Data Set Name: ae.sas7bdat

Num	Variable	Type	Len	Format	Label
1	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
2	RxDesc	Char	7	$7.	Treatment Description
3	Eventabateafterstoppingdrug	Char	14	$14.	Did the eventreaction abate after stopping drug
4	AECategory	Char	35	$35.	Category
5	AECausalityByReporter	Char	22	$22.	Causality by reporter
6	AESerious	Char	3	$3.	Serious
7	AEInitialAEID	Num	8		AE Initial AEID
8	AESelectTerm	Num	8		AE Select Term
9	AESupraOrdinateTerm	Num	8		Adverse Event SupraOrdinate Term sub category
10	AEAssociations_Death	Num	8		AEAssociations: Death
11	severity_index	Num	8		Severity Index
12	AEPatientOutcome	Char	100		AE Patient Outcome
13	AEexpected	Char	100		AE Expected?
14	AEPrimarySecondary	Char	100		Is this event a primary or secondary event
15	AESelectTermstr	Char	250		AE Select Term
16	seriousae	Num	8		Serious AE?
17	ae_eval_id	Num	8		AE_EVAL_ID
18	AECausalityByReviewer	Char	22	$22.	Causality by reviewer
19	CTCAE_VERSION	Num	8		CTCAE_VERSION
20	AETerm	Char	100		Term
21	AE_Submitted	Num	8		Date AE Initially Submitted
22	severity	Num	8		Severity Index
23	dtfollow	Num	8	MMDDYY10.	Date at Follow-Up
24	dtreported	Num	8	MMDDYY10.	Date at Report
25	dtresolved	Num	8	MMDDYY10.	Date Resolved
26	dte	Num	8	MMDDYY10.	Date of Visit
27	dtae	Num	8	MMDDYY10.	Date at Occurrence
28	aedetails_abbr	Char	400		Adverse Event Details
29	MaskID	Num	8		Participant Mask ID#

Data Set Name: autoab.sas7bdat

Num	Variable	Type	Len	Format	Label
1	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
2	RxDesc	Char	7	$7.	Treatment Description
3	DRAW_DATE	Num	8	MMDDYY10.	Draw Date
4	GAD65	Num	8		Anti-GAD65 autoantibody (TrialNet Standard/Local Assay)
5	GAD65H	Num	8		Anti-GAD65 autoantibody (NIDDK Harmonized Assay)
6	IA2H	Num	8		Anti-IA-2 autoantibody (NIDDK Harmonized Assay)
7	ICA	Num	8		Islet Cell Antigen
8	ICA512	Num	8		Anti-ICA512 (IA-2) autoantibody (TrialNet Standard/Local Assay)
9	MIAA	Num	8		Micro Insulin autoantibody
10	MaskID	Num	8		Participant Mask ID#

Data Set Name: bmi.sas7bdat

Num	Variable	Type	Len	Format	Label
1	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
2	RxDesc	Char	7	$7.	Treatment Description
3	HeightCM	Num	8		Collection Of physical Assesments height in cm
4	WeightKG	Num	8		Collection Of physical Assesments weight in kg
5	dtexam	Num	8	MMDDYY10.	Date of Visit
6	time_point	Char	48		Time Point
7	MaskID	Num	8		Participant Mask ID#

1	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
2	RxDesc	Char	7	$7.	Treatment Description

Data Set Name: cpepm.sas7bdat

Num	Variable	Type	Len	Format	Label
1	PEP0	Num	8		0 minute C-Peptide
2	PEP15	Num	8		15 minute C-Peptide
3	PEP30	Num	8		30 minute C-Peptide
4	PEP60	Num	8		60 minute C-Peptide
5	PEP90	Num	8		90 minute C-Peptide
6	PEP120	Num	8		120 minute C-Peptide
7	DRAW_DATE	Num	8	MMDDYY10.	Draw Date
8	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
9	RxDesc	Char	7	$7.	Treatment Description
10	MaskID	Num	8		Participant Mask ID#

Data Set Name: cpepo.sas7bdat

Num	Variable	Type	Len	Format	Label
1	PEP0	Num	8		0 minute C-Peptide
2	PEP15	Num	8		15 minute C-Peptide
3	PEP30	Num	8		30 minute C-Peptide
4	PEP60	Num	8		60 minute C-Peptide
5	PEP90	Num	8		90 minute C-Peptide
6	PEP120	Num	8		120 minute C-Peptide
7	DRAW_DATE	Num	8	MMDDYY10.	Draw Date
8	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
9	RxDesc	Char	7	$7.	Treatment Description
10	MaskID	Num	8		Participant Mask ID#

Data Set Name: gtt.sas7bdat

Num	Variable	Type	Len	Format	Label
1	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
2	RxDesc	Char	7	$7.	Treatment Description
3	DRAW_DATE	Num	8	MMDDYY10.	Draw Date
4	GLUM10	Num	8		Glucose level at -10 min
5	GLU0	Num	8		Glucose level at 0 min
6	GLU30	Num	8		Glucose level at 30 min
7	GLU60	Num	8		Glucose level at 60 min
8	GLU90	Num	8		Glucose level at 90 min
9	GLU120	Num	8		Glucose level at 120 min
10	MaskID	Num	8		Participant Mask ID#

Data Set Name: hba1c.sas7bdat

Num	Variable	Type	Len	Format	Label
1	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
2	RxDesc	Char	7	$7.	Treatment Description
3	DRAW_DATE	Num	8	MMDDYY10.	Draw Date
4	hba1c	Num	8		HbA1c Result
5	MaskID	Num	8		Participant Mask ID#

1	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
2	RxDesc	Char	7	$7.	Treatment Description

Data Set Name: hla.sas7bdat

Num	Variable	Type	Len	Format	Label
1	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
2	RxDesc	Char	7	$7.	Treatment Description
3	DRAW_DATE	Num	8	MMDDYY10.	Draw Date
4	DR3	Char	20		Absence/Presence of DRB1*0301, DQA1*0501, DQB1*0201
5	DR4	Char	20		Absence/Presence of DRB1*04##, DQA1*0301 or 0303, DQB1*0302
6	HLA	Char	20		Absence/Presence of DQA1*0102, DQB1*0602
7	HLAa	Char	30		HLA Haplotype a (DRB1, DQA1, DQB1)
8	HLAb	Char	30		HLA Haplotype ß (DRB1, DQA1, DQB1)
9	MaskID	Num	8		Participant Mask ID#

Data Set Name: insulin.sas7bdat

Num	Variable	Type	Len	Format	Label
1	INS1	Num	8		Insulin level at 1 min (RIA)
2	INS3	Num	8		Insulin level at 3 min (RIA)
3	INST1	Num	8		Insulin level at 1 min (TOSOH)
4	INST3	Num	8		Insulin level at 3 min (TOSOH)
5	DRAW_DATE	Num	8	MMDDYY10.	Draw Date
6	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
7	RxDesc	Char	7	$7.	Treatment Description
8	MaskID	Num	8		Participant Mask ID#

Data Set Name: mastable.sas7bdat

Num	Variable	Type	Len	Format	Label
1	PROTOCOL_ID	Num	8		PROTOCOL_ID
2	REG	Num	8		Current Status: Registered
3	ELIG	Num	8		Current Status: Eligible
4	DTREG	Num	8	MMDDYY10.	Registration Date
5	FIRSTORSECONDDEGREERELATIVEDIA	Char	3	$3.	Have any of your first or second degree been diagnosed with T1D since the completion of Natural History Family History FormNH01F
6	WEIGHINKG	Num	8		Collection Of physical Assesments weight in kg
7	SEX	Char	6	$6.	Participant Sex
8	RACE	Char	15		Race
9	ETHNIC	Char	15		Ethnicity
10	STRATUM2	Char	11		Stratum
11	TREATMENTDATE	Num	8	MMDDYY10.	Treatment Assign Date
12	RXDESC	Char	7	$7.	Treatment Description
13	REASONFORWITHDRAWAL	Char	45	$45.	Record the primary reason for withdrawal
14	DTWITHDRAWAL	Num	8	MMDDYY10.	Withdrawal Date
15	DTREACTIVATE	Num	8	MMDDYY10.	Reactivation Date
16	DTSTATUSCHANGE	Num	8	MMDDYY10.	Change of Status Date
17	CHANGESTATUS	Char	98		Change of Status
18	DRUG_STOPPED	Char	14	$14.	Change in Study Drug Status
19	DTDRUGSTOPPED	Num	8	MMDDYY10.	Date of Change in Study Drug Status
20	LAST_IVGTT	Num	8	MMDDYY10.	Date of Last IVGTT
21	LAST_OGTT	Num	8	MMDDYY10.	Date of Last OGTT
22	LAST_PHYSICAL_EXAM	Num	8	MMDDYY10.	Date of Last Physical Exam
23	DTFOLLOWUP	Num	8	MMDDYY10.	Date of Last Follow-up Visit
24	DTIDDM	Num	8	MMDDYY10.	Type 1 Diabetes Date of Diagnosis
25	DTFULAB	Num	8	MMDDYY10.	Date of Last Sample
26	MASKID	Num	8		Participant Mask ID#
27	AGEREG	Num	8		Age at Registration

