

**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: 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

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
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

Num	Variable	Type	Len	Format	Label
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

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
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

Num	Variable	Type	Len	Format	Label
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

Num	Variable	Type	Len	Format	Label
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: *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: demographics.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	Ethnicity	Char	37	\$37.	Ethnicity
2	Sex	Char	6	\$6.	Sex
3	BirthMonth	Char	3	\$3.	Date of Birth Month
4	Age	Num	8		Age years
5	BirthDay	Num	8		Date of Birth DAY
6	BirthYear	Num	8		Date of Birth Year
7	Race_AmericanIndianorAlaskaNat	Num	8		Race: American Indian or Alaska Native
8	Race_Asian	Num	8		Race: Asian
9	Race_BlackorAfricanAmerican	Num	8		Race: Black or African American
10	Race_NativeHawaiianorOtherPaci	Num	8		Race: Native Hawaiian or Other Pacific Islander
11	Race_Refused	Num	8		Race: Refused
12	Race_Unknownornotreported	Num	8		Race: Unknown or not reported
13	Race_White	Num	8		Race: White
14	MaskID	Num	8		Participant Mask ID#
15	Visit	Char	100		Visit
16	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
17	DOB_Month	Num	8		Date of Birth - Month
18	DOB_Year	Num	8		Date of Birth - Year

**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: eligibility.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	AnticipatesPregnancy	Char	14	\$14.	Subject anticipates becoming pregnant
2	Between6and45yearsOfAge	Char	3	\$3.	Subject is between 6 and 45 years of age inclusive
3	Breastfeeding	Char	14	\$14.	Subject is currently breastfeeding
4	CpepLevelsGE0point2pmolml	Char	8	\$8.	Subject has stimulated Cpeptide levels 02 pmolml
5	EligibilityCommitteeOverride	Char	3	\$3.	Subject is eligible per eligibility committee
6	ForgoImmunizations	Char	3	\$3.	Subject is willing to forgo live vaccinations during the 12 months of treatment and for an additional 3 months
7	HasAnActiveInfection	Char	3	\$3.	Subject has an active infection
8	HasCurrentOrPastHIVHepatitisBO	Char	2	\$2.	Subject has serologic evidence of current or past HIV Hepatitis B or C infection
9	HasPositivePPDresult	Char	8	\$8.	Subject has a positive PPD test result
10	HasReproductivePotentialAndRef	Char	14	\$14.	Subject has reproductive potential and refuses to undergo pregnancy testing during the course of study
11	HasReproductivePotentialAndRef2	Char	14	\$14.	Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study
12	HistoryOfMalignancies	Char	2	\$2.	Subject has a history of malignancies
13	ImmunodeficientOrHasChronicLym	Char	2	\$2.	Subject is immunodeficient or has clinically significant chronic lymphopenia
14	IsPregnant	Char	14	\$14.	Subject is currently pregnant
15	IsSexuallyActiveAndRefuseUseBi	Char	14	\$14.	Subject is sexually active and refuses to use an effective form of birth control
16	NoCompletingPregnancyTestAtThi	Char	14	\$14.	Subject refused or did not complete the pregnancy test at this visit
17	NoLiveImmunizationsInPastMonth	Char	3	\$3.	Subject has not had any live immunizations in the preceding month
18	OneDiabetesRelatedAutoantibody	Char	3	\$3.	Subject has at least one diabetesrelated autoantibody present
19	OtherRiskFactors	Char	3	\$3.	Subject has complicating medical issues or abnormal clinical laboratory results that in the opinion of the investigator would interfere with study conduct or cause increased risk including preexisting cardiac disease COPD neurological or blood count abnorm
20	ParticipatingInOtherT1Dtreatme	Char	2	\$2.	Subject is currently participating in another type 1 diabetes treatment study
21	PermissionSampleStorage	Char	3	\$3.	If yes was permission given for samples of the participants blood to be stored for other tests
22	PermissionSampleStorageDNA	Char	11	\$11.	If yes with or without DNA
23	RequiresImmunosuppressiveAgents	Char	2	\$2.	Subject requires use of other immunosuppressive agents
24	TakingMedsThatInfluenceGlucose	Char	2	\$2.	Subject is taking any medications that are known to influence glucose tolerance
25	UsingNonInsulinPharmaceuticals	Char	2	\$2.	Subject is currently using noninsulin pharmaceuticals to affect glycemic control

