

**Data Set Name: adverseevent.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ReportType	Char	9	\$9.	AE Report Type
2	Eventabateafterstoppingdrug	Char	14	\$14.	Did the eventreaction abate after stopping drug
3	EventReappearAfterReintro	Char	14	\$14.	Did the eventreaction reappear after reintroduction
4	AEPrimarySecondary1	Char	9	\$9.	Is this event a primary or secondary event
5	TreatmentLocationOther	Char	108	\$108.	AE Treatment Location Other
6	ElectronicSignature	Char	1	\$1.	Electronic Signature
7	Category	Char	35	\$35.	Category
8	CausalityByReporter	Char	22	\$22.	Causality by reporter
9	ReasonForFollowup	Char	55	\$55.	AE Reason for followup
10	TreatmentLocation	Char	14	\$14.	Adverse Event Treatment Location
11	AEEExpected1	Char	3	\$3.	Expected
12	AEPatientOutcome1	Char	35	\$35.	Patient Outcome
13	FollowUpInstanceNumber	Num	8		AE Followup instance number
14	InitialAEID	Num	8		AE Initial AEID
15	Other	Num	8		Adverse Event Other
16	PrimaryAEID	Num	8		If this is a secondary event please enter primary adverse event ID
17	ReporterStaffCode	Num	8		AE Reporter Staff Code
18	SelectTerm	Num	8	ALLFMT.	AE Select Term
19	SupraOrdinateTerm	Num	8	ALLFMT.	Adverse Event SupraOrdinate Term sub category
20	Assoc_Death	Num	8		AEAssociations: Death
21	Assoc_DevBirthDefect	Num	8		AEAssociations: Development of a congenital anomaly or birth defect
22	Assoc_DevPermntSeriousCondition	Num	8		AEAssociations: Development of a permanent/ serious/ disabling /incapacitating condition
23	Assoc_Hospital_ProlongedHospital	Num	8		AEAssociations: Hospitalization or prolonged hospitalization
24	Assoc_AnotherCondnRepSHazards	Num	8		AEAssociations: Is another condition which investigators judge to represent significant hazards
25	Assoc_Lifethreatening	Num	8		AEAssociations: Life threatening
26	severity_index	Num	8		
27	Serious	Char	10		Serious
28	AEID	Num	8		
29	MaskID	Num	8		Participant Mask ID#
30	Visit	Char	100		Visit
31	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
32	Date_at_Death	Num	8	MMDDYY10.	Date at Death
33	Date_at_FollowUp	Num	8	MMDDYY10.	Date at Follow-Up
34	Date_at_Occurence	Num	8	MMDDYY10.	Date at Occurence
35	Date_at_Report	Num	8	MMDDYY10.	Date at Report

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
36	Date_Resolved	Num	8	MMDDYY10.	Date Resolved
37	Date_Study_Drug_Started1	Num	8	MMDDYY10.	Date Study Drug Started #1
38	Date_Study_Drug_Started2	Num	8	MMDDYY10.	Date Study Drug Started #2
39	Date_Study_Drug_Started3	Num	8	MMDDYY10.	Date Study Drug Started #3
40	Date_Study_Drug_Started4	Num	8	MMDDYY10.	Date Study Drug Started #4
41	Date_Study_Drug_Started5	Num	8	MMDDYY10.	Date Study Drug Started #5
42	Date_Study_Drug_Stopped1	Num	8	MMDDYY10.	Date Study Drug Stopped #1
43	Date_Study_Drug_Stopped2	Num	8	MMDDYY10.	Date Study Drug Stopped #2
44	Date_Study_Drug_Stopped3	Num	8	MMDDYY10.	Date Study Drug Stopped #3
45	Date_Study_Drug_Stopped4	Num	8	MMDDYY10.	Date Study Drug Stopped #4
46	Date_Study_Drug_Stopped5	Num	8	MMDDYY10.	Date Study Drug Stopped #5

**Data Set Name: aereview.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	AEAdditionalInfoRequested	Char	3	\$3.	AE Additional information requested
2	AEReviewPriorSimilarSAEs	Char	3	\$3.	AE Review Have there been prior occurrences of similar SAEs reported in this study
3	AEReviewReportingTimeframe	Char	27	\$27.	AE Review Reporting time frame to regulatory authorities
4	AEReviewTreatmentUnblindedForC	Char	2	\$2.	AE Review Does treatment need to be unblinded for determination of causality
5	AEAdditionalInfoRequestedDetail	Char	499	\$499.	AE Additional information requested details
6	AEReviewDSMBReviewComments	Char	1	\$1.	AE Review Requires DSMB Review Comments
7	AEReviewFormComments	Char	341	\$341.	Adverse Event Review Form Comments
8	AEReviewPriorSimilarSAEsSummary	Char	160	\$160.	AE Review If prior occurrences of similar SAEs provide brief summary
9	AECausalityByReviewer	Char	22	\$22.	Causality by reviewer
10	AEPatientOutcome	Char	1	\$1.	Patient Outcome
11	RecommendConsentChange	Char	3	\$3.	Recommend changes to the consent form
12	RecommendProtocolChange	Char	2	\$2.	Recommend changes to the protocol
13	AEReviewRequireDSMBReview	Num	8		AE Review Requires urgent and immediate review by full DSMB committee
14	AEID	Num	8		AEID
15	MaskID	Num	8		Participant Mask ID#
16	Visit	Char	100		Visit
17	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: cbc\_wdiff\_results.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	BasophilsResultAbormalClinical	Char	2	\$2.	Basophils results abnormal clinically significant
2	BasophilsResultsNormal	Char	3	\$3.	Basophils results normal
3	EosinophilsResultAbormalClinic	Char	3	\$3.	Eosinophils results abnormal clinically significant
4	EosinophilsResultsNormal	Char	3	\$3.	Eosinophils results normal
5	HematocritResultAbormalClinica	Char	3	\$3.	Hematocrit results abnormal clinically significant
6	HematocritResultsNormal	Char	3	\$3.	Hematocrit results normal
7	HemoglobinResultAbormalClinica	Char	3	\$3.	Hemoglobin results abnormal clinically significant
8	HemoglobinResultsNormal	Char	3	\$3.	Hemoglobin Results Normal
9	LymphocytesResultAbormalClinic	Char	3	\$3.	Lymphocytes results abnormal clinically significant
10	LymphocytesResultsNormal	Char	3	\$3.	Lymphocytes results normal
11	MCHCResultAbormalClinicallySig	Char	3	\$3.	MCHC results abnormal clinically significant
12	MCHCresultsNormal	Char	3	\$3.	MCHC results normal
13	MCHResultAbormalClinicallySign	Char	3	\$3.	MCH results abnormal clinically significant
14	MCHresultsNormal	Char	3	\$3.	MCH results normal
15	MCVResultAbormalClinicallySign	Char	3	\$3.	MCV results abnormal clinically significant
16	MCVresultsNormal	Char	3	\$3.	MCV results normal
17	MonocytesResultAbormalClinical	Char	3	\$3.	Monocytes results abnormal clinically significant
18	MonocytesResultsNormal	Char	3	\$3.	Monocytes results normal
19	PMNLeukocytesResultAbormalClin	Char	3	\$3.	PMN leukocytes results abnormal clinically significant
20	PMNleukocytesResultsNormal	Char	3	\$3.	PMN leukocytes results normal
21	PlateletCountResultAbormalClin	Char	3	\$3.	Platelet count results abnormal clinically significant
22	PlateletCountResultsNormal2	Char	3	\$3.	Platelet count results normal
23	RBCResultAbormalClinicallySign	Char	3	\$3.	RBC results abnormal clinically significant
24	RBCResultsNormal	Char	3	\$3.	RBC results normal
25	WBCResultAbormalClinicallySign	Char	3	\$3.	WBC results abnormal clinically significant
26	WBCresultsNormal	Char	3	\$3.	WBC results normal
27	BasophilsNotDone	Num	8		Basophils Not Done
28	EosinophilsNotDone	Num	8		Eosinophils Not Done
29	HematocritNotDone	Num	8		Hematocrit Not Done
30	HemoglobinNotDone	Num	8		Hemoglobin Not Done
31	LymphocytesNotDone	Num	8		Lymphocytes Not Done
32	MCHCNotDone	Num	8		MCHC count Not Done
33	MCHNotDone	Num	8		MCH count Not Done
34	MCVNotDone	Num	8		MCV Not Done
35	MonocytesNotDone	Num	8		Monocytes Not Done
36	PMNLeukocytesNotDone	Num	8		PMN leukocytes Not Done

Num	Variable	Type	Len	Format	Label
37	PlateletCountNotDone	Num	8		Platelet count Not Done
38	RBCNotDone	Num	8		RBC Not Done
39	WBCNotDone	Num	8		WBC Not Done
40	BasophilsResults	Num	8		Basophils results
41	BasophilsResultsOR	Num	8		Basophils results OR
42	EosinophilsResults	Num	8		Eosinophils results
43	EosinophilsResultsOR	Num	8		Eosinophils results OR
44	HematocritResults	Num	8		Hematocrit results
45	HemoglobinResults	Num	8		Hemoglobin Results
46	LymphocytesResults	Num	8		Lymphocytes results
47	LymphocytesResultsOR	Num	8		Lymphocytes results OR
48	MCHCresults	Num	8		MCHC results
49	MCHresults	Num	8		MCH results
50	MCVresults	Num	8		MCV results
51	MonocytesResults	Num	8		Monocytes results
52	MonocytesResultsOR	Num	8		Monocytes results OR
53	PMNleukocytesResults	Num	8		PMN leukocytes results
54	PMNleukocytesResultsOR	Num	8		PMN leukocytes results OR
55	PlateletCountResultsNormal	Num	8		Platelet count results
56	RBCResults	Num	8		RBC results
57	WBCresults	Num	8		WBC results
58	MaskID	Num	8		Participant Mask ID#
59	Visit	Char	100		Visit
60	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
61	Date_At_BloodDraw	Num	8	MMDDYY10.	Date at blood draw
62	Date_At_TestsRun	Num	8	MMDDYY10.	Date at tests run

**Data Set Name: change\_in\_study\_drug.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ChangeInDrugStatus	Char	13	\$13.	change in study drug Change in study drug status
2	IsThereChangeInStudyStatus	Char	3	\$3.	change in study drug Is there a change in study status at this time
3	ParticipantIsInformed	Char	2	\$2.	change in study drug Was the participant informed of hisher treatment group assignment
4	ReasonStudyDrugStopped	Char	37	\$37.	change in study drug Reason the study drug was stopped
5	ReasonStudyDrugStoppedOther	Char	56	\$56.	change in study drug IF OTHER specify
6	ChangeInDrugStatusEffectivemon	Char	3	\$3.	change in study drug Date change in study drug status effective month
7	LastDateOfTreatmentmonth	Char	3	\$3.	report information last date of treatment month
8	ReportDateForChangeDrugStatusm	Char	3	\$3.	report information date of report month
9	ChangeInDrugStatusEffectiveday	Num	8		change in study drug Date change in study drug status effective day
10	ChangeInDrugStatusEffectiveyea	Num	8		change in study drug Date change in study drug status effective year
11	LastDateOfTreatmentday	Num	8		report information last date of treatment day
12	LastDateOfTreatmentyr	Num	8		report information last date of treatment year
13	ReportDateForChangeDrugStatusd	Num	8		report information date of report day
14	ReportDateForChangeDrugStatusy	Num	8		report information date of report year
15	MaskID	Num	8		Participant Mask ID#
16	Visit	Char	100		Visit
17	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: concomitant\_meds.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	IsContinuing1	Char	3	\$3.	Continuing
2	IsContinuing2	Char	3	\$3.	Continuing
3	IsContinuing3	Char	3	\$3.	Continuing
4	IsContinuing4	Char	3	\$3.	Continuing
5	IsContinuing5	Char	3	\$3.	Continuing
6	IsContinuing6	Char	3	\$3.	Continuing
7	IsContinuing7	Char	3	\$3.	Continuing
8	IsContinuing8	Char	3	\$3.	Continuing
9	IsContinuing9	Char	3	\$3.	Continuing
10	IsContinuing10	Char	3	\$3.	Continuing
11	IsContinuing11	Char	3	\$3.	Continuing
12	IsContinuing12	Char	3	\$3.	Continuing
13	IsContinuing13	Char	3	\$3.	Continuing
14	IsContinuing14	Char	3	\$3.	Continuing
15	IsContinuing15	Char	3	\$3.	Continuing
16	IsContinuing16	Char	3	\$3.	Continuing
17	IsContinuing17	Char	3	\$3.	Continuing
18	IsContinuing18	Char	3	\$3.	Continuing
19	IsContinuing19	Char	3	\$3.	Continuing
20	IsContinuing20	Char	3	\$3.	Continuing
21	IsContinuing21	Char	3	\$3.	Continuing
22	IsContinuing22	Char	3	\$3.	Continuing
23	IsContinuing23	Char	3	\$3.	Continuing
24	IsContinuing24	Char	3	\$3.	Continuing
25	IsContinuing25	Char	3	\$3.	Continuing
26	IsContinuing26	Char	3	\$3.	Continuing
27	IsContinuing27	Char	3	\$3.	Continuing
28	IsContinuing28	Char	3	\$3.	Continuing
29	IsContinuing29	Char	3	\$3.	Continuing
30	IsContinuing30	Char	3	\$3.	Continuing
31	IsContinuing31	Char	3	\$3.	Continuing
32	IsContinuing32	Char	3	\$3.	Continuing
33	IsContinuing33	Char	3	\$3.	Continuing
34	IsContinuing34	Char	3	\$3.	Continuing
35	IsContinuing35	Char	3	\$3.	Continuing
36	IsContinuing36	Char	3	\$3.	Continuing

Num	Variable	Type	Len	Format	Label
37	IsContinuing37	Char	3	\$3.	Continuing
38	IsContinuing38	Char	3	\$3.	Continuing
39	IsContinuing39	Char	3	\$3.	Continuing
40	IsContinuing40	Char	3	\$3.	Continuing
41	IsContinuing41	Char	3	\$3.	Continuing
42	IsContinuing42	Char	2	\$2.	Continuing
43	IsContinuing43	Char	2	\$2.	Continuing
44	IsContinuing44	Char	2	\$2.	Continuing
45	IsContinuing45	Char	2	\$2.	Continuing
46	IsContinuing46	Char	2	\$2.	Continuing
47	IsContinuing47	Char	2	\$2.	Continuing
48	IsContinuing48	Char	2	\$2.	Continuing
49	IsContinuing49	Char	2	\$2.	Continuing
50	IsContinuing50	Char	2	\$2.	Continuing
51	IsContinuing51	Char	2	\$2.	Continuing
52	IsContinuing52	Char	2	\$2.	Continuing
53	ConMedsFrequencyOtherDetail1	Char	51	\$51.	Frequency specify detail if OTHER is selected
54	ConMedsFrequencyOtherDetail2	Char	51	\$51.	Frequency specify detail if OTHER is selected
55	ConMedsFrequencyOtherDetail3	Char	65	\$65.	Frequency specify detail if OTHER is selected
56	ConMedsFrequencyOtherDetail4	Char	30	\$30.	Frequency specify detail if OTHER is selected
57	ConMedsFrequencyOtherDetail5	Char	25	\$25.	Frequency specify detail if OTHER is selected
58	ConMedsFrequencyOtherDetail6	Char	36	\$36.	Frequency specify detail if OTHER is selected
59	ConMedsFrequencyOtherDetail7	Char	39	\$39.	Frequency specify detail if OTHER is selected
60	ConMedsFrequencyOtherDetail8	Char	21	\$21.	Frequency specify detail if OTHER is selected
61	ConMedsFrequencyOtherDetail9	Char	47	\$47.	Frequency specify detail if OTHER is selected
62	ConMedsFrequencyOtherDetail10	Char	36	\$36.	Frequency specify detail if OTHER is selected
63	ConMedsFrequencyOtherDetail11	Char	72	\$72.	Frequency specify detail if OTHER is selected
64	ConMedsFrequencyOtherDetail12	Char	26	\$26.	Frequency specify detail if OTHER is selected
65	ConMedsFrequencyOtherDetail13	Char	36	\$36.	Frequency specify detail if OTHER is selected
66	ConMedsFrequencyOtherDetail14	Char	14	\$14.	Frequency specify detail if OTHER is selected
67	ConMedsFrequencyOtherDetail15	Char	19	\$19.	Frequency specify detail if OTHER is selected
68	ConMedsFrequencyOtherDetail16	Char	38	\$38.	Frequency specify detail if OTHER is selected
69	ConMedsFrequencyOtherDetail17	Char	19	\$19.	Frequency specify detail if OTHER is selected
70	ConMedsFrequencyOtherDetail18	Char	86	\$86.	Frequency specify detail if OTHER is selected
71	ConMedsFrequencyOtherDetail19	Char	86	\$86.	Frequency specify detail if OTHER is selected
72	ConMedsFrequencyOtherDetail20	Char	17	\$17.	Frequency specify detail if OTHER is selected
73	ConMedsFrequencyOtherDetail21	Char	8	\$8.	Frequency specify detail if OTHER is selected
74	ConMedsFrequencyOtherDetail22	Char	12	\$12.	Frequency specify detail if OTHER is selected
75	ConMedsFrequencyOtherDetail23	Char	11	\$11.	Frequency specify detail if OTHER is selected