Data Set Name: rel.sas7bdat

Num	Variable	Type	Len	Format	Label
1	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
2	RxDesc	Char	7	$7.	Treatment Description
3	PROTOCOL_ID	Num	8		Protocol ID
4	relation	Char	21		Proband
5	MaskID	Num	8		Participant Mask ID#

Num	Variable	Type	Len	Format	Label
1	TreatmentDate	Num	8	MMDDYY10.	Treatment Assign Date
2	RxDesc	Char	7	$7.	Treatment Description

Data Set Name: rx.sas7bdat

Num	Variable	Type	Len	Format	Label
1	CapsulesDispensed	Num	8		Number of capsules dispensed
2	CapsulesReturned	Num	8		Number of capsules returned
3	dtdispensed	Num	8	MMDDYY10.	Date Capsules were Dispensed
4	dtreturned	Num	8	MMDDYY10.	Date Capsules were Returned
5	dttmp	Num	8	MMDDYY10.	Date of Visit
6	MaskID	Num	8		Participant Mask ID#

1	CapsulesDispensed	Num	8		Number of capsules dispensed
2	CapsulesReturned	Num	8		Number of capsules returned

Data Set Name: tn07_3monthvisit.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	VisitAtSiteOtherThanPrimaryStu	Char	3	$3.	Dis the visit occur at a site other than at the primary study site
5	VisitAtSiteOtherThanPrimaryStu2	Num	8		If yes record site number for reimbursement
6	AnyChangesInHealthSinceLastSch	Char	3	$3.	Have there been any changes in health since the last scheduled visit
7	AnyChangesInConcomitantMedicat	Char	3	$3.	Have there been any changes in concomitant medications since last scheduled visit
8	SeatedArmBPSystolic	Num	8		Physical Assessments Seated aremBP systolic
9	SeatedArmBPDiastolic	Num	8		Physical Assessments Seated aremBP Diastolic
10	WeightinKg	Num	8		Physical Assessments weight
11	Weightinlbs	Num	8		Physical Assessments weight in lbs
12	HeightinCm	Num	8		Physical Assessments Height in cm
13	HeightinIn	Num	8		Physical Assessments Height in in
14	ParticipantHasReproductivePote	Char	3	$3.	If FEMALE does the participant have reproductive potential
15	FemalePArticipantSexuallyActiv	Char	3	$3.	Is the female participant sexually active
16	CurrentlyUsingFormOfBirthContr	Char	3	$3.	If yes to question D1 above Does she currently use a form of birth control
17	PlanOfBecomingPregnantInNext6M	Char	2	$2.	If yes to question D1 above Does she plan on becoming pregnant in the next 6 months
18	UrinePregnancyTestCompletedAtT	Char	3	$3.	If yes to question D1 above Was urine pregnancy test completed at this visit
19	UrinePregnancyTestPositive	Char	2	$2.	If yes was the test result positive
20	InitialDoseOfStudyDrugDay	Num	8		Record the day that participant took hisher initial dose of study drug
21	InitialDoseOfStudyDrugMonth	Char	3	$3.	Record the month that participant took hisher initial dose of study drug
22	InitialDoseOfStudyDrugYear	Num	8		Record the year that participant took hisher initial dose of study drug
23	ParticipantCurrentlyTakingStud	Char	3	$3.	Is the participant currently taking study drug
24	HbA1cCompletedVisitDate	Char	3	$3.	The specimens drawn during this visit HbA1c completed on this visit date
25	HbA1cSpecifyCompletedDay	Num	8		The specimens drawn during this visit HbA1c If not done at this visit specify day completed day
26	HbA1cSpecifyCompletedmonth	Char	3	$3.	The specimens drawn during this visit HbA1c If not done at this visit specify day completed month
27	HbA1cSpecifyCompletedYear	Num	8		The specimens drawn during this visit HbA1c If not done at this visit specify day completed year
28	SerumForAutoantibodiesComplete	Char	3	$3.	The specimens drawn during this visit Serum for autoantibodies completed on visit date
29	SerumForAutoantibodiesSpecifyC	Num	8		The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed day
30	SerumForAutoantibodiesSpecifyC2	Char	3	$3.	The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed month
31	SerumForAutoantibodiesSpecifyC3	Num	8		The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed year
32	SamplesForStorageCompletedVisi	Char	3	$3.	The specimens drawn during this visit Samples for storage completed on this visit date

Num	Variable	Type	Len	Format	Label
33	SamplesForStorageSpecifyComple	Num	8		The specimens drawn during this visit Samples for storage If not done at this visit specify day completed day
34	SamplesForStorageSpecifyComple2	Char	3	$3.	The specimens drawn during this visit Samples for storage If not done at this visit specify day completed month
35	SamplesForStorageSpecifyComple3	Num	8		The specimens drawn during this visit Samples for storage If not done at this visit specify day completed year
36	DispensationOfStudyDrugComplet	Char	3	$3.	Dispensationreturn of study drug completed on this visit date
37	DispensationOfStudyDrugSpecify3	Num	8		Dispensationreturn of study drug If not done at this visit specify day completed day
38	DispensationOfStudyDrugSpecify	Char	3	$3.	Dispensationreturn of study drug If not done at this visit specify day completed month
39	DispensationOfStudyDrugSpecify2	Num	8		Dispensationreturn of study drug If not done at this visit specify day completed year

Data Set Name: tn07_6monthvisit.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	VisitAtSiteOtherThanPrimaryStu	Char	3	$3.	Dis the visit occur at a site other than at the primary study site
5	VisitAtSiteOtherThanPrimaryStu2	Num	8		If yes record site number for reimbursement
6	AnyChangesInHealthSinceLastSch	Char	3	$3.	Have there been any changes in health since the last scheduled visit
7	AnyChangesInConcomitantMedicat	Char	3	$3.	Have there been any changes in concomitant medications since last scheduled visit
8	SeatedArmBPSystolic	Num	8		Physical Assessments Seated aremBP systolic
9	SeatedArmBPDiastolic	Num	8		Physical Assessments Seated aremBP Diastolic
10	WeightinKg	Num	8		Physical Assessments weight
11	Weightinlbs	Num	8		Physical Assessments weight in lbs
12	HeightinCm	Num	8		Physical Assessments Height in cm
13	HeightinIn	Num	8		Physical Assessments Height in in
14	AbdominalCircumferenceinCm	Num	8		Physical Assessments Abdominal Circumference in cm
15	AbdominalCircumferenceinIn	Num	8		Physical Assessments Abdominal Circumference in Inches
16	ParticipantHasReproductivePote	Char	3	$3.	If FEMALE does the participant have reproductive potential
17	FemalePArticipantSexuallyActiv	Char	3	$3.	Is the female participant sexually active
18	CurrentlyUsingFormOfBirthContr	Char	3	$3.	If yes to question D1 above Does she currently use a form of birth control
19	PlanOfBecomingPregnantInNext6M	Char	2	$2.	If yes to question D1 above Does she plan on becoming pregnant in the next 6 months
20	UrinePregnancyTestCompletedAtT	Char	3	$3.	If yes to question D1 above Was urine pregnancy test completed at this visit
21	UrinePregnancyTestPositive	Char	3	$3.	If yes was the test result positive
22	DosesMissedSinceLastStudyVisit	Num	8		How many doses has the participant missed since the last study visit
23	ParticipantCurrentlyTakingStud	Char	3	$3.	Is the participant currently taking study drug
24	HbA1cCompletedVisitDate	Char	3	$3.	The specimens drawn during this visit HbA1c completed on this visit date
25	HbA1cSpecifyCompletedDay	Num	8		The specimens drawn during this visit HbA1c If not done at this visit specify day completed day
26	HbA1cSpecifyCompletedmonth	Char	3	$3.	The specimens drawn during this visit HbA1c If not done at this visit specify day completed month
27	HbA1cSpecifyCompletedYear	Num	8		The specimens drawn during this visit HbA1c If not done at this visit specify day completed year
28	OGTTPerrformedOnVisitDate	Char	3	$3.	The specimens drawn during this visit OGTT performed on this visit date
29	OGTTSpecifyPerformedDay	Num	8		The specimens drawn during this visit OGTT If NOT performed at this visit specify date performed
30	OGTTSpecifyPerformedMonth	Char	3	$3.	The specimens drawn during this visit OGTT If NOT performed at this visit specify month performed
31	OGTTSpecifyPerformedYear	Num	8		The specimens drawn during this visit OGTT If NOT performed at this visit specify year performed
32	SerumForAutoantibodiesComplete	Char	3	$3.	The specimens drawn during this visit Serum for autoantibodies completed on visit date
33	SerumForAutoantibodiesSpecifyC	Num	8		The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed day

