

**Data Set Name: trim\_act.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITID	Char	2	\$2.	Visit ID
3	TA101	Num	8	8.	1. How much time did asthma keep you from getting as much done
4	TA102	Num	8	8.	2. How often have you had shortness of breath
5	TA103	Num	8	8.	3. How often did asthma symptoms wake you up at night
6	TA104	Num	8	8.	4. How often have you used your rescue inhaler/nebulizer
7	TA105	Num	8	8.	5. How would you rate asthma control during the past 4 weeks
8	ACT	Num	8	8.	Total score ACT

**Data Set Name: trim\_asui.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	ID	Char	7	\$7.	Participant ID
2	VISITID	Char	2	\$2.	Visit ID
3	AS101	Num	8	8.	1. How many days were you bothered by coughing
4	AS102	Num	8	8.	2. How severe was your cough
5	AS103	Num	8	8.	3. How many days were you bothered by wheezing
6	AS104	Num	8	8.	4. How severe was your wheezing
7	AS105	Num	8	8.	5. How many days were you bothered by shortness of breath
8	AS106	Num	8	8.	6. How severe was your shortness of breath
9	AS107	Num	8	8.	7. How many days were you awakened at night by your asthma
10	AS108	Num	8	8.	8. How much of a problem was being awakened at night
11	AS109	Num	8	8.	9. How many days were bothered by side effects of asthma medication
12	AS110	Num	8	8.	10. How severe were the side effects of your asthma medication
13	ASUI	Num	8	8.	Total score ASUI

**Data Set Name: trim\_ba1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Visit date (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	BA106	Char	9	\$9.	Form version date
5	BA107	Num	8	8.	7. Gender (1=Male, 2=Female)
6	BA108	Num	8	8.	8. Ethnicity (1=Hispanic, 2=Not Hispanic)
7	BA109	Char	2	\$2.	9. Race (1=White, 2=Non-White)
8	BA112	Num	8	8.	12. Age
9	BA113	Num	8	8.	13. Age of onset of asthma
10	BA114	Num	8	8.	14. How many times had doctors/ED/hospital visit
11	BA115	Num	8	8.	15. How many times have required course of prednisone
12	BA116	Char	1	\$1.	16. Has allergies that makes asthma worse
13	BA117	Num	8	8.	17. When last seen by doctor for breathing problems
14	BA118	Num	8	8.	18. When last visit hospital/ER/urgent care for breathing problems
15	BA119	Num	8	8.	19. When last spent a night in hospital for breathing problems
16	BA120	Num	8	8.	20. When last have an ICU admission for asthma attack
17	BA122A	Char	1	\$1.	22a. Weight loss in last 6 months
18	BA122B	Num	8	8.	22b. How much weight lost
19	BA123A	Char	1	\$1.	23a. Weight gain in last 6 months
20	BA123B	Num	8	8.	23b. How much weight gained
21	BA124_A	Char	1	\$1.	24a. Ever tried weight loss plan - DASH
22	BA124_B	Char	1	\$1.	24b. Ever tried weight loss plan - South Beach
23	BA124_C	Char	1	\$1.	24c. Ever tried weight loss plan - Calorie counting
24	BA124_D	Char	1	\$1.	24d. Ever tried weight loss plan - Atkins
25	BA124_E	Char	1	\$1.	24e. Ever tried weight loss plan - Paleo
26	BA124_F	Char	1	\$1.	24f. Ever tried weight loss plan - Other
27	BA124_G	Char	1	\$1.	24g. None of the above
28	BA125A	Char	1	\$1.	25a. Ever enrolled in Weight Watchers
29	BA125B	Num	8	8.	25b. How many times
30	BA126A	Char	1	\$1.	26a. Ever enrolled in Jenny Craig
31	BA126B	Num	8	8.	26b. How many times
32	BA127_A	Char	1	\$1.	27a. Ever enrolled in weight loss program - Nutrisystem
33	BA127_B	Char	1	\$1.	27b. Ever enrolled in weight loss program - Personal Trainer Food
34	BA127_C	Char	1	\$1.	27c. Ever enrolled in weight loss program - AdvoCare
35	BA127_D	Char	1	\$1.	27d. Ever enrolled in weight loss program - Medifast
36	BA127_E	Char	1	\$1.	27e. Ever enrolled in weight loss program - Herbalife

Num	Variable	Type	Len	Format	Label
37	BA127_F	Char	1	\$1.	27f. Ever enrolled in weight loss program - Other
38	BA127_G	Char	1	\$1.	27g. None of the above
39	BA128A	Num	8	8.	28a. How many days exercised - 5-30 minutes
40	BA128B	Num	8	8.	28b. How many days exercised - 31-60 minutes
41	BA128C	Num	8	8.	28c. How many days exercised - > 60 minutes
42	BA129	Char	1	\$1.	29. Ever used MyFitnessPal
43	BA130	Char	1	\$1.	30. Ever used an activity monitor
44	BA130S	Char	19	\$19.	30. Specify for activity monitor
45	BA131	Char	1	\$1.	31. Has a current gym/healthclub membership
46	BA132	Num	8	8.	32. Smoking status (1=Current, 2=Former, 3=Never)
47	BA133	Num	8	8.	33. How many years have you smoked
48	BA134	Num	8	8.	34. How many packs cigarettes per day smoked
49	BA135	Num	8	8.	35. Total number of pack years
50	BA136	Num	8	8.	36. Ever used e-cigarettes
51	BA138	Char	1	\$1.	38. Exposed to second hand smoke
52	BA139	Char	1	\$1.	39. Frequently go places where exposed to second hand smoke
53	BA140A	Num	8	8.	40a. How often had - Cough
54	BA140B	Num	8	8.	40b. How often had - Sputum
55	BA140C	Num	8	8.	40c. How often had - Chest tightness
56	BA140D	Num	8	8.	40d. How often had - Wheeze/whistling/musical sound in chest
57	BA140E	Num	8	8.	40e. How often had - Shortness of breath
58	BA140F	Num	8	8.	40f. How often had - Nighttime asthma symptoms
59	BA141	Char	1	\$1.	41. Ever diagnosed with diabetes
60	BA142	Num	8	8.	42. Age of onset of diabetes
61	BA143A	Char	1	\$1.	43a. COPD (Chronic Obstructive Pulmonary Disease)
62	BA143B	Char	1	\$1.	43b. Gastroesophageal reflux (GERD)
63	BA143C	Char	1	\$1.	43c. Eczema
64	BA143D	Char	1	\$1.	43d. Hay fever or allergic rhinitis
65	BA143E	Char	1	\$1.	43e. Food allergies
66	BA143F	Char	1	\$1.	43f. Other allergies
67	BA143G	Char	1	\$1.	43g. Cancer
68	BA143H	Char	1	\$1.	43h. High cholesterol
69	BA143I	Char	1	\$1.	43i. Thyroid disease
70	BA143J	Char	1	\$1.	43j. Coronary artery disease
71	BA143K	Char	1	\$1.	43k. Congestive heart failure
72	BA143L	Char	1	\$1.	43l. Stroke
73	BA143M	Char	1	\$1.	43m. Hypertension
74	BA143N	Char	1	\$1.	43n. Renal failure
75	BA143O	Char	1	\$1.	43o. Liver disorders