Num	Variable	Type	Len	Format	Label
26	Within3mosOfT1Ddiagnosis	Char	3	\$3.	Subject is within 3 months 100 days of diagnosis of type 1 diabetes based on ADA criteria
27	maleorfemale	Char	6	\$6.	Is patient male or female
28	signedInformedConsent	Char	8	\$8.	Subject has signed written informed consent for participation
29	weighsAtLeast20kg	Char	3	\$3.	Subject weighs at least 20 kg 44 lb at study entry
30	willComplyWithIntensiveDiabete	Char	3	\$3.	Subject is willing to comply with intensive diabetes management
31	InformedConsentDateMonth	Char	3	\$3.	Informed consent date month
32	InformedConsentDateDay	Num	8		Informed consent date day
33	InformedConsentDateYear	Num	8		Informed consent date year
34	MaskID	Num	8		Participant Mask ID#
35	Visit	Char	100		Visit
36	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: 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	HalfSiblingIndicateSameMoth8	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
10	HalfSiblingIndicateSameMoth9	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
11	SexOfRelativewithAIDisease1	Char	6	\$6.	Sex of Relative
12	SexOfRelativewithAIDisease2	Char	6	\$6.	Sex of Relative
13	SexOfRelativewithAIDisease3	Char	6	\$6.	Sex of Relative
14	SexOfRelativewithAIDisease4	Char	6	\$6.	Sex of Relative
15	SexOfRelativewithAIDisease5	Char	6	\$6.	Sex of Relative
16	SexOfRelativewithAIDisease6	Char	6	\$6.	Sex of Relative
17	SexOfRelativewithAIDisease7	Char	4	\$4.	Sex of Relative
18	SexOfRelativewithAIDisease8	Char	6	\$6.	Sex of Relative
19	SexOfRelativewithAIDisease9	Char	6	\$6.	Sex of Relative
20	relativehavet1d1	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
21	relativehavet1d2	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
22	relativehavet1d3	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
23	relativehavet1d4	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
24	relativehavet1d5	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
25	relativehavet1d6	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
26	relativehavet1d7	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
27	relativehavet1d8	Char	2	\$2.	4 Does Relative have Type 1 Diabetes
28	relativehavet1d9	Char	2	\$2.	4 Does Relative have Type 1 Diabetes
29	Relativewitht1d1	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
30	Relativewitht1d2	Char	22	\$22.	3 Relative with Type 1 Diabetes or Other AI Disease
31	Relativewitht1d3	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
32	Relativewitht1d4	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
33	Relativewitht1d5	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
34	Relativewitht1d6	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
35	Relativewitht1d7	Char	13	\$13.	3 Relative with Type 1 Diabetes or Other AI Disease
36	Relativewitht1d8	Char	13	\$13.	3 Relative with Type 1 Diabetes or Other AI Disease



