0=No) |
| 6 | SER_1060 | Num | 8 | 2. | 2. | Life-threatening event (1=Yes,0=No) |
| 7 | SER_1070 | Num | 8 | 2. | 2. | Inpatient hospitalization required    (1=Yes,0=No) |
| 8 | SER_1100 | Num | 8 | 2. | 2. | Hospitalization prolonged   (1=Yes,0=No) |
| 9 | SER_1110 | Num | 8 | 2. | 2. | Disabling or incapacitating   (1=Yes,0=No) |
| 10 | SER_1120 | Num | 8 | 2. | 2. | Overdose (1=Yes,0=No) |
| 11 | SER_1130 | Num | 8 | 2. | 2. | Cancer (1=Yes,0=No) |
| 12 | SER_1140 | Num | 8 | 2. | 2. | Congenital anomaly    (1=Yes,0=No) |
| 13 | SER_1150 | Num | 8 | 2. | 2. | Serious laboratory abnormality with clinical symptoms    (1=Yes,0=No) |
| 14 | SER_1160 | Num | 8 | 2. | 2. | Height failure (per protocol MOP)    (1=Yes,0=No) |
| 15 | SER_1170 | Num | 8 | 2. | 2. | Pregnancy    (1=Yes,0=No) |
| 16 | SER_1180 | Num | 8 | 2. | 2. | Other (1=Yes,0=No) |
| 17 | SER_1190 | Num | 8 | 2. | 2. | What in your opinion caused the event? 1=Yes,0=No |
| 18 | SER_1200 | Num | 8 | 2. | 2. | Withdrawal of study drug(s)    (1=Yes,0=No) |
| 19 | SER_1210 | Num | 8 | 2. | 2. | Concurrent medication   (1=Yes,0=No) |
| 20 | SER_1220 | Num | 8 | 2. | 2. | 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 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 27 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 28 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 29 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 30 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 31 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: sexam_ped.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | PSE_1060 | Num | 8 | 2. | 2. | What type of height measurement was obtained? 1=Standing height, 2=Length |
| 2 | PSE_1070 | Num | 8 | 6.1 | 6.1 | First measurement __ __ __ . __ cm |
| 3 | PSE_1080 | Num | 8 | 6.1 | 6.1 | Second measurement __ __ __ . __ cm |
| 4 | PSE_1090 | Num | 8 | 6.1 | 6.1 | Third measurement __ __ __ . __ cm |
| 5 | PSE_1100 | Num | 8 | 6.1 | 6.1 | Average height or length measurement __ __ __ . __ cm |
| 6 | PSE_1110 | Num | 8 | 2. | 2. | In your judgment, was the participant's height or length measurement acceptable? 1=Yes,0=No |
| 7 | PSE_1130 | Num | 8 | 6.1 | 6.1 | Weight (shoes off, light clothing) __ __ __ . __ kg |
| 8 | PSE_1140 | Num | 8 | 2. | 2. | Does the participant have evidence of oral candidiasis? 1=Yes,0=No |
| 9 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 10 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 11 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 12 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 13 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 14 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: sigex.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | SIG_1000 | Num | 8 | 2. | 2. | Did the participant fail to respond within 48 hours to the treatment failure rescue algorithm? 1=Yes,0=No |
| 2 | SIG_1010 | Num | 8 | 2. | 2. | Did the participant use at least 16 puffs as needed albuterol per 24 hours for a period of 48 hours? 1=Yes,0=No |
| 3 | SIG_1020 | Num | 8 | 2. | 2. | Did the participant experience prebronchodilator FEV1 values < 50Pct of the baseline prebronchodilator value obtained at Visit 1 on two consecutive spirometric determinations made on different days? 1=Yes, 0=No, 9=Not evaluated |
| 4 | SIG_1030 | Num | 8 | 2. | 2. | Did the participant experience prebronchodilator FEV1 values < 40Pct of predicted on two consecutive spirometric determinations made on different days? 1=Yes, 0=No, 9=Not evaluated |
| 5 | SIG_1040 | Num | 8 | 2. | 2. | Did the study or treating physician prescribe the participant oral/parenteral corticosteroids for the treatment of his/her asthma? 1=Yes,0=No |
| 6 | SIG_1050 | Num | 8 | 2. | 2. | Did the participant experience a significant asthma exacerbation in the opinion of the study investigator or personal physician? 1=Yes,0=No |
| 7 | SIG_1060 | Num | 8 | 2. | 2. | Did the participant experience a significant asthma exacerbation? 1=Yes,0=No |
| 8 | SIG_1080 | Num | 8 | 2. | 2. | Did the participant seek care for significant asthma exacerbation conditions? 1=Yes,0=No |
| 9 | SIG_1090 | Num | 8 | 2. | 2. | What type of care was sought: Study Investigator or Coordinator? 1=Yes,0=No |
| 10 | SIG_1100 | Num | 8 | 2. | 2. | What type of care was sought: Study Investigator or Coordinator? 1=Scheduled clinic visit, 2=Unscheduled clinic visit, 3=Phone contact |
| 11 | SIG_1110 | Num | 8 | 2. | 2. | What type of care was sought: Primary Care or Other Physician? 1=Yes,0=No |
| 12 | SIG_1120 | Num | 8 | 2. | 2. | What type of care was sought: Primary Care or Other Physician? 1=Scheduled clinic visit, 2=Unscheduled clinic visit, 3=Phone contact |