Num	Variable	Type	Len	Format	Label
76	BA143P	Char	1	\$1.	43p. Immunodeficiency states
77	BA143Q	Char	1	\$1.	43q. Anxiety/depression/bipolar disorder/PTSD/suicidal ideation
78	BA143R	Char	1	\$1.	43r. Irritable bowel syndrome (IBS)
79	BA143S	Char	1	\$1.	43s. Inflammatory bowel disease (IBD)
80	BA143T	Char	1	\$1.	43t. Other condition(s)
81	BA144	Num	8	8.	44. Approximate weight at 18 years
82	BA145	Num	8	8.	45. Age of first menstrual period
83	BA145S	Char	2	\$2.	45. Specify age of first menstrual period
84	BA148	Num	8	8.	48. Highest level of education completed
85	BA149	Num	8	8.	49. How pay for prescription drugs
86	BA150_GRP	Num	8		50. Daily work schedule (re-grouped, 1=FT, 2=PT, 3=Student, 4=Household Work, 5=Disabled, 6=Retired/Not Working)

**Data Set Name: trim\_bc1.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Visit date (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	BC106	Char	9	\$9.	Form version date
5	BC107A	Char	1	\$1.	7a. Serum aliquot 1 available
6	BC107B	Char	1	\$1.	7b. Serum aliquot 2 available
7	BC107C	Char	1	\$1.	7c. Serum aliquot 3 available
8	BC107D	Char	1	\$1.	7d. Serum aliquot 4 available
9	BC107E	Char	1	\$1.	7e. Serum aliquot 5 available
10	BC107F	Char	1	\$1.	7f. Serum aliquot 6 available
11	BC107G	Char	1	\$1.	7g. Blood sent to lab for glucose
12	BC107H	Char	3	\$3.	7h. Glucose result

**Data Set Name: trim\_cv1.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Visit date (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	CV106	Char	9	\$9.	Form version date
5	CV107	Num	8	8.	7. Number of Diary Cards not returned
6	CV108_A	Char	1	\$1.	8a. None missing
7	CV108_B	Char	1	\$1.	8b. Participant forgot to return
8	CV108_C	Char	1	\$1.	8c. Did not complete
9	CV108_D	Char	1	\$1.	8d. Lost or destroyed
10	CV108_E	Char	1	\$1.	8e. In the mail
11	CV108_F	Char	1	\$1.	8f. Other reason
12	CV109A	Num	8	8.	9a. Headache
13	CV109B	Num	8	8.	9b. Congestion, runny nose, sneezing
14	CV109C	Num	8	8.	9c. Acute upper respiratory tract infection
15	CV109D	Num	8	8.	9d. Chest discomfort
16	CV109E	Num	8	8.	9e. Chest pain
17	CV109F	Num	8	8.	9f. Bloating/gas
18	CV109G	Num	8	8.	9g. Acid reflux/GERD
19	CV109H	Num	8	8.	9h. Nausea
20	CV109I	Num	8	8.	9i. Diarrhea
21	CV109J	Num	8	8.	9j. Abdominal pain
22	CV109K	Num	8	8.	9k. Skin rashes
23	CV109L	Num	8	8.	9l. Muscle pain/aches
24	CV109M	Num	8	8.	9m. Other symptom #1
25	CV109N	Num	8	8.	9n. Other symptom #2
26	CV109O	Num	8	8.	9o. Other symptom #3
27	CV110	Num	8	8.	10. Are you pregnant
28	CV111	Num	8	8.	11. Currently using adequate birth control
29	CV112	Char	1	\$1.	12. Currently using CPAP machine
30	CV113_A	Char	1	\$1.	13a. Hypertension
31	CV113_B	Char	1	\$1.	13b. Pneumonia
32	CV113_C	Char	1	\$1.	13c. Bronchitis
33	CV113_D	Char	1	\$1.	13d. Strep throat
34	CV113_E	Char	1	\$1.	13e. Acute sinusitis
35	CV113_F	Char	1	\$1.	13f. Diabetes
36	CV113_G	Char	1	\$1.	13g. Other new diagnosis

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
37	CV113_H	Char	1	\$1.	13h. No new diagnosis
38	CV114A	Char	1	\$1.	14a. Have you experienced serious adverse event
39	CV114C	Num	8	8.	14c. Number of hospitalizations
40	CV115	Num	8	8.	15. How many times seen/contacted health care provider for asthma
41	CV116	Num	8	8.	16. How many times seen/contacted health care provider for upper airway symptoms
42	CV117	Char	1	\$1.	17. Other significant medical events/illnesses
43	CV118	Char	1	\$1.	18. Is this the final study visit
44	CV119A	Char	1	\$1.	19a. Exit letter
45	CV119B	Char	1	\$1.	19b. Final spirometry test results
46	CV119C	Char	1	\$1.	19c. Treatment unmasking
47	CV120	Char	1	\$1.	20. Drug returned



**Data Set Name: trim\_da1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Visit date (days from RZ)
3	VISITID	Char	12	\$12.	VisitID
4	DA106	Char	9	\$9.	Form version date
5	DA107	Char	1	\$1.	7. Was study drug dispensed
6	DA108	Char	48	\$48.	8. Why study drug not dispensed
7	DA109	Char	4	\$4.	9. Bottle ID
8	DA110	Char	4	\$4.	10. Tear off label from dispensed bottle
9	DA111	Num	8	7.	11. Expiration date
10	DA112_A	Char	1	\$1.	12a. Randomization (V2)
11	DA112_B	Char	1	\$1.	12b. Scheduled drug refill (V3-V6)
12	DA112_C	Char	1	\$1.	12c. Replacement of lost drug
13	DA112_D	Char	1	\$1.	12d. Other