Num	Variable	Type	Len	Format	Label
76	ConMedsFrequencyOtherDetail24	Char	13	\$13.	Frequency specify detail if OTHER is selected
77	ConMedsFrequencyOtherDetail25	Char	11	\$11.	Frequency specify detail if OTHER is selected
78	ConMedsFrequencyOtherDetail26	Char	3	\$3.	Frequency specify detail if OTHER is selected
79	ConMedsFrequencyOtherDetail27	Char	13	\$13.	Frequency specify detail if OTHER is selected
80	ConMedsFrequencyOtherDetail28	Char	13	\$13.	Frequency specify detail if OTHER is selected
81	ConMedsFrequencyOtherDetail29	Char	16	\$16.	Frequency specify detail if OTHER is selected
82	ConMedsFrequencyOtherDetail30	Char	13	\$13.	Frequency specify detail if OTHER is selected
83	ConMedsFrequencyOtherDetail31	Char	34	\$34.	Frequency specify detail if OTHER is selected
84	ConMedsFrequencyOtherDetail32	Char	1	\$1.	Frequency specify detail if OTHER is selected
85	ConMedsFrequencyOtherDetail33	Char	4	\$4.	Frequency specify detail if OTHER is selected
86	ConMedsFrequencyOtherDetail34	Char	8	\$8.	Frequency specify detail if OTHER is selected
87	ConMedsFrequencyOtherDetail35	Char	1	\$1.	Frequency specify detail if OTHER is selected
88	ConMedsFrequencyOtherDetail36	Char	4	\$4.	Frequency specify detail if OTHER is selected
89	ConMedsFrequencyOtherDetail37	Char	6	\$6.	Frequency specify detail if OTHER is selected
90	ConMedsFrequencyOtherDetail38	Char	1	\$1.	Frequency specify detail if OTHER is selected
91	ConMedsFrequencyOtherDetail39	Char	1	\$1.	Frequency specify detail if OTHER is selected
92	ConMedsFrequencyOtherDetail40	Char	1	\$1.	Frequency specify detail if OTHER is selected
93	ConMedsFrequencyOtherDetail41	Char	1	\$1.	Frequency specify detail if OTHER is selected
94	ConMedsFrequencyOtherDetail42	Char	8	\$8.	Frequency specify detail if OTHER is selected
95	ConMedsFrequencyOtherDetail43	Char	8	\$8.	Frequency specify detail if OTHER is selected
96	ConMedsFrequencyOtherDetail44	Char	1	\$1.	Frequency specify detail if OTHER is selected
97	ConMedsFrequencyOtherDetail45	Char	1	\$1.	Frequency specify detail if OTHER is selected
98	ConMedsFrequencyOtherDetail46	Char	1	\$1.	Frequency specify detail if OTHER is selected
99	ConMedsFrequencyOtherDetail47	Char	1	\$1.	Frequency specify detail if OTHER is selected
100	ConMedsFrequencyOtherDetail48	Char	1	\$1.	Frequency specify detail if OTHER is selected
101	ConMedsFrequencyOtherDetail49	Char	1	\$1.	Frequency specify detail if OTHER is selected
102	ConMedsFrequencyOtherDetail50	Char	1	\$1.	Frequency specify detail if OTHER is selected
103	ConMedsFrequencyOtherDetail51	Char	3	\$3.	Frequency specify detail if OTHER is selected
104	ConMedsFrequencyOtherDetail52	Char	3	\$3.	Frequency specify detail if OTHER is selected
105	ConMedsIntervalOtherDetails1	Char	40	\$40.	Interval specify details if OTHER is selected
106	ConMedsIntervalOtherDetails2	Char	54	\$54.	Interval specify details if OTHER is selected
107	ConMedsIntervalOtherDetails3	Char	40	\$40.	Interval specify details if OTHER is selected
108	ConMedsIntervalOtherDetails4	Char	53	\$53.	Interval specify details if OTHER is selected
109	ConMedsIntervalOtherDetails5	Char	13	\$13.	Interval specify details if OTHER is selected
110	ConMedsIntervalOtherDetails6	Char	142	\$142.	Interval specify details if OTHER is selected
111	ConMedsIntervalOtherDetails7	Char	13	\$13.	Interval specify details if OTHER is selected
112	ConMedsIntervalOtherDetails8	Char	34	\$34.	Interval specify details if OTHER is selected
113	ConMedsIntervalOtherDetails9	Char	11	\$11.	Interval specify details if OTHER is selected
114	ConMedsIntervalOtherDetails10	Char	36	\$36.	Interval specify details if OTHER is selected

Num	Variable	Type	Len	Format	Label
115	ConMedsIntervalOtherDetails11	Char	44	\$44.	Interval specify details if OTHER is selected
116	ConMedsIntervalOtherDetails12	Char	16	\$16.	Interval specify details if OTHER is selected
117	ConMedsIntervalOtherDetails13	Char	10	\$10.	Interval specify details if OTHER is selected
118	ConMedsIntervalOtherDetails14	Char	34	\$34.	Interval specify details if OTHER is selected
119	ConMedsIntervalOtherDetails15	Char	27	\$27.	Interval specify details if OTHER is selected
120	ConMedsIntervalOtherDetails16	Char	9	\$9.	Interval specify details if OTHER is selected
121	ConMedsIntervalOtherDetails17	Char	44	\$44.	Interval specify details if OTHER is selected
122	ConMedsIntervalOtherDetails18	Char	23	\$23.	Interval specify details if OTHER is selected
123	ConMedsIntervalOtherDetails19	Char	14	\$14.	Interval specify details if OTHER is selected
124	ConMedsIntervalOtherDetails20	Char	14	\$14.	Interval specify details if OTHER is selected
125	ConMedsIntervalOtherDetails21	Char	7	\$7.	Interval specify details if OTHER is selected
126	ConMedsIntervalOtherDetails22	Char	14	\$14.	Interval specify details if OTHER is selected
127	ConMedsIntervalOtherDetails23	Char	43	\$43.	Interval specify details if OTHER is selected
128	ConMedsIntervalOtherDetails24	Char	17	\$17.	Interval specify details if OTHER is selected
129	ConMedsIntervalOtherDetails25	Char	19	\$19.	Interval specify details if OTHER is selected
130	ConMedsIntervalOtherDetails26	Char	16	\$16.	Interval specify details if OTHER is selected
131	ConMedsIntervalOtherDetails27	Char	6	\$6.	Interval specify details if OTHER is selected
132	ConMedsIntervalOtherDetails28	Char	7	\$7.	Interval specify details if OTHER is selected
133	ConMedsIntervalOtherDetails29	Char	6	\$6.	Interval specify details if OTHER is selected
134	ConMedsIntervalOtherDetails30	Char	26	\$26.	Interval specify details if OTHER is selected
135	ConMedsIntervalOtherDetails31	Char	16	\$16.	Interval specify details if OTHER is selected
136	ConMedsIntervalOtherDetails32	Char	6	\$6.	Interval specify details if OTHER is selected
137	ConMedsIntervalOtherDetails33	Char	4	\$4.	Interval specify details if OTHER is selected
138	ConMedsIntervalOtherDetails34	Char	1	\$1.	Interval specify details if OTHER is selected
139	ConMedsIntervalOtherDetails35	Char	4	\$4.	Interval specify details if OTHER is selected
140	ConMedsIntervalOtherDetails36	Char	4	\$4.	Interval specify details if OTHER is selected
141	ConMedsIntervalOtherDetails37	Char	44	\$44.	Interval specify details if OTHER is selected
142	ConMedsIntervalOtherDetails38	Char	1	\$1.	Interval specify details if OTHER is selected
143	ConMedsIntervalOtherDetails39	Char	1	\$1.	Interval specify details if OTHER is selected
144	ConMedsIntervalOtherDetails40	Char	1	\$1.	Interval specify details if OTHER is selected
145	ConMedsIntervalOtherDetails41	Char	1	\$1.	Interval specify details if OTHER is selected
146	ConMedsIntervalOtherDetails42	Char	1	\$1.	Interval specify details if OTHER is selected
147	ConMedsIntervalOtherDetails43	Char	1	\$1.	Interval specify details if OTHER is selected
148	ConMedsIntervalOtherDetails44	Char	1	\$1.	Interval specify details if OTHER is selected
149	ConMedsIntervalOtherDetails45	Char	1	\$1.	Interval specify details if OTHER is selected
150	ConMedsIntervalOtherDetails46	Char	1	\$1.	Interval specify details if OTHER is selected
151	ConMedsIntervalOtherDetails47	Char	1	\$1.	Interval specify details if OTHER is selected
152	ConMedsIntervalOtherDetails48	Char	1	\$1.	Interval specify details if OTHER is selected
153	ConMedsIntervalOtherDetails49	Char	1	\$1.	Interval specify details if OTHER is selected

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
154	ConMedsIntervalOtherDetails50	Char	1	\$1.	Interval specify details if OTHER is selected
155	ConMedsIntervalOtherDetails51	Char	1	\$1.	Interval specify details if OTHER is selected
156	ConMedsIntervalOtherDetails52	Char	1	\$1.	Interval specify details if OTHER is selected
157	Indication1	Char	109	\$109.	Indication
158	Indication2	Char	67	\$67.	Indication
159	Indication3	Char	83	\$83.	Indication
160	Indication4	Char	113	\$113.	Indication
161	Indication5	Char	54	\$54.	Indication
162	Indication6	Char	53	\$53.	Indication
163	Indication7	Char	59	\$59.	Indication
164	Indication8	Char	60	\$60.	Indication
165	Indication9	Char	62	\$62.	Indication
166	Indication10	Char	41	\$41.	Indication
167	Indication11	Char	62	\$62.	Indication
168	Indication12	Char	55	\$55.	Indication
169	Indication13	Char	71	\$71.	Indication
170	Indication14	Char	62	\$62.	Indication
171	Indication15	Char	64	\$64.	Indication
172	Indication16	Char	63	\$63.	Indication
173	Indication17	Char	64	\$64.	Indication
174	Indication18	Char	64	\$64.	Indication
175	Indication19	Char	76	\$76.	Indication
176	Indication20	Char	69	\$69.	Indication
177	Indication21	Char	66	\$66.	Indication
178	Indication22	Char	42	\$42.	Indication
179	Indication23	Char	98	\$98.	Indication
180	Indication24	Char	57	\$57.	Indication
181	Indication25	Char	57	\$57.	Indication
182	Indication26	Char	28	\$28.	Indication
183	Indication27	Char	25	\$25.	Indication
184	Indication28	Char	26	\$26.	Indication
185	Indication29	Char	19	\$19.	Indication
186	Indication30	Char	27	\$27.	Indication
187	Indication31	Char	26	\$26.	Indication
188	Indication32	Char	25	\$25.	Indication
189	Indication33	Char	54	\$54.	Indication
190	Indication34	Char	27	\$27.	Indication
191	Indication35	Char	27	\$27.	Indication
192	Indication36	Char	22	\$22.	Indication

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
193	Indication37	Char	27	\$27.	Indication
194	Indication38	Char	14	\$14.	Indication
195	Indication39	Char	14	\$14.	Indication
196	Indication40	Char	20	\$20.	Indication
197	Indication41	Char	33	\$33.	Indication
198	Indication42	Char	19	\$19.	Indication
199	Indication43	Char	21	\$21.	Indication
200	Indication44	Char	9	\$9.	Indication
201	Indication45	Char	27	\$27.	Indication
202	Indication46	Char	33	\$33.	Indication
203	Indication47	Char	33	\$33.	Indication
204	Indication48	Char	14	\$14.	Indication
205	Indication49	Char	14	\$14.	Indication
206	Indication50	Char	15	\$15.	Indication
207	Indication51	Char	15	\$15.	Indication
208	Indication52	Char	8	\$8.	Indication
209	Medication1	Char	79	\$79.	Medication
210	Medication2	Char	98	\$98.	Medication
211	Medication3	Char	56	\$56.	Medication
212	Medication4	Char	64	\$64.	Medication
213	Medication5	Char	50	\$50.	Medication
214	Medication6	Char	53	\$53.	Medication
215	Medication7	Char	59	\$59.	Medication
216	Medication8	Char	46	\$46.	Medication
217	Medication9	Char	61	\$61.	Medication
218	Medication10	Char	55	\$55.	Medication
219	Medication11	Char	59	\$59.	Medication
220	Medication12	Char	47	\$47.	Medication
221	Medication13	Char	69	\$69.	Medication
222	Medication14	Char	53	\$53.	Medication
223	Medication15	Char	53	\$53.	Medication
224	Medication16	Char	54	\$54.	Medication
225	Medication17	Char	44	\$44.	Medication
226	Medication18	Char	45	\$45.	Medication
227	Medication19	Char	45	\$45.	Medication
228	Medication20	Char	58	\$58.	Medication
229	Medication21	Char	55	\$55.	Medication
230	Medication22	Char	40	\$40.	Medication
231	Medication23	Char	23	\$23.	Medication

Num	Variable	Type	Len	Format	Label
232	Medication24	Char	34	\$34.	Medication
233	Medication25	Char	32	\$32.	Medication
234	Medication26	Char	32	\$32.	Medication
235	Medication27	Char	37	\$37.	Medication
236	Medication28	Char	35	\$35.	Medication
237	Medication29	Char	32	\$32.	Medication
238	Medication30	Char	32	\$32.	Medication
239	Medication31	Char	31	\$31.	Medication
240	Medication32	Char	29	\$29.	Medication
241	Medication33	Char	46	\$46.	Medication
242	Medication34	Char	40	\$40.	Medication
243	Medication35	Char	18	\$18.	Medication
244	Medication36	Char	15	\$15.	Medication
245	Medication37	Char	29	\$29.	Medication
246	Medication38	Char	37	\$37.	Medication
247	Medication39	Char	25	\$25.	Medication
248	Medication40	Char	48	\$48.	Medication
249	Medication41	Char	39	\$39.	Medication
250	Medication42	Char	33	\$33.	Medication
251	Medication43	Char	35	\$35.	Medication
252	Medication44	Char	25	\$25.	Medication
253	Medication45	Char	28	\$28.	Medication
254	Medication46	Char	21	\$21.	Medication
255	Medication47	Char	23	\$23.	Medication
256	Medication48	Char	37	\$37.	Medication
257	Medication49	Char	25	\$25.	Medication
258	Medication50	Char	22	\$22.	Medication
259	Medication51	Char	19	\$19.	Medication
260	Medication52	Char	9	\$9.	Medication
261	AssessDateMonth44	Char	3	\$3.	Assess Date month
262	AssessDateMonth45	Char	3	\$3.	Assess Date month
263	AssessDateMonth46	Char	3	\$3.	Assess Date month
264	AssessDateMonth47	Char	3	\$3.	Assess Date month
265	AssessDateMonth48	Char	3	\$3.	Assess Date month
266	AssessDateMonth49	Char	3	\$3.	Assess Date month
267	AssessDateMonth50	Char	3	\$3.	Assess Date month
268	AssessDateMonth51	Char	3	\$3.	Assess Date month
269	AssessDateMonth52	Char	3	\$3.	Assess Date month
270	ConMedsFrequencyChoices1	Char	5	\$5.	Frequency choices