| 13 | SIG_1130 | Num | 8 | 2. | 2. | What type of care was sought: Emergency Department visit? 1=Yes,0=No |
| 14 | SIG_1140 | Num | 8 | 2. | 2. | What type of care was sought: Urgent care visit? 1=Yes,0=No |
| 15 | SIG_1150 | Num | 8 | 2. | 2. | Was the participant hospitalized? 1=Yes,0=No |
| 16 | SIG_1160 | Num | 8 | 5.1 | 5.1 | Duration of hospital stay (0-99.9 days) |
| 17 | SIG_1170 | Num | 8 | 2. | 2. | Was intubation or ventilation assistance required? 1=Yes,0=No |
| 18 | SIG_1180 | Num | 8 | 2. | 2. | Was the participant admitted to the intensive care unit? 1=Yes,0=No |
| 19 | SIG_1190 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study ICS) since significant asthma exacerbation conditions started, Inhaled corticosteroids (1=Yes,0=No) |
| 20 | SIG_1200 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study ICS) since significant asthma exacerbation conditions started, Nebulized bronchodilator (1=Yes, 0=No ) |
| 21 | SIG_1210 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study ICS) since significant asthma exacerbation conditions started, Oral corticosteroids (1=Yes, 0=No ) |

| Num | Variable | Type | Len | Format | Informat | Label |
|-----|----------|------|-----|--------|----------|-------|
| 22 | SIG_1220 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study ICS) since significant asthma exacerbation conditions started, IM or IV steroids (1=Yes, 0=No ) |
| 23 | SIG_1230 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study ICS) since significant asthma exacerbation conditions started, Antibiotics (1=Yes, 0=No ) |
| 24 | SIG_1240 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study ICS) since significant asthma exacerbation conditions started, Other (1=Yes, 0=No ) |
| 25 | SIG_1250 | Num | 8 | 2. | 2. | Why do you think the participant experienced a significant asthma exacerbation? 1=Common cold, 2=Allergies, 3=Pollution or chemical irritant, 4=Too little asthma maintenance medication, 5=Exercise, 6=Other |
| 26 | SIG_1070 | Num | 8 | | | Date exacerbation conditions were met |
| 27 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 28 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 29 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 30 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 31 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 32 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: sigex_follow.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | SFU_1000 | Num | 8 | 2. | 2. | Which phone contact following Asthma Exacerbation visit is being performed? 1=Phone Contact #1 , 2=Phone Contact #2 , 3=Phone Contact #3 |
| 2 | SFU_1010 | Num | 8 | 2. | 2. | Since the most recent Asthma Exacerbation contact, has the participant sought additional care for significant asthma exacerbation conditions? 1=Yes,0=No |
| 3 | SFU_1020 | Num | 8 | 2. | 2. | What type of care was sought: Study Investigator or Coordinator? 1=Yes,0=No |
| 4 | SFU_1030 | Num | 8 | 2. | 2. | What type of care was sought: Study Investigator or Coordinator? 1=Scheduled clinic visit, 2=Unscheduled clinic visit, 3=Phone contact |
| 5 | SFU_1040 | Num | 8 | 2. | 2. | What type of care was sought: Primary Care or Other Physician? 1=Yes,0=No |
| 6 | SFU_1050 | Num | 8 | 2. | 2. | What type of care was sought: Primary Care or Other Physician? 1=Scheduled clinic visit, 2=Unscheduled clinic visit, 3=Phone contact |
| 7 | SFU_1060 | Num | 8 | 2. | 2. | What type of care was sought: Emergency Department visit? 1=Yes,0=No |
| 8 | SFU_1070 | Num | 8 | 2. | 2. | What type of care was sought: Urgent care visit? 1=Yes,0=No |
| 9 | SFU_1080 | Num | 8 | 2. | 2. | Was the participant hospitalized? 1=Yes,0=No |
| 10 | SFU_1090 | Num | 8 | 5.1 | 5.1 | Duration of hospital stay (0-99.9 days) |
| 11 | SFU_1100 | Num | 8 | 2. | 2. | Was intubation or ventilation assistance required? 1=Yes,0=No |
| 12 | SFU_1110 | Num | 8 | 2. | 2. | Was the participant admitted to the intensive care unit? 1=Yes,0=No |
| 13 | SFU_1120 | Num | 8 | 2. | 2. | Due to persistent symptoms, has the participant started taking any of the following medications since the most recent Asthma Exacerbation contact, Inhaled corticosteroids (1=Yes,0=No) |
| 14 | SFU_1130 | Num | 8 | 2. | 2. | Due to persistent symptoms, has the participant started taking any of the following medications since the most recent Asthma Exacerbation contact, Nebulized bronchodilator (1=Yes,0=No) |
| 15 | SFU_1140 | Num | 8 | 2. | 2. | Due to persistent symptoms, has the participant started taking any of the following medications since the most recent Asthma Exacerbation contact, Oral corticosteroids (1=Yes,0=No) |