**Data Set Name: trim\_dr1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Visit date (days from RZ)
3	VISITID	Char	12	\$12.	VisitID
4	DR106	Char	9	\$9.	Form version date
5	DR107	Char	4	\$4.	7. Bottle ID #1
6	DR108	Num	8	8.	8. Date bottle #1 dispensed
7	DR109	Num	8	8.	9. Number of tablets remaining
8	DR110	Char	4	\$4.	10. Bottle ID #2
9	DR111	Num	8	7.	11. Date bottle #2 dispensed
10	DR112	Num	8	8.	12. Number of tablets remaining
11	DR113	Num	8	8.	13. How often participant taking study drug
12	DR114	Num	8	8.	14. Participant took study drug
13	DR115_A	Char	1	\$1.	15a. Forgot to take study drug
14	DR115_B	Char	1	\$1.	15b. Forgot to escalate study drug
15	DR115_C	Char	1	\$1.	15c. Lost study drug
16	DR115_D	Char	1	\$1.	15d. Did not have study drug on hand
17	DR115_E	Char	1	\$1.	15e. Side effects
18	DR115_F	Char	1	\$1.	15f. Too busy
19	DR115_G	Char	1	\$1.	15g. Other

**Data Set Name: trim\_el1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date of randomization (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	EL106	Char	9	\$9.	Form version date
5	EL107	Char	1	\$1.	7. Evidence of 12% increase in FEV1
6	EL108	Char	1	\$1.	8. On asthma controller therapy
7	EL109	Char	1	\$1.	9. Participant signed consent
8	EL110	Char	1	\$1.	10. History bariatric surgery
9	EL111	Char	1	\$1.	11. Participation in investigational study
10	EL112	Char	1	\$1.	12. Use of theophylline
11	EL113	Char	1	\$1.	13. Use of roflumilast
12	EL114	Num	8	8.	14. Pregnant, lactating, or unwilling to use contraception
13	EL115	Char	1	\$1.	15. Physician diagnosed COPD
14	EL116	Char	1	\$1.	16. Diagnosis of liver cirrhosis
15	EL117	Char	1	\$1.	17. Current/former smoker
16	EL118A	Char	1	\$1.	18a. Rifadun (rifampicin)
17	EL118B	Char	1	\$1.	18b. Luminal (phenobarbital)
18	EL118C	Char	1	\$1.	18c. Carnexiv, Tegretol (carbamazepine)
19	EL118D	Char	1	\$1.	18d. Dilantin (phenytoin)
20	EL118E	Char	1	\$1.	18e. Ery-Tab (erythromycin)
21	EL118F	Char	1	\$1.	18f. Nizoral (ketoconazole)
22	EL118G	Char	1	\$1.	18g. Tagamet (cimetidine)
23	EL118H	Char	1	\$1.	18h. Luvox (fluvoxamine)
24	EL118I	Char	1	\$1.	18i. Penetrex (enoxacin)
25	EL118J	Char	1	\$1.	18j. Femodene (oral contraceptives containing ethinyl estradiol with gestodene)
26	EL118K	Char	1	\$1.	18k. Other (specify)
27	EL121	Char	1	\$1.	20. Major psychiatric disorders
28	EL122A	Num	8	8.	22a. Item 10 score from HQ form
29	EL122B	Char	1	\$1.	22b. Uncontrolled depression as defined by score of $\geq 15$ on PHQ-9
30	EL123A	Num	8	8.	23a. Item 9 score from HQ form
31	EL123B	Char	1	\$1.	23b. Suicidal ideation as defined by score $\geq 1$ on PHQ-9
32	EL124A	Num	8	8.	24a. Item 19 score from HQ form
33	EL124B	Char	1	\$1.	24b. Uncontrolled anxiety as defined by score of $\geq 10$ on GAD-7
34	EL125	Char	1	\$1.	25. Have conditions that puts him/her at risk from participating
35	EL126	Char	1	\$1.	26. Intention to move out of area within next 6 months
36	EL127A	Char	1	\$1.	27a. Blood specimens collected

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
37	EL127B	Char	1	\$1.	27b. Questionnaires completed
38	EL127D	Char	1	\$1.	27d. Pregnancy test administered
39	EL128	Char	1	\$1.	28. Participant meets all eligibility criteria
40	EL133	Num	8	8.	33. Date study physician signed

**Data Set Name: trim\_epac.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	TRTID	Char	40	\$40.	Treatment ID
3	TXASSIGN	Char	3	\$3.	Treatment Assignment Code
4	RES_PT	Num	8	8.	Indicator (1=at least once; 0=never) of increased rescue medication use
5	RES_EX	Num	8	8.	Number of times increased use of bronchodilator rescue medication was necessary
6	RES_DAYS	Num	8	8.	Days of follow up for increased rescue medication use outcome
7	PF_PT	Num	8	8.	Indicator (1=at least one; 0=none) of PEF exacerbation
8	PF_EX	Num	8	8.	Number PEF exacerbations for 2 consecutive days (i.e., yellow zone event)
9	PF_DAYS	Num	8	8.	Days of follow-up for peak flow outcome
10	ORAL_PT	Num	8	8.	Indicator (1=at least once; 0=never) of oral corticosteroid use
11	ORAL_EX	Num	8	8.	Number of times oral corticosteroid added to treat asthma
12	ORAL_DAYS	Num	8	8.	Days of follow up for oral corticosteroid use outcome
13	CARE_PT	Num	8	8.	Indicator (1=at least once; 0=never) of unscheduled contact with a health care provider
14	CARE_EX	Num	8	8.	Number of unscheduled contacts with health care provider for asthma symptoms
15	CARE_DAYS	Num	8	8.	Days of follow up for unscheduled contact outcome
16	AWK_PT	Num	8	8.	Indicator (1=at least once; 0=never) of sleep disturbance
17	AWK_EX	Num	8	8.	Number of times sleep disturbance occurred (awakened at night by asthma)
18	AWK_DAYS	Num	8	8.	Days of follow up for sleep disturbance outcome
19	ANY_PT	Num	8	8.	Indicator (1=at least once; 0=never) of poor asthma control
20	ANY_EX	Num	8	8.	Number of episodes of poor asthma control
21	ANY_DAYS	Num	8	8.	Days of follow up any for the above symptoms