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
271	ConMedsFrequencyChoices2	Char	5	\$5.	Frequency choices
272	ConMedsFrequencyChoices3	Char	5	\$5.	Frequency choices
273	ConMedsFrequencyChoices4	Char	5	\$5.	Frequency choices
274	ConMedsFrequencyChoices5	Char	5	\$5.	Frequency choices
275	ConMedsFrequencyChoices6	Char	5	\$5.	Frequency choices
276	ConMedsFrequencyChoices7	Char	5	\$5.	Frequency choices
277	ConMedsFrequencyChoices8	Char	5	\$5.	Frequency choices
278	ConMedsFrequencyChoices9	Char	5	\$5.	Frequency choices
279	ConMedsFrequencyChoices10	Char	5	\$5.	Frequency choices
280	ConMedsFrequencyChoices11	Char	5	\$5.	Frequency choices
281	ConMedsFrequencyChoices12	Char	5	\$5.	Frequency choices
282	ConMedsFrequencyChoices13	Char	5	\$5.	Frequency choices
283	ConMedsFrequencyChoices14	Char	5	\$5.	Frequency choices
284	ConMedsFrequencyChoices15	Char	5	\$5.	Frequency choices
285	ConMedsFrequencyChoices16	Char	5	\$5.	Frequency choices
286	ConMedsFrequencyChoices17	Char	5	\$5.	Frequency choices
287	ConMedsFrequencyChoices18	Char	5	\$5.	Frequency choices
288	ConMedsFrequencyChoices19	Char	5	\$5.	Frequency choices
289	ConMedsFrequencyChoices20	Char	5	\$5.	Frequency choices
290	ConMedsFrequencyChoices21	Char	5	\$5.	Frequency choices
291	ConMedsFrequencyChoices22	Char	5	\$5.	Frequency choices
292	ConMedsFrequencyChoices23	Char	5	\$5.	Frequency choices
293	ConMedsFrequencyChoices24	Char	5	\$5.	Frequency choices
294	ConMedsFrequencyChoices25	Char	5	\$5.	Frequency choices
295	ConMedsFrequencyChoices26	Char	5	\$5.	Frequency choices
296	ConMedsFrequencyChoices27	Char	5	\$5.	Frequency choices
297	ConMedsFrequencyChoices28	Char	5	\$5.	Frequency choices
298	ConMedsFrequencyChoices29	Char	5	\$5.	Frequency choices
299	ConMedsFrequencyChoices30	Char	5	\$5.	Frequency choices
300	ConMedsFrequencyChoices31	Char	5	\$5.	Frequency choices
301	ConMedsFrequencyChoices32	Char	5	\$5.	Frequency choices
302	ConMedsFrequencyChoices33	Char	5	\$5.	Frequency choices
303	ConMedsFrequencyChoices34	Char	5	\$5.	Frequency choices
304	ConMedsFrequencyChoices35	Char	3	\$3.	Frequency choices
305	ConMedsFrequencyChoices36	Char	5	\$5.	Frequency choices
306	ConMedsFrequencyChoices37	Char	5	\$5.	Frequency choices
307	ConMedsFrequencyChoices38	Char	2	\$2.	Frequency choices
308	ConMedsFrequencyChoices39	Char	2	\$2.	Frequency choices
309	ConMedsFrequencyChoices40	Char	2	\$2.	Frequency choices

Num	Variable	Type	Len	Format	Label
310	ConMedsFrequencyChoices41	Char	2	\$2.	Frequency choices
311	ConMedsFrequencyChoices42	Char	5	\$5.	Frequency choices
312	ConMedsFrequencyChoices43	Char	5	\$5.	Frequency choices
313	ConMedsFrequencyChoices44	Char	3	\$3.	Frequency choices
314	ConMedsFrequencyChoices45	Char	3	\$3.	Frequency choices
315	ConMedsFrequencyChoices46	Char	3	\$3.	Frequency choices
316	ConMedsFrequencyChoices47	Char	3	\$3.	Frequency choices
317	ConMedsFrequencyChoices48	Char	2	\$2.	Frequency choices
318	ConMedsFrequencyChoices49	Char	2	\$2.	Frequency choices
319	ConMedsFrequencyChoices50	Char	2	\$2.	Frequency choices
320	ConMedsFrequencyChoices51	Char	5	\$5.	Frequency choices
321	ConMedsFrequencyChoices52	Char	5	\$5.	Frequency choices
322	ConMedsIntervalChoices1	Char	5	\$5.	Interval choices
323	ConMedsIntervalChoices2	Char	5	\$5.	Interval choices
324	ConMedsIntervalChoices3	Char	5	\$5.	Interval choices
325	ConMedsIntervalChoices4	Char	5	\$5.	Interval choices
326	ConMedsIntervalChoices5	Char	5	\$5.	Interval choices
327	ConMedsIntervalChoices6	Char	5	\$5.	Interval choices
328	ConMedsIntervalChoices7	Char	5	\$5.	Interval choices
329	ConMedsIntervalChoices8	Char	5	\$5.	Interval choices
330	ConMedsIntervalChoices9	Char	5	\$5.	Interval choices
331	ConMedsIntervalChoices10	Char	5	\$5.	Interval choices
332	ConMedsIntervalChoices11	Char	5	\$5.	Interval choices
333	ConMedsIntervalChoices12	Char	5	\$5.	Interval choices
334	ConMedsIntervalChoices13	Char	5	\$5.	Interval choices
335	ConMedsIntervalChoices14	Char	5	\$5.	Interval choices
336	ConMedsIntervalChoices15	Char	5	\$5.	Interval choices
337	ConMedsIntervalChoices16	Char	5	\$5.	Interval choices
338	ConMedsIntervalChoices17	Char	5	\$5.	Interval choices
339	ConMedsIntervalChoices18	Char	5	\$5.	Interval choices
340	ConMedsIntervalChoices19	Char	5	\$5.	Interval choices
341	ConMedsIntervalChoices20	Char	5	\$5.	Interval choices
342	ConMedsIntervalChoices21	Char	5	\$5.	Interval choices
343	ConMedsIntervalChoices22	Char	5	\$5.	Interval choices
344	ConMedsIntervalChoices23	Char	5	\$5.	Interval choices
345	ConMedsIntervalChoices24	Char	5	\$5.	Interval choices
346	ConMedsIntervalChoices25	Char	5	\$5.	Interval choices
347	ConMedsIntervalChoices26	Char	5	\$5.	Interval choices
348	ConMedsIntervalChoices27	Char	5	\$5.	Interval choices

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
349	ConMedsIntervalChoices28	Char	5	\$5.	Interval choices
350	ConMedsIntervalChoices29	Char	3	\$3.	Interval choices
351	ConMedsIntervalChoices30	Char	5	\$5.	Interval choices
352	ConMedsIntervalChoices31	Char	5	\$5.	Interval choices
353	ConMedsIntervalChoices32	Char	3	\$3.	Interval choices
354	ConMedsIntervalChoices33	Char	5	\$5.	Interval choices
355	ConMedsIntervalChoices34	Char	3	\$3.	Interval choices
356	ConMedsIntervalChoices35	Char	5	\$5.	Interval choices
357	ConMedsIntervalChoices36	Char	5	\$5.	Interval choices
358	ConMedsIntervalChoices37	Char	5	\$5.	Interval choices
359	ConMedsIntervalChoices38	Char	3	\$3.	Interval choices
360	ConMedsIntervalChoices39	Char	3	\$3.	Interval choices
361	ConMedsIntervalChoices40	Char	3	\$3.	Interval choices
362	ConMedsIntervalChoices41	Char	3	\$3.	Interval choices
363	ConMedsIntervalChoices42	Char	3	\$3.	Interval choices
364	ConMedsIntervalChoices43	Char	3	\$3.	Interval choices
365	ConMedsIntervalChoices44	Char	3	\$3.	Interval choices
366	ConMedsIntervalChoices45	Char	3	\$3.	Interval choices
367	ConMedsIntervalChoices46	Char	3	\$3.	Interval choices
368	ConMedsIntervalChoices47	Char	3	\$3.	Interval choices
369	ConMedsIntervalChoices48	Char	3	\$3.	Interval choices
370	ConMedsIntervalChoices49	Char	3	\$3.	Interval choices
371	ConMedsIntervalChoices50	Char	3	\$3.	Interval choices
372	ConMedsIntervalChoices51	Char	3	\$3.	Interval choices
373	ConMedsIntervalChoices52	Char	3	\$3.	Interval choices
374	ConMedsRoute1	Char	26	\$26.	Route
375	ConMedsRoute2	Char	26	\$26.	Route
376	ConMedsRoute3	Char	26	\$26.	Route
377	ConMedsRoute4	Char	26	\$26.	Route
378	ConMedsRoute5	Char	26	\$26.	Route
379	ConMedsRoute6	Char	26	\$26.	Route
380	ConMedsRoute7	Char	26	\$26.	Route
381	ConMedsRoute8	Char	26	\$26.	Route
382	ConMedsRoute9	Char	26	\$26.	Route
383	ConMedsRoute10	Char	26	\$26.	Route
384	ConMedsRoute11	Char	26	\$26.	Route
385	ConMedsRoute12	Char	26	\$26.	Route
386	ConMedsRoute13	Char	26	\$26.	Route
387	ConMedsRoute14	Char	26	\$26.	Route

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
388	ConMedsRoute15	Char	12	\$12.	Route
389	ConMedsRoute16	Char	9	\$9.	Route
390	ConMedsRoute17	Char	26	\$26.	Route
391	ConMedsRoute18	Char	26	\$26.	Route
392	ConMedsRoute19	Char	26	\$26.	Route
393	ConMedsRoute20	Char	7	\$7.	Route
394	ConMedsRoute21	Char	9	\$9.	Route
395	ConMedsRoute22	Char	26	\$26.	Route
396	ConMedsRoute23	Char	9	\$9.	Route
397	ConMedsRoute24	Char	7	\$7.	Route
398	ConMedsRoute25	Char	7	\$7.	Route
399	ConMedsRoute26	Char	12	\$12.	Route
400	ConMedsRoute27	Char	26	\$26.	Route
401	ConMedsRoute28	Char	26	\$26.	Route
402	ConMedsRoute29	Char	12	\$12.	Route
403	ConMedsRoute30	Char	26	\$26.	Route
404	ConMedsRoute31	Char	26	\$26.	Route
405	ConMedsRoute32	Char	7	\$7.	Route
406	ConMedsRoute33	Char	4	\$4.	Route
407	ConMedsRoute34	Char	9	\$9.	Route
408	ConMedsRoute35	Char	26	\$26.	Route
409	ConMedsRoute36	Char	7	\$7.	Route
410	ConMedsRoute37	Char	7	\$7.	Route
411	ConMedsRoute38	Char	4	\$4.	Route
412	ConMedsRoute39	Char	4	\$4.	Route
413	ConMedsRoute40	Char	4	\$4.	Route
414	ConMedsRoute41	Char	4	\$4.	Route
415	ConMedsRoute42	Char	4	\$4.	Route
416	ConMedsRoute43	Char	4	\$4.	Route
417	ConMedsRoute44	Char	12	\$12.	Route
418	ConMedsRoute45	Char	4	\$4.	Route
419	ConMedsRoute46	Char	4	\$4.	Route
420	ConMedsRoute47	Char	4	\$4.	Route
421	ConMedsRoute48	Char	4	\$4.	Route
422	ConMedsRoute49	Char	4	\$4.	Route
423	ConMedsRoute50	Char	4	\$4.	Route
424	ConMedsRoute51	Char	4	\$4.	Route
425	ConMedsRoute52	Char	26	\$26.	Route
426	StartDateMonth44	Char	3	\$3.	Start Date month

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
427	StartDateMonth45	Char	3	\$3.	Start Date month
428	StartDateMonth46	Char	3	\$3.	Start Date month
429	StartDateMonth47	Char	3	\$3.	Start Date month
430	StartDateMonth48	Char	3	\$3.	Start Date month
431	StartDateMonth49	Char	3	\$3.	Start Date month
432	StartDateMonth50	Char	3	\$3.	Start Date month
433	StartDateMonth51	Char	3	\$3.	Start Date month
434	StartDateMonth52	Char	3	\$3.	Start Date month
435	StopDateMonth44	Char	3	\$3.	Stop Date month
436	StopDateMonth45	Char	3	\$3.	Stop Date month
437	StopDateMonth46	Char	3	\$3.	Stop Date month
438	StopDateMonth47	Char	3	\$3.	Stop Date month
439	StopDateMonth48	Char	3	\$3.	Stop Date month
440	StopDateMonth49	Char	3	\$3.	Stop Date month
441	StopDateMonth50	Char	3	\$3.	Stop Date month
442	StopDateMonth51	Char	3	\$3.	Stop Date month
443	StopDateMonth52	Char	3	\$3.	Stop Date month
444	Units1	Char	11	\$11.	Units
445	Units2	Char	11	\$11.	Units
446	Units3	Char	11	\$11.	Units
447	Units4	Char	11	\$11.	Units
448	Units5	Char	11	\$11.	Units
449	Units6	Char	11	\$11.	Units
450	Units7	Char	11	\$11.	Units
451	Units8	Char	11	\$11.	Units
452	Units9	Char	11	\$11.	Units
453	Units10	Char	11	\$11.	Units
454	Units11	Char	11	\$11.	Units
455	Units12	Char	11	\$11.	Units
456	Units13	Char	11	\$11.	Units
457	Units14	Char	11	\$11.	Units
458	Units15	Char	11	\$11.	Units
459	Units16	Char	11	\$11.	Units
460	Units17	Char	11	\$11.	Units
461	Units18	Char	11	\$11.	Units
462	Units19	Char	4	\$4.	Units
463	Units20	Char	11	\$11.	Units
464	Units21	Char	11	\$11.	Units
465	Units22	Char	11	\$11.	Units

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
466	Units23	Char	11	\$11.	Units
467	Units24	Char	11	\$11.	Units
468	Units25	Char	3	\$3.	Units
469	Units26	Char	3	\$3.	Units
470	Units27	Char	7	\$7.	Units
471	Units28	Char	3	\$3.	Units
472	Units29	Char	5	\$5.	Units
473	Units30	Char	5	\$5.	Units
474	Units31	Char	11	\$11.	Units
475	Units32	Char	11	\$11.	Units
476	Units33	Char	4	\$4.	Units
477	Units34	Char	11	\$11.	Units
478	Units35	Char	5	\$5.	Units
479	Units36	Char	3	\$3.	Units
480	Units37	Char	4	\$4.	Units
481	Units38	Char	3	\$3.	Units
482	Units39	Char	7	\$7.	Units
483	Units40	Char	11	\$11.	Units
484	Units41	Char	11	\$11.	Units
485	Units42	Char	11	\$11.	Units
486	Units43	Char	3	\$3.	Units
487	Units44	Char	3	\$3.	Units
488	Units45	Char	3	\$3.	Units
489	Units46	Char	3	\$3.	Units
490	Units47	Char	3	\$3.	Units
491	Units48	Char	3	\$3.	Units
492	Units49	Char	7	\$7.	Units
493	Units50	Char	3	\$3.	Units
494	Units51	Char	3	\$3.	Units
495	Units52	Char	2	\$2.	Units
496	AssessDateDay44	Num	8		Assess Date day
497	AssessDateDay45	Num	8		Assess Date day
498	AssessDateDay46	Num	8		Assess Date day
499	AssessDateDay47	Num	8		Assess Date day
500	AssessDateDay48	Num	8		Assess Date day
501	AssessDateDay49	Num	8		Assess Date day
502	AssessDateDay50	Num	8		Assess Date day
503	AssessDateDay51	Num	8		Assess Date day
504	AssessDateDay52	Num	8		Assess Date day

Num	Variable	Type	Len	Format	Label
505	AssessDateYear44	Num	8		Assess Date year
506	AssessDateYear45	Num	8		Assess Date year
507	AssessDateYear46	Num	8		Assess Date year
508	AssessDateYear47	Num	8		Assess Date year
509	AssessDateYear48	Num	8		Assess Date year
510	AssessDateYear49	Num	8		Assess Date year
511	AssessDateYear50	Num	8		Assess Date year
512	AssessDateYear51	Num	8		Assess Date year
513	AssessDateYear52	Num	8		Assess Date year
514	Dose1	Num	8		Dose
515	Dose2	Num	8		Dose
516	Dose3	Num	8		Dose
517	Dose4	Num	8		Dose
518	Dose5	Num	8		Dose
519	Dose6	Num	8		Dose
520	Dose7	Num	8		Dose
521	Dose8	Num	8		Dose
522	Dose9	Num	8		Dose
523	Dose10	Num	8		Dose
524	Dose11	Num	8		Dose
525	Dose12	Num	8		Dose
526	Dose13	Num	8		Dose
527	Dose14	Num	8		Dose
528	Dose15	Num	8		Dose
529	Dose16	Num	8		Dose
530	Dose17	Num	8		Dose
531	Dose18	Num	8		Dose
532	Dose19	Num	8		Dose
533	Dose20	Num	8		Dose
534	Dose21	Num	8		Dose
535	Dose22	Num	8		Dose
536	Dose23	Num	8		Dose
537	Dose24	Num	8		Dose
538	Dose25	Num	8		Dose
539	Dose26	Num	8		Dose
540	Dose27	Num	8		Dose
541	Dose28	Num	8		Dose
542	Dose29	Num	8		Dose
543	Dose30	Num	8		Dose