| 16 | SFU_1150 | Num | 8 | 2. | 2. | Due to persistent symptoms, has the participant started taking any of the following medications since the most recent Asthma Exacerbation contact, IM or IV steroids (1=Yes,0=No) |
| 17 | SFU_1160 | Num | 8 | 2. | 2. | Due to persistent symptoms, has the participant started taking any of the following medications since the most recent Asthma Exacerbation contact, Antibiotics (1=Yes,0=No) |
| 18 | SFU_1170 | Num | 8 | 2. | 2. | Due to persistent symptoms, has the participant started taking any of the following medications since the most recent Asthma Exacerbation contact, Other (1=Yes,0=No) |
| 19 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 20 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 21 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 22 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 23 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 24 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: snq.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | SNQ_1000 | Num | 8 | 2. | 2. | Runny Nose   (0=Never1=1-4 times per month, 2=2-6 times per week, 3=Daily) |
| 2 | SNQ_1010 | Num | 8 | 2. | 2. | Post nasal drip   (0=Never1=1-4 times per month, 2=2-6 times per week, 3=Daily) |
| 3 | SNQ_1020 | Num | 8 | 2. | 2. | Need to blow your nose   (0=Never1=1-4 times per month, 2=2-6 times per week, 3=Daily) |
| 4 | SNQ_1030 | Num | 8 | 2. | 2. | Facial pain/pressure     (0=Never1=1-4 times per month, 2=2-6 times per week, 3=Daily) |
| 5 | SNQ_1040 | Num | 8 | 2. | 2. | Nasal obstruction   (0=Never1=1-4 times per month, 2=2-6 times per week, 3=Daily) |
| 6 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 7 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 8 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 9 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 10 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 11 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: spiro.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | SPI_1010 | Char | 4 | $4. | $4. | Time spirometry started (based on 24-hour clock) |
| 2 | SPI_1020 | Num | 8 | 5.2 | 5.2 | The reported FEV1 and FVC are the best volumes of all acceptable maneuvers. 1.Highest FVC |
| 3 | SPI_1040 | Num | 8 | 4. | 4. | Highest FEV1 (Pct predicted) |
| 4 | SPI_1050 | Num | 8 | 6.2 | 6.2 | The reported flow rates correspond to the maneuver where FEV1 + FVC is maximized. FEF Max |
| 5 | SPI_1060 | Num | 8 | 5.2 | 5.2 | FEF25-75 |
| 6 | SPI_1070 | Num | 8 | 2. | 2. | In your judgment, was the subject's spirometry technique acceptable? 0=No, 1=Yes |
| 7 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 8 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 9 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 10 | SPI_1030 | Num | 8 | | | Highest FEV1 |
| 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 | AM_TRIAL_TYPE | Num | 8 | 2. | 2. | TRIAL_TYPE |
| 2 | AM_FVC | Num | 8 | 7.2 | 7.2 | FVC |
| 3 | AM_FEV1 | Num | 8 | 7.2 | 7.2 | FEV1 |
| 4 | AM_PEF | Num | 8 | 4. | 4. | PEF |
| 5 | AM_FEF2575 | Num | 8 | 7.2 | 7.2 | FEF2575 |
| 6 | AM_FET | Num | 8 | 7.2 | 7.2 | FET |
| 7 | DRY_1 | Num | 8 | 2. | 2. | Number of times the participant woke up last night due to asthma symptoms # Times woke up due to asthma (0-9) |
| 8 | DRY_2 | Num | 8 | 2. | 2. | Number of puffs the participant will take from the WHITE study inhaler this morning # Puffs from WHITE inhaler in AM (0-9) |
| 9 | DRY_3 | Num | 8 | 2. | 2. | only) Number of puffs the participant will take from the BLUE study inhaler this morning # Puffs from BLUE inhaler in AM (0-9) |
| 10 | DRY_4 | Num | 8 | 2. | 2. | Has the participant taken any puffs from his/her RED RESCUE albuterol inhaler in the past 4 hours? 1=yes, 0=no |
| 11 | DRY_5 | Num | 8 | 2. | 2. | Shortness of Breath Score Shortness of Breath Score overnight (0,1,2,3) |
| 12 | DRY_6 | Num | 8 | 2. | 2. | Chest tightness score Chest Tightness Score overnight (0,1,2,3) |
| 13 | DRY_7 | Num | 8 | 2. | 2. | Wheezing score Wheezing Score overnight (0,1,2,3) |
| 14 | DRY_8 | Num | 8 | 2. | 2. | Coughing score Coughing Score overnight (0,1,2,3) |
| 15 | DRY_9 | Num | 8 | 2. | 2. | Phlegm/Mucus score Phlegm/Mucus Score overnight (0,1,2,3) |
| 16 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 17 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 18 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 19 | DDATE | Num | 8 | | | date 'fixed' for analysis so that associated AM and PM always have same ddate |
| 20 | PM_TRIAL_TYPE | Num | 8 | 2. | 2. | TRIAL_TYPE |