**Data Set Name: trim\_ev1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	EV100F	Char	9	\$9.	Form version date
5	EV101_A	Char	1	\$1.	1a. To improve asthma
6	EV101_B	Char	1	\$1.	1b. To help lose weight
7	EV101_C	Char	1	\$1.	1c. Medical care
8	EV101_D	Char	1	\$1.	1d. Contribution to science
9	EV101_E	Char	1	\$1.	1e. Other
10	EV102	Num	8	8.	2. Rate experience in the study
11	EV103	Num	8	8.	3. Idea which study medication assigned
12	EV104	Char	1	\$1.	4. Want to continue with treatment
13	EV105	Num	8	8.	5. How asthma has changed
14	EV107_A	Char	1	\$1.	7a. Weight Watchers
15	EV107_B	Char	1	\$1.	7b. Jenny Craig
16	EV107_C	Char	1	\$1.	7c. DASH
17	EV107_D	Char	1	\$1.	7d. South Beach
18	EV107_E	Char	1	\$1.	7e. Calorie counting
19	EV107_F	Char	1	\$1.	7f. Atkins
20	EV107_G	Char	1	\$1.	7g. Paleo
21	EV107_H	Char	1	\$1.	7h. Other
22	EV107_I	Char	1	\$1.	7i. None of the above
23	EV108_A	Char	1	\$1.	8a. Nutrisystem
24	EV108_B	Char	1	\$1.	8b. Personal Trainer Food
25	EV108_C	Char	1	\$1.	8c. AdvCare
26	EV108_D	Char	1	\$1.	8d. Medifast
27	EV108_E	Char	1	\$1.	8e. HerbalLife
28	EV108_F	Char	1	\$1.	8f. Other
29	EV108_G	Char	1	\$1.	8g. None of the above
30	EV109	Char	1	\$1.	9. Joined a gym/health club
31	EV110	Char	1	\$1.	10. Used MyFitnessPal
32	EV111	Char	1	\$1.	11. Used an activity monitor
33	EV112	Char	1	\$1.	12. Was it helpful
34	EV113	Char	1	\$1.	13. Did you lose weight
35	EV114	Char	1	\$1.	14. If you lost weight, was it as much as you hoped
36	EV116	Num	8	8.	16. Would recommend this program

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
37	EV118A	Char	1	\$1.	18a. Exit letter for participant
38	EV118B	Char	1	\$1.	18b. Exit letter for physician
39	EV118C	Char	1	\$1.	18c. Unmasking envelope
40	EV119	Num	8	8.	19. Date reviewed
41	EV122	Num	8	8.	22. Who administered the questionnaire
42	EV123_A	Char	1	\$1.	23a. Participant (self-administered)
43	EV123_B	Char	1	\$1.	23b. Other

**Data Set Name: trim\_gsrs.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITID	Char	2	\$2.	Visit ID
3	GS101	Num	8	8.	1. Bothered by pain/discomfort in upper abdomen/pit of stomach
4	GS102	Num	8	8.	2. Bothered by heartburn
5	GS103	Num	8	8.	3. Bothered by acid reflux
6	GS104	Num	8	8.	4. Bothered by hunger pains in stomach
7	GS105	Num	8	8.	5. Bothered by nausea
8	GS106	Num	8	8.	6. Bothered by rumbling in your stomach
9	GS107	Num	8	8.	7. Has stomach felt bloated
10	GS108	Num	8	8.	8. Bothered by burping
11	GS109	Num	8	8.	9. Bothered by passing gas/flatus
12	GS110	Num	8	8.	10. Bothered by constipation
13	GS111	Num	8	8.	11. Bothered by diarrhea
14	GS112	Num	8	8.	12. Bothered by loose stools
15	GS113	Num	8	8.	13. Bothered by hard stools
16	GS114	Num	8	8.	14. Bothered by an urgent need to have a bowel movement
17	GS115	Num	8	8.	15. Have you had the sensation of not completely emptying your bowels
18	GSRS	Num	8	8.	Total score GSRS



**Data Set Name: trim\_mc1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date of methacholine challenge (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	MC106	Char	9	\$9.	Form version date
5	MC107	Char	1	\$1.	7. Complete MCT Worksheet
6	MC108	Num	8	8.	8. Pre-diluent FEV1
7	MC109	Char	1	\$1.	9. Was spirometry maneuver acceptable/reproducible
8	MC110	Char	1	\$1.	10. Is pre-diluent FEV1 < 1.5 liters
9	MC111	Num	8	8.	11. Pre-diluent FVC
10	MC112	Num	8	8.	12. Predicted FEV1
11	MC113	Num	8	8.	13. Pre-diluent FEV1 predicted < 60%
12	MC114	Char	1	\$1.	14. Is pre-diluent FEV1 % predicted < 60%
13	MC115	Char	1	\$1.	15. Was spirometry maneuver acceptable/reproducible
14	MC116	Num	8	8.	16. Post-diluent FEV1
15	MC117	Num	8	8.	17. Post-diluent FVC
16	MC118	Char	1	\$1.	18. Is post-diluent FEV1 <= 80% of pre-diluent FEV1
17	MC119	Num	8	8.	19. Target FEV1
18	MC120B	Char	7	\$7.	20b. Vial J - Dose
19	MC120C	Num	8	8.	20c. Vial J - FEV1
20	MC120D	Num	8	8.	20d. Vial J - FVC
21	MC120E	Num	8	8.	20e. Vial J - Column c <= target FEV1
22	MC121B	Char	6	\$6.	21b. Vial I - Dose
23	MC121C	Num	8	8.	21c. Vial I - FEV1
24	MC121D	Num	8	8.	21d. Vial I - FVC
25	MC121E	Num	8	8.	21e. Vial I - Column c <= target FEV1
26	MC122B	Char	5	\$5.	22b. Vial H - Dose
27	MC122C	Num	8	8.	22c. Vial H - FEV1
28	MC122D	Num	8	8.	22d. Vial H - FVC
29	MC122E	Num	8	8.	22e. Vial H - Column c <= target FEV1
30	MC123B	Char	4	\$4.	23b. Vial G - Dose
31	MC123C	Num	8	8.	23c. Vial G - FEV1
32	MC123D	Num	8	8.	23d. Vial G - FVC
33	MC123E	Num	8	8.	23e. Vial G - Column c <= target FEV1
34	MC124B	Char	3	\$3.	24b. Vial F - Dose
35	MC124C	Num	8	8.	24c. Vial F - FEV1
36	MC124D	Num	8	8.	24d. Vial F - FVC