Num	Variable	Type	Len	Format	Label
37	RelativewithT1d9	Char	14	\$14.	3 Relative with Type 1 Diabetes or Other AI Disease
38	TypeOfAutoImmune11	Char	26	\$26.	1Type of Autoimmune Disease
39	TypeOfAutoImmune12	Char	26	\$26.	1Type of Autoimmune Disease
40	TypeOfAutoImmune13	Char	26	\$26.	1Type of Autoimmune Disease
41	TypeOfAutoImmune14	Char	26	\$26.	1Type of Autoimmune Disease
42	TypeOfAutoImmune15	Char	26	\$26.	1Type of Autoimmune Disease
43	TypeOfAutoImmune16	Char	26	\$26.	1Type of Autoimmune Disease
44	TypeOfAutoImmune17	Char	1	\$1.	1Type of Autoimmune Disease
45	TypeOfAutoImmune18	Char	15	\$15.	1Type of Autoimmune Disease
46	TypeOfAutoImmune19	Char	26	\$26.	1Type of Autoimmune Disease
47	TypeOfAutoImmune21	Char	35	\$35.	2Type of Autoimmune Disease
48	TypeOfAutoImmune22	Char	26	\$26.	2Type of Autoimmune Disease
49	TypeOfAutoImmune23	Char	24	\$24.	2Type of Autoimmune Disease
50	TypeOfAutoImmune24	Char	24	\$24.	2Type of Autoimmune Disease
51	TypeOfAutoImmune25	Char	5	\$5.	2Type of Autoimmune Disease
52	TypeOfAutoImmune26	Char	1	\$1.	2Type of Autoimmune Disease
53	TypeOfAutoImmune27	Char	1	\$1.	2Type of Autoimmune Disease
54	TypeOfAutoImmune28	Char	1	\$1.	2Type of Autoimmune Disease
55	TypeOfAutoImmune29	Char	1	\$1.	2Type of Autoimmune Disease
56	NumRelativesWithT1D	Num	8		How many of your first and second degree relatives have type 1 diabetes including deceased
57	AgeAtDiagnosis1	Num	8		Age at Diagnosis
58	AgeAtDiagnosis2	Num	8		Age at Diagnosis
59	AgeAtDiagnosis3	Num	8		Age at Diagnosis
60	AgeAtDiagnosis4	Num	8		Age at Diagnosis
61	AgeAtDiagnosis5	Num	8		Age at Diagnosis
62	AgeAtDiagnosis6	Num	8		Age at Diagnosis
63	AgeAtDiagnosis7	Num	8		Age at Diagnosis
64	AgeAtDiagnosis8	Num	8		Age at Diagnosis
65	AgeAtDiagnosis9	Num	8		Age at Diagnosis
66	MaskID	Num	8		Participant Mask ID#
67	Visit	Char	100		Visit
68	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: 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: optional\_visit\_6a.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	ParticipantConsentToParticipat	Char	3	\$3.	Does the participant consent to participating in visit 6a the additional 2 hour MMTT conducted one week after visit 6
2	DateConsentedToParticipateInVi	Char	2	\$2.	Date participant consented to participate in visit 6a Day
3	DateConsentedToParticipateInVi3	Char	4	\$4.	Date participant consented to participate in visit 6a Year
4	DateConsentedToParticipateInVi2	Char	3	\$3.	Date participant consented to participate in visit 6a Month
5	MaskID	Num	8		Participant Mask ID#
6	Visit	Char	100		Visit
7	Date_of_Visit	Num	8	MMDDYY10.	Date of 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: *physical\_exam.sas7bdat***

Num	Variable	Type	Len	Format	Label
1	AbdomenFindings	Char	12	\$12.	Abdomen findings
2	GenitaliaFindings	Char	12	\$12.	Genitalia findings
3	HEENTFindings	Char	12	\$12.	HEENT findings
4	HeartFindings	Char	12	\$12.	Heart findings
5	LungsFindings	Char	12	\$12.	Lungs findings
6	LymphaticsFindings	Char	12	\$12.	Lymphatics findings
7	MusculoskeletalFindings	Char	12	\$12.	Musculoskeletal findings
8	NeckThyroidFindings	Char	12	\$12.	NeckThyroid findings
9	NeurologicFindings	Char	12	\$12.	Neurologic findings
10	PhysicalExamPerformedAtThisVis	Char	3	\$3.	Was a physical exam performed at this visit
11	PulsesFindings	Char	12	\$12.	Pulses findings
12	SkinFindings	Char	12	\$12.	Skin findings
13	TannerGenitalia	Char	18	\$18.	Genitalia male
14	TannerPubicHair	Char	18	\$18.	Pubic Hair both
15	TannerStageBreast	Char	18	\$18.	Tanner Stage Breast
16	OtherFindings1	Char	12	\$12.	Other findings
17	OtherFindings2	Char	12	\$12.	Other findings
18	OtherFindings3	Char	1	\$1.	Other findings
19	AbdomenAbnormalExplain	Char	109	\$109.	Abdomen Abnormal Explain
20	GenitaliaAbnormalExplain	Char	137	\$137.	Genitalia Abnormal Explain
21	HeartAbnormalExplain	Char	102	\$102.	Heart Abnormal Explain
22	LungsAbnormalExplain	Char	45	\$45.	Lungs Abnormal Explain
23	LymphaticsAbnormalExplain	Char	273	\$273.	Lymphatics Abnormal Explain
24	MusculoskeletalAbnormalExplain	Char	226	\$226.	Musculoskeletal Abnormal Explain
25	NeckThyroidAbnormalExplain	Char	105	\$105.	NeckThyroid Abnormal Explain
26	NeurologicAbnormalExplain	Char	363	\$363.	Neurologic Abnormal Explain
27	PulsesAbnormalExplain	Char	39	\$39.	Pulses Abnormal Explain
28	SkinAbnormalExplain	Char	234	\$234.	Skin Abnormal Explain
29	OtherAbnormalExplain1	Char	171	\$171.	Other Abnormal Explain
30	OtherAbnormalExplain2	Char	52	\$52.	Other Abnormal Explain
31	OtherAbnormalExplain3	Char	1	\$1.	Other Abnormal Explain
32	AbdominalCircumferenceNotDone	Num	8		Abdominal Circumference not done
33	BloodPressureNotDone	Num	8		BloodPressure not done
34	HeartRateNotDone	Num	8		heartRate not done
35	HeightNotDone	Num	8		Height not done
36	RespiratoryRateNotDone	Num	8		respiratory rate not done