Num	Variable	Type	Len	Format	Label
34	SerumForAutoantibodiesSpecifyC2	Char	3	$3.	The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed month
35	SerumForAutoantibodiesSpecifyC3	Num	8		The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed year
36	SamplesForStorageCompletedVisi	Char	3	$3.	The specimens drawn during this visit Samples for storage completed on this visit date
37	SamplesForStorageSpecifyComple	Num	8		The specimens drawn during this visit Samples for storage If not done at this visit specify day completed day
38	SamplesForStorageSpecifyComple2	Char	3	$3.	The specimens drawn during this visit Samples for storage If not done at this visit specify day completed month
39	SamplesForStorageSpecifyComple3	Num	8		The specimens drawn during this visit Samples for storage If not done at this visit specify day completed year
40	DispensationOfStudyDrugComplet	Char	3	$3.	Dispensationreturn of study drug completed on this visit date
41	DispensationOfStudyDrugSpecify	Num	8		Dispensationreturn of study drug If not done at this visit specify day completed day
42	DispensationOfStudyDrugSpecify2	Char	3	$3.	Dispensationreturn of study drug If not done at this visit specify day completed month
43	DispensationOfStudyDrugSpecify3	Num	8		Dispensationreturn of study drug If not done at this visit specify day completed year

Data Set Name: tn07_additionalconsent.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	InformedConsentObtainedDay	Num	8		Date written informed consent obtained day
5	InformedConsentObtainedMonth	Char	3	$3.	Date written informed consent obtained month
6	InformedConsentObtainedYear	Num	8		Date written informed consent obtained year
7	ParticipantPermissionOnOnsetFo	Char	68	$68.	On the consent form did the participant give permission to store samples for future testing

Data Set Name: tn07_adverseevents.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	AdverseEventID	Num	8		Adverse Event ID
4	AETerm	Char	100		AE Term
5	severity	Num	8		Severity Index
6	AEReportType	Char	9	$9.	AE Report Type
7	AEReportDtDay	Num	8		Adverse Event Report Date Day
8	AEReportDtMonth	Num	8		Adverse Event Report Date Month
9	AEReportDtYear	Num	8		Adverse Event Report Date Year
10	AEOccurDtDay	Num	8		Date of Adverse Event Occurrence Day
11	AEOccurDtMonth	Num	8		Date of Adverse Event Occurrence Month
12	AEOccurDtYear	Num	8		Date of Adverse Event Occurrence Year
13	AEPrimarySecondary1_1	Char	9	$9.	Is this event a primary or secondary event
14	AECategory	Char	35	$35.	Category
15	AEDetails	Char	3999	$3999.	Adverse Event Details
16	AETreatLocation	Char	14	$14.	Adverse Event Treatment Location
17	AETreatLocationOther	Char	108	$108.	AE Treatment Location Other
18	AEExpected1_1	Char	3	$3.	Expected
19	AECausalityByReporter	Char	22	$22.	Causality by reporter
20	AEAssociations_Developmentofacon	Num	8		AEAssociations: Development of a congenital anomaly or birth defect
21	AEAssociations_Developmentofaper	Num	8		AEAssociations: Development of a permanent/ serious/ disabling /incapacitating condition
22	AEAssociations_Death	Num	8		AEAssociations: Death
23	AEAssociations_Hospitalizationor	Num	8		AEAssociations: Hospitalization or prolonged hospitalization
24	AEAssociations_Lifethreatening	Num	8		AEAssociations: Life threatening
25	AEAssociations_Isanothercinditio	Num	8		AEAssociations: Is another condition which investigators judge to represent significant hazards
26	AEPatientOutcome1_1	Char	35	$35.	Patient Outcome
27	AEResolveDtDay	Num	8		Adverse Event Resolved Date Day
28	AEResolveDtMonth	Num	8		Adverse Event Resolved Date Month
29	AEResolveDtYear	Num	8		Adverse Event Resolved Date Year
30	AEDateDeathDay	Num	8		AE Date of Death Day
31	AEDateDeathMonth	Num	8		AE Date of Death Month
32	AEDateDeathYear	Num	8		AE Date of Death Year
33	Comments	Char	3025	$3025.	Comments
34	StudyDrugStartDateDay1_1	Num	8		Study Drug Start Date Day
35	StudyDrugStartDateMonth1_1	Char	3	$3.	Study Drug Start Date Month
36	StudyDrugStartDateYear1_1	Num	8		Study Drug Start Date Year

Num	Variable	Type	Len	Format	Label
37	StudyDrugStopDateDay1_1	Num	8		Study Drug Stop Date Day
38	StudyDrugStopDateMonth1_1	Char	3	$3.	Study Drug Stop Date Month
39	StudyDrugStopDateYear1_1	Num	8		Study Drug Stop Date Year
40	StudyDrugStartDateDay2_1	Num	8		Study Drug Start Date Day
41	StudyDrugStartDateMonth2_1	Char	3	$3.	Study Drug Start Date Month
42	StudyDrugStartDateYear2_1	Num	8		Study Drug Start Date Year
43	StudyDrugStopDateDay2_1	Num	8		Study Drug Stop Date Day
44	StudyDrugStopDateMonth2_1	Char	3	$3.	Study Drug Stop Date Month
45	StudyDrugStopDateYear2_1	Num	8		Study Drug Stop Date Year
46	StudyDrugStartDateDay3_1	Num	8		Study Drug Start Date Day
47	StudyDrugStartDateMonth3_1	Char	3	$3.	Study Drug Start Date Month
48	StudyDrugStartDateYear3_1	Num	8		Study Drug Start Date Year
49	StudyDrugStopDateDay3_1	Num	8		Study Drug Stop Date Day
50	StudyDrugStopDateMonth3_1	Char	3	$3.	Study Drug Stop Date Month
51	StudyDrugStopDateYear3_1	Num	8		Study Drug Stop Date Year
52	StudyDrugStartDateDay4_1	Num	8		Study Drug Start Date Day
53	StudyDrugStartDateMonth4_1	Char	3	$3.	Study Drug Start Date Month
54	StudyDrugStartDateYear4_1	Num	8		Study Drug Start Date Year
55	StudyDrugStopDateDay4_1	Num	8		Study Drug Stop Date Day
56	StudyDrugStopDateMonth4_1	Char	3	$3.	Study Drug Stop Date Month
57	StudyDrugStopDateYear4_1	Num	8		Study Drug Stop Date Year
58	StudyDrugStartDateDay5_1	Num	8		Study Drug Start Date Day
59	StudyDrugStartDateMonth5_1	Char	3	$3.	Study Drug Start Date Month
60	StudyDrugStartDateYear5_1	Num	8		Study Drug Start Date Year
61	StudyDrugStopDateDay5_1	Num	8		Study Drug Stop Date Day
62	StudyDrugStopDateMonth5_1	Char	1	$1.	Study Drug Stop Date Month
63	StudyDrugStopDateYear5_1	Num	8		Study Drug Stop Date Year
64	Eventabateafterstoppingdrug	Char	14	$14.	Did the eventreaction abate after stopping drug
65	Eventreappearafterreintroducti	Char	14	$14.	Did the eventreaction reappear after reintroduction
66	AEFollowupDateDay	Num	8		AE Followup Date Day
67	AEFollowupDateMonth	Num	8		AE Followup Date Month
68	AEFollowupDateYear	Num	8		AE Followup Date Year
69	AEReasonForFollowup	Char	55	$55.	AE Reason for followup
70	AEFollowupNumber	Num	8		AE Followup instance number
71	AESelectTerm	Num	8		AE Select Term