Num	Variable	Type	Len	Format	Label
37	MC124E	Num	8	8.	24e. Vial F - Column c <= target FEV1
38	MC125B	Char	3	\$3.	25b. Vial E - Dose
39	MC125C	Num	8	8.	25c. Vial E - FEV1
40	MC125D	Num	8	8.	25d. Vial E - FVC
41	MC125E	Num	8	8.	25e. Vial E - Column c <= target FEV1
42	MC126B	Char	3	\$3.	26b. Vial D - Dose
43	MC126C	Num	8	8.	26c. Vial D - FEV1
44	MC126D	Num	8	8.	26d. Vial D - FVC
45	MC126E	Num	8	8.	26e. Vial D - Column c <= target FEV1
46	MC127B	Char	3	\$3.	27b. Vial C - Dose
47	MC127C	Num	8	8.	27c. Vial C - FEV1
48	MC127D	Num	8	8.	27d. Vial C - FVC
49	MC127E	Num	8	8.	27e. Vial C - Column c <= target FEV1
50	MC131	Char	1	\$1.	31. Is vial C FEV1 >= 90% pre-diluent FEV1
51	MC132	Num	8	8.	32. Post-BD FEV1
52	MC133	Num	8	8.	33. Post-BD FVC
53	MC134	Char	1	\$1.	34. Is post-BD FEV1 >= 90% pre-diluent FEV1
54	MC135	Num	8	8.	35. 2nd Post-BD FEV1
55	MC136	Num	8	8.	36. 2nd Post-BD FVC
56	MC137	Char	1	\$1.	37. Is 2nd Post-BD FEV1 >= 90% pre-diluent FEV1
57	MC138	Char	1	\$1.	38. Experienced any complications of the MCT
58	MC140	Char	1	\$1.	40. FEV1 <= target FEV1
59	MC141	Num	8	8.	41. PD20 FEV1

**Data Set Name: trim\_md1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date form completed (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	MD106	Char	9	\$9.	Form version date
5	MD107	Char	1	\$1.	7. Was visit missed completely
6	MD108_A	Char	1	\$1.	8a. Biospecimen Collection
7	MD108_B	Char	1	\$1.	8b. Clinic Visit
8	MD108_C	Char	1	\$1.	8c. Drug Dispensing
9	MD108_D	Char	1	\$1.	8d. Drug Return/Capsule Count
10	MD108_E	Char	1	\$1.	8e. Methacholine Challenge
11	MD108_F	Char	1	\$1.	8f. Physical Exam
12	MD108_G	Char	1	\$1.	8g. Physical Measurements
13	MD108_H	Char	1	\$1.	8h. Pulmonary Function
14	MD108_I	Char	1	\$1.	8i. Study Evaluation
15	MD108_J	Char	1	\$1.	8j. Treatment Termination
16	MD108_K	Char	1	\$1.	8k. Unmasking
17	MD108_L	Char	1	\$1.	8l. Other
18	MD108_M	Char	1	\$1.	8m. N/A, no forms missed
19	MD109_A	Char	1	\$1.	9a. Asthma Control Test
20	MD109_B	Char	1	\$1.	9b. Asthma Symptom Utility Index
21	MD109_C	Char	1	\$1.	9c. Gastrointestinal Symptom Rating Scale
22	MD109_D	Char	1	\$1.	9d. Marks Quality of Life Questionnaire
23	MD109_E	Char	1	\$1.	9e. Patient Health Questionnaire
24	MD109_F	Char	1	\$1.	9f. Quality of Life by RAND Health
25	MD109_G	Char	1	\$1.	9g. Other
26	MD109_H	Char	1	\$1.	9h. N/A, no questionnaires missed
27	MD110	Char	1	\$1.	10. Any Asthma Diary Cards missing
28	MD111A	Num	8	8.	11a. First interval - Start date
29	MD111B	Num	8	8.	11b. First interval - End date
30	MD112A	Num	8	8.	12a. First interval - Start date
31	MD112B	Num	8	8.	12b. First interval - End date
32	MD113_A	Char	1	\$1.	13a. Participant ill
33	MD113_B	Char	1	\$1.	13b. Participant was temporarily away
34	MD113_C	Char	1	\$1.	13c. Participant has permanently moved
35	MD113_D	Char	1	\$1.	13d. Participant refused
36	MD113_E	Char	1	\$1.	13e. Unable to contact participant

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
37	MD113_F	Char	1	\$1.	13f. Participant forgot
38	MD113_G	Char	1	\$1.	13g. Problem at facility
39	MD113_H	Char	1	\$1.	13h. Other

**Data Set Name: trim\_mqlq.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITID	Char	2	\$2.	Visit ID
3	MQ101	Num	8	8.	1. Troubled by episodes of shortness of breath
4	MQ102	Num	8	8.	2. Troubled by wheezing
5	MQ103	Num	8	8.	3. Troubled by tightness in chest
6	MQ104	Num	8	8.	4. Restricted walking/doing light housework
7	MQ105	Num	8	8.	5. Restricted walking up hills/doing heavy housework
8	MQ106	Num	8	8.	6. Felt tired or general lack of energy
9	MQ107	Num	8	8.	7. Unable to sleep at night
10	MQ108	Num	8	8.	8. Felt sad or depressed
11	MQ109	Num	8	8.	9. Felt frustrated with myself
12	MQ110	Num	8	8.	10. Felt anxious, under tension or stressed
13	MQ111	Num	8	8.	11. Felt asthma is preventing me from achieving what I want
14	MQ112	Num	8	8.	12. Asthma/shortness of breath interfered with social life
15	MQ113	Num	8	8.	13. Been limited in going places because bad for asthma
16	MQ114	Num	8	8.	14. Been limited in going places because afraid of asthma attack
17	MQ115	Num	8	8.	15. Been restricted in sports/hobbies/other recreations because of asthma
18	MQ116	Num	8	8.	16. Have felt generally restricted
19	MQ117	Num	8	8.	17. Have felt asthma is controlling my life
20	MQ118	Num	8	8.	18. Been worried about my present/future health because of asthma
21	MQ119	Num	8	8.	19. Been worried about asthma shortening my life
22	MQ120	Num	8	8.	20. Felt dependent on my asthma inhalers
23	MQLQ	Num	8	8.	Total score MQLQ