Num	Variable	Type	Len	Format	Label
37	TemperatureNotDone	Num	8		temperature not done
38	WeightNotDone	Num	8		weight not done
39	AbdominalCircumference	Num	8		Abdominal Circumference
40	BPD	Num	8		Seated arm blood pressure Diastolic
41	BPS	Num	8		Seated arm blood pressure Systolic
42	HeartRateBPM	Num	8		heartRate count
43	HeightCM	Num	8		Height CM
44	RespiratoryRatePerMin	Num	8		respiratory rate per min
45	TemperatureC	Num	8		temperature C
46	WeightKG	Num	8		WeightKGDoube
47	MaskID	Num	8		Participant Mask ID#
48	Visit	Char	100		Visit
49	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit



**Data Set Name: positive\_ebvpcr\_conf\_testing.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	EBVPCRResultAtScreening	Char	12	\$12.	What was the participants EBVPCR result at screening
2	DatePositiveResultLearnedMonth	Char	3	\$3.	When did you learn of the positive EBVPCR result Month
3	DateTestedPositiveMonth	Char	3	\$3.	What is the date of the visit where the subject tested positive for EBVPCR Month
4	TwoConfirmatoryTestingDoneMont	Char	3	\$3.	When was the two confirmatory testing done Month
5	DatePositiveResultLearnedDay	Num	8		When did you learn of the positive EBVPCR result Day
6	DatePositiveResultLearnedYear	Num	8		When did you learn of the positive EBVPCR result Year
7	DateTestedPositiveDay	Num	8		What is the date of the visit where the subject tested positive for EBVPCR Day
8	DateTestedPositiveYear	Num	8		What is the date of the visit where the subject tested positive for EBVPCR Year
9	TwoConfirmatoryTestingDoneDay	Num	8		When was the two confirmatory testing done Day
10	TwoConfirmatoryTestingDoneYear	Num	8		When was the two confirmatory testing done Year
11	MaskID	Num	8		Participant Mask ID#
12	Visit	Char	100		Visit
13	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

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

Num	Variable	Type	Len	Format	Label
1	HaveReproductiveOrChildbearing	Char	3	\$3.	Does the participant have reproductive or childbearing potential
2	PartnerKnownToBePregnant	Char	2	\$2.	Is the subjects partner known to be pregnant
3	PartnerPlanToBecomePregnantWit	Char	2	\$2.	Does the subjects partner plan to become pregnant within the next year
4	PartnerUsingBirthControl	Char	3	\$3.	Is the subject or subjects partner using birth control abstinence or acceptable method
5	PlanToBecomePregnantWithinTheN	Char	2	\$2.	Does the subject plan to become pregnant within the next year
6	SubjectUsingBirthControl	Char	3	\$3.	Is the subject using birth control abstinence or acceptable method
7	UrinePregnancyTestCompletedAtT	Char	3	\$3.	Was a urine pregnancy test completed at this visit
8	UrinePregnancyTestResultPositi	Char	2	\$2.	Was the test result positive
9	MaskID	Num	8		Participant Mask ID#
10	Visit	Char	100		Visit
11	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**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	SubjectRandomizedIneligibilityA	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*