Data Set Name: tn07_adverseeventsreview.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Visit Date
3	AECausalityByReviewer	Char	22	$22.	Causality by reviewer
4	RecommendProtocolChange	Char	2	$2.	Recommend changes to the protocol
5	RecommendConsentChange	Char	3	$3.	Recommend changes to the consent form
6	AEReviewFormComments	Char	341	$341.	Review form comments
7	AEAdditionalInfoRequested	Char	3	$3.	Additional information requested
8	AEAdditionalInfoRequestedDetai	Char	499	$499.	Adverse event additional information requested details
9	AEReviewRequireDSMBReview	Num	8		Requires urgent and immediate review by full DSMB committee
10	AEReviewDSMBReviewComments	Char	1	$1.	Review requires DSMB review comments
11	AEReviewPriorSimilarSAEs	Char	3	$3.	Have there been prior occurrences of similar reported in this study
12	AEReviewReportingTimeframe	Char	27	$27.	Reporting time frame to regulatory authorities
13	AEReviewTreatmentUnblindedForC	Char	2	$2.	Does treatment need to be unblinded for determination of causality
14	AEReviewPriorSimilarSAEsSummar	Char	280	$280.	If prior occurrences of similar serious adverse events provide a brief summary
15	AdverseEventID	Num	8		Adverse Event ID

Data Set Name: tn07_annualvisit.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	VisitAtSiteOtherThanPrimaryStu	Char	3	$3.	Dis the visit occur at a site other than at the primary study site
5	VisitAtSiteOtherThanPrimaryStu2	Num	8		If yes record site number for reimbursement
6	AnyChangesInHealthSinceLastSch	Char	3	$3.	Have there been any changes in health since the last scheduled visit
7	AnyChangesInConcomitantMedicat	Char	3	$3.	Have there been any changes in concomitant medications since last scheduled visit
8	SeatedArmBPSystolic	Num	8		Physical Assessments Seated aremBP systolic
9	SeatedArmBPDiastolic	Num	8		Physical Assessments Seated aremBP Diastolic
10	WeightinKg	Num	8		Physical Assessments weight
11	Weightinlbs	Num	8		Physical Assessments weight in lbs
12	HeightinCm	Num	8		Physical Assessments Height in cm
13	HeightinIn	Num	8		Physical Assessments Height in in
14	AbdominalCircumferenceinCm	Num	8		Physical Assessments Abdominal Circumference in cm
15	AbdominalCircumferenceinIn	Num	8		Physical Assessments Abdominal Circumference in Inches
16	HeentNormalOnExam	Char	3	$3.	Review of systems Heent Normal on exam
17	HeentReportedNormal	Char	3	$3.	Review of systems Heent Participant reported normal
18	HeentAbnormalExplain	Char	275	$275.	Review of systems Heent Either abnormal Explain
19	NeckNormalOnExam	Char	3	$3.	Review of systems Neck Normal on exam
20	NeckReportedNormal	Char	3	$3.	Review of systems Neck Participant reported normal
21	NeckAbnormalExplain	Char	113	$113.	Review of systems Neck If Either Abnormal Expalin
22	ThyroidNormalOnExam	Char	3	$3.	Review of systems Thyroid Normal on exam
23	ThyroidreportedNormal	Char	3	$3.	Review of systems Thyroid Participant reported normal
24	ThyroidAbnormalExplain	Char	90	$90.	Review of systems Thyroid If either abnormal explain
25	LungsNormalOnExam	Char	3	$3.	Review of systems Lungs Normal on exam
26	LungsReportedNormal	Char	3	$3.	Review of systems Lungs Participant reported normal
27	LungsAbnormalExplain	Char	158	$158.	Review of systems Lungs If either abnormal explain
28	ChestNormalOnExam	Char	3	$3.	Review of systems ChestBreasts Normal on exam
29	ChestReportedNormal	Char	3	$3.	Review of systems ChestBreastsParticipant reported normal
30	ChestAbnormalExplain	Char	107	$107.	Review of systems ChestBreasts If either abnormal explain
31	HeartNormalOnExam	Char	3	$3.	Review of systems HeartCirculatory Normal on exam
32	HeartReportedNormal	Char	3	$3.	Review of systems HeartCirculatoryParticipant reported normal
33	HeartAbnormalExplain	Char	182	$182.	Review of systems HeartCirculatory If either abnormal explain
34	MusculoskeletalNormalOnExam	Char	3	$3.	Review of systems Musculoskeletal Normal on exam
35	MusculoskeletalReportedNormal	Char	3	$3.	Review of systems Musculoskeletal Participant reported normal
36	MusculoskeletalAbnormalExpalin	Char	261	$261.	Review of systems Musculoskeletal If either abnormal explain
37	NeurologicNormalOnExam	Char	3	$3.	Review of systems Neurologic Normal on exam

Num	Variable	Type	Len	Format	Label
38	NeurologicReportedNormal	Char	3	$3.	Review of systems Neurologic Participant reported normal
39	NeurologicAbnormalExplain	Char	235	$235.	Review of systems Neurologic If either abnormal explain
40	GenitourinaryOrTestesNormalOnE	Char	3	$3.	Review of systems GenitourinaryTestes Normal on exam
41	GenitourinaryOrTestesreportedN	Char	3	$3.	Review of systems GenitourinaryTestes Participant reported normal
42	GenitourinaryAbnormalExplain	Char	169	$169.	Review of systems GenitourinaryTestes If either abnormal explain
43	SkinOrNailsNormalOnExam	Char	3	$3.	Review of systems SkinNails Normal on Exam
44	sSkinOrNailsReportedNormal	Char	3	$3.	Review of systems SkinNails Participant Reported Normal
45	SkinOrNailsAbnormalExplain	Char	324	$324.	Review of systems SkinNails If either abnormal explain
46	LymphNodesNormalOnExam	Char	3	$3.	Review of systems Lymph nodes normal on exam
47	LymphNodesReportedNormal	Char	3	$3.	Review of systems Lymph nodes Paticipant Reported Normal
48	LymphNodesEitherAbnormalExplai	Char	89	$89.	Review of systems Lymph nodes If either abnormal explain
49	OtherNormalOnExam	Char	3	$3.	Review of systems Other Normal on Exam
50	OtherReportedNormal	Char	3	$3.	Review of systems Other Paticipant Reported Normal
51	OtherSpecify	Char	172	$172.	Review of systems Other Specify
52	PtherAbnormalExplain	Char	172	$172.	Review of systems Other If either abnormal explain
53	TannerStageBreast	Char	18	$18.	Tanner Stage Breast Female
54	TannerStageGenitalia	Char	18	$18.	Tanner Stage Genitalia Male
55	TannerStagePublicHair	Char	18	$18.	Tanner Stage Public Hair both
56	ParticipantHasReproductivePote	Char	3	$3.	If FEMALE does the participant have reproductive potential
57	FemalePArticipantSexuallyActiv	Char	3	$3.	Is the female participant sexually active
58	CurrentlyUsingFormOfBirthContr	Char	3	$3.	If yes to question D1 above Does she currently use a form of birth control
59	PlanOfBecomingPregnantInNext6M	Char	2	$2.	If yes to question D1 above Does she plan on becoming pregnant in the next 6 months
60	UrinePregnancyTestCompletedAtT	Char	3	$3.	If yes to question D1 above Was urine pregnancy test completed at this visit
61	UrinePregnancyTestPositive	Char	2	$2.	If yes was the test result positive
62	DosesMissedSinceLastStudyVisit	Num	8		How many doses has the participant missed since the last study visit
63	ParticipantCurrentlyTakingStud	Char	3	$3.	Is the participant currently taking study drug
64	HbA1cCompletedVisitDate	Char	3	$3.	The specimens drawn during this visit HbA1c completed on this visit date
65	HbA1cSpecifyCompletedDay	Num	8		The specimens drawn during this visit HbA1c If not done at this visit specify day completed day
66	HbA1cSpecifyCompletedmonth	Char	3	$3.	The specimens drawn during this visit HbA1c If not done at this visit specify day completed month
67	HbA1cSpecifyCompletedYear	Num	8		The specimens drawn during this visit HbA1c If not done at this visit specify day completed year
68	OGTTPerrformedOnVisitDate	Char	3	$3.	The specimens drawn during this visit OGTT performed on this visit date
69	OGTTSpecifyPerformedDay	Num	8		The specimens drawn during this visit OGTT If NOT performed at this visit specify date performed
70	OGTTSpecifyPerformedMonth	Char	3	$3.	The specimens drawn during this visit OGTT If NOT performed at this visit specify month performed
71	OGTTSpecifyPerformedYear	Num	8		The specimens drawn during this visit OGTT If NOT performed at this visit specify year performed
72	SerumForAutoantibodiesComplete	Char	3	$3.	The specimens drawn during this visit Serum for autoantibodies completed on visit date