**Data Set Name: trim\_pd1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date deviation reported (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	PD106	Char	9	\$9.	Form version date
5	PD101A	Char	1	\$1.	Does event affect a single participant
6	SEQN	Num	8	8.	7. Sequence number
7	PD108	Char	1	\$1.	8. Did event involve multiple participants
8	PD109	Num	8	8.	9. Date of deviation
9	PD110	Num	8	8.	10. Type of deviation
10	PD111	Char	1	\$1.	11. Did protocol deviation place participant at greater risk
11	PD112	Char	1	\$1.	12. Was event unexpected
12	PD113	Num	8	8.	13. Was event related to research study
13	PD114	Char	1	\$1.	14. Does protocol deviation require reporting as UP
14	PD117A	Num	8	8.	17a. Date of current status
15	PD118	Char	1	\$1.	18. Is event IRB reportable
16	PD119	Num	8	8.	19. Date reported to IRB

**Data Set Name: trim\_pe1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date of exam (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	PE106	Char	9	\$9.	Form version date
5	PE107A	Num	8	8.	7a. Systolic blood pressure
6	PE107B	Num	8	8.	7b. Diastolic blood pressure
7	PE108	Num	8	8.	8. Heart rate
8	PE109	Num	8	8.	9. Temperature
9	PE109U	Num	8	8.	9. Celsius or fahrenheit
10	PE110	Num	8	8.	10. Respiration rate
11	PE111	Num	8	8.	11. General appearance
12	PE112	Num	8	8.	12. Chest
13	PE113	Num	8	8.	13. Heart
14	PE114	Num	8	8.	14. HEENT/Neck
15	PE115	Num	8	8.	15. Respiratory
16	PE116	Num	8	8.	16. Abdomen
17	PE117	Num	8	8.	17. Extremities
18	PE118	Num	8	8.	18. Skin
19	PE119	Num	8	8.	19. Neurological
20	PE120	Num	8	8.	20. Other
21	PE121	Char	1	\$1.	21. Examiner TRIM certified
22	PE123	Char	3	\$3.	23. Study physician PIN
23	PE124	Char	1	\$1.	24. Study physician signature

**Data Set Name: trim\_pf1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date completed (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	PF106	Char	9	\$9.	Form version date
5	PF107	Num	8	8.	7. Predominant ethnicity
6	PF108A	Char	1	\$1.	8a. Taken short-acting bronchodilator
7	PF108B	Char	1	\$1.	8b. Taken long-acting bronchodilator
8	PF109	Num	8	8.	9. Peak flow measurement
9	PF110	Char	7	\$7.	10. Start time
10	PF110U	Num	8	8.	10. AM or PM
11	PF111	Num	8	8.	11. Pre-BD FVC
12	PF112	Num	8	8.	12. Pre-BD FEV1
13	PF113	Num	8	8.	13. Predicted FEV1
14	PF114	Num	8	8.	14. Percent predicted pre-BD FEV1
15	PF115	Char	1	\$1.	15. Was post-BD testing done
16	PF116	Num	8	8.	16. Post-BD FVC
17	PF117	Num	8	8.	17. Post-BD FEV1
18	PF118	Num	8	8.	18. Percent predicted post-BD FEV1
19	PF119	Num	8	8.	19. Percent reversibility
20	PF121	Char	3	\$3.	21. Examiner PIN



**Data Set Name: trim\_phq.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITID	Char	2	\$2.	Visit ID
3	PHQ9	Num	8	8.	Total score PHQ-9
4	GAD7	Num	8	8.	Total score GAD-7
5	HQ101	Num	8		1. Little interest/pleasure in doing things
6	HQ102	Num	8		2. Feeling down, depressed, or hopeless
7	HQ103	Num	8		3. Trouble falling/staying asleep or sleeping too much
8	HQ104	Num	8		4. Feeling tired or having little energy
9	HQ105	Num	8		5. Poor appetite or overeating
10	HQ106	Num	8		6. Feeling bad about yourself, that you are a failure or have let yourself/family down
11	HQ107	Num	8		7. Trouble concentrating on things, such as reading the newspaper/watching television
12	HQ108	Num	8		8. Moving/speaking so slowly other people notice or being so fidgety/restless that you move around more than usual
13	HQ109	Num	8		9. Thoughts you would be better off dead or hurting yourself in some way
14	HQ112	Num	8		12. Feeling nervous, anxious or on edge
15	HQ113	Num	8		13. Not being able to stop or control worrying
16	HQ114	Num	8		14. Worrying too much about different things
17	HQ115	Num	8		15. Trouble relaxing
18	HQ116	Num	8		16. Being so restless that it is hard to sit still
19	HQ117	Num	8		17. Becoming easily annoyed or irritable
20	HQ118	Num	8		18. Feeling afraid as if something awful might happen

**Data Set Name: trim\_pm1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date of exam (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	PM106	Char	9	\$9.	Form version date
5	BMI	Num	8	4.1	Body Mass Index
6	PM108A	Num	8	8.	8a. Weight in pounds
7	PM108B	Num	8	8.	8b. Weight in kilograms
8	PM109A	Num	8	8.	9a. Hip circumference in inches
9	PM109B	Num	8	8.	9b. Hip circumference in centimeters
10	PM110A	Num	8	8.	10a. Waist circumference in inches
11	PM110B	Num	8	8.	10b. Waist circumference in centimeters
12	PM111A	Num	8	8.	11a. Systolic blood pressure
13	PM111B	Num	8	8.	11b. Diastolic blood pressure
14	PM111C	Num	8	8.	11c. Heart rate
15	PM111D	Num	8	8.	11d. Arm used for blood pressure