Num	Variable	Type	Len	Format	Informat	Label
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: screening\_informed\_consent.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	PermissionSampleStorageDNA	Char	11	\$11.	If yes with or without DNA
2	WasPermissionGivenForBloodSamp	Char	14	\$14.	On the consent form was permission given for samples of the participants blood to be stored for other tests
3	InformedConsentMonth	Char	3	\$3.	Date written informed consent for screening was obtained month
4	InformedConsentDay	Num	8		Date written informed consent for screening was obtained day
5	InformedConsentYear	Num	8		Date written informed consent for screening was obtained year
6	MaskID	Num	8		Participant Mask ID#
7	Visit	Char	100		Visit
8	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: screening\_medical\_history.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	AddisonsDisease	Char	2	\$2.	Addisons Disease Adrenal Insufficiency
2	AllergiesEver	Char	3	\$3.	Ever had allergies
3	Alopecia	Char	3	\$3.	Alopecia
4	AsthmaEver	Char	7	\$7.	Ever had asthma
5	AutoimmuneThyroidDisease	Char	7	\$7.	Autoimmune Thyroid Disease Hypothyroidism or Hashimotos Disease
6	CardiovascularFindings	Char	12	\$12.	Cardiovascular findings
7	CeliacDisease	Char	3	\$3.	Celiac Disease Gluten Allergy or Celiac Sprue
8	ConstitutionalSymptomsFindings	Char	12	\$12.	Constitutional Symptoms eg fever weight change fatigue findings
9	DKAatDiagnosis	Char	7	\$7.	Did you have Diabetic Ketoacidosis DKA at time of diagnosis
10	DKAsinceDiagnosis	Char	2	\$2.	Since diagnosis have you ever experienced Diabetic Ketoacidosis
11	DermatologicFindings	Char	12	\$12.	Dermatologic findings
12	DiagnosedAutoimmuneDiseaseEver	Char	3	\$3.	Have you ever ben diagnosed with an autoimmune diseases
13	EczemaEver	Char	7	\$7.	Ever had Eczema
14	EndocrineFindings	Char	12	\$12.	Endocrine findings
15	FrequentOtherInfectionsEver	Char	7	\$7.	Ever had frequent other infections
16	GastrointestinalFindings	Char	12	\$12.	Gastrointestinal findings
17	GenitourinaryFindings	Char	12	\$12.	Genitourinary findings
18	GravesDisease	Char	3	\$3.	Graves Disease Hyperthyroidism
19	HaveThereBeenAnyChangesInHealt	Char	3	\$3.	Have there been any changes in health since the last visit
20	HematopoeticFindings	Char	12	\$12.	Hematopoetic findings
21	HospitalizedDuringDiagnosis	Char	3	\$3.	Were you admitted to a hospital during the diagnosis period
22	HospitalizedOtherThanDiabetes	Char	7	\$7.	Have you ever been hospitalized other than for diabetes
23	HypogonadismOrPrematureMenopau	Char	2	\$2.	Hypogonadism or Premature Menopause
24	Hypoparathyroidism	Char	2	\$2.	Hypoparathyroidism
25	ICUDuringDiagnosis	Char	3	\$3.	If yes were you admitted to an Intensive Care Unit ICU while in the hospital
26	InflammatoryBowelDisease	Char	2	\$2.	Inflammatory Bowel Disease
27	LeukopeniaOrNeutropeniaEver	Char	7	\$7.	Ever had leukopenianeutropenia
28	Lupus	Char	2	\$2.	Lupus
29	LymphaticFindings	Char	12	\$12.	Lymphatic findings
30	MultipleSclerosis	Char	2	\$2.	Multiple Sclerosis
31	MusculoskeletalFindings	Char	12	\$12.	Musculoskeletal findings
32	NeurologicalFindings	Char	12	\$12.	Neurological Findings
33	OtherConditionsDiseasesEver	Char	7	\$7.	Ever had other conditionsdiseases