Num	Variable	Type	Len	Format	Label
73	SerumForAutoantibodiesSpecifyC	Num	8		The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed day
74	SerumForAutoantibodiesSpecifyC2	Char	3	$3.	The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed month
75	SerumForAutoantibodiesSpecifyC3	Num	8		The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed year
76	SamplesForStorageCompletedVisi	Char	3	$3.	The specimens drawn during this visit Samples for storage completed on this visit date
77	SamplesForStorageSpecifyComple	Num	8		The specimens drawn during this visit Samples for storage If not done at this visit specify day completed day
78	SamplesForStorageSpecifyComple2	Char	3	$3.	The specimens drawn during this visit Samples for storage If not done at this visit specify day completed month
79	SamplesForStorageSpecifyComple3	Num	8		The specimens drawn during this visit Samples for storage If not done at this visit specify day completed year
80	LifeStylePerformedOnVisitDate	Char	3	$3.	Lifestyle Questionnaire Performed on this visit date
81	LifeStylePerformedDay	Num	8		Lifestyle Questionnaire If NOT performed at this visit specify performed day
82	LifeStylePerformedMonth	Char	3	$3.	Lifestyle Questionnaire If NOT performed at this visit specify performed month
83	LifeStylePerformedYear	Num	8		Lifestyle Questionnaire If NOT performed at this visit specify performed year
84	DispensationOfStudyDrugComplet	Char	3	$3.	Dispensationreturn of study drug completed on this visit date
85	DispensationOfStudyDrugSpecify	Num	8		Dispensationreturn of study drug If not done at this visit specify day completed day
86	DispensationOfStudyDrugSpecify2	Char	3	$3.	Dispensationreturn of study drug If not done at this visit specify day completed month
87	DispensationOfStudyDrugSpecify3	Num	8		Dispensationreturn of study drug If not done at this visit specify day completed year
88	AbdomenNormalOnExam	Char	3	$3.	Review of systems Abdomen Normal on exam
89	AbdomenreportedNormal	Char	3	$3.	Review of systems Abdomen Participant reported normal
90	AbdomenEitherAbnormalExplain	Char	302	$302.	Review of systems Abdomen If Either Abnormal Explain

Data Set Name: tn07_changeinstatus.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	DateStatusChangeDay	Num	8		Date change in status became effective Day
5	DateStatusChangeYear	Num	8		Date change in status became effective Year
6	DateStatusChangeMonth	Char	3	$3.	Date change in status became effective Month
7	ChangeOfStatusOccuring	Char	98	$98.	Change in status that has occurred
8	DoWDay	Num	8		Date of withdrawal Day
9	DoWMonth	Char	3	$3.	Date of withdrawal Month
10	DoWYear	Num	8		Date of withdrawal Year
11	ReasonForWithdrawal	Char	45	$45.	Record the primary reason for withdrawal
12	ReasonForWithdrawalOTHER	Char	789	$789.	If OTHER Specify
13	ReasonWithdrewConsentSpecify	Char	770	$770.	Reason Withdrew Consent specify
14	ReasonAdverseEventSpecify	Char	106	$106.	Reason Adverse Event specify
15	WillingToBeContacted	Char	3	$3.	Is the subject still willing to be contacted
16	DoRDay	Num	8		Date of reactivation Day
17	DoRMonth	Char	3	$3.	Date of reactivation Month
18	DoRYear	Num	8		Date of reactivation Year
19	PregnancyCompletionDay	Num	8		If YES what is the estimated date of completion of pregnancy Day
20	PregnancyCompletionMonth	Char	3	$3.	If YES what is the estimated date of completion of pregnancy Month
21	PregnancyCompletionYear	Num	8		If YES what is the estimated date of completion of pregnancy Year

Data Set Name: tn07_changeinstudydrug.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	StudyStatusDiscontinuing	Char	29	$29.	Change in study status Discontinuing
4	StudyDrugStatusEffectiveDay	Num	8		Change in study drug status effective day
5	StudyDrugStatusEffectiveMonth	Char	3	$3.	Change in study drug status effective month
6	StudyDrugStatusEffectiveYear	Num	8		Change in study drug status effective year
7	StudyDrugStoppedReas_Selfdiscont	Num	8		StudyDrugStoppedReas: Self-discontinued by participant
8	StudyDrugStoppedReas_Development	Num	8		StudyDrugStoppedReas: Development of T1D
9	StudyDrugStoppedReas_AdverseEven	Num	8		StudyDrugStoppedReas: Adverse Event
10	StudyDrugStoppedReas_Pregnancy	Num	8		StudyDrugStoppedReas: Pregnancy
11	StudyDrugStoppedReas_Studydiscon	Num	8		StudyDrugStoppedReas: Study discontinuation
12	StudyDrugStoppedReas_Other	Num	8		StudyDrugStoppedReas: Other
13	StudyDrugStoppedReasonSpecify	Char	337	$337.	If OTHER specify
14	ParticipantInformedOfTreatment	Char	3	$3.	Was the participant informed of hisher treatment group assignment
15	ReturnOfRemainingStudyDrug	Char	3	$3.	Did the participant return the remaining study drug
16	ChangeInStudyStatus	Char	3	$3.	Is there a change in study status at this time

Data Set Name: tn07_concomitantmeds.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	AssessDateDay	Num	8		Assessment date day
5	AssessDateMonth	Char	3		Assessment date month
6	AssessDateYear	Num	8		Assessment date year
7	Medication	Char	154		Medication
8	Dose	Num	8		Dose
9	Units	Char	11		Units
10	UnitIfOtherSpecify	Char	73		Units specify detail if OTHER is selected
11	ConMedsFrequencyChoices	Char	5		Frequency Choices
12	ConMedsFrequencyOtherDetail	Char	390		Frequency specify detail if OTHER is selected
13	ConMedsIntervalChoices	Char	5		Interval Choices
14	ConMedsIntervalOtherDetails	Char	142		Interval specify details if OTHER is selected
15	ConMedsRoute	Char	26		Route
16	ConMedsRouteOtherDetails	Char	24		Route specify detail if OTHER is selected
17	Indication	Char	354		Indication
18	StartDateDay	Num	8		Start date day
19	StartDateMonth	Char	3		Start date month
20	StartDateYear	Num	8		Start date year
21	IsContinuing	Char	3		Is Continuing
22	StopDateDay	Num	8		Stop date day
23	StopDateMonth	Char	3		Stop date month
24	StopDateYear	Num	8		Stop date year