**Data Set Name: trim\_sc1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date of exam (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	SC106	Char	9	\$9.	Form version date
5	SC107	Char	1	\$1.	7. Participant signed consent
6	SC108	Num	8	8.	8. Age at screening
7	SC109	Char	1	\$1.	9. 18 years or older
8	SC110	Char	1	\$1.	10. Physician diagnosed asthma
9	SC111	Char	1	\$1.	11. On controller therapy for asthma
10	SC112A	Num	8	8.	12a. BMI
11	SC112B	Char	1	\$1.	12b. BMI greater than 30
12	SC113A	Char	1	\$1.	13a. Asthma Control Test score less than 20
13	SC113B	Char	1	\$1.	13b. Use of rescue inhaler > 2 times per week
14	SC113C	Char	1	\$1.	13c. Nocturnal asthma awakening 1 or more times per week
15	SC113D	Char	1	\$1.	13d. ED/hospital visit for asthma
16	SC113E	Char	1	\$1.	13e. Prednisine course for asthma
17	SC114	Char	1	\$1.	14. More than one checked 'yes' in item 13
18	SC115	Char	1	\$1.	15. History of bariatric surgery
19	SC116	Char	1	\$1.	16. Participation in investigational study
20	SC117	Char	1	\$1.	17. Use of theophylline
21	SC118	Char	1	\$1.	18. Use of roflumilast
22	SC119	Num	8	8.	19. Currently pregnant/lactating/unwilling to use contraception
23	SC120	Char	1	\$1.	20. Physician diagnosed COPD
24	SC121	Char	1	\$1.	21. Diagnosis of liver cirrhosis
25	SC122	Char	1	\$1.	22. Current or former smoker
26	SC123A	Char	1	\$1.	23a. Rifampicin
27	SC123B	Char	1	\$1.	23b. Phenobarbital
28	SC123C	Char	1	\$1.	23c. Carbamazepine
29	SC123D	Char	1	\$1.	23d. Phenytoin
30	SC123E	Char	1	\$1.	23e. Erythromycin
31	SC123F	Char	1	\$1.	23f. Ketoconazole
32	SC123G	Char	1	\$1.	23g. Cimetidine
33	SC123H	Char	1	\$1.	23h. Fluvoxamine
34	SC123I	Char	1	\$1.	23i. Enoxacin
35	SC123J	Char	1	\$1.	23j. Oral contraceptives
36	SC123K	Char	1	\$1.	23k. Other

Num	Variable	Type	Len	Format	Label
37	SC124A	Num	8	8.	24a. Counts of illegal drug use
38	SC124B	Char	1	\$1.	24b. Number greater than 0
39	SC125A	Num	8	8.	25a. Counts of cannabis use
40	SC125B	Char	1	\$1.	25b. Number greater than 0
41	SC126	Char	1	\$1.	26. Major psychiatric disorder
42	SC127A	Num	8	8.	27a. Item 10 score from HQ form
43	SC127B	Char	1	\$1.	27b. Uncontrolled depression
44	SC128A	Num	8	8.	28a. Item 9 score from HQ form
45	SC128B	Char	1	\$1.	28b. Suicidal ideation
46	SC129A	Num	8	8.	29a. Item 19 score from HQ form
47	SC129B	Char	1	\$1.	29b. Uncontrolled anxiety
48	SC130	Char	1	\$1.	30. Participant have any conditions that puts him/her at risk
49	SC131	Char	1	\$1.	31. Intention to move out of area
50	SC132A	Num	8	8.	32a. Peak flow #1
51	SC132B	Num	8	8.	32b. Peak flow #2
52	SC132C	Num	8	8.	32c. Peak flow #3
53	SC133	Char	1	\$1.	33. Participant is eligible
54	SC134	Char	1	\$1.	34. Participant is enrolled

**Data Set Name: trim\_sf36.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITID	Char	2	\$2.	Visit ID
3	SF101	Num	8	8.	1. In general, your health is
4	SF102	Num	8	8.	2. Compared to one year ago, how would rate your health
5	SF103	Num	8	8.	3. Health limit you, vigorous activities
6	SF104	Num	8	8.	4. Health limit you, moderate activities
7	SF105	Num	8	8.	5. Health limit you, lifting/carrying groceries
8	SF106	Num	8	8.	6. Health limit you, climbing several flights of stairs
9	SF107	Num	8	8.	7. Health limit you, climbing one flight of stairs
10	SF108	Num	8	8.	8. Health limit you, bending, kneeling, or stooping
11	SF109	Num	8	8.	9. Health limit you, walking more than a mile
12	SF110	Num	8	8.	10. Health limit you, walking several blocks
13	SF111	Num	8	8.	11. Health limit you, walking one block
14	SF112	Num	8	8.	12. Health limit you, bathing or dressing yourself
15	SF120	Num	8	8.	20. Physical health/emotional problems, interfered with normal social activities
16	SF121	Num	8	8.	21. How much bodily pain have you had
17	SF122	Num	8	8.	22. How much did pain interfere with your normal work
18	SF123	Num	8	8.	23. Did you feel full of pep
19	SF124	Num	8	8.	24. Have you been a very nervous person
20	SF125	Num	8	8.	25. Have you felt so down in the dumps that nothing could cheer you up
21	SF126	Num	8	8.	26. Have you felt calm and peaceful
22	SF127	Num	8	8.	27. Did you have lots of energy
23	SF128	Num	8	8.	28. Have you felt downhearted and blue
24	SF129	Num	8	8.	29. Did you feel worn out
25	SF130	Num	8	8.	30. Have you been a happy person
26	SF131	Num	8	8.	31. Did you feel tired
27	SF132	Num	8	8.	32. How much of the time has your physical health/emotional problems interfered with social activities
28	SF133	Num	8	8.	33. I seem to get sick a little easier than other people
29	SF134	Num	8	8.	34. I am as healthy as anybody I know
30	SF135	Num	8	8.	35. I expect my health to get worse
31	SF136	Num	8	8.	36. My health is excellent
32	SF36	Num	8	8.	Total score sf36