Num	Variable	Type	Len	Format	Label
34	PerniciousAnemia	Char	2	\$2.	Pernicious Anemia
35	Psoriasis	Char	3	\$3.	Psoriasis
36	PsychiatricFindings	Char	12	\$12.	Psychiatric findings
37	RespiratoryFindings	Char	12	\$12.	Respiratory findings
38	RheumatologicDisease	Char	2	\$2.	Rheumatologic Disease
39	VaccinationsOtherThanStudyMed	Char	3	\$3.	Since the last scheduled visit have you had any vaccinations other than those administered as part of the study
40	Vitiligo	Char	3	\$3.	Vitiligo
41	OtherAutoimmuneDisease1	Char	3	\$3.	Other autoimmune disease
42	OtherFindings1	Char	12	\$12.	Other findings
43	OtherFindings2	Char	12	\$12.	Other findings
44	CardiovascularAbnormalExplain	Char	334	\$334.	Cardiovascular abnormal explain
45	ConstitutionalSymptomsAbnormal	Char	231	\$231.	Constitutional Symptoms Abnormal Explain
46	FrequentOtherInfectionsSpecify	Char	231	\$231.	Ever had frequent other infections specify
47	GastrointestinalAbnormalExplai	Char	357	\$357.	Gastrointestinal abnormal explain
48	GenitourinaryAbnormalExplain	Char	160	\$160.	Genitourinary Abnormal Explain
49	HematopoeticAbnormalExplain	Char	262	\$262.	Hematopoetic Abnormal Explain
50	HospitalizedOtherThanDiabetesW	Char	181	\$181.	If yes what for
51	LymphaticAbnormalExplain	Char	176	\$176.	Lymphatic Abnormal Explain
52	MusculoskeletalAbnormalExplain	Char	434	\$434.	Musculoskeletal abnormal explain
53	NeurologicalAbnormalExplain	Char	327	\$327.	Neurological Abnormal Explain
54	OtherConditionsDiseasesSpecify	Char	511	\$511.	Ever had other conditionsdiseases specify
55	PsychiatricAbnormalExplain	Char	158	\$158.	Psychiatric Abnormal Explain
56	OtherAbnormalExplain2	Char	151	\$151.	Other abnormal explain
57	OtherAutoimmuneDiseaseSpeci1	Char	19	\$19.	Other autoimmune disease specify
58	VaccinationTypeSpecify1	Char	27	\$27.	Vaccination type specify
59	VaccinationTypeSpecify2	Char	17	\$17.	Vaccination type specify
60	AddisonsDiseaseDiagnosisDateMo	Char	1	\$1.	Addisons Disease Adrenal Insufficiency diagnosis date month
61	AlopeciaDiagnosisDateMonth	Char	3	\$3.	Alopecia diagnosis date month
62	AutoimmuneThyroidDiseaseDiagno2	Char	3	\$3.	Autoimmune Thyroid Disease Hypothyroidism or Hashimotos Disease diagnosis date month
63	CeliacDiseaseDiagnosisDateMont	Char	3	\$3.	Celiac Disease Gluten Allergy or Celiac Sprue diagnosis date month
64	DateOfT1DdiagnosisMonth	Char	3	\$3.	Date of diagnosis of T1D month
65	GravesDiseaseDiagnosisDateMont	Char	3	\$3.	Graves Disease Hyperthyroidism diagnosis date month
66	HypogonadismOrPrematureMenopau3	Char	1	\$1.	Hypogonadism or Premature Menopause diagnosis date month
67	HypoparathyroidismDiagnosisDat2	Char	1	\$1.	Hypoparathyroidism diagnosis date month
68	InflammatoryBowelDiseaseDiagno2	Char	1	\$1.	Inflammatory Bowel Disease diagnosis date month