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
544	Dose31	Num	8		Dose
545	Dose32	Num	8		Dose
546	Dose33	Num	8		Dose
547	Dose34	Num	8		Dose
548	Dose35	Num	8		Dose
549	Dose36	Num	8		Dose
550	Dose37	Num	8		Dose
551	Dose38	Num	8		Dose
552	Dose39	Num	8		Dose
553	Dose40	Num	8		Dose
554	Dose41	Num	8		Dose
555	Dose42	Num	8		Dose
556	Dose43	Num	8		Dose
557	Dose44	Num	8		Dose
558	Dose45	Num	8		Dose
559	Dose46	Num	8		Dose
560	Dose47	Num	8		Dose
561	Dose48	Num	8		Dose
562	Dose49	Num	8		Dose
563	Dose50	Num	8		Dose
564	Dose51	Num	8		Dose
565	Dose52	Num	8		Dose
566	StartDateDay44	Num	8		Start Date day
567	StartDateDay45	Num	8		Start Date day
568	StartDateDay46	Num	8		Start Date day
569	StartDateDay47	Num	8		Start Date day
570	StartDateDay48	Num	8		Start Date day
571	StartDateDay49	Num	8		Start Date day
572	StartDateDay50	Num	8		Start Date day
573	StartDateDay51	Num	8		Start Date day
574	StartDateDay52	Num	8		Start Date day
575	StartDateYear44	Num	8		Start Date year
576	StartDateYear45	Num	8		Start Date year
577	StartDateYear46	Num	8		Start Date year
578	StartDateYear47	Num	8		Start Date year
579	StartDateYear48	Num	8		Start Date year
580	StartDateYear49	Num	8		Start Date year
581	StartDateYear50	Num	8		Start Date year
582	StartDateYear51	Num	8		Start Date year

Num	Variable	Type	Len	Format	Label
583	StartDateYear52	Num	8		Start Date year
584	StopDateDay44	Num	8		Stop Date day
585	StopDateDay45	Num	8		Stop Date day
586	StopDateDay46	Num	8		Stop Date day
587	StopDateDay47	Num	8		Stop Date day
588	StopDateDay48	Num	8		Stop Date day
589	StopDateDay49	Num	8		Stop Date day
590	StopDateDay50	Num	8		Stop Date day
591	StopDateDay51	Num	8		Stop Date day
592	StopDateDay52	Num	8		Stop Date day
593	StopDateYear44	Num	8		Stop Date year
594	StopDateYear45	Num	8		Stop Date year
595	StopDateYear46	Num	8		Stop Date year
596	StopDateYear47	Num	8		Stop Date year
597	StopDateYear48	Num	8		Stop Date year
598	StopDateYear49	Num	8		Stop Date year
599	StopDateYear50	Num	8		Stop Date year
600	StopDateYear51	Num	8		Stop Date year
601	StopDateYear52	Num	8		Stop Date year
602	MaskID	Num	8		Participant Mask ID#
603	Visit	Char	100		Visit
604	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
605	Date_At_Assessment1	Num	8	MMDDYY10.	Date at Assessment #1
606	Date_At_Assessment2	Num	8	MMDDYY10.	Date at Assessment #2
607	Date_At_Assessment3	Num	8	MMDDYY10.	Date at Assessment #3
608	Date_At_Assessment4	Num	8	MMDDYY10.	Date at Assessment #4
609	Date_At_Assessment5	Num	8	MMDDYY10.	Date at Assessment #5
610	Date_At_Assessment6	Num	8	MMDDYY10.	Date at Assessment #6
611	Date_At_Assessment7	Num	8	MMDDYY10.	Date at Assessment #7
612	Date_At_Assessment8	Num	8	MMDDYY10.	Date at Assessment #8
613	Date_At_Assessment9	Num	8	MMDDYY10.	Date at Assessment #9
614	Date_At_Assessment10	Num	8	MMDDYY10.	Date at Assessment #10
615	Date_At_Assessment11	Num	8	MMDDYY10.	Date at Assessment #11
616	Date_At_Assessment12	Num	8	MMDDYY10.	Date at Assessment #12
617	Date_At_Assessment13	Num	8	MMDDYY10.	Date at Assessment #13
618	Date_At_Assessment14	Num	8	MMDDYY10.	Date at Assessment #14
619	Date_At_Assessment15	Num	8	MMDDYY10.	Date at Assessment #15
620	Date_At_Assessment16	Num	8	MMDDYY10.	Date at Assessment #16
621	Date_At_Assessment17	Num	8	MMDDYY10.	Date at Assessment #17

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
622	Date_At_Assessment18	Num	8	MMDDYY10.	Date at Assessment #18
623	Date_At_Assessment19	Num	8	MMDDYY10.	Date at Assessment #19
624	Date_At_Assessment20	Num	8	MMDDYY10.	Date at Assessment #20
625	Date_At_Assessment21	Num	8	MMDDYY10.	Date at Assessment #21
626	Date_At_Assessment22	Num	8	MMDDYY10.	Date at Assessment #22
627	Date_At_Assessment23	Num	8	MMDDYY10.	Date at Assessment #23
628	Date_At_Assessment24	Num	8	MMDDYY10.	Date at Assessment #24
629	Date_At_Assessment25	Num	8	MMDDYY10.	Date at Assessment #25
630	Date_At_Assessment26	Num	8	MMDDYY10.	Date at Assessment #26
631	Date_At_Assessment27	Num	8	MMDDYY10.	Date at Assessment #27
632	Date_At_Assessment28	Num	8	MMDDYY10.	Date at Assessment #28
633	Date_At_Assessment29	Num	8	MMDDYY10.	Date at Assessment #29
634	Date_At_Assessment30	Num	8	MMDDYY10.	Date at Assessment #30
635	Date_At_Assessment31	Num	8	MMDDYY10.	Date at Assessment #31
636	Date_At_Assessment32	Num	8	MMDDYY10.	Date at Assessment #32
637	Date_At_Assessment33	Num	8	MMDDYY10.	Date at Assessment #33
638	Date_At_Assessment34	Num	8	MMDDYY10.	Date at Assessment #34
639	Date_At_Assessment35	Num	8	MMDDYY10.	Date at Assessment #35
640	Date_At_Assessment36	Num	8	MMDDYY10.	Date at Assessment #36
641	Date_At_Assessment37	Num	8	MMDDYY10.	Date at Assessment #37
642	Date_At_Assessment38	Num	8	MMDDYY10.	Date at Assessment #38
643	Date_At_Assessment39	Num	8	MMDDYY10.	Date at Assessment #39
644	Date_At_Assessment40	Num	8	MMDDYY10.	Date at Assessment #40
645	Date_At_Assessment41	Num	8	MMDDYY10.	Date at Assessment #41
646	Date_At_Assessment42	Num	8	MMDDYY10.	Date at Assessment #42
647	Date_At_Assessment43	Num	8	MMDDYY10.	Date at Assessment #43
648	Date_At_Start1	Num	8	MMDDYY10.	Date at Start #1
649	Date_At_Start2	Num	8	MMDDYY10.	Date at Start #2
650	Date_At_Start3	Num	8	MMDDYY10.	Date at Start #3
651	Date_At_Start4	Num	8	MMDDYY10.	Date at Start #4
652	Date_At_Start5	Num	8	MMDDYY10.	Date at Start #5
653	Date_At_Start6	Num	8	MMDDYY10.	Date at Start #6
654	Date_At_Start7	Num	8	MMDDYY10.	Date at Start #7
655	Date_At_Start8	Num	8	MMDDYY10.	Date at Start #8
656	Date_At_Start9	Num	8	MMDDYY10.	Date at Start #9
657	Date_At_Start10	Num	8	MMDDYY10.	Date at Start #10
658	Date_At_Start11	Num	8	MMDDYY10.	Date at Start #11
659	Date_At_Start12	Num	8	MMDDYY10.	Date at Start #12
660	Date_At_Start13	Num	8	MMDDYY10.	Date at Start #13

Num	Variable	Type	Len	Format	Label
661	Date_At_Start14	Num	8	MMDDYY10.	Date at Start #14
662	Date_At_Start15	Num	8	MMDDYY10.	Date at Start #15
663	Date_At_Start16	Num	8	MMDDYY10.	Date at Start #16
664	Date_At_Start17	Num	8	MMDDYY10.	Date at Start #17
665	Date_At_Start18	Num	8	MMDDYY10.	Date at Start #18
666	Date_At_Start19	Num	8	MMDDYY10.	Date at Start #19
667	Date_At_Start20	Num	8	MMDDYY10.	Date at Start #20
668	Date_At_Start21	Num	8	MMDDYY10.	Date at Start #21
669	Date_At_Start22	Num	8	MMDDYY10.	Date at Start #22
670	Date_At_Start23	Num	8	MMDDYY10.	Date at Start #23
671	Date_At_Start24	Num	8	MMDDYY10.	Date at Start #24
672	Date_At_Start25	Num	8	MMDDYY10.	Date at Start #25
673	Date_At_Start26	Num	8	MMDDYY10.	Date at Start #26
674	Date_At_Start27	Num	8	MMDDYY10.	Date at Start #27
675	Date_At_Start28	Num	8	MMDDYY10.	Date at Start #28
676	Date_At_Start29	Num	8	MMDDYY10.	Date at Start #29
677	Date_At_Start30	Num	8	MMDDYY10.	Date at Start #30
678	Date_At_Start31	Num	8	MMDDYY10.	Date at Start #31
679	Date_At_Start32	Num	8	MMDDYY10.	Date at Start #32
680	Date_At_Start33	Num	8	MMDDYY10.	Date at Start #33
681	Date_At_Start34	Num	8	MMDDYY10.	Date at Start #34
682	Date_At_Start35	Num	8	MMDDYY10.	Date at Start #35
683	Date_At_Start36	Num	8	MMDDYY10.	Date at Start #36
684	Date_At_Start37	Num	8	MMDDYY10.	Date at Start #37
685	Date_At_Start38	Num	8	MMDDYY10.	Date at Start #38
686	Date_At_Start39	Num	8	MMDDYY10.	Date at Start #39
687	Date_At_Start40	Num	8	MMDDYY10.	Date at Start #40
688	Date_At_Start41	Num	8	MMDDYY10.	Date at Start #41
689	Date_At_Start42	Num	8	MMDDYY10.	Date at Start #42
690	Date_At_Start43	Num	8	MMDDYY10.	Date at Start #43
691	Date_At_Stop1	Num	8	MMDDYY10.	Date at Stop #1
692	Date_At_Stop2	Num	8	MMDDYY10.	Date at Stop #2
693	Date_At_Stop3	Num	8	MMDDYY10.	Date at Stop #3
694	Date_At_Stop4	Num	8	MMDDYY10.	Date at Stop #4
695	Date_At_Stop5	Num	8	MMDDYY10.	Date at Stop #5
696	Date_At_Stop6	Num	8	MMDDYY10.	Date at Stop #6
697	Date_At_Stop7	Num	8	MMDDYY10.	Date at Stop #7
698	Date_At_Stop8	Num	8	MMDDYY10.	Date at Stop #8
699	Date_At_Stop9	Num	8	MMDDYY10.	Date at Stop #9

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
700	Date_At_Stop10	Num	8	MMDDYY10.	Date at Stop #10
701	Date_At_Stop11	Num	8	MMDDYY10.	Date at Stop #11
702	Date_At_Stop12	Num	8	MMDDYY10.	Date at Stop #12
703	Date_At_Stop13	Num	8	MMDDYY10.	Date at Stop #13
704	Date_At_Stop14	Num	8	MMDDYY10.	Date at Stop #14
705	Date_At_Stop15	Num	8	MMDDYY10.	Date at Stop #15
706	Date_At_Stop16	Num	8	MMDDYY10.	Date at Stop #16
707	Date_At_Stop17	Num	8	MMDDYY10.	Date at Stop #17
708	Date_At_Stop18	Num	8	MMDDYY10.	Date at Stop #18
709	Date_At_Stop19	Num	8	MMDDYY10.	Date at Stop #19
710	Date_At_Stop20	Num	8	MMDDYY10.	Date at Stop #20
711	Date_At_Stop21	Num	8	MMDDYY10.	Date at Stop #21
712	Date_At_Stop22	Num	8	MMDDYY10.	Date at Stop #22
713	Date_At_Stop23	Num	8	MMDDYY10.	Date at Stop #23
714	Date_At_Stop24	Num	8	MMDDYY10.	Date at Stop #24
715	Date_At_Stop25	Num	8	MMDDYY10.	Date at Stop #25
716	Date_At_Stop26	Num	8	MMDDYY10.	Date at Stop #26
717	Date_At_Stop27	Num	8	MMDDYY10.	Date at Stop #27
718	Date_At_Stop28	Num	8	MMDDYY10.	Date at Stop #28
719	Date_At_Stop29	Num	8	MMDDYY10.	Date at Stop #29
720	Date_At_Stop30	Num	8	MMDDYY10.	Date at Stop #30
721	Date_At_Stop31	Num	8	MMDDYY10.	Date at Stop #31
722	Date_At_Stop32	Num	8	MMDDYY10.	Date at Stop #32
723	Date_At_Stop33	Num	8	MMDDYY10.	Date at Stop #33
724	Date_At_Stop34	Num	8	MMDDYY10.	Date at Stop #34
725	Date_At_Stop35	Num	8	MMDDYY10.	Date at Stop #35
726	Date_At_Stop36	Num	8	MMDDYY10.	Date at Stop #36
727	Date_At_Stop37	Num	8	MMDDYY10.	Date at Stop #37
728	Date_At_Stop38	Num	8	MMDDYY10.	Date at Stop #38
729	Date_At_Stop39	Num	8	MMDDYY10.	Date at Stop #39
730	Date_At_Stop40	Num	8	MMDDYY10.	Date at Stop #40
731	Date_At_Stop41	Num	8	MMDDYY10.	Date at Stop #41
732	Date_At_Stop42	Num	8	MMDDYY10.	Date at Stop #42
733	Date_At_Stop43	Num	8	MMDDYY10.	Date at Stop #43

**Data Set Name: ctl01\_screening.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	CBCCollected	Char	3	\$3.	CBC with Differential Collected on this visit dateanalysis done at local lab
2	CardiovascularNormal	Char	3	\$3.	CardiovascularNormal
3	ChemistriesCollected	Char	3	\$3.	Chemistries
4	EBVCMVCollected	Char	3	\$3.	EBVCMV Serology
5	EBVPCRCollected	Char	3	\$3.	EBV PCR
6	EndocrineNormal	Char	3	\$3.	Endocrine other than T1D Normal
7	Ethnicity	Char	22	\$22.	Ethnicity check one
8	GastrointestinalNormal	Char	3	\$3.	Gastrointestinal Normal
9	HEENTNormal	Char	3	\$3.	HEENT Normal
10	HIVHEPBCCollected	Char	3	\$3.	HIV Hep B and C
11	IntegumentNormal	Char	3	\$3.	Integument Normal
12	MusculoskeletalNormal	Char	3	\$3.	Musculoskeletal Normal
13	NeurologicalNormal	Char	3	\$3.	Neurological Normal
14	OtherAbnormalities	Char	3	\$3.	Are there any additional abnormalities not already indicated above
15	PBMCCollected	Char	3	\$3.	PBMCplasma
16	PPDCollected	Char	3	\$3.	PPD Test
17	ParticipantHeardOfStudyFrom	Char	20	\$20.	How did the participant first hear about this study check one
18	PermissionGivenForDNAStorageOf	Char	3	\$3.	On the screening consent form was permission given for DNA samples to be stored
19	PermissionGivenForNonDNAStorag	Char	3	\$3.	On the screening consent form was permission given for nonDNA samples to be stored
20	PhysicalAbnormalities	Char	3	\$3.	Were there any abnormalities on the physical exam
21	PregnancyTestAtVisit	Char	3	\$3.	Was a urine pregnancy test completed at this visit
22	PregnancyTestAtVisitPositive	Char	2	\$2.	If Yes Was the test result positive
23	PulmonaryNormal	Char	3	\$3.	Pulmonary Normal
24	ReproductiveNormal	Char	3	\$3.	Reproductive Normal
25	SerumforABCCollected	Char	3	\$3.	Serum for Autoantibodies
26	Sex	Char	6	\$6.	Sex
27	TakingOtherMed	Char	3	\$3.	Are you currently taking any other prescription medications nonprescription medications or supplements other than insulin
28	TakingSteroids	Char	3	\$3.	Are any of these medications steroids Steroid use is an exclusion criterion for this study
29	TannerGenitalia	Char	18	\$18.	Genitalia male
30	TannerPubicHair	Char	18	\$18.	Pubic Hair both
31	TannerStageBreast	Char	18	\$18.	Tanner Stage Breast
32	VisitAtDifferentSite	Char	3	\$3.	Did visit occur at a site other than the primary study site