**Data Set Name: trim\_sr1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date event reported to site (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	SR106	Char	9	\$9.	Form version date
5	SEQN	Num	8	8.	Sequential number of this SR form
6	SR108	Num	8	8.	8. Age
7	SR109	Num	8	8.	9. Sex (1=Male, 2=Female)
8	SR112	Num	8	8.	12. Date of event onset
9	SR113	Char	50	\$50.	13. Event
10	SR114_A	Char	1	\$1.	14a. Death
11	SR114_B	Char	1	\$1.	14b. Life threatening event
12	SR114_C	Char	1	\$1.	14c. Medically significant, requiring hospitalization
13	SR114_D	Char	1	\$1.	14d. Severely or permanently disabling
14	SR114_E	Char	1	\$1.	14e. Event requiring medical/surgical intervention
15	SR114_F	Char	1	\$1.	14f. Congenital anomaly
16	SR114_G	Char	1	\$1.	14g. Event requiring medical/surgical intervention
17	SR114_H	Char	1	\$1.	14h. Other
18	SR115	Char	1	\$1.	15. Was adverse event unexpected
19	SR116	Num	8	8.	16. Relationship of adverse event to study
20	SR117_A	Char	1	\$1.	17a. Cardiovascular
21	SR117_B	Char	1	\$1.	17b. Dermatological
22	SR117_C	Char	1	\$1.	17c. Gastrointestinal
23	SR117_D	Char	1	\$1.	17d. Hematological
24	SR117_E	Char	1	\$1.	17e. Metabolic
25	SR117_F	Char	1	\$1.	17f. Musculoskeletal
26	SR117_G	Char	1	\$1.	17g. Neurological
27	SR117_H	Char	1	\$1.	17h. Psychological
28	SR117_I	Char	1	\$1.	17i. Pulmonary/respiratory
29	SR117_J	Char	1	\$1.	17j. Renal/urologic
30	SR117_K	Char	1	\$1.	17k. Hepatobiliary
31	SR117_L	Char	1	\$1.	17l. Other
32	SR118_A	Char	1	\$1.	18a. None
33	SR118_B	Char	1	\$1.	18b. Hospitalization/prolonged hospitalization
34	SR118_C	Char	1	\$1.	18c. Remedial therapy: non-pharmacological
35	SR118_D	Char	1	\$1.	18d. Remedial therapy: pharmacological
36	SR118_E	Char	1	\$1.	18e. Study exit

Num	Variable	Type	Len	Format	Label
37	SR119A	Char	1	\$1.	19a. Was participant hospitalized
38	SR119C	Num	8	8.	19c. Date admitted
39	NSR119D	Num	8	8.	19d. Date discharged
40	SR120	Num	8	8.	20. Current status of the adverse event
41	SR121A	Num	8	8.	21a. Date of death
42	SR122	Num	8	8.	22. Date resolved
43	SR123	Char	3	\$3.	23. PI PIN
44	SR124	Char	1	\$1.	24. PI signature
45	SR125	Num	8	8.	25. Date signed
46	SR130A	Num	8	8.	30a. Follow-up #1 - Date of current status

**Data Set Name: trim\_tt1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	VISITDATE	Num	8	7.	Date completed (days from RZ)
3	VISITID	Char	4	\$4.	VisitID
4	TT106	Char	9	\$9.	Form version date
5	TT107	Num	8	8.	7. Type of termination
6	TT108	Char	9	\$9.	8. Date study drug last taken
7	TT109	Num	8	8.	9. Last dose taken
8	TT110_A	Char	1	\$1.	10a. Participant completed study
9	TT110_B	Char	1	\$1.	10b. Adverse event
10	TT110_C	Char	1	\$1.	10c. Participant unable to tolerate
11	TT110_D	Char	1	\$1.	10d. Participant request
12	TT110_E	Char	1	\$1.	10e. Lost to follow-up
13	TT110_F	Char	1	\$1.	10f. Other
14	TT111	Char	1	\$1.	11. Was study drug collected from participant
15	TT112	Char	95	\$95.	12. Why drug was not returned and plan to retrieve drug



*Data Set Name: trim\_txcodes.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	TRTID	Char	40	\$40.	Treatment ID

**Data Set Name: trim\_up1.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ID	Char	7	\$7.	Participant ID
2	UP101A	Char	1	\$1.	Does event affect a single participant
3	VISITDATE	Num	8	7.	Date deviation reported or identified by site (days from RZ)
4	VISITID	Char	4	\$4.	VisitID
5	UP106	Char	9	\$9.	Form version date
6	SEQN	Num	8	8.	7. Sequential number of this UP report
7	UP108	Char	1	\$1.	8. Did event involve multiple participants
8	UP109	Char	55	\$55.	9. Event
9	UP110	Num	8	9.	10. Date of onset for event/unanticipated problem
10	UP111_A	Char	1	\$1.	11a. Protocol deviation
11	UP111_B	Char	1	\$1.	11b. Noncompliance
12	UP111_C	Char	1	\$1.	11c. Unanticipated medical problem
13	UP111_D	Char	1	\$1.	11d. Other
14	UP112	Num	8	9.	12. Status id event
15	UP113	Num	8	9.	13. Date resolved
16	UP114_A	Char	1	\$1.	14a. Cardiovascular
17	UP114_B	Char	1	\$1.	14b. Dermatological
18	UP114_C	Char	1	\$1.	14c. Gastrointestinal
19	UP114_D	Char	1	\$1.	14d. Hematological
20	UP114_E	Char	1	\$1.	14e. Metabolic
21	UP114_F	Char	1	\$1.	14f. Musculoskeletal
22	UP114_G	Char	1	\$1.	14g. Neurological
23	UP114_H	Char	1	\$1.	14h. Psychological
24	UP114_I	Char	1	\$1.	14i. Pulmonary/Respiratory
25	UP114_J	Char	1	\$1.	14j. Renal/Urologic
26	UP114_K	Char	1	\$1.	14k. Hepatobiliary
27	UP114_L	Char	1	\$1.	14l. Other
28	UP114_M	Char	1	\$1.	14m. None/Not applicable
29	UP115	Char	1	\$1.	15. Did/does event place participant(s) at greater risk
30	UP116	Char	1	\$1.	16. Was event unexpected
31	UP117	Num	8	8.	17. Was event related to study
32	UP118	Char	3	\$3.	18. PI PIN
33	UP119	Char	1	\$1.	19. PI signature
34	UP120	Num	8	9.	20. Date of signature
35	UP125A	Num	8	9.	25a. Date corrective action plan implemented
36	UP126A	Num	8	9.	26a. Follow-up #1 - Date of current status

Num	Variable	Type	Len	Format	Label
37	UP127A	Num	8	9.	27a. Follow-up #2 - Date of current status