| 21 | PM_FVC | Num | 8 | 7.2 | 7.2 | FVC |
| 22 | PM_FEV1 | Num | 8 | 7.2 | 7.2 | FEV1 |
| 23 | PM_PEF | Num | 8 | 4. | 4. | PEF |
| 24 | PM_FEF2575 | Num | 8 | 7.2 | 7.2 | FEF2575 |
| 25 | PM_FET | Num | 8 | 7.2 | 7.2 | FET |
| 26 | DRY_10 | Num | 8 | 2. | 2. | Number of puffs the participant will take from the WHITE study inhaler tonight # Puffs from WHITE inhaler in PM (0-9) |
| 27 | DRY_11 | Num | 8 | 2. | 2. | Has the participant taken any puffs from his/her RED RESCUE albuterol inhaler during the past 4 hours? 1=yes, 0=no |
| 28 | DRY_12 | Num | 8 | 2. | 2. | Shortness of Breath Score Shortness of Breath Score since waking this morning (0,1,2,3) |
| 29 | DRY_13 | Num | 8 | 2. | 2. | Chest tightness score Chest Tightness Score since waking this morning (0,1,2,3) |
| 30 | DRY_14 | Num | 8 | 2. | 2. | Wheezing score Wheezing Score since waking this morning (0,1,2,3) |
| 31 | DRY_15 | Num | 8 | 2. | 2. | Coughing score Coughing Score since waking this morning (0,1,2,3) |

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 32 | DRY_16 | Num | 8 | 2. | 2. | Phlegm/Mucus score Phlegm/Mucus Score since waking this morning (0,1,2,3) |
| 33 | DRY_17 | Num | 8 | 2. | 2. | Did your regular exercise cause unusually severe shortness of breath during the past 24 hours? 1=Yes, 0=No, 9=N/A |
| 34 | DRY_18 | Num | 8 | 3. | 3. | Number of RED RESCUE albuterol puffs taken in the past 24 hours to prevent symptoms    # Preventive   RED RESCUE puffs   in past 24 hours? |
| 35 | DRY_19 | Num | 8 | 3. | 3. | Number of RED RESCUE albuterol puffs taken for asthma symptoms or low peak flow during past 24 hours   # RED RESCUE   puffs for symptoms   in past 24 hours? |
| 36 | DRY_20 | Num | 8 | 3. | 3. | Number of times used RED RESCUE albuterol inhaler for asthma symptoms during past 24 hours   # Times used   RED RESCUE for symptoms in past 24 hours? |
| 37 | DRY_21 | Num | 8 | 2. | 2. | Did RED RESCUE albuterol relieve symptoms for less than 4 hours after treatment during past 24 hours? 1=Yes,0=No |
| 38 | DRY_22 | Num | 8 | 2. | 2. | Was the participant seen by a healthcare provider   for an unscheduled visit in the past 24 hours due to asthma symptoms? 1=Yes,0=No |
| 39 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 40 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 41 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## *Data Set Name: sputlab.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | SLA_1010 | Char | 4 | $4. | $4. | Processing: Time processing started (based on 24-hour clock) __ __ __ __ (0 - 2359) |
| 2 | SLA_1020 | Num | 8 | 7.1 | 7.1 | Processing Sample: Total Cell Count: __ __ __ __. __x 10^4 cells/ml (0 - 9999.9) |
| 3 | SLA_1030 | Num | 8 | 2. | 2. | Was the participant's sputum sample processed within 4 hours after collection? 1=Yes,0=No |
| 4 | SLA_1000 | Num | 8 | | | Processing Sample: Processing Date __ __ / __ __ / 20 __ __ |
| 5 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 6 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 7 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: sputread.sas7bdat

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | SRE_1010 | Num | 8 | 2. | 2. | Rate slide's quality:   (1=Very good, 2=Good, 3=Acceptable, 4=Poor but readable, 5=Not readable) |
| 2 | SRE_1020 | Num | 8 | 2. | 2. | Record the number on the slide(s) that was (were) read (0 - 9) |
| 3 | SRE_1030 | Num | 8 | 2. | 2. | Record the number on the slide(s) that was (were) read: These are numbers that were assigned to the slides at each site. (0 -9) |
| 4 | SRE_1040 | Num | 8 | 7.1 | 7.1 | Total Cell Count: __ __ __ __ . __  x 10^4 cells/ml (0 - 9999.9) |
| 5 | SRE_1050 | Num | 8 | 5.1 | 5.1 | Differential Cell Counts: Squamous Cells __ __ . __ Pct (0.0 - 99.9) |
| 6 | SRE_1060 | Num | 8 | 5.1 | 5.1 | Differential Cell Counts: Epithelial Cells __ __ . __ Pct (0.0 - 99.9) |
| 7 | SRE_1070 | Num | 8 | 5.1 | 5.1 | Differential Cell Counts: Macrophages __ __ . __ Pct (0.0 - 99.9) |
| 8 | SRE_1080 | Num | 8 | 5.1 | 5.1 | Differential Cell Counts: Neutrophils __ __ . __ Pct (0 -99.9) |
| 9 | SRE_1090 | Num | 8 | 5.1 | 5.1 | Differential Cell Counts: Eosinophils __ __ . __ Pct (0 - 99.9) |
| 10 | SRE_1100 | Num | 8 | 5.1 | 5.1 | Differential Cell Counts: Lymphocytes __ __ . __ Pct (0 -99.9) |
| 11 | SRE_1000 | Num | 8 | | | Date of Read __ __ / __ __ / 20 __ __ |
| 12 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 13 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 14 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: sputum.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | SPU_1000 | Num | 8 | 5.1 | 5.1 | For this protocol, what was the duration of sputum induction the first time the participant's sample was processed within 4 hours after collection? |