Num	Variable	Type	Len	Format	Label
33	_4HourMMTCollected	Char	3	\$3.	4hour MMTT
34	CardiovascularAbnormal	Char	56	\$56.	If ABNORMAL Explain
35	EndocrineAbnormal	Char	47	\$47.	If ABNORMAL Explain
36	GastrointestinalAbnormal	Char	40	\$40.	If ABNORMAL Explain
37	HEENTExplain	Char	134	\$134.	HEENT If Abnormal Explain
38	IntegumentAbnormal	Char	63	\$63.	If ABNORMAL Explain
39	MusculoskeletalAbnormal	Char	65	\$65.	If ABNORMAL Explain
40	NeurologicalAbnormal	Char	47	\$47.	If ABNORMAL Explain
41	OtherAbnormalitiesDescribe	Char	72	\$72.	if YES describe
42	PhysicalAbnormalitiesSpecify	Char	101	\$101.	If YES Specify
43	PulmonaryAbnormal	Char	52	\$52.	Pulmonary If ABNORMAL Explain
44	ReproductiveAbnormal	Char	44	\$44.	If ABNORMAL Explain
45	SpecifyParticipantHeardFrom	Char	46	\$46.	If OTHER specify
46	SpecifyRace	Char	17	\$17.	if OTHER Specify
47	TakingSteroidsSpecify	Char	36	\$36.	If YES specify
48	TakingOtherMedSpecify1	Char	38	\$38.	If YES list medicationssupplements
49	TakingOtherMedSpecify2	Char	51	\$51.	If YES list medicationssupplements
50	TakingOtherMedSpecify3	Char	37	\$37.	If YES list medicationssupplements
51	TakingOtherMedSpecify4	Char	32	\$32.	If YES list medicationssupplements
52	TakingOtherMedSpecify5	Char	31	\$31.	If YES list medicationssupplements
53	TakingOtherMedSpecify6	Char	1	\$1.	If YES list medicationssupplements
54	TakingOtherMedSpecify7	Char	1	\$1.	If YES list medicationssupplements
55	TakingOtherMedSpecify8	Char	1	\$1.	If YES list medicationssupplements
56	TakingOtherMedSpecify9	Char	1	\$1.	If YES list medicationssupplements
57	TakingOtherMedSpecify10	Char	1	\$1.	If YES list medicationssupplements
58	TakingOtherMedSpecify11	Char	1	\$1.	If YES list medicationssupplements
59	TakingOtherMedSpecify12	Char	1	\$1.	If YES list medicationssupplements
60	BirthMonth	Char	3	\$3.	Date of Birth Month
61	CBCCollectedMonth	Char	1	\$1.	If NO date sampled collected Month
62	ChemistriesCollectedMonth	Char	1	\$1.	If NO date sample collected MONTH
63	ConsentWrittenMonth	Char	3	\$3.	Date written informed consent for screening obtained Month
64	EBVCMVCollected2	Char	1	\$1.	If NO date sample collected MONTH
65	EBVPCRCollectedMonth	Char	1	\$1.	If NO date sample collected Month
66	HIVHEPBCCollectedMONTH	Char	1	\$1.	HIV Hep B and C Month
67	PBMCCollectedMonth	Char	3	\$3.	If NO date sample collected Month
68	PPDCollectedMonth	Char	3	\$3.	If NO date sample collected Month
69	SerumforABCcollectedMONTH	Char	3	\$3.	If NO date sample collected MONTH
70	_4HourMMTCollectedMonth	Char	3	\$3.	If NO date sample collected Month
71	Age	Num	8		Age years

Num	Variable	Type	Len	Format	Label
72	BPDiatolic	Num	8		Seated arm blood pressure diatolic
73	BPSystolic	Num	8		Seated arm blood pressure Systolic
74	BirthDay	Num	8		Date of Birth DAY
75	BirthYear	Num	8		Date of Birth Year
76	CBCCollectedDay	Num	8		If NO date sampled collected DAY
77	CBCCollectedMonth2	Num	8		If NO date sampled collected Year
78	ChemistriesCollectedDay	Num	8		If NO date sample collected DAY
79	ChemistriesCollectedYear	Num	8		If NO date sample collected Year
80	ConsentWrittenDAY	Num	8		Date written informed consent for screening obtained DAY
81	ConsentWrittenYear	Num	8		Date written informed consent for screening obtained Year
82	EBVCMVCollectedDay	Num	8		If NO date sample collected DAY
83	EBVCMVCollectedYEAR	Num	8		If NO date sample collected YEAR
84	EBVPCRCollectedDay	Num	8		If NO date sample collected Day
85	EBVPCRCollectedYear	Num	8		If NO date sample collected Year
86	HIVHEPBCCollectedDay	Num	8		If NO date sample collected DAY
87	HIVHEPBCCollectedYear	Num	8		If NO date sample collected YEAR
88	PBMCCollectedDay	Num	8		If NO date sample collected Day
89	PBMCCollectedYear	Num	8		If NO date sample collected Year
90	PPDCollectedDay	Num	8		If NO date sample collected Day
91	PPDCollectedYear	Num	8		If NO date sample collected Year
92	PhysicalHeightCM	Num	8		Collect the following physical assements Height cm
93	PhysicalHeightIN	Num	8		Collect the following physical assements Height in
94	PhysicalWeightKG	Num	8		Collect the following physical assements Weight kg
95	PhysicalWeightLBS	Num	8		Collect the following physical assements Weight lbs
96	SerumforABCcollectedDAY	Num	8		If NO date sample collected DAY
97	SerumforABCcollectedYEAR	Num	8		If NO date sample collected YEAR
98	SiteNumber	Num	8		If YES Record Site Number for reimbursement
99	_4HourMMTCollectedDAY	Num	8		If NO date sample collected Day
100	_4HourMMTCollectedYear	Num	8		If NO date sample collected Year
101	_3DigitRaceEthnicity1	Num	8		Record the 3digit code for raceethnicity International sites only
102	_3DigitRaceEthnicity2	Num	8		Record the 3digit code for raceethnicity International sites only
103	_3DigitRaceEthnicity3	Num	8		Record the 3digit code for raceethnicity International sites only
104	Race_AmericanIndianorAlaskanNa	Num	8		Race: American Indian or Alaskan Native
105	Race_Asian	Num	8		Race: Asian
106	Race_BlackorAfricanAmerican	Num	8		Race: Black or African American
107	Race_NativeHawaiianorOtherPaci	Num	8		Race: Native Hawaiian or Other Pacific Islander
108	Race_Other	Num	8		Race: Other
109	Race_White	Num	8		Race: White
110	MaskID	Num	8		Participant Mask ID#

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
111	Visit	Char	100		Visit
112	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
113	DOB_Month	Num	8		Date of Birth - Month
114	DOB_Year	Num	8		Date of Birth - Year

**Data Set Name: *ctl01e\_prerandomization\_exit.sas7bdat***

Num	Variable	Type	Len	Format	Label
1	IfOTHERaSpecify	Char	148	\$148.	If OTHER a Specify
2	DateSceningDiscontinuedMonth	Char	3	\$3.	Date Screening Discontinued Month
3	DateSceningDiscontinuedDAY	Num	8		Date Screening Discontinued Day
4	DateSceningDiscontinuedYear	Num	8		Date Screening Discontinued Year
5	ReasonsForDiscontinu_Other	Num	8		ReasonsForDiscontin: Other
6	ReasonsForDiscontinu_Subjectdoe1	Num	8		ReasonsForDiscontin: Subject does not have at least one diabetes-related autoantibody present
7	ReasonsForDiscontinu_Subjectdoe2	Num	8		ReasonsForDiscontin: Subject does not have stimulated C-peptide levels = 0.2 pmol/ml
8	ReasonsForDiscontinu_Subjecthasa	Num	8		ReasonsForDiscontin: Subject has an active infection or positive PPD test
9	ReasonsForDiscontinu_Subjecthasc	Num	8		ReasonsForDiscontin: Subject has complicating medical issues that would interfere with study conduct or cause increased risk
10	ReasonsForDiscontinu_Subjecthas1	Num	8		ReasonsForDiscontin: Subject has history of malignancies
11	ReasonsForDiscontinu_Subjecthas2	Num	8		ReasonsForDiscontin: Subject has history of immunodeficiency or lymphopenia
12	ReasonsForDiscontinu_Subjecthass	Num	8		ReasonsForDiscontin: Subject has serologic evidence of HIV, Hep B, or Hep C infection
13	ReasonsForDiscontinu_Subjectisc1	Num	8		ReasonsForDiscontin: Subject is currently pregnant or lactating
14	ReasonsForDiscontinu_Subjectisc2	Num	8		ReasonsForDiscontin: Subject is currently participating in another type 1 diabetes treatment study
15	ReasonsForDiscontinu_Subjectisfe	Num	8		ReasonsForDiscontin: Subject is female with preproductive potential and is not willing to avoid pregnancy.
16	ReasonsForDiscontinu_Subjectisn1	Num	8		ReasonsForDiscontin: Subject is not within 3-months (100 days) of diagnosis of type 1 diabetes
17	ReasonsForDiscontinu_Subjectisn2	Num	8		ReasonsForDiscontin: Subject is not between the ages of 6 and 45 years
18	ReasonsForDiscontinu_Subjectisn3	Num	8		ReasonsForDiscontin: Subject is not willing to forgo live vaccinations during treatment and for at least 3 months after the last dose of study medication
19	ReasonsForDiscontinu_Subjectisn4	Num	8		ReasonsForDiscontin: Subject is not at least three months from last live immunization received
20	ReasonsForDiscontinu_Subjectisn5	Num	8		ReasonsForDiscontin: Subject is not willing to comply with intensive diabetes management
21	ReasonsForDiscontinu_Subjectreq1	Num	8		ReasonsForDiscontin: Subject requires use of other immunosuppressive agents
22	ReasonsForDiscontinu_Subjectreq2	Num	8		ReasonsForDiscontin: Subject requires use of non-insulin pharmaceuticals that affect glycemic control or influence glucose tolerance
23	ReasonsForDiscontinu_Subjectweig	Num	8		ReasonsForDiscontin: Subject weighs less than 20kg (44lb)
24	ReasonsForDiscontinu_Subjectwith	Num	8		ReasonsForDiscontin: Subject withdrew consent
25	MaskID	Num	8		Participant Mask ID#

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
26	Visit	Char	100		Visit
27	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: *ctl02\_screening\_med\_history.sas7bdat***

Num	Variable	Type	Len	Format	Label
1	AdmittedToHospitalDuringDiagno	Char	3	\$3.	Were you admitted to a hospital during the diagnosis period
2	AdmittedToICU	Char	3	\$3.	If YES Were you admitted to an Intensive Care Unit ICU while in the hospital
3	Allergies	Char	3	\$3.	Allergies
4	Asthma	Char	3	\$3.	Asthma
5	DKAAtTimeOfDiagnosis	Char	3	\$3.	Did you have Diabetic Ketoacidosis DKA at time of diagnosis
6	DiagnosedWithAIDisease	Char	3	\$3.	Have you ever been diagnosed with an autoimmune diseases
7	FrequentInfections	Char	3	\$3.	Frequent Infections
8	HospitalizedForSomethingOtherT	Char	3	\$3.	Have you ever been hospitalized other than for diabetes
9	InitialDiagnosisBasedOn	Char	59	\$59.	Was your initial diagnosis based on check one
10	LeukopeniaOrNeutropenia	Char	3	\$3.	Leukopenia andor Neutropenia
11	Other	Char	3	\$3.	Other
12	RecievedTetanusVaccination	Char	3	\$3.	Have you ever recieved the Teanus vaccination
13	UpToDateOnVaccinations	Char	3	\$3.	To your knowledge are you or your child up to date on your childhood vaccinations
14	VisitAtOtherSiteThanPrimaryStu	Char	3	\$3.	Did visit occur at a site other than the primary study site
15	experiencedDiabeticKetoacidosi	Char	3	\$3.	Have you ever experienced Diabetic Ketoacidosis
16	DiagnosedBeforeDiabetesDiag1	Char	3	\$3.	Was this diagnosed before your diagnosis of diabetes
17	DiagnosedBeforeDiabetesDiag2	Char	1	\$1.	Was this diagnosed before your diagnosis of diabetes
18	DiagnosedBeforeDiabetesDiag3	Char	1	\$1.	Was this diagnosed before your diagnosis of diabetes
19	FrequentInfectionsSpecify	Char	35	\$35.	If YES Specify
20	HbA1cMeasurement	Char	4	\$4.	Most recent HbA1c if unknown write
21	HospitalizedForSomethingOtherT2	Char	132	\$132.	If YES What For
22	AIDiseaseDiagnosedWithOTHER1	Char	1	\$1.	If OTHER Specify
23	AIDiseaseDiagnosedWithOTHER2	Char	1	\$1.	If OTHER Specify
24	AIDiseaseDiagnosedWithOTHER3	Char	1	\$1.	If OTHER Specify
25	Other1	Char	59	\$59.	Other
26	Other2	Char	40	\$40.	Other
27	Other3	Char	4	\$4.	Other
28	Other4	Char	1	\$1.	Other
29	DateOfT1DMONTH	Char	3	\$3.	Date of diagnosis of type 1 diabetes Month
30	HbA1cMeasurementMonth	Char	3	\$3.	If known record date HbA1c was measured Month
31	RecievedTetanusVaccinationMont	Char	3	\$3.	If yes record date of most recent vaccination Month
32	AIDiseaseDiagnosedWith1	Char	50	\$50.	If YES Record below the code for the autoimmune disases you have been diagnosed with
33	AIDiseaseDiagnosedWith2	Char	1	\$1.	If YES Record below the code for the autoimmune disases you have been diagnosed with

Num	Variable	Type	Len	Format	Label
34	AIDiseaseDiagnosedWith3	Char	1	\$1.	If YES Record below the code for the autoimmune disases you have been diagnosed with
35	DateOfT1DDAY	Num	8		Date of diagnosis of type 1 diabetes Day
36	DateOfT1DYear	Num	8		Date of diagnosis of type 1 diabetes Year
37	HbA1cMeasurementDAY	Num	8		If known record date HbA1c was measured Day
38	HbA1cMeasurementYear	Num	8		If known record date HbA1c was measured Year
39	RecievedTetanusVaccinationDAY	Num	8		If yes record date of most recent vaccination DAY
40	RecievedTetanusVaccinationYear	Num	8		If yes record date of most recent vaccination Year
41	SiteNumberForReimbursement	Num	8		If YES Record Site Number for reimbursement
42	SymptomsHadAtDiagnos_Blurredvisi	Num	8		SymptomsHadAtDiagnos: Blurred vision
43	SymptomsHadAtDiagnos_Frequentinf	Num	8		SymptomsHadAtDiagnos: Frequent infections
44	SymptomsHadAtDiagnos_Frequenturi	Num	8		SymptomsHadAtDiagnos: Frequent urination
45	SymptomsHadAtDiagnos_IncreasedEa	Num	8		SymptomsHadAtDiagnos: Increased Eating
46	SymptomsHadAtDiagnos_Increasedth	Num	8		SymptomsHadAtDiagnos: Increased thirst
47	SymptomsHadAtDiagnos_Nosymptoms	Num	8		SymptomsHadAtDiagnos: No symptoms
48	SymptomsHadAtDiagnos_Weightloss	Num	8		SymptomsHadAtDiagnos: Weight loss
49	MaskID	Num	8		Participant Mask ID#
50	Visit	Char	100		Visit
51	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: *ctl04\_family\_history.sas7bdat***

Num	Variable	Type	Len	Format	Label
1	AnyRelativesDiagnosedwithAIoth	Char	3	\$3.	Have any of your first and second degree relatives been diagnosed with an autoimmune AI disease other than type 1 diabetes
2	HalfSiblingIndicateSameMoth1	Char	11	\$11.	If Half Sibling Indicate same Mother or same Father
3	HalfSiblingIndicateSameMoth2	Char	11	\$11.	If Half Sibling Indicate same Mother or same Father
4	HalfSiblingIndicateSameMoth3	Char	11	\$11.	If Half Sibling Indicate same Mother or same Father
5	HalfSiblingIndicateSameMoth4	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
6	HalfSiblingIndicateSameMoth5	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
7	HalfSiblingIndicateSameMoth6	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
8	HalfSiblingIndicateSameMoth7	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
9	SexOfRelativewithAIDisease1	Char	6	\$6.	Sex of Relative
10	SexOfRelativewithAIDisease2	Char	6	\$6.	Sex of Relative
11	SexOfRelativewithAIDisease3	Char	6	\$6.	Sex of Relative
12	SexOfRelativewithAIDisease4	Char	6	\$6.	Sex of Relative
13	SexOfRelativewithAIDisease5	Char	6	\$6.	Sex of Relative
14	SexOfRelativewithAIDisease6	Char	6	\$6.	Sex of Relative
15	SexOfRelativewithAIDisease7	Char	6	\$6.	Sex of Relative
16	relativehavet1d1	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
17	relativehavet1d2	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
18	relativehavet1d3	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
19	relativehavet1d4	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
20	relativehavet1d5	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
21	relativehavet1d6	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
22	relativehavet1d7	Char	2	\$2.	4 Does Relative have Type 1 Diabetes
23	Relativewitht1d1	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
24	Relativewitht1d2	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
25	Relativewitht1d3	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
26	Relativewitht1d4	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
27	Relativewitht1d5	Char	13	\$13.	3 Relative with Type 1 Diabetes or Other AI Disease
28	Relativewitht1d6	Char	14	\$14.	3 Relative with Type 1 Diabetes or Other AI Disease
29	Relativewitht1d7	Char	14	\$14.	3 Relative with Type 1 Diabetes or Other AI Disease
30	TypeOfAutoImmune11	Char	35	\$35.	1Type of Autoimmune Disease
31	TypeOfAutoImmune12	Char	26	\$26.	1Type of Autoimmune Disease
32	TypeOfAutoImmune13	Char	26	\$26.	1Type of Autoimmune Disease
33	TypeOfAutoImmune14	Char	26	\$26.	1Type of Autoimmune Disease
34	TypeOfAutoImmune15	Char	24	\$24.	1Type of Autoimmune Disease
35	TypeOfAutoImmune16	Char	18	\$18.	1Type of Autoimmune Disease
36	TypeOfAutoImmune17	Char	24	\$24.	1Type of Autoimmune Disease