Num	Variable	Type	Len	Format	Label
69	LupusDiagnosisDateMonth	Char	1	\$1.	Lupus diagnosis date Month
70	MostRecentHbA1cDateMonth	Char	3	\$3.	Most recent HbA1c date month
71	MultipleSclerosisDiagnosisDate2	Char	1	\$1.	Multiple Sclerosis diagnosis date month
72	PerniciousAnemiaDiagnosisDateM	Char	1	\$1.	Pernicious Anemia diagnosis date month
73	PsoriasisDiagnosisDateMonth	Char	3	\$3.	Psoriasis diagnosis date month
74	RheumatologicDiseaseDiagnosisD2	Char	1	\$1.	Rheumatologic Disease diagnosis date month
75	VitiligoDiagnosisDateMonth	Char	3	\$3.	Vitiligo diagnosis date month
76	OtherAutoimmuneDiseaseDiagn1_2	Char	3	\$3.	Other autoimmune disease diagnosis date month
77	VaccinationDateMonth1	Char	3	\$3.	Vaccination date month
78	VaccinationDateMonth2	Char	3	\$3.	Vaccination date month
79	AddisonsDiseaseDiagnosisDateDa	Num	8		Addisons Disease Adrenal Insufficiency diagnosis date day
80	AddisonsDiseaseDiagnosisDateYe	Num	8		Addisons Disease Adrenal Insufficiency diagnosis date year
81	AlopeciaDiagnosisDateDay	Num	8		Alopecia diagnosis date day
82	AlopeciaDiagnosisDateYear	Num	8		Alopecia diagnosis date year
83	AutoimmuneThyroidDiseaseDiagno	Num	8		Autoimmune Thyroid Disease Hypothyroidism or Hashimotos Disease diagnosis date day
84	AutoimmuneThyroidDiseaseDiagno3	Num	8		Autoimmune Thyroid Disease Hypothyroidism or Hashimotos Disease diagnosis date year
85	CeliacDiseaseDiagnosisDateDay	Num	8		Celiac Disease Gluten Allergy or Celiac Sprue diagnosis date day
86	CeliacDiseaseDiagnosisDateYear	Num	8		Celiac Disease Gluten Allergy or Celiac Sprue diagnosis date year
87	DateOfT1DdiagnosisDay	Num	8		Date of diagnosis of T1D day
88	DateOfT1DdiagnosisYear	Num	8		Date of diagnosis of T1D year
89	GravesDiseaseDiagnosisDateDay	Num	8		Graves Disease Hyperthyroidism diagnosis date day
90	GravesDiseaseDiagnosisDateYear	Num	8		Graves Disease Hyperthyroidism diagnosis date year
91	HypogonadismOrPrematureMenopau2	Num	8		Hypogonadism or Premature Menopause diagnosis date day
92	HypogonadismOrPrematureMenopau4	Num	8		Hypogonadism or Premature Menopause diagnosis date year
93	HypoparathyroidismDiagnosisDat	Num	8		Hypoparathyroidism diagnosis date day
94	HypoparathyroidismDiagnosisDat3	Num	8		Hypoparathyroidism diagnosis date year
95	InflammatoryBowelDiseaseDiagno	Num	8		Inflammatory Bowel Disease diagnosis date day
96	InflammatoryBowelDiseaseDiagno3	Num	8		Inflammatory Bowel Disease diagnosis date year
97	LupusDiagnosisDateDay	Num	8		Lupus diagnosis date day
98	LupusDiagnosisDateYear	Num	8		Lupus diagnosis date year
99	MostRecentHbA1c	Num	8		Most recent HbA1c
100	MostRecentHbA1cDateDay	Num	8		Most recent HbA1c date day
101	MostRecentHbA1cDateYear	Num	8		Most recent HbA1c date year
102	MultipleSclerosisDiagnosisDate	Num	8		Multiple Sclerosis diagnosis date day
103	MultipleSclerosisDiagnosisDate3	Num	8		Multiple Sclerosis diagnosis date year
104	PerniciousAnemiaDiagnosisDateD	Num	8		Pernicious Anemia diagnosis date day