| 2 | SPU_1010 | Char | 4 | $4. | $4. | Sputum induction start time (based on 24-hour clock) |
| 3 | SPU_1020 | Char | 4 | $4. | $4. | Sputum induction stop time (based on 24-hour clock) |
| 4 | SPU_1030 | Num | 8 | 5.1 | 5.1 | Duration of sputum induction collection phase at this visit -- minutes (0 - 99.9) |
| 5 | SPU_1040 | Num | 8 | 2. | 2. | Was the duration ? 1=Yes,0=No |
| 6 | SPU_1050 | Num | 8 | 6.1 | 6.1 | Volume of sputum sample at this visit -- ml (0.0 - 999.9) |
| 7 | SPU_1060 | Num | 8 | 2. | 2. | Is the volume adequate for processing? 1=Yes,0=No |
| 8 | SPU_1070 | Num | 8 | 2. | 2. | Is the sample adequate for laboratory analysis? 1=Yes,0=No |
| 9 | SPU_1080 | Num | 8 | 5.2 | 5.2 | Participant's FEV1 immediately after completion of sputum induction: -- (0.0 -9.99 L) |
| 10 | SPU_1090 | Num | 8 | 4. | 4. | FEV1 (Pct predicted) (0 - 999) |
| 11 | SPU_1100 | Char | 4 | $4. | $4. | Time of FEV1 in Q7a (based on 24-hour clock) |
| 12 | SPU_1110 | Num | 8 | 5.1 | 5.1 | Percent difference in FEV1 ((Reference - Q7a) / Reference) X100 (-99.9 - 99.9 Pct) |
| 13 | SPU_1120 | Num | 8 | 2. | 2. | Did the participant's FEV1 drop > 10Pct from reference FEV1 as indicated in Q7d? 1=Yes,0=No |
| 14 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 15 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 16 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: sputum_add_trt.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | SAD_1000 | Num | 8 | 5.2 | 5.2 | Participant's FEV1 after initial 2 puffs of albuterol: 1a.FEV1 __ . __ __ L (0 -9.99) |
| 2 | SAD_1010 | Num | 8 | 4. | 4. | Participant's FEV1 after initial 2 puffs of albuterol: 1b. FEV1 (Pct predicted)__ __ __ Pct predicted (0 - 999) |
| 3 | SAD_1020 | Char | 4 | $4. | $4. | Participant's FEV1 after initial 2 puffs of albuterol: 1c. Time of FEV1 from Q1a (based on 24-hour clock) __ __ __ __ (0 - 2359) |
| 4 | SAD_1030 | Num | 8 | 2. | 2. | Participant's FEV1 after initial 2 puffs of albuterol: 1d. Was the FEV1 from Q1a >=the sputum induction reversal reference value in the gray box above? 1=Yes,0=No |
| 5 | SAD_1040 | Num | 8 | 5.2 | 5.2 | Participant's FEV1 after 2 additional puffs of albuterol: 2a. FEV1 __ . __ __ L (0 - 9.99) |
| 6 | SAD_1050 | Num | 8 | 4. | 4. | Participant's FEV1 after 2 additional puffs of albuterol: 2b. FEV1 (Pct predicted) __ __ __ Pct predicted (0 - 999) |
| 7 | SAD_1060 | Char | 4 | $4. | $4. | Participant's FEV1 after 2 additional puffs of albuterol: 2c. Time of FEV1 from Q2a (based on 24-hour clock)__ __ __ __ (0 - 2359) |
| 8 | SAD_1070 | Num | 8 | 2. | 2. | Participant's FEV1 after 2 additional puffs of albuterol: 2d.Was the FEV1 from Q2a ? 1=Yes,0=No |
| 9 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 10 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 11 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 12 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 13 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 14 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

## Data Set Name: sputumchk.sas7bdat

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | SCH_1000 | Num | 8 | 2. | 2. | Was the participant's FEV1 after reversal from the methacholine challenge greater yhan 90Pct of the baseline FEV1 (1=Yes,0=No) |
| 2 | SCH_1010 | Num | 8 | 2. | 2. | If NO, has the participant received permission from the supervising physician to proceed with sputum induction testing? 1=Yes,0=No |
| 3 | SCH_1020 | Num | 8 | 2. | 2. | Physician's Signature:_____ (1=signature present, NULL=signature missing) |
| 4 | SCH_1030 | Num | 8 | 5.2 | 5.2 | Participant's FEV1 used for assessment of eligibility for sputum induction __ . __ __ L (0 - 9.99) |
| 5 | SCH_1040 | Num | 8 | 4. | 4. | Participant's FEV1 (Pct predicted) used for assessment of eligibility for sputum induction __ __ __ Pct predicted (O-999) |
| 6 | SCH_1050 | Num | 8 | 2. | 2. | Was the participant's FEV1   from Q3 ? 1=Yes,0=No |
| 7 | SCH_1055 | Num | 8 | 2. | 2. | Has the participant used any smokeless tobacco products   today? 1=Yes,0=No |
| 8 | SCH_1060 | Num | 8 | 2. | 2. | Is there any other reason the participant should not proceed with sputum induction? 1=Yes,0=No |
| 9 | SCH_1070 | Num | 8 | 2. | 2. | Is the participant eligible for sputum induction? 1=Yes,0=No |
| 10 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 11 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 12 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: term.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | TER_1000 | Num | 8 | 2. | 2. | Has the participant completed the study through Visit 9? 1=Yes,0=No |