Num	Variable	Type	Len	Format	Label
37	TypeOfAutoImmune18	Char	18	\$18.	1Type of Autoimmune Disease
38	TypeOfAutoImmune21	Char	26	\$26.	2Type of Autoimmune Disease
39	TypeOfAutoImmune22	Char	26	\$26.	2Type of Autoimmune Disease
40	TypeOfAutoImmune23	Char	1	\$1.	2Type of Autoimmune Disease
41	TypeOfAutoImmune24	Char	1	\$1.	2Type of Autoimmune Disease
42	TypeOfAutoImmune25	Char	1	\$1.	2Type of Autoimmune Disease
43	TypeOfAutoImmune26	Char	1	\$1.	2Type of Autoimmune Disease
44	TypeOfAutoImmune27	Char	1	\$1.	2Type of Autoimmune Disease
45	TypeOfAutoImmune28	Char	1	\$1.	2Type of Autoimmune Disease
46	NumRelativesWithT1D	Num	8		How many of your first and second degree relatives have type 1 diabetes including deceased
47	AgeAtDiagnosis1	Num	8		Age at Diagnosis
48	AgeAtDiagnosis2	Num	8		Age at Diagnosis
49	AgeAtDiagnosis3	Num	8		Age at Diagnosis
50	AgeAtDiagnosis4	Num	8		Age at Diagnosis
51	AgeAtDiagnosis5	Num	8		Age at Diagnosis
52	AgeAtDiagnosis6	Num	8		Age at Diagnosis
53	AgeAtDiagnosis7	Num	8		Age at Diagnosis
54	MaskID	Num	8		Participant Mask ID#
55	Visit	Char	100		Visit
56	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: *ctl05\_eligibility.sas7bdat***

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	CurrentlyPregnanyOr3MonthsAfte	Char	2	\$2.	Subject is currently pregnant or less than three months postpartum
2	EligibilityCommitteeOverride	Char	3	\$3.	Subject is eligible per eligibility committee
3	HasAbnormalLabTests	Char	2	\$2.	Subject has abnormal laboratory tests that in the opinion of the investigator would preclude participation in the trial
4	HasComplicatingMedicalProblems	Char	2	\$2.	Subject has complicating medical issues that in the opinion of the investigator would interfere with the trial
5	HasEBVInfection	Char	2	\$2.	Subject has active EBV infection EBV seronegative and EBV PCR positive
6	HasHadLiveVaccinations3MonthsP	Char	2	\$2.	Subject has had any live vaccinations in the preceeding three months 90 days
7	HasHepBCOrHIV	Char	2	\$2.	Subject has current or past serologic evidence of Hepatitis B or C or HIV infection
8	HasOneDiabetesAntiBody	Char	3	\$3.	Subject has atleast one diabetes related autoantibody Note Insulin antibodies must be drawn within oneweek of start of insulin therapy
9	HasPPDTestResult	Char	3	\$3.	Subject has a positive PPD test result
10	IsInAnotherT1DStudy	Char	2	\$2.	Subject is currently participating in another type 1 diabetes treatment study
11	Issubjectmaleorfemale	Char	6	\$6.	Is subject male or female
12	PersonIs6To45YearsOld	Char	3	\$3.	Subject is between 6 and 45 years of age inclusive
13	PersonWillingToAttendAllFollow	Char	3	\$3.	Subject is willing to attend all scheduled followup visits at the designated clinic
14	PersonWillingToBeRandomizedToG	Char	3	\$3.	Subject is willing to be randomized to either group assignment
15	PersonWillingToComplyWithDiabe	Char	3	\$3.	Subject is willing to comply with intesnive diabetes management
16	PersonWithin100DaysofDiagnosis	Char	3	\$3.	Subject is within 3months 100 days of diagnosis of type 1 diabetes based on ADA criteria
17	PlansOnBeingPregnant	Char	2	\$2.	Subject anticipates becoming pregnant during the study
18	RefusedOrDidNotCompletePregTes	Char	2	\$2.	Subject refused or did not complete the pregnancy test at this visit
19	RefusesToReportPregnacnies	Char	2	\$2.	Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study
20	RefusesToTakePregTest	Char	2	\$2.	Subject has reproductive potential and refuses to undergo pregnancy testing during the course of the study
21	RefusesToUseBirthControl	Char	2	\$2.	Subject is sexually active and refuses to use an effective form of birth control
22	RequiresUseOfSteroids	Char	2	\$2.	Subject requires chronic use of systemic steroids or other immunosuppressive agents for other conditions
23	SimulatedCpepGE2pmolml	Char	3	\$3.	Subject has stimulated Cpetide levels 2pmolml
24	TakingNonInsulinMedAffectingGl	Char	2	\$2.	Subject is taking any noninsulin medications that affect glucose homeostasis

Num	Variable	Type	Len	Format	Label
25	Weighs20kgAtStart	Char	3	\$3.	Subject weighs at least 20 kg 44lb at study entry
26	WillingForgoLiveVaccinationsFo	Char	3	\$3.	Subject willing to forgo any live vaccinations during treatment and for 3 months after the last does of study medication
27	MaskID	Num	8		Participant Mask ID#
28	Visit	Char	100		Visit
29	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: *ctl07\_study\_drug\_admin.sas7bdat***

Num	Variable	Type	Len	Format	Label
1	AccetaminophenGiven	Char	3	\$3.	Was acetaminophen given to the participant
2	AnyGrade3OrHigherProblemsWithT	Char	2	\$2.	Were there any grade 3 or greater problems with the previous infusion
3	AnyProblemsDuringStudy	Char	3	\$3.	Did the participant experience any problems during study drug administration
4	DiphendramineGiven	Char	3	\$3.	Was diphenhydramine given to the participant
5	EBVPCRPositive	Char	3	\$3.	If EBV seronegative was the previous EBV PCR result positive
6	FullDoseInfused	Char	3	\$3.	Was the full dose infused
7	HadAFebrileIllnessLast10Days	Char	3	\$3.	Has the subject had a febrile illness within the last ten days
8	OtherMedsGiven	Char	3	\$3.	Were any other medications given
9	PregnancyTestPositive	Char	3	\$3.	If FEMALE with reproductive or childbearing potential was the pregnancy test result positive
10	PreviousCBCIndicateGrade3OrMor	Char	3	\$3.	Does the previous CBC indicate grade 3 or greater lymphopenia
11	Weight10PercentDifferentThanLa	Char	3	\$3.	Is the current weight 10 different than the previous visit weight
12	AccetaminophenGivenTime	Char	5	\$5.	Time dose given 24 hour clock
13	DiphendramineGivenDoseTime	Char	5	\$5.	Time dose given
14	EndInfusionTime	Char	5	\$5.	End of Infusion Time
15	InfusionTimeStarted	Char	5	\$5.	Time infusion started
16	InfusionTimeStopped	Char	5	\$5.	Time infusion stopped
17	OtherMedsGivenDoseTime	Char	5	\$5.	Time dose given
18	OtherMedsGivenSpecify	Char	49	\$49.	If YES Specify
19	PostInfusionTime	Char	5	\$5.	15 Min Post Infusion Time
20	PreInfusionTime	Char	5	\$5.	PreInfusion Time 24 hour clock
21	_15MinTime	Char	5	\$5.	15 Min Time
22	_30MinPostInfusionTime	Char	5	\$5.	30 Min Post Infusion Time
23	_60MinPostInfusionTime	Char	5	\$5.	60 Min Post Infusion Time
24	_60MinPostInfusionTime2	Char	3	\$3.	60 Min Post Infusion Systolic
25	AccetaminophenGivenDose	Num	8		Dose
26	DosageMG	Num	8		What is the Dose Dose Dosing weight x 10mg/kg MG
27	DoseUsed	Num	8		If NO Record the dose of the drug infused MG
28	EndInfusionDiastolic	Num	8		End of Infusion Diastolic
29	EndInfusionHeartRate	Num	8		End of Infusion Heart rate
30	EndInfusionRespiratoryRate	Num	8		End of Infusion Respiratory rate
31	EndInfusionSystolic	Num	8		End of Infusion Systolic
32	EndInfusionTemperatureC	Num	8		End of Infusion Temperature C
33	EndInfusionTemperatureF	Num	8		End of Infusion Temperature F
34	InfusionTemperatureC	Num	8		PreInfusion Temperature C

Num	Variable	Type	Len	Format	Label
35	OtherMedsGivenDose	Num	8		Dose
36	ParticipantWTKGCurrentVisit	Num	8		Participant Weight KG Current Visit
37	ParticipantWTKGPreviousVisit	Num	8		Participant Weight KG Previous Visit
38	ParticipantWTLBCurrentVisit	Num	8		Participant Weight LB Current Visit
39	ParticipantWTLBPreviousVisit	Num	8		Participant Weight LB Previous Visit
40	PostInfusionDiastolic	Num	8		15 Min Post Infusion Diastolic
41	PostInfusionHeartRate	Num	8		15 Min Post Infusion Heart rate
42	PostInfusionRespiratoryRate	Num	8		15 Min Post Infusion Respiratory rate
43	PostInfusionSystolic	Num	8		15 Min Post Infusion Systolic
44	PostInfusionTemperatureC	Num	8		15 Min Post Infusion Temperature C
45	PostInfusionTemperatureF	Num	8		15 Min Post Infusion Temperature F
46	PreInfusionDiastolic	Num	8		PreInfusion Diastolic
47	PreInfusionHeartRate	Num	8		PreInfusion Heart rate
48	PreInfusionRespiratory	Num	8		PreInfusion Respiratory rate
49	PreInfusionSystolic	Num	8		PreInfusion Systolic
50	PreInfusionTemperatureF	Num	8		PreInfusion Temperature F
51	WeightUsedToDetermineDosageKG	Num	8		Record weight used to determine dosage KG
52	WeightUsedToDetermineDosageLB	Num	8		Record weight used to determine dosage LB
53	_15MinDiastolic	Num	8		15 Min Diastolic
54	_15MinHeartRate	Num	8		15 Min Heart rete
55	_15MinRespiratoryRate	Num	8		15 Min Respiratory rate
56	_15MinSystolic	Num	8		15 Min Systolic
57	_15MinTemperatureC	Num	8		15 Min Temperature C
58	_15MinTemperatureF	Num	8		15 Min Temperature F
59	_30MinPostInfusionDiastolic	Num	8		30 Min Post Infusion Diastolic
60	_30MinPostInfusionHeartRate	Num	8		30 Min Post Infusion Heart rate
61	_30MinPostInfusionRespiratory	Num	8		30 Min Post Infusion Respiratory rate
62	_30MinPostInfusionSystolic	Num	8		30 Min Post Infusion Systolic
63	_30MinPostInfusionTemperature	Num	8		30 Min Post Infusion Temperature C
64	_30MinPostInfusionTemperature2	Num	8		30 Min Post Infusion Temperature F
65	_60MinPostInfusionDiastolic	Num	8		60 Min Post Infusion Diastolic
66	_60MinPostInfusionHeartRate	Num	8		60 Min Post Infusion Heart Rate
67	_60MinPostInfusionRespiratory	Num	8		60 Min Post Infusion Respiratory rate
68	_60MinPostInfusionTemperature	Num	8		60 Min Post Infusion Temperature C
69	_60MinPostInfusionTemperature2	Num	8		60 Min Post Infusion Temperature F
70	diphenydramedose	Num	8		diphenydramine dose
71	MaskID	Num	8		Participant Mask ID#
72	Visit	Char	100		Visit
73	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: ctl12\_visit\_form.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	AnyAbnormalities	Char	3	\$3.	Were there any abnormalities on the physical exam
2	AnySymptomsInjuriesIllnessSide	Char	3	\$3.	During the interval since the last scheduled clinic test have you had any symptoms injuries infections illnesses or side effects or worsening of preexisting conditions
3	AnyVaccinationsOtherThanStudy	Char	3	\$3.	Since the last scheduled visit have you had any vaccinations other than those administered as part of the study
4	CBCCollected	Char	3	\$3.	CBC with Differential analysis done at local lab
5	ChemCollected	Char	3	\$3.	Chemistries
6	EBVCMVCollected	Char	3	\$3.	EBVCMV Viral Serology
7	EBVPCRCollected	Char	3	\$3.	EBV PCR for EBV seronegative only as routine others for clinical indication only
8	FlowCytometryCollected	Char	3	\$3.	Flow cytometry
9	FluPICollected	Char	3	\$3.	Flu PostImmunization Serology
10	HLACollected	Char	3	\$3.	HLA
11	HaveChildbearingPotential	Char	3	\$3.	If FEMALE does the participant have reproductive or childbearing potential
12	HbA1cTest	Char	3	\$3.	HbA1c
13	OnBirthControlMedication	Char	3	\$3.	Are you currently taking birth control medication
14	OtherSerologyCollected	Char	3	\$3.	Other Serology
15	PBMCCollected	Char	3	\$3.	Frozen PBMCPlasma
16	PKACollected	Char	3	\$3.	PK Analysis
17	PlanOnPregnancyBeforeStudyEnd	Char	3	\$3.	Do you plan on becoming pregnant before the study end
18	PregnancyTestPositive	Char	3	\$3.	If YES Was the test result positive
19	RNACollected	Char	3	\$3.	RNA
20	SerumAABCollected	Char	3	\$3.	Serum for Autoantibodies
21	SerumCollected	Char	3	\$3.	Serum
22	TetanusPICollected	Char	3	\$3.	Tetanus PostImmunization Serology Visit 27 only
23	UrinPregnancyTestTakenThisVisi	Char	3	\$3.	Was a urine pregnancy test completed at this visit
24	UseAFormOfBirthControl	Char	3	\$3.	IF YES continue otherwise proceed to Section D Do you currently use a form of birth control Females of reproductive age are expected to use a form of birth control or practice abstinence
25	VisitAtOtherSiteThanPrimaryStu	Char	3	\$3.	Did visit occur at site other than the primary study site
26	_2HourMMTT	Char	3	\$3.	2hour MMTT
27	_4HourMMTT	Char	3	\$3.	4hour MMTT
28	AnyVaccinationsOtherThanStudyS	Char	136	\$136.	If YES Specify
29	CBCCollectedMonth	Char	3	\$3.	CBC with Differential Month
30	ChemCollectedMonth	Char	3	\$3.	Chemistries Month
31	EBVCMVCollectedMonth	Char	3	\$3.	EBVCMV Viral Serology Month

Num	Variable	Type	Len	Format	Label
32	EBVPCRCollectedMonth	Char	3	\$3.	EBV PCR for EBV seronegative only as routine others for clinical indication only Month
33	FloyCytometryCollectedMonth	Char	3	\$3.	Flow cytometry Month
34	FluPICollectedMonth	Char	3	\$3.	Flu PostImmunization Serology Month
35	HLACollectedMonth	Char	3	\$3.	HLA Month
36	HbA1cTestMonth	Char	3	\$3.	HbA1c Month
37	OtherSerologyCollectedMonth	Char	3	\$3.	Other Serology Month
38	PBMCCollectedMonth	Char	3	\$3.	Frozen PBMCPlasma Month
39	PKACollectedMonth	Char	3	\$3.	PK Analysis Month
40	RNACollectedMonth	Char	3	\$3.	RNA Month
41	SerumAABCollectedMonth	Char	3	\$3.	Serum for Autoantibodies Month
42	SerumCollectedMonth	Char	3	\$3.	Serum Month
43	TetanusPICollectedMonth	Char	3	\$3.	Tetanus PostImmunization Serology Visit 27 only Month
44	_2HourMMTTMonth	Char	3	\$3.	2hour MMTT Month
45	_4HourMMTTMonth	Char	3	\$3.	4hour MMTTMonth
46	BPDiastolic	Num	8		Seated blood pressure Diastolic mmHG
47	BPSystolic	Num	8		Seated blood pressure Systolic mmHG
48	CBCCollectedDay	Num	8		CBC with Differential Day
49	CBCCollectedYear	Num	8		CBC with Differential Year
50	ChemCollectedDAY	Num	8		Chemistries Day
51	ChemCollectedYear	Num	8		Chemistries Year
52	EBVCMVCollectedDay	Num	8		EBVCMV Viral Serology Day
53	EBVCMVCollectedYear	Num	8		EBVCMV Viral Serology Year
54	EBVPCRCollectedDay	Num	8		EBV PCR for EBV seronegative only as routine others for clinical indication only Day
55	EBVPCRCollectedYear	Num	8		EBV PCR for EBV seronegative only as routine others for clinical indication only Year
56	FloyCytometryCollectedDay	Num	8		Flow cytometry Day
57	FloyCytometryCollectedYear	Num	8		Flow cytometry Year
58	FluPICollectedDay	Num	8		Flu PostImmunization Serology Day
59	FluPICollectedYear	Num	8		Flu PostImmunization Serology Year
60	HLACollectedDay	Num	8		HLA Day
61	HLACollectedYear	Num	8		HLA Year
62	HbA1cTestDay	Num	8		HbA1c Day
63	HbA1cTestYear	Num	8		HbA1c Year
64	HeightCM	Num	8		Height CM
65	HeightIN	Num	8		Height IN
66	OtherSerologyCollectedDay	Num	8		Other Serology Day
67	OtherSerologyCollectedYear	Num	8		Other Serology Year
68	PBMCCollectedDay	Num	8		Frozen PBMCPlasma Day