Data Set Name: tn07_diabetesonset.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	DiagnosisDay	Num	8		Diagnosis day
4	DiagnosisMonth	Char	3	$3.	Diagnosis month
5	DiagnosisYear	Num	8		Diagnosis year
6	DiagnosisBy	Char	19	$19.	Diagnosis made by
7	DiagnosisByOthersSpecify	Char	97	$97.	If other facility specify
8	InsulinTreatmentStartedDay	Num	8		Day insulin treatment started
9	InsulinTreatmentStartedMonth	Char	3	$3.	Month insulin treatment started
10	InsulinTreatmentStartedYear	Num	8		Year insulin treatment started
11	DateInsulinTreatmentStartedUnk	Num	8		Date Insulin treatment started Unknown
12	HospitalizedAtDiagnosisTime	Char	3	$3.	Was the participant hospitalized at the time of diagnosis
13	AdmissionDay	Num	8		Day of admission
14	AdmissionMonth	Char	3	$3.	Month of admission
15	AdmissionYear	Num	8		Year of admission
16	DischargeDay	Num	8		Day of discharge
17	DischargeMonth	Char	3	$3.	Month of discharge
18	DischargeYear	Num	8		Year of discharge
19	Polyuria	Char	3	$3.	Did the participant experience Polyuria
20	PolyuriaMonth	Char	3	$3.	Month polyuria experienced
21	PolyuriaYear	Num	8		Year polyuria experienced
22	Polydipsia	Char	3	$3.	Did the participant experience Polydipsia
23	PolydipsiaMonth	Char	3	$3.	Month polydipsia experienced
24	Polydipsiayear	Num	8		Year polydipsia experienced
25	Polyphagia	Char	3	$3.	Did the participant experience Polyphagia
26	PolyphagiaMonth	Char	3	$3.	Month polyphagia experienced
27	PolyphagiaYear	Num	8		Year polyphagia experienced
28	Fatigue	Char	3	$3.	Did the participant experience fatigue
29	FatigueMonth	Char	3	$3.	Month fatigue experienced
30	FatigueYear	Num	8		Year fatigue experienced
31	UnexplainedWeightLoss	Char	3		Did the participant experience unexplained weight loss
32	UnexplainedWeightLossMonth	Char	3		Month of unexplained weight loss
33	UnexplainedWeightLossYear	Num	8		Year of unexplained weight loss
34	WeightLostInKgs	Num	8		Amount of weight loss in kgs
35	WeightLostInLbs	Num	8		Amount of weight loss in lbs
36	Ketoacidosis	Char	3	$3.	Did the participant experience ketoacidosis
37	KetoacidosisMonth23	Char	3	$3.	Did the participant experience Ketoacidosismonth

Num	Variable	Type	Len	Format	Label
38	KetoacidosisYear23	Num	8		Did the participant experience Ketoacidosisyear
39	PlasmaGlucoseResult	Num	8		Plasma glucose result
40	PlasmaGlucoseUnits	Char	6	$6.	Plasma glucose units
41	PlasmaGlucoseRefRangeLow	Num	8		Plasma glucose low reference range
42	PlasmaGlucoseRefRangeHigh	Num	8		Plasma glucose high reference range
43	PlasmaGlucoseday	Num	8		Plasma glucose day
44	PlasmaGlucoseMonth	Char	3	$3.	Plasma glucose month
45	PlasmaGlucoseYear	Num	8		Plasma glucose year
46	pHResult	Num	8		pH(serum) result
47	pHUnits	Char	7	$7.	pH(serum) units
48	pHReferenceRangeLow	Num	8		pH(serum) low reference range
49	pHReferenceRangeHigh	Num	8		pH(serum) high reference range
50	pHday	Num	8		pH(serum) day
51	pHMonth	Char	3	$3.	pH(serum) month
52	pHYear	Num	8		pH(serum) year
53	SerumKetonesResult	Num	8		Serum ketones result
54	SerumKetonesUnits	Char	7	$7.	Serum ketones units
55	SerumKetonesRefRangeLow	Num	8		Serum ketones low reference range
56	SerumKetonesRefRangeHigh	Num	8		Serum ketones high reference range
57	SerumKetonesday	Num	8		Serum ketones day
58	SerumKetonesMonth	Char	3	$3.	Serum ketones month
59	SerumKetonesYear	Num	8		Serum ketones year
60	AnionGapResult	Num	8		Anion gap result
61	AnionGapUnits	Char	22	$22.	Anion gap units
62	AnionGapRefRangeLow	Num	8		Anion gap low reference range
63	AnionGapRefRangeHigh	Num	8		Anion gap high reference range
64	AnionGapDay	Num	8		Anion gap day
65	AnionGapMonth	Char	3	$3.	Anion gap month
66	AnionGapYear	Num	8		Anion gap year
67	BicarbonateResult	Num	8		Bicarbonate result
68	BicarbonateUnits	Char	22	$22.	Bicarbonate units
69	BicarbonateRefRangeLow	Num	8		Bicarbonate low reference range
70	BicarbonateRefRangeHigh	Num	8		Bicarbonate high reference range
71	BicarbonateDay	Num	8		bicarbonate day
72	BicarbonateMonth	Char	3	$3.	Bicarbonate month
73	BicarbonateYear	Num	8		Bicarbonate year
74	UrineKetonesResult	Num	8		Urine ketones result
75	UrineKetonesUnits23	Char	7	$7.	Urine ketones units
76	UrineKetonesRefRangeLow	Num	8		Urine ketones low reference range

Num	Variable	Type	Len	Format	Label
77	UrineKetonesRefRangeHigh	Num	8		Urine ketones high reference range
78	UrineKetonesDay	Num	8		Urine ketones day
79	UrineKetonesMonth	Char	3	$3.	Urine ketones month
80	UrineKetonesYear	Num	8		Urine ketones year
81	Result1_1	Num	8		Glucose level result
82	Units1_1	Char	6	$6.	Glucose level units
83	LowerReferenceRange1_1	Num	8		Glucose level low reference range
84	HigherReferenceRange1_1	Num	8		Glucose level high reference range
85	GlucoseDay1_1	Num	8		Glucose day
86	GlucoseMonth1_1	Char	3	$3.	Glucose month
87	GlucoseYear1_1	Num	8		Glucose year
88	GlucoseType1_1	Char	9	$9.	Glucose type
89	MeasuredBy1_1	Char	9	$9.	Glucose levels measured by
90	Result2_1	Num	8		Glucose level result
91	Units2_1	Char	6	$6.	Glucose level units
92	LowerReferenceRange2_1	Num	8		Glucose level low reference range
93	HigherReferenceRange2_1	Num	8		Glucose level high reference range
94	GlucoseDay2_1	Num	8		Glucose day
95	GlucoseMonth2_1	Char	3	$3.	Glucose month
96	GlucoseYear2_1	Num	8		Glucose year
97	GlucoseType2_1	Char	9	$9.	Glucose type
98	MeasuredBy2_1	Char	9	$9.	Glucose levels measured by
99	Result3_1	Num	8		Glucose level result
100	Units3_1	Char	6	$6.	Glucose level units
101	LowerReferenceRange3_1	Num	8		Glucose level lower reference range
102	HigherReferenceRange3_1	Num	8		Glucose level higher reference range
103	GlucoseDay3_1	Num	8		Glucose day
104	GlucoseMonth3_1	Char	3	$3.	Glucose month
105	GlucoseYear3_1	Num	8		Glucose year
106	GlucoseType3_1	Char	9	$9.	Glucose type
107	MeasuredBy3_1	Char	9	$9.	Glucose levels measured by
108	Result4_1	Num	8		Glucose level result
109	Units4_1	Char	6	$6.	Glucose level units
110	LowerReferenceRange4_1	Num	8		Glucose level low reference range
111	HigherReferenceRange4_1	Num	8		Glucose level high reference range
112	GlucoseDay4_1	Num	8		Glucose day
113	GlucoseMonth4_1	Char	3	$3.	Glucose month
114	GlucoseYear4_1	Num	8		Glucose year
115	GlucoseType4_1	Char	9	$9.	Glucose type