| 2 | TER_1010 | Num | 8 | 2. | 2. | Who initiated termination of the participant? 1=Participant, 2=Clinical Staff |
| 3 | TER_1020 | Num | 8 | 3. | 3. | 1=no longer interested in participating*, 2=no longer willing to follow protocol*, 3=difficult access to clinic , 4=unable to make visits during clinic hours, 5=moving out of the area, 6=unable to continue due to personal constraints*, 7=unable to continue |
| 4 | TER_1040 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to pregnancy? 1=Yes, 0=No, 9=N/A |
| 5 | TER_1050 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to loss to follow-up? 1=Yes,0=No |
| 6 | TER_1070 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to loss to follow-up, type of contact (1=In-person visit, 2=Phone call) |
| 7 | TER_1080 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to an asthma-related adverse event? 1=Yes,0=No |
| 8 | TER_1090 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to a medication-related adverse event? 1=Yes,0=No |
| 9 | TER_1100 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to an adverse event not related to asthma or medications? 1=Yes,0=No |
| 10 | TER_1110 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to ineligibility during the Supervised Washout ? 1=Yes,0=No |
| 11 | TER_1120 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to non-compliance with medication dosing? 1=Yes,0=No |
| 12 | TER_1130 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to non-compliance with diary completion? 1=Yes,0=No |
| 13 | TER_1140 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to non-compliance with visit attendance? 1=Yes,0=No |
| 14 | TER_1150 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to non-compliance with peak flow monitoring? 1=Yes,0=No |
| 15 | TER_1160 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to significant asthma exacerbation or two treatment failures during run-in ? 1=Yes,0=No |
| 16 | TER_1170 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to ineligibility during the run-in period   for reasons other than compliance or exacerbation/treatment failure or high sputum eosinophils ? 1=Yes,0=No |
| 17 | TER_1180 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to other reason? 1=Yes,0=No |
| 18 | TER_1185 | Num | 8 | 2. | 2. | Did clinical staff terminate the participant due to ineligibility due to high sputum eosinophils in the run-in ? 1=Yes,0=No |
| 19 | TER_1200 | Char | 1 | $1. | $1. | Did clinical staff terminate the participant due to... Indicate the letter corresponding to the primary reason the participant was terminated. (a-n) |
| 20 | TER_1060 | Num | 8 | | | Did clinical staff terminate the participant due to loss to follow-up, date of last contact with participant |
| 21 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 22 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 23 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |

| 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: txfail.sas7bdat

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | TXF_1000 | Num | 8 | 2. | 2. | Did the participant seek care for treatment failure conditions? 1=Yes,0=No |
| 2 | TXF_1010 | Num | 8 | 2. | 2. | What type of care was sought: Study Investigator or Coordinator? 1=Yes,0=No |
| 3 | TXF_1020 | Num | 8 | 2. | 2. | What type of care was sought: Study Investigator or Coordinator? 1=Scheduled clinic visit, 2=Unscheduled clinic visit, 3=Phone contact, other than call to notify clinic as instructed in spirotel |
| 4 | TXF_1030 | Num | 8 | 2. | 2. | What type of care was sought: Primary Care or Other Physician? 1=Yes,0=No |
| 5 | TXF_1040 | Num | 8 | 2. | 2. | What type of care was sought: Primary Care or Other Physician? 1=Scheduled clinic visit, 2=Unscheduled clinic visit, 3=Phone contact |
| 6 | TXF_1050 | Num | 8 | 2. | 2. | What type of care was sought: Emergency Department visit? 1=Yes,0=No |
| 7 | TXF_1060 | Num | 8 | 2. | 2. | What type of care was sought: Urgent care visit? 1=Yes,0=No |
| 8 | TXF_1070 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study medication and high-dose ICS taken as instructed for treatment failure) since treatment failure conditions started:   Inhaled corticosteroids (1=Yes,0=No) |
| 9 | TXF_1080 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study medication and high-dose ICS taken as instructed for treatment failure) since treatment failure conditions started:   Nebulized bronchodilator (1=Yes,0=No) |