Num	Variable	Type	Len	Format	Label
69	PBMCCollectedYear	Num	8		Frozen PBMCPlasma Year
70	PKACollectedDay	Num	8		PK Analysis Day
71	PKACollectedYear	Num	8		PK Analysis Year
72	RNAcollectedDAY	Num	8		DNA Day
73	RNAcollectedYear	Num	8		DNA Year
74	SerumAABCcollectedDay	Num	8		Serum for Autoantibodies Day
75	SerumAABCcollectedYear	Num	8		Serum for Autoantibodies Year
76	SerumCollectedDay	Num	8		Serum Day
77	SerumCollectedYear	Num	8		Serum Year
78	TetanusPICollectedDay	Num	8		Tetanus PostImmunization Serology Visit 27 only Day
79	TetanusPICollectedYear	Num	8		Tetanus PostImmunization Serology Visit 27 only Year
80	VisitSiteForReimbursement	Num	8		If YES Record Site Number for reimbursement
81	WeightKG	Num	8		Weight KG
82	WeightLB	Num	8		Weight LB
83	_2HourMMTTDay	Num	8		2hour MMTT Day
84	_2HourMMTTYear	Num	8		2hour MMTT Year
85	_4HourMMTTDAY	Num	8		4hour MMTT Day
86	_4HourMMTTYear	Num	8		4hour MMTT Year
87	MaskID	Num	8		Participant Mask ID#
88	Visit	Char	100		Visit
89	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: ctl13m\_mortality\_event.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	AutopsyAvailable	Char	3	\$3.	Will an autopsy report be available
2	AutopsyPerformed	Char	1	\$1.	Has an autopsy been performed at this point
3	AutopsyPerformedAvailable	Char	1	\$1.	IF YES Is the autopsy available
4	AutopsyReport	Char	2	\$2.	Autopsy Report
5	DeathCertificate	Char	2	\$2.	Death Certificate
6	DeathCertificateObtained	Char	2	\$2.	Has a death certificate been obtained
7	DeathCertificateRequested	Char	2	\$2.	If NO Has one been requested
8	DeathPlace	Char	5	\$5.	Where di the death occur
9	DeathType	Char	7	\$7.	Type of Report
10	DeathWas	Char	17	\$17.	The death was
11	HospitalReport	Char	2	\$2.	Hospital report on fatal illness
12	InterviewOfAttendingPhysician	Char	2	\$2.	Interview of attending physician
13	InterviewOfFamilyMember	Char	3	\$3.	Interview of family member
14	Other	Char	3	\$3.	Other
15	ParticipantOnStudyMedAtTimeOfD	Char	3	\$3.	Was the participant recieving study medications at the time of the death event
16	ParticipantRecievingInfusionAt	Char	3	\$3.	Was the participant recieving study infusion at the time of death event
17	ParticipantWas	Char	7	\$7.	At the time of onset of the terminal event the participant was
18	ContributoryCoD	Char	33	\$33.	Describe any contributory causes of death
19	DeathPlaceOther	Char	17	\$17.	If OTHER Specify
20	ImmediateCauseOfDeath	Char	24	\$24.	Describe the immediate cause of death
21	OtherSpecify	Char	47	\$47.	If OTHER Specify
22	SpecifyCausesOfDeathPresentAtR	Char	7	\$7.	Specify which of the immediate underlying andor contributory causes of death were presnt at randomization
23	UnderlyingCauseofDeath	Char	20	\$20.	Describe the underlying cause of death
24	DODMonth	Char	3	\$3.	Date of Death Month
25	DateOfDeathUnknown	Num	8		Date of death Unknown
26	DODDay	Num	8		Date of Death Day
27	DODYear	Num	8		Date of Death Year
28	MaskID	Num	8		Participant Mask ID#
29	Visit	Char	100		Visit
30	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: diabetes\_management.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	AreThere3GlucoseValuesAvailabl	Char	7	\$7.	Are there atleast three glucose values available for atleast three days
2	AvgAllRecordedGlucosesMmoll	Char	6	\$6.	Average of all recorded glucoses over three days units
3	AvgRecordedFastingGlucosesmmol	Char	6	\$6.	Average of recorded fasting glucoses over three days units
4	ExperiencedAnyHypoglycemicEven	Char	3	\$3.	Have you experienced any sevre hypoglycemic events loss of consciousness seizure or assistance required from another person due to an altered state or consciousness since trhe last visit
5	HighestGlucosemmol	Char	6	\$6.	Highest recorded glucose over three days units
6	InsulDoseInfoAvailableFor3Days	Char	7	\$7.	Is the insulin dose information available for atleast three days
7	InsulinRoutineDaily	Char	27	\$27.	Daily insulin routines check one
8	LowestGlucosemmoll	Char	6	\$6.	Lowest recorded glucose over three days units
9	RecordedGlucoseDuringFirstSeve2	Char	6	\$6.	What was the recorded glucose during the first severe hypoglycemic event units
10	RecordedGlucoseDuringSecondSev2	Char	1	\$1.	What was the recorded glucose during the second severe hypoglycemic event units Record
11	RecordedGlucoseDuringThirdSeve2	Char	1	\$1.	What was the recorded glucose during the third severe hypoglycemic event units Record
12	SubjectUsingCGMS	Char	7	\$7.	Is the person using a Continuous Glucose Monitoring System CGMS
13	InsulinInjectionSite	Char	121	\$121.	diabetes mgmt insulin 2 Site location of most recent last 24 hour period insulin injection eg left tricep
14	AverageUnitsOfftermediateInsul	Num	8		Average unitsday of intermediatelong acting insulin average over 3 day period
15	AvgAllRecordedGlucosesMgDL	Num	8		Average of all recorded glucoses over three days
16	AvgRecordedFastingGlucosesmgdl	Num	8		Average of recorded fasting glucoses over three days
17	AvgUnitsShortActingInsulin	Num	8		Average unitsday of short acting insulin
18	DiabetesEducator	Num	8		Study associated Diabetes Educator
19	Endocrinologist	Num	8		Study associated Endocrinologist
20	HighestGlucosemgdl	Num	8		Highest recorded glucose over three days
21	HowManyHypoglycemicEvents	Num	8		If Yes How many severe hypoglycemic events have ocurred since the last visit
22	LowestGlucosemgdl	Num	8		Lowest recorded glucose over three days
23	NonStudyDiabetesEducator	Num	8		NonStudy associated Diabetes Educator
24	NonStudyEndocrinologist	Num	8		NonStudy associated Endocrinologist
25	NonStudyOtherHealthCareProvide	Num	8		NonStudy associated other health care provider
26	OtherHealthCareProvider	Num	8		Study associatedother health care provider
27	RecordedGlucoseDuringFirstSeve	Num	8		What was the recorded glucose during the first severe hypoglycemic event
28	RecordedGlucoseDuringSecondSev	Num	8		What was the recorded glucose during the second severe hypoglycemic event units

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
29	RecordedGlucoseDuringThirdSeve	Num	8		What was the recorded glucose during the third severe hypoglycemic event
30	TotalOfHBGMonitoringsLessThan6	Num	8		Number of home blood glucose monitorings over three days that were less than 65mgdl
31	TotalOfHomeBloodGlucoseOver3Da	Num	8		Total number of home blood glucose monitorings over three days
32	MaskID	Num	8		Participant Mask ID#
33	Visit	Char	100		Visit
34	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: followup\_eligible\_participant.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	BiweeklyInjectionVisitSchedule	Char	1	\$1.	Biweekly Injection Visit Schedule
2	ConcernsAboutReceivingPlaceboR	Char	20	\$20.	Concerns about receiving placebo Rank
3	ConflictingResponsibilitiesRan	Char	20	\$20.	Conflicting Responsibilities Rank
4	DoesNotTolerateOGTTRank	Char	20	\$20.	Does not tolerate OGTTIVGTTs well Rank
5	DoesNotWantToBeBlindedRank	Char	16	\$16.	Does not want to be blinded to individual test results during the study Rank
6	FamilyWishesToWaitUntilOlderRa	Char	16	\$16.	Family wishes to wait until participant is older Rank
7	FearOfStudyDrugRisksRank	Char	20	\$20.	Fear of Study Drug Risks Rank
8	IndicateTheStudyParticipantWas	Char	31	\$31.	Please indicate which TrialNet Study this participant was offered
9	IsParticipantCurrentlyEligible	Char	20	\$20.	If participant was offered an intervention study please indicate if participant is currently eligible or potentially eligible
10	IsTheParticipantInterested	Char	8	\$8.	Is the participant interested in participating in the above study
11	LostToFollowUp	Char	16	\$16.	Lost to FollowUp
12	MonetaryCompensationRank	Char	16	\$16.	Monetary Compensation Rank
13	MonthlyInfusionVisitScheduleRa	Char	20	\$20.	Monthly Infusion Visit Schedule Rank
14	OtherRank	Char	20	\$20.	Other Rank
15	PregnantNursingOrPlanningChild	Char	16	\$16.	Pregnant nursing or planning children in the future Rank
16	TimeCommitmentRank	Char	20	\$20.	Time Commitment Rank
17	UnableUnwillingToTravelRank	Char	20	\$20.	Unable Unwilling to Travel Rank
18	UnwillingToTakeInvestigational	Char	16	\$16.	Unwilling to take investigational drug Rank
19	_2DayInfusionPeriod	Char	1	\$1.	2 Day Infusion Period
20	_2WeekIfusionPeriodRank	Char	20	\$20.	2 week Infusion Period Rank
21	willingToConsiderAtALaterTime	Char	3	\$3.	Did the participant indicate they may be willing to consider participating in the study at a later time
22	AdditionalComments	Char	948	\$948.	Additional comments describing participants Situation
23	ParticipantWasContactedByOther	Char	48	\$48.	Participant was contacted by Other Specify
24	ReasonsNotInterestedOtherSpeci	Char	1289	\$1289.	Reasons the participant is not currently interested Other Specify
25	ParticipantWasContac_Other	Num	8		ParticipantWasContac: Other
26	ParticipantWasContac_SiteCoordin	Num	8		ParticipantWasContac: Site Coordinator
27	ParticipantWasContac_SitePI	Num	8		ParticipantWasContac: Site PI
28	ReasonsNotInterested_2DayInfusio	Num	8		ReasonsNotInterested: 2 Day Infusion Period
29	ReasonsNotInterested_2weekInfusi	Num	8		ReasonsNotInterested: 2 week Infusion Period
30	ReasonsNotInterested_BiweeklyInj	Num	8		ReasonsNotInterested: Biweekly Injection Visit Schedule
31	ReasonsNotInterested_Concernsabo	Num	8		ReasonsNotInterested: Concerns about receiving placebo
32	ReasonsNotInterested_Conflicting	Num	8		ReasonsNotInterested: Conflicting Responsibilities ( Work, School, Family)

Num	Variable	Type	Len	Format	Label
33	ReasonsNotInterested_Doesnotwant	Num	8		ReasonsNotInterested: Does not want to be blinded to individual test results during the study
34	ReasonsNotInterested_Familywishe	Num	8		ReasonsNotInterested: Family wishes to wait until participant is older
35	ReasonsNotInterested_FearofStudy	Num	8		ReasonsNotInterested: Fear of Study Drug Risks
36	ReasonsNotInterested_LosttoFollo	Num	8		ReasonsNotInterested: Lost to Follow-Up
37	ReasonsNotInterested_MonetaryCom	Num	8		ReasonsNotInterested: Monetary Compensation
38	ReasonsNotInterested_MonthlyInfu	Num	8		ReasonsNotInterested: Monthly Infusion Visit Schedule
39	ReasonsNotInterested_Other	Num	8		ReasonsNotInterested: Other
40	ReasonsNotInterested_Participant	Num	8		ReasonsNotInterested: Participant does not tolerate OGTT/IVGTTs well
41	ReasonsNotInterested_Pregnantnur	Num	8		ReasonsNotInterested: Pregnant, nursing or planning children in the future
42	ReasonsNotInterested_Refusednore	Num	8		ReasonsNotInterested: Refused; no reason given
43	ReasonsNotInterested_TimeCommitm	Num	8		ReasonsNotInterested: Time Commitment
44	ReasonsNotInterested_UnableUnwil	Num	8		ReasonsNotInterested: Unable/ Unwilling to Travel
45	ReasonsNotInterested_Unwillingto	Num	8		ReasonsNotInterested: Unwilling to take investigational drug
46	MaskID	Num	8		Participant Mask ID#
47	Visit	Char	100		Visit
48	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: h1n1\_vacc\_form.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	DidSubjectReceiveH1N1Vaccinati	Char	3	\$3.	H1N1 Vaccination Did subject receive H1N1 Vaccination
2	DidSubjectReceiveH1N1Vaccinati2	Char	3	\$3.	H1N1 Vaccination Did subject receive H1N1 Vaccination booster
3	H1N1VaccinationBoosterType	Char	16	\$16.	H1N1 Vaccination Receive H1N1 Vaccination booster If yes type
4	H1N1VaccinationType	Char	16	\$16.	H1N1 Vaccination Received H1N1 Vaccination If yes type
5	MaskID	Num	8		Participant Mask ID#
6	Visit	Char	100		Visit
7	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
8	Date_At_H1N1VaccBooster	Num	8	MMDDYY10.	Date at H1N1V Vacc Booster
9	Date_At_H1N1Vacc	Num	8	MMDDYY10.	Date at H1N1V Vacc

**Data Set Name: nh07\_changeofstatus.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	ChangeOfStatusOccuring	Char	98	\$98.	Change in status that has occurred
2	IsParticipantWillingBeContacte	Char	1	\$1.	Is the participant still willing to be contacted
3	ParticipantCompletedEntireStud	Char	3	\$3.	Participant completed entire study
4	ReasonForWithdrawal	Char	45	\$45.	Record the primary reason for withdrawal
5	WillingToBeContacted	Char	3	\$3.	Is the subject still willing to be contacted
6	WillingToContinueAfterPregnanc	Char	3	\$3.	Is the participant willing to continue participation as a Control after completion of pregnancy
7	WithdrewConsentWhy	Char	1	\$1.	If withdrew consent selected record the reason why
8	ReasonAdverseEventSpecify	Char	106	\$106.	Reason Adverse Event specify
9	ReasonForWithdrawalOTHER	Char	789	\$789.	If OTHER Specify
10	ReasonWithdrewConsentSpecify	Char	770	\$770.	Reason Withdrew Consent specify
11	WithdrewConsentWhyIfOther	Char	1	\$1.	If withdrew consent selected record the reason why If OTHER specify
12	DateCompletionMM	Char	3	\$3.	Date of completionMM
13	DateCompletionDD	Num	8		Date of completionDD
14	DateCompletionYYYY	Num	8		Date of completionYYYY
15	PhiX174VisitNumber	Num	8		If PhiX174 Visit ONLY ie Weeks 6 7 8 13 14 16 53 54 58 60 or 62 Record week number
16	MaskID	Num	8		Participant Mask ID#
17	Visit	Char	100		Visit
18	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
19	Date_at_Change_of_Status	Num	8	MMDDYY10.	Date at Change of Status
20	Date_at_Reactivation	Num	8	MMDDYY10.	Date at Reactivation
21	Date_at_Withdrawal	Num	8	MMDDYY10.	Date at Withdrawal
22	Date_at_Last_Visit	Num	8	MMDDYY10.	If Other, Date of Last Visit
23	Date_at_Pregnancy_Completion	Num	8	MMDDYY10.	Date at Pregnancy Completion