Num	Variable	Type	Len	Format	Label
116	MeasuredBy4_1	Char	9	$9.	Glucose levels measured by
117	Result5_1	Num	8		Glucose level result
118	Units5_1	Char	6	$6.	Glucose level units
119	LowerReferenceRange5_1	Num	8		Glucose level low reference range
120	HigherReferenceRange5_1	Num	8		Glucose level high reference range
121	GlucoseDay5_1	Num	8		Glucose day
122	GlucoseMonth5_1	Char	3	$3.	Glucose month
123	GlucoseYear5_1	Num	8		Glucose year
124	GlucoseType5_1	Char	9	$9.	Glucose type
125	MeasuredBy5_1	Char	9	$9.	Glucose levels measured by
126	Result6_1	Num	8		Glucose level result
127	Units6_1	Char	6	$6.	Glucose level units
128	LowerReferenceRange6_1	Num	8		Glucose level low reference range
129	HigherReferenceRange6_1	Num	8		Glucose level high reference range
130	GlucoseDay6_1	Num	8		Glucose day
131	GlucoseMonth6_1	Char	3	$3.	Glucose month
132	GlucoseYear6_1	Num	8		Glucose year
133	GlucoseType6_1	Char	9	$9.	Glucose type
134	MeasuredBy6_1	Char	9	$9.	Glucose levels measured by
135	Result7_1	Num	8		Glucose level result
136	Units7_1	Char	6	$6.	Glucose level units
137	LowerReferenceRange7_1	Num	8		Glucose level low reference range
138	HigherReferenceRange7_1	Num	8		Glucose level high reference range
139	GlucoseDay7_1	Num	8		Glucose day
140	GlucoseMonth7_1	Char	3	$3.	Glucose month
141	GlucoseYear7_1	Num	8		Glucose year
142	GlucoseType7_1	Char	9	$9.	Glucose type
143	MeasuredBy7_1	Char	9	$9.	Glucose levels measured by
144	Result8_1	Num	8		Glucose level result
145	Units8_1	Char	6	$6.	Glucose level units
146	LowerReferenceRange8_1	Num	8		Glucose level low reference range
147	HigherReferenceRange8_1	Num	8		Glucose level high reference range
148	GlucoseDay8_1	Num	8		Glucose day
149	GlucoseMonth8_1	Char	3	$3.	Glucose month
150	GlucoseYear8_1	Num	8		Glucose year
151	GlucoseType8_1	Char	7	$7.	Glucose type
152	MeasuredBy8_1	Char	9	$9.	Glucose levels measured by
153	Result9_1	Num	8		Glucose level result
154	Units9_1	Char	6	$6.	Glucose level units

Num	Variable	Type	Len	Format	Label
155	LowerReferenceRange9_1	Num	8		Glucose level low reference range
156	HigherReferenceRange9_1	Num	8		Glucose level high reference range
157	GlucoseDay9_1	Num	8		Glucose day
158	GlucoseMonth9_1	Char	3	$3.	Glucose month
159	GlucoseYear9_1	Num	8		Glucose year
160	GlucoseType9_1	Char	6	$6.	Glucose type
161	MeasuredBy9_1	Char	9	$9.	Glucose levels measured by
162	Result10_1	Num	8		Glucose level result
163	Units10_1	Char	6	$6.	Glucose level units
164	LowerReferenceRange10_1	Num	8		Glucose level low reference range
165	HigherReferenceRange10_1	Num	8		Glucose level high reference range
166	GlucoseDay10_1	Num	8		Glucose day
167	GlucoseMonth10_1	Char	3	$3.	Glucose month
168	GlucoseYear10_1	Num	8		Glucose year
169	GlucoseType10_1	Char	7	$7.	Glucose type
170	MeasuredBy10_1	Char	9	$9.	Glucose levels measured by
171	Result11_1	Num	8		Glucose level result
172	Units11_1	Char	6	$6.	Glucose level units
173	LowerReferenceRange11_1	Num	8		Glucose level low reference range
174	HigherReferenceRange11_1	Num	8		Glucose level high reference range
175	GlucoseDay11_1	Num	8		Glucose day
176	GlucoseMonth11_1	Char	3	$3.	Glucose month
177	GlucoseYear11_1	Num	8		Glucose year
178	GlucoseType11_1	Char	6	$6.	Glucose type
179	MeasuredBy11_1	Char	9	$9.	Glucose levels measured by
180	Result12_1	Num	8		Glucose level result
181	Units12_1	Char	1	$1.	Glucose level units
182	LowerReferenceRange12_1	Num	8		Glucose level low reference range
183	HigherReferenceRange12_1	Num	8		Glucose level high reference range
184	GlucoseDay12_1	Num	8		Glucose day
185	GlucoseMonth12_1	Char	3	$3.	Glucose month
186	GlucoseYear12_1	Num	8		Glucose year
187	GlucoseType12_1	Char	6	$6.	Glucose type
188	MeasuredBy12_1	Char	9	$9.	Glucose levels measured by
189	HbA1cResult	Num	8		Other laboratory values hba1c result
190	HbA1cLowerReferenceRange	Num	8		Other laboratory values hba1c low reference range
191	HbA1chigherrReferenceRange	Num	8		Other laboratory values hba1c high reference range
192	HbA1cDay	Num	8		Other laboratory values hba1c day
193	HbA1cMonth	Char	3	$3.	Other laboratory values hba1c month

Num	Variable	Type	Len	Format	Label
194	HbA1cYear	Num	8		Other laboratory values hba1c year
195	Currentvisitorlastscheduledvis	Char	8	$8.	Current visit or last scheduled visit preceding diagnosis of diabetes

Data Set Name: tn07_eligibility.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	ParticipantBetween3and45Or3and	Char	3	$3.	Inclusion Is the participant between 3 and 45 years of age and a sibling offspring or parent of an individualwith T1D OR participant between 3 and 20 years of age with another relative with T1D
5	ParticipantWillingToAcceptRand	Char	3	$3.	Inclusion Is the participant willing to accept random assignments
6	DidParticipantConfirmedPositiv	Char	3	$3.	Inclusion Does the participant have confirmed positive mIAA with in the past 6 months
7	ParticipantHasAtleastOnesample	Char	3	$3.	Inclusion Does the participant have at least one other antibody present on two separate samples One of which was drawn with in the past six months
8	ParticipantHasOGTTPast7weeks	Char	3	$3.	Inclusion Does the participant have a normal OGTT within the past 7 weeks
9	TwoConsecutiveNormalOGTTs	Char	3	$3.	If yes has the participant had two consecutive normal OGTTs since the abnormal OGTT
10	ParticipantHasT1D	Char	3	$3.	Exclusion Does the participant have T1D
11	participantPreviouslyEnrolledI	Char	2	$2.	Exclusion Has the participant previously been enrolled in another clinical trial for T1D prevention
12	participantImmunodeficient	Char	2	$2.	Exclusion Is the participant immunodeficient
13	ParticantHaDiseaseWhichPrevent	Char	2	$2.	Exclusion Does the participant have a disease which would limit hisher ability to participate in the study
14	ParticipantTreatedWithImmunosu	Char	3	$3.	Exclusion Has the participant been treated with immunosuppressive drugs or glucocorticoids within the past 2 years for a period of more than 3 months
15	ParticipantHasHLADQ10102DQB106	Char	3	$3.	Exclusion Does the participant have the HLA DQA10102 DQB10602 Haplotype
16	ParticipanttakingMedicationsAf	Char	3	$3.	Exclusion is the participant taking any medications that affect glucose homeostasis
17	ParticipantHasTreatmentWithIns	Char	3	$3.	Exclusion Does the participant have a history of treatment with insulin or any oral hypoglycemic agents
18	ParticipantEverHadAbnormalOGTT	Char	3	$3.	Exclusion Has the participant ever had an abnormal OGTT
19	ParticipantPregnantOrPlanningb	Char	2	$2.	Exclusion Is the participant pregnant or planning on becoming pregnant during the course of the study
20	AnyoneInFamilyWhoIsRandomizedI	Char	3	$3.	Is there anyone in your immediate family or living n your household who is currently randomized in the Oral Insulin Trial
21	HowManyIndivdualsInFamilyWhoAr	Num	8		If Yes specify how many individuals
22	FamilyMemberParticipantId1_1	Char	9	$9.	Participant ID
23	FamilyMemberParticipantRela1_1	Char	17	$17.	Participant Relationship
24	FamilyMemberParticipantId2_1	Char	1	$1.	Participant ID
25	FamilyMemberParticipantRela2_1	Char	1	$1.	Participant Relationship
26	FamilyMemberParticipantId3_1	Char	1	$1.	Participant ID
27	FamilyMemberParticipantRela3_1	Char	1	$1.	Participant Relationship
28	FamilyMemberParticipantId4_1	Char	1	$1.	Participant ID
29	FamilyMemberParticipantRela4_1	Char	1	$1.	Participant Relationship
30	FamilyMemberParticipantId5_1	Char	1	$1.	Participant ID
31	FamilyMemberParticipantRela5_1	Char	1	$1.	Participant Relationship
32	FamilyMemberParticipantId6_1	Char	1	$1.	Participant ID