| 10 | TXF_1090 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study medication and high-dose ICS taken as instructed for treatment failure) since treatment failure conditions started: Oral corticosteroids form.   (1=Yes,0=No) |
| 11 | TXF_1100 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study medication and high-dose ICS taken as instructed for treatment failure) since treatment failure conditions started:   IM or IV steroids form.   (1=Yes,0=No) |
| 12 | TXF_1110 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study medication and high-dose ICS taken as instructed for treatment failure) since treatment failure conditions started: Antibiotics (1=Yes,0=No) |
| 13 | TXF_1120 | Num | 8 | 2. | 2. | Has the participant taken any of the following medications (excluding study medication and high-dose ICS taken as instructed for treatment failure) since treatment failure conditions started:   Other (1=Yes,0=No) |
| 14 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 15 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 16 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: txfail_chk.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | TCH_1000 | Num | 8 | 2. | 2. | Did the participant awaken from asthma three or more times in a two-week period or on two consecutive nights? 1=Yes,0=No |
| 2 | TCH_1010 | Num | 8 | 2. | 2. | Did the participant use albuterol for relief of symptoms four or more times/day for two or more consecutive days? 1=Yes,0=No |
| 3 | TCH_1020 | Num | 8 | 2. | 2. | Did albuterol relieve symptoms for less than four hours after treatment? 1=Yes,0=No |
| 4 | TCH_1030 | Num | 8 | 2. | 2. | Did the participant use albuterol for relief of symptoms daily for seven days, and this use exceeded two times the weekly use of albuterol in the baseline period? 1=Yes,0=No |
| 5 | TCH_1040 | Num | 8 | 2. | 2. | Did regular exercise cause unusually severe shortness of breath on two or more days during a seven day period? 1=Yes,0=No |
| 6 | TCH_1050 | Num | 8 | 2. | 2. | Did the participant experience a significant asthma exacerbation? 1=Yes,0=No |
| 7 | TCH_1060 | Num | 8 | 2. | 2. | Did the participant experience a treatment failure? 1=Yes,0=No |
| 8 | TCH_1080 | Num | 8 | 2. | 2. | Has the participant experienced two treatment failures in the current treatment period ? 1=Yes,0=No |
| 9 | TCH_1090 | Num | 8 | 2. | 2. | Does the study physician feel the study treatment contributed directly to the treatment failure, such that it is in the participants best interest to discontinue the current blinded treatment? 1=Yes,0=No |
| 10 | TCH_1100 | Num | 8 | 2. | 2. | Did the participant begin daily treatment with high-dose ICS for 10 days? 1=Yes,0=No |
| 11 | TCH_1110 | Num | 8 | 2. | 2. | Did the participant begin daily treatment with high-dose ICS for 10 days? 1=Did not think symptoms werebad enough, 2=Other |
| 12 | TCH_1070 | Num | 8 | | | Date treatment failure conditions were met |
| 13 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 14 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 15 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: washout.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | WSH_1000 | Num | 8 | 2. | 2. | During this last treatment period , has the participant experienced a treatment failure or asthma exacerbation? 1=Yes,0=No |
| 2 | WSH_1010 | Num | 8 | 2. | 2. | Has the participant experienced two or more treatment failures in this last treatment period, or does the study physician feel the study treatment contributed directly to the treatment failure such that it is in the participants best interest to discontinu |
| 3 | WSH_1020 | Num | 8 | 2. | 2. | As of today, have 2 weeks passed since the participants final dose of open-label Asmanex? 1=Yes,0=No |
| 4 | WSH_1040 | Num | 8 | 2. | 2. | As of today, have 6 weeks passed since the participants final dose of open-label Asmanex? 1=Yes,0=No |
| 5 | WSH_1050 | Num | 8 | 2. | 2. | As of today, have 3 weeks passed since the participants final dose of open-label Asmanex? 1=Yes,0=No |
| 6 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 7 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 8 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 9 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 10 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 11 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |

*Data Set Name: wpai_asthma.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|-----|----------|------|-----|--------|----------|-------|
| 1 | WPA_1000 | Num | 8 | 2. | 2. | Are you currently employed ? 1=Yes,0=No |
| 2 | WPA_1010 | Num | 8 | 6.1 | 6.1 | In general, how many hours per week do you usually work? |