Num	Variable	Type	Len	Format	Label
105	PerniciousAnemiaDiagnosisDateY	Num	8		Pernicious Anemia diagnosis date year
106	PsoriasisDiagnosisDateDay	Num	8		Psoriasis diagnosis date day
107	PsoriasisDiagnosisDateYear	Num	8		Psoriasis diagnosis date year
108	RheumatologicDiseaseDiagnosisD	Num	8		Rheumatologic Disease diagnosis date day
109	RheumatologicDiseaseDiagnosisD3	Num	8		Rheumatologic Disease diagnosis date year
110	VitiligoDiagnosisDateYear	Num	8		Vitiligo diagnosis date year
111	VitiligoDiagnosisDateday	Num	8		Vitiligo diagnosis date day
112	OtherAutoimmuneDiseaseDiagn1_1	Num	8		Other autoimmune disease diagnosis date day
113	OtherAutoimmuneDiseaseDiagn1_3	Num	8		Other autoimmune disease diagnosis date year
114	VaccinationDateDay1	Num	8		Vaccination date day
115	VaccinationDateDay2	Num	8		Vaccination date day
116	VaccinationDateYear1	Num	8		Vaccination date year
117	VaccinationDateYear2	Num	8		Vaccination date year
118	InitialDiagnosisBase_Formaltesti	Num	8		InitialDiagnosisBase: Formal testing for diabetes (OGTT)
119	InitialDiagnosisBase_Randomblood	Num	8		InitialDiagnosisBase: Random blood glucose check
120	InitialDiagnosisBase_Routinescre	Num	8		InitialDiagnosisBase: Routine screening for diabetes without presence of symptoms
121	InitialDiagnosisBase_SymptomsofD	Num	8		InitialDiagnosisBase: Symptoms of Diabetes
122	SymptomsAtTimeOfDiag_Blurredvisi	Num	8		SymptomsAtTimeOfDiag: Blurred vision
123	SymptomsAtTimeOfDiag_Frequentinf	Num	8		SymptomsAtTimeOfDiag: Frequent infections
124	SymptomsAtTimeOfDiag_Frequenturi	Num	8		SymptomsAtTimeOfDiag: Frequent urination
125	SymptomsAtTimeOfDiag_IncreasedEa	Num	8		SymptomsAtTimeOfDiag: Increased Eating
126	SymptomsAtTimeOfDiag_Increasedth	Num	8		SymptomsAtTimeOfDiag: Increased thirst
127	SymptomsAtTimeOfDiag_Nosymptoms	Num	8		SymptomsAtTimeOfDiag: No symptoms
128	SymptomsAtTimeOfDiag_Weightloss	Num	8		SymptomsAtTimeOfDiag: Weight loss
129	MaskID	Num	8		Participant Mask ID#
130	Visit	Char	100		Visit
131	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

**Data Set Name: study\_drug\_administration.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	AnyOtherProblemsDuringStudyDru	Char	3	\$3.	Did the subject experience any other problems during study drug administration
2	ItchingGrade	Char	1	\$1.	Itching Grade
3	PainGrade	Char	1	\$1.	Pain Grade
4	RednessGrade	Char	1	\$1.	Redness Grade
5	SwellingGrade	Char	1	\$1.	Swelling Grade
6	WasSubcutaneousInjectionGiven	Char	3	\$3.	Was subcutaneous injection given
7	subjectExperienceAnyProblemsFo	Char	3	\$3.	Did the subject experience any problems following the drug administration
8	AnyOtherProblemsDuringStudyDru2	Char	189	\$189.	Any other problems during study drug administration If YES Specify
9	InjectionSiteLocation	Char	70	\$70.	If injection was given please indicate the injection site location
10	ItchingDuration	Char	4	\$4.	Itching Duration
11	ItchingTimePostInjection	Char	4	\$4.	Itching Time Post Injection
12	PainDuration	Char	2	\$2.	Pain Duration
13	PainTimePostInjection	Char	2	\$2.	Pain Time Post Injection
14	RednessDuration	Char	4	\$4.	Redness Duration
15	RednessTimePostInjection	Char	4	\$4.	Redness Time Post Injection
16	SubcutaneousInjectionNotGivenW	Char	302	\$302.	If NO specify why
17	SwellingDuration	Char	4	\$4.	Swelling Duration
18	SwellingTimePostInjection	Char	4	\$4.	Swelling Time Post Injection
19	MaskID	Num	8		Participant Mask ID#
20	Visit	Char	100		Visit
21	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

*Data Set Name: treatment\_table.sas7bdat*

Num	Variable	Type	Len	Format	Label
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		