**Data Set Name: nh09\_followupmissedvisit.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	MotherBabyWillingToContinueTak	Char	3	\$3.	Is the participant motherbaby willing to continue taking the study substance
2	ParticipantAgreeToContinue	Char	3	\$3.	If Yes did the participant agree to continue in the study
3	ParticipantContacted	Char	3	\$3.	Was the participant contacted
4	ParticipantExpectedToContinue	Char	3	\$3.	Is the participant expected to continue with future followup visits
5	ParticipantWillingToContinueMe	Char	1	\$1.	IF YES Is the participant willing to continue taking the study medication as described by the protocol
6	ReasonForMissedVisit	Char	83	\$83.	What was the primary reason for the missed visit
7	ReasonParticipantMissed	Char	710	\$710.	Provide additional information about the reason the visit was missed if known
8	MissedVisitInfant	Char	1	\$1.	Which visit was missed
9	VistMissed	Char	18	\$18.	Which visit was missed
10	MaskID	Num	8		Participant Mask ID#
11	Visit	Char	100		Visit
12	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: nh20\_permparticipantsitetrnsfr.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	Reason	Char	68	\$68.	Reason for Transfer
2	OtherSpecify	Char	146	\$146.	If Other Specify
3	PhiX174VisitWeekNumber	Num	8		If PhiX174 Visit ONLY ie Weeks 6 7 8 13 14 16 53 54 58 59 60 or 62 Record week number
4	MaskID	Num	8		Participant Mask ID#
5	Visit	Char	100		Visit
6	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
7	Date_At_EffectiveTransfer	Num	8	MMDDYY10.	Date at effective transfer
8	Date_At_OtherVisit	Num	8	MMDDYY10.	Date at Other Visit

**Data Set Name: phix\_admin.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	AnyProblemsThisVisit	Char	3	\$3.	Did the participant experience any problems during this visit
2	GivenIntramuscularImmunization	Char	3	\$3.	Was the participant given hisher intramuscular immunization
3	GivenWeightAdjustedDosePhiX174	Char	3	\$3.	Was the participant given hisher weightadjusted dose of PhiX174 intravenously at this visit
4	PreImmunizationSerologyCollect	Char	3	\$3.	Was the preimmunization serology specimen collected at this visit
5	_15MinPostImmunization	Char	3	\$3.	Was the 15minute postimmunization specimen collected at this visit
6	AnyProblemsThisVisitExplain	Char	21	\$21.	If YES Explain
7	GivenIntramuscularImmunization2	Char	154	\$154.	If NO Explain
8	GivenWeightAdjustedDosePhiX1742	Char	72	\$72.	If NO Explain
9	PreImmunizationSerologyCollect2	Char	174	\$174.	If NO Explain
10	_15MinPostImmunizationExplain	Char	31	\$31.	If NO Explain
11	ParticipantWeightKG	Num	8		Participant Weight KG
12	PhiX174InjectedML	Num	8		Total dose of PhiX174 injected ml
13	MaskID	Num	8		Participant Mask ID#
14	Visit	Char	100		Visit
15	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
16	Date_At_PreImmunSerology	Num	8	MMDDYY10.	Date at preimmunization serology specimen

**Data Set Name: pregnancy\_confirmation.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	CodedMedStopped	Char	1	\$1.	Has the coded medication been stopped
2	HadComplicationOfPreg	Char	7	\$7.	Has the participant ever experienced a complication of pregnancy
3	NeonatalDeath	Char	2	\$2.	Has the participant ever experienced a pregnancy that resulted in neonatal death
4	ParticipantCarryingPregnancyTo	Char	7	\$7.	Is the participant planning on carrying the pregnancy to term
5	ParticpantsObCareProviderInfor	Char	7	\$7.	Has the participants obstetric care provider been informed of her participation in this study
6	PostTermDelivryGT37GWeeks	Char	2	\$2.	Has the participant ever experienced a postterm delivery 37 gestational weeks
7	PostTermDelivryLT42GWeeks	Char	2	\$2.	Has the participant ever experienced a postterm delivery 42 gestational weeks
8	SpontaneousMiscarage	Char	3	\$3.	Has the participant ever experienced a spontaneous miscarage
9	StillBirth	Char	2	\$2.	Has the participant ever experienced a pregnancy that resulted in a still birth
10	WillingToContinueFUVisits	Char	7	\$7.	Is the participant willing to continue with future followup visits
11	LastAttendedVisit	Char	8	\$8.	Last attended study visit prior to the confirmed pregnancy
12	DateDeliveryUnknown	Num	8		Estimated date of delivery unknown
13	DateMenCycleUnknown	Num	8		Date of last menstrual cycle unknown
14	DatePregTestUnknown	Num	8		Date of positive pregnancy test unknown
15	PriorPregnancyNumberUnkown	Num	8		record total number of prior pregnancies unkown
16	PhiX174VisitNumber	Num	8		If PhiX174 Visit ONLY ie weeks 6 7 8 13 14 16 53 54 58 59 60 or 62 Record week number
17	TotalNumOfPregNotIncluThisOne	Num	8		Indicate the total number of prior pregnancies not including this one
18	MaskID	Num	8		Participant Mask ID#
19	Visit	Char	100		Visit
20	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
21	Date_At_EstDelivery	Num	8	MMDDYY10.	Date at Estimated date of delivery
22	Date_At_LastMenstrualCycle	Num	8	MMDDYY10.	Date at last menstrual cycle
23	Date_At_PositivePregTest	Num	8	MMDDYY10.	Date at positive pregnancy test
24	Date_At_OtherVisit	Num	8	MMDDYY10.	Date at Other Visit

**Data Set Name: pregnancy\_outcome.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	BreastFeeding	Char	7	\$7.	Is the participant currently breastfeeding
2	ComplicationsInDelivery	Char	7	\$7.	Were there any complications during the delivery
3	HbA1cMeasure	Char	7	\$7.	Was an HbA1c measured at any time during the pregnancy
4	LiveBirths	Char	3	\$3.	Did the pregnancy result in a live birth or multiple live births
5	Miscarriage	Char	3	\$3.	Did the pregnancy result in a miscarriage
6	OutcomeUKNDueToLossOfParticpan	Char	2	\$2.	Is the outcome of the pregnancy unknown due to loss of participant to followup
7	PregnancyAbortion	Char	3	\$3.	Was the pregnancy terminated as a result of an induced abortion
8	ReasonForAbortionMedicallyIndi	Char	2	\$2.	Was the reason for the abortion medically indicated
9	StillBirth	Char	2	\$2.	Did the pregnancy result in a stillbirth
10	StillBirthHaveAnyOtherComplica	Char	1	\$1.	Did the stillbirth have any other complications
11	StillBirthHaveMalformations	Char	1	\$1.	Did the stillbirth have any congenital malformations
12	InfantBornCongenitalMalform1	Char	7	\$7.	Was the infant born with any congenital malformations
13	InfantBornCongenitalMalform2	Char	1	\$1.	Was the infant born with any congenital malformations
14	InfantBornCongenitalMalform3	Char	1	\$1.	Was the infant born with any congenital malformations
15	InfantBornOtherComplication1	Char	7	\$7.	Was the infant born with other complications
16	InfantBornOtherComplication2	Char	1	\$1.	Was the infant born with other complications
17	InfantBornOtherComplication3	Char	1	\$1.	Was the infant born with other complications
18	InfantDischargedFromHopsita1	Char	3	\$3.	Was the infant discharged from the hospital alive
19	InfantDischargedFromHopsita2	Char	1	\$1.	Was the infant discharged from the hospital alive
20	InfantDischargedFromHopsita3	Char	1	\$1.	Was the infant discharged from the hospital alive
21	InfantInNICU1	Char	7	\$7.	Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time
22	InfantInNICU2	Char	1	\$1.	Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time
23	InfantInNICU3	Char	1	\$1.	Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time
24	Sex1	Char	4	\$4.	Sex
25	Sex2	Char	1	\$1.	Sex
26	Sex3	Char	1	\$1.	Sex
27	ReasonForAbortionMedicallyIndi2	Char	1	\$1.	Specify reason
28	StillBirthHaveAnyOtherComplica2	Char	1	\$1.	If YES Specify
29	StillBirthHaveMalformationsSpe	Char	1	\$1.	If YES Specify
30	InfantBornCongenitalMalformS1	Char	1	\$1.	Was the infant born with any congenital malformations Specify
31	InfantBornCongenitalMalformS2	Char	1	\$1.	Was the infant born with any congenital malformations Specify

Num	Variable	Type	Len	Format	Label
32	InfantBornCongenitalMalformS3	Char	1	\$1.	Was the infant born with any congenital malformations Specify
33	InfantBornOtherComplicationS1	Char	1	\$1.	Was the infant born with other complications Specify
34	InfantBornOtherComplicationS2	Char	1	\$1.	Was the infant born with other complications Specify
35	InfantBornOtherComplicationS3	Char	1	\$1.	Was the infant born with other complications Specify
36	InfantDeathCause1	Char	1	\$1.	Specify cause of death
37	InfantDeathCause2	Char	1	\$1.	Specify cause of death
38	InfantDeathCause3	Char	1	\$1.	Specify cause of death
39	NumberOfinfantsUnknown	Num	8		Record number of infants the birth resulted in Unknown
40	RecordHbA1cUnknown	Num	8		Record HbA1c unknown
41	BirthWeightGMUnknown1	Num	8		Birth weight gm unknown
42	BirthWeightGMUnknown2	Num	8		Birth weight gm unknown
43	BirthWeightGMUnknown3	Num	8		Birth weight gm unknown
44	BirthWeightLBUnknown1	Num	8		Birth weight lb unknown
45	BirthWeightLBUnknown2	Num	8		Birth weight lb unknown
46	BirthWeightLBUnknown3	Num	8		Birth weight lb unknown
47	FiveMinuteAPGARScoreUnknown1	Num	8		Five minute APGAR score unknown
48	FiveMinuteAPGARScoreUnknown2	Num	8		Five minute APGAR score unknown
49	FiveMinuteAPGARScoreUnknown3	Num	8		Five minute APGAR score unknown
50	GestationalAgeUnknown1	Num	8		Gestational age unknown
51	GestationalAgeUnknown2	Num	8		Gestational age unknown
52	GestationalAgeUnknown3	Num	8		Gestational age unknown
53	OneMinuteAPGARScoreUnknown1	Num	8		One minute APGAR score unknown
54	OneMinuteAPGARScoreUnknown2	Num	8		One minute APGAR score unknown
55	OneMinuteAPGARScoreUnknown3	Num	8		One minute APGAR score unknown
56	BirthWeightLBS	Num	8		Birth Weight lbs oz
57	HbA1cMeasure2	Num	8		Indicate HbA1c
58	NumberOfInfants	Num	8		Record number of infants both living and deceased the birth resulted in
59	PregnancyIDNumber	Num	8		Record the Pregnancy Identification Number
60	BirthWeight1	Num	8		Birth weight gm
61	BirthWeight2	Num	8		Birth weight gm
62	BirthWeight3	Num	8		Birth weight gm
63	BirthWeightLbs1	Num	8		Birth weight lbs
64	BirthWeightLbs2	Num	8		Birth weight lbs
65	BirthWeightLbs3	Num	8		Birth weight lbs
66	BirthWeightOz1	Num	8		Birth weight oz
67	BirthWeightOz2	Num	8		Birth weight oz
68	BirthWeightOz3	Num	8		Birth weight oz

Num	Variable	Type	Len	Format	Label
69	GestationalAge1	Num	8		Gestational age
70	GestationalAge2	Num	8		Gestational age
71	GestationalAge3	Num	8		Gestational age
72	_1MinAPGARScore1	Num	8		One minute APGAR score
73	_1MinAPGARScore2	Num	8		One minute APGAR score
74	_1MinAPGARScore3	Num	8		One minute APGAR score
75	_5MinAPGARScore1	Num	8		Five minute APGAR score
76	_5MinAPGARScore2	Num	8		Five minute APGAR score
77	_5MinAPGARScore3	Num	8		Five minute APGAR score
78	MaskID	Num	8		Participant Mask ID#
79	Visit	Char	100		Visit
80	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
81	Date_At_PregnancyEnd	Num	8	MMDDYY10.	Date at Pregnancy End
82	Date_At_InfantDeath1	Num	8	MMDDYY10.	Date at Infant Death #1
83	Date_At_InfantDeath2	Num	8	MMDDYY10.	Date at Infant Death #2
84	Date_At_InfantDeath3	Num	8	MMDDYY10.	Date at Infant Death #3
85	Date_At_HbA1c	Num	8	MMDDYY10.	Date at HbA1c
86	Date_At_InfantHospDisch1	Num	8	MMDDYY10.	Date at Infant Hospital Discharge #1
87	Date_At_InfantHospDisch2	Num	8	MMDDYY10.	Date at Infant Hospital Discharge #2
88	Date_At_InfantHospDisch3	Num	8	MMDDYY10.	Date at Infant Hospital Discharge #3

**Data Set Name: protocol\_deviation.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	Deviation	Char	1	\$1.	Protocol Deviation
2	DeviationError	Char	49	\$49.	Protocol deviationprocedural error
3	DeviationReportedFor	Char	6	\$6.	Protocol deviation reported for
4	PNotified	Char	3	\$3.	Was PI notified
5	ProtocolDeviation	Char	87	\$87.	Protocol Deviation
6	ProtocolDeviation2	Char	83	\$83.	Protocol Deviation
7	ProtocolDeviationApprovedByElg	Char	3	\$3.	Was protocol deviation approved by the Eligibility Committee
8	RequiredBloodCollectionProcedu	Char	1	\$1.	Required procedureblood collection not completed Specify
9	SubjectRandomizedInelgibilityA	Char	3	\$3.	If Ineligible subject randomized checked approved by Eligibility Committee
10	TN16ProtocolDeviation	Char	88	\$88.	TN16 Protocol deviation
11	TestingErrorProcedure	Char	1	\$1.	Testing procedure error
12	DescribeCorrectionAction	Char	175	\$175.	Describe corrective action taken if necessary depending on circumstances
13	DescribeDeviation	Char	204	\$204.	Describe Deviation procedural error and circumstances
14	DeviationOccurenceSpecify	Char	1	\$1.	IF OTHER Specify Deviation
15	ExlcudedMedicationSpecify	Char	1	\$1.	Excluded Medications Specify
16	ExplanProtocolDeviation	Char	1	\$1.	Explanation for protocol deviation
17	OtherSpecify	Char	116	\$116.	Other Specify
18	OtherSpecify2	Char	159	\$159.	If Other Specify
19	OtherSpecify3	Char	1	\$1.	Other Specifiy
20	ProtocolChair	Char	1	\$1.	If yes who was the protocol chair
21	ProtocolDeviationSpecify	Char	119	\$119.	If OTHER Specify deviation
22	ProtocolDeviationOtherSubcateg	Char	53	\$53.	Protocol Deviation Other subcategory
23	StudyVisitCompletedFor	Char	13	\$13.	Study visit this form being completed for
24	PhiX174WeekNumber	Num	8		If PhiX174 Visit ONLY ie Weeks 6 7 8 13 14 16 53 54 58 59 60 62 Record week number
25	MaskID	Num	8		Participant Mask ID#
26	Visit	Char	100		Visit
27	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
28	Date_at_Deviation	Num	8	MMDDYY10.	Date at Deviation
29	Date_at_Other	Num	8	MMDDYY10.	Date at Other
30	Date_at_Protocol_Deviation	Num	8	MMDDYY10.	Date at Protocol Deviation

**Data Set Name: registration.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	status	Char	20		Participant Status
2	MaskID	Num	8		Participant Mask ID#
3	Date_of_Study_Start	Num	8	MMDDYY10.	Date of Study Start
4	Date_of_Registration	Num	8	MMDDYY10.	Date of Registration

**Data Set Name: research\_labs.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Informat</b>	<b>Label</b>
1	MaskID	Num	8			Participant Mask ID#
2	Date_of_Draw	Num	8	MMDDYY10.		Date of Draw
3	Event_Title	Char	100			Specimen Collection Form
4	SPEC_NAME	Char	250			Specimen Name
5	SampleMaskID	Char	10			Sample Mask ID#
6	TEST_NAME	Char	150	\$150.	\$150.	Test Name
7	RESULT	Char	1000	\$1000.	\$1000.	Result
8	ResultType	Char	6			Result Type
9	Visit	Char	100			Visit
10	Date_at_Test_Results_Reported	Num	8	MMDDYY10.		Date at Test Results Reports
11	Date_at_Evaluation	Num	8	MMDDYY10.		Date at Sample Evaluation
12	Date_Received	Num	8	MMDDYY10.		Date when Sample Received at Lab
13	Date_Shipped	Num	8	MMDDYY10.		Date when Sample Shipped
14	LabID	Num	8			LabID

**Data Set Name: treatment\_table.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	ORDERING_INDEX	Num	8		ORDERING_INDEX
2	CONSUMED	Num	8		CONSUMED
3	TreatmentName	Char	100		
4	RegistrationGroup	Char	100		
5	Treatment_Start_Date	Num	8	MMDDYY10.	
6	Randomization_Date	Num	8	MMDDYY10.	
7	Data_Entry_User_ID	Num	8		User ID of Data Entry Personnel
8	MaskID	Num	8		Participant Mask ID#
9	SequenceNumber	Num	8		