| 3 | WPA_1020 | Num | 8 | 6.1 | 6.1 | During the past seven days, how many hours did you miss from work because of problems associated with your asthma? |
| 4 | WPA_1030 | Num | 8 | 3. | 3. | During the past seven days, how much did asthma affect your productivity while you were working? |
| 5 | WPA_1040 | Num | 8 | 2. | 2. | Do you currently attend classes in an academic setting ? 1=Yes,0=No |
| 6 | WPA_1050 | Num | 8 | 6.1 | 6.1 | In general, how many hours per week do you usually attend classes? |
| 7 | WPA_1060 | Num | 8 | 6.1 | 6.1 | During the past seven days, how many hours did you miss from class or school because of problems associated with your asthma? |
| 8 | WPA_1070 | Num | 8 | 3. | 3. | During the past seven days, how much did asthma affect your productivity while in school or attending classes in an academic setting? |
| 9 | WPA_1080 | Num | 8 | 3. | 3. | During the past seven days, how much did your asthma affect your ability to do your regular daily activities, other than work at a job or attend classes? |
| 10 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 11 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 12 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 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: wurss_21.sas7bdat*

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 1 | HOW_SICK_TODAY | Num | 8 | 2. | 2. | How sick today? 0=Not Sick, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely |
| 2 | RUNNY_NOSE | Num | 8 | 2. | 2. | Runny Nose:    (0=Do Not Have this Symptom, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 3 | PLUGGED_NOSE | Num | 8 | 2. | 2. | PLUGGED_NOSE   (0=Do Not Have this Symptom, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 4 | SNEEZING | Num | 8 | 2. | 2. | SNEEZING   (0=Do Not Have this Symptom, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 5 | SORE_THROAT | Num | 8 | 2. | 2. | SORE_THROAT   (0=Do Not Have this Symptom, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 6 | SCRATCHY_THROAT | Num | 8 | 2. | 2. | SCRATCHY_THROAT   (0=Do Not Have this Symptom, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 7 | COUGH | Num | 8 | 2. | 2. | COUGH (0=Do Not Have this Symptom, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 8 | HOARSENESS | Num | 8 | 2. | 2. | HOARSENESS   (0=Do Not Have this Symptom, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 9 | HEAD_CONGESTION | Num | 8 | 2. | 2. | HEAD_CONGESTION   (0=Do Not Have this Symptom, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 10 | CHEST_CONGESTION | Num | 8 | 2. | 2. | CHEST_CONGESTION   (0=Do Not Have this Symptom, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 11 | FEELING_TIRED | Num | 8 | 2. | 2. | FEELING_TIRED (0=Do Not Have this Symptom, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 12 | THINK_CLEARLY | Num | 8 | 2. | 2. | THINK_CLEARLY   (0=Not at all, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 13 | SLEEP_WELL | Num | 8 | 2. | 2. | SLEEP_WELL   (0=Not at all, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 14 | BREATH_EASILY | Num | 8 | 2. | 2. | BREATH_EASILY   (0=Not at all, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 15 | WALK | Num | 8 | 2. | 2. | WALK   (0=Not at all, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 16 | DAILY_ACTIVITIES | Num | 8 | 2. | 2. | DAILY_ACTIVITIES   (0=Not at all, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 17 | WORK_OUTSIDE_HOME | Num | 8 | 2. | 2. | WORK_OUTSIDE_HOME   (0=Not at all, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 18 | WORK_INSIDE_HOME | Num | 8 | 2. | 2. | WORK_INSIDE_HOME   (0=Not at all, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 19 | INTERACT | Num | 8 | 2. | 2. | INTERACT   (0=Not at all, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 20 | LIVE_LIFE | Num | 8 | 2. | 2. | LIVE_LIFE   (0=Not at all, 1=Very Mildy, 2 and 3=Mildly, 4 and 5=Moderately, 6 and 7=Severely) |
| 21 | MY_COLD_IS | Num | 8 | 2. | 2. | MY_COLD_IS   (1=Very much better, 2=Somewhat better, 3=A little better, 4=The same, 5=A little worse, 6=Somewhat worse, 7=Very much worse) |

| Num | Variable | Type | Len | Format | Informat | Label |
|---|---|---|---|---|---|---|
| 22 | VNUM_C | Char | 3 | $3. | $3. | Visit Number (character) |
| 23 | VNUM | Num | 8 | | | Visit Number (numeric) |
| 24 | VDATE | Num | 8 | | | Number of days from Visit 1 to this visit |
| 25 | WDATE | Num | 8 | | | Date (number of days from Visit 1) |
| 26 | RAND_ID | Char | 6 | | | Randomized Master ID |
| 27 | ENROLL_TYPE | Char | 15 | | | Enrollment Type (Screen Fail, Randomized, Healthy Control) |
| 28 | ENROLL_ORDER | Num | 8 | | | Enrollment Order Number |