

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

Num	Variable	Type	Len	Format	Label
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