Num	Variable	Type	Len	Format	Label
33	FamilyMemberParticipantRela6_1	Char	1	$1.	Participant Relationship
34	FamilyMemberParticipantId7_1	Char	1	$1.	Participant ID
35	FamilyMemberParticipantRela7_1	Char	1	$1.	Participant Relationship
36	ParticipantRandomized	Char	3	$3.	Was the participant randomized
37	RandomizationDateDay	Num	8		Date of Randomization day
38	RandomizationDateMonth	Char	3	$3.	Date of Randomization month
39	RandomizationDateYear	Num	8		Date of Randomization year
40	RandomizationNumber	Char	8	$8.	Randomization Number
41	NoRandomizationSpecifyWhy	Char	1	$1.	If NO Explain
42	IVGTTIfneededPerformedOnVisitD	Char	3	$3.	The specimens that should be drawn during this visit IVGTTif needed performed on this visit date
43	IVGTTIfNotPerformedCollectedDa	Num	8		The specimens that should be drawn during this visit IVGTTif needed If Not performed on this date specify collected day
44	IVGTTIfNotPerformedCollectedMo	Char	3	$3.	The specimens that should be drawn during this visit IVGTTif needed If Not performed on this date specify collected month
45	IVGTTIfNotPerformedCollectedYe	Num	8		The specimens that should be drawn during this visit IVGTTif needed If Not performed on this date specify collected year
46	DispensationOfSTudyDrugPerform	Char	3	$3.	The specimens that should be drawn during this visit Dispensation of study drug performed on this visit date
47	DispensationOfSTudyDrugNotPerf	Num	8		The specimens that should be drawn during this visit Dispensation of study drug if Not performed on visit date specify collected day
48	DispensationOfSTudyDrugNotPerf2	Char	3	$3.	The specimens that should be drawn during this visit Dispensation of study drug if Not performed on visit date specify collected month
49	DispensationOfSTudyDrugNotPerf3	Num	8		The specimens that should be drawn during this visit Dispensation of study drug if Not performed on visit date specify collected year
50	EligibilityCommitteeOverride	Char	3	$3.	Subject is eligible per eligibility committee

Data Set Name: tn07_followupdrugallocation.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	VisitDateDay	Num	8		Visit Date Day
5	VisitDateMonth	Char	3	$3.	Visit Date Month
6	VisitDateYear	Num	8		Visit Date Year
7	HaveYouCollectedAllBottlesOfRe	Char	3	$3.	Have you collected all bottles of returned study drug empty partially full and full and determined the number of new bottles that need to be allocated to the participant
8	HaveYouCompletedTheDrugAllocat	Char	3	$3.	Have you completed the Drug Allocation Request Form and faxed it to EMINENT
9	HaveYouReceivedTheDrugAllocati	Char	3	$3.	Have you received the Drug Allocation Assignment Report from EMINENT
10	DateofDrugAllocationAssignment	Num	8		Date of Drug Allocation Assignment Day
11	DateofDrugAllocationAssignment2	Char	3	$3.	Date of Drug Allocation Assignment Month
12	DateofDrugAllocationAssignment3	Num	8		Date of Drug Allocation Assignment Year
13	AllocationID	Num	8		Allocation ID
14	HaveYouPulledFromTheReserveSup	Char	3	$3.	Have you pulled from the reserve supply the bottles indicated on the Drug Allocation Assignment Report from EMINENT
15	HaveYouDispensed7BottlesOfStud	Char	3	$3.	Have you dispensed 7 bottles of study drug to the participant including any full unopened bottles that were redispensed and all newly allocated bottles as listed on the Allocation Assignment Report
16	WereThereAnyUnusualCircumstanc	Char	3	$3.	Were there any unusual circumstances
17	IfYESdescribe	Char	631	$631.	If YES Describe

Data Set Name: tn07_h1n1vaccination.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	DidSubjectReceiveH1N1Vaccinati	Char	3	$3.	H1N1 Vaccination Did subject receive H1N1 Vaccination
5	H1N1VaccinationType	Char	16	$16.	H1N1 Vaccination Received H1N1 Vaccination If yes type
6	H1N1VaccinationDateDay	Num	8		H1N1 Vaccination Received H1N1 Vaccination If yes vaccination date day
7	H1N1VaccinationDateMonth	Char	3	$3.	H1N1 Vaccination Received H1N1 Vaccination If yes vaccination date month
8	H1N1VaccinationDateYear	Num	8		H1N1 Vaccination Received H1N1 Vaccination If yes vaccination date year
9	DidSubjectReceiveH1N1Vaccinati2	Char	3	$3.	H1N1 Vaccination Did subject receive H1N1 Vaccination booster
10	H1N1VaccinationBoosterType	Char	16	$16.	H1N1 Vaccination Receive H1N1 Vaccination booster If yes type
11	H1N1VaccinationBoosterDateDay	Num	8		H1N1 Vaccination Receive H1N1 Vaccination booster If yes booster date day
12	H1N1VaccinationBoosterDateMont	Char	3	$3.	H1N1 Vaccination Receive H1N1 Vaccination booster If yes booster date month
13	H1N1VaccinationBoosterDateYear	Num	8		H1N1 Vaccination Receive H1N1 Vaccination booster If yes booster date year

Data Set Name: tn07_initialvisit.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	SiteVisitOtherThanPrimaryStudy	Char	3	$3.	Did the visit occur at a site other than at the primary study site
5	SiteVisitOtherThanPrimaryStudy2	Char	4	$4.	If YES record site number for reimbursement
6	InformedConsentObtainedDay	Num	8		Date written informed consent obtained day
7	InformedConsentObtainedMonth	Char	3	$3.	Date written informed consent obtained month
8	InformedConsentObtainedYear	Num	8		Date written informed consent obtained year
9	ParticipantPermissionOnOnsetFo	Char	68	$68.	On the consent form did the participant give permission to store samples for future testing
10	FirstOrSecondDegreeRelativeDia	Char	3	$3.	Have any of your first or second degree been diagnosed with T1D since the completion of Natural History Family History FormNH01F
11	RelativeWithT1D1_1	Char	22	$22.	Relative with type 1 diabetes
12	SexOfRelativeWithT1D1_1	Char	6	$6.	Sex of Relative
13	AgeOfRelativeWithT1D1_1	Num	8		Current Age of Relative
14	AgeOfOnsetInRelative1_1	Num	8		Age of T1D Onset in relative
15	AgeRelativeStartedInsulin1_1	Num	8		Age relative started insulin
16	RelativeComments1_1	Char	154	$154.	Relative Comments
17	RelativeWithT1D2_1	Char	17	$17.	Relative with type 1 diabetes
18	SexOfRelativeWithT1D2_1	Char	6	$6.	Sex of Relative
19	AgeOfRelativeWithT1D2_1	Num	8		Current Age of Relative
20	AgeOfOnsetInRelative2_1	Num	8		Age of T1D Onset in relative
21	AgeRelativeStartedInsulin2_1	Num	8		Age relative started insulin
22	RelativeComments2_1	Char	39	$39.	Relative Comments
23	RelativeWithT1D3_1	Char	17	$17.	Relative with type 1 diabetes
24	SexOfRelativeWithT1D3_1	Char	6	$6.	Sex of Relative
25	AgeOfRelativeWithT1D3_1	Num	8		Current Age of Relative
26	AgeOfOnsetInRelative3_1	Num	8		Age of T1D Onset in relative
27	AgeRelativeStartedInsulin3_1	Num	8		Age relative started insulin
28	RelativeComments3_1	Char	40	$40.	Relative Comments
29	RelativeWithT1D4_1	Char	13	$13.	Relative with type 1 diabetes
30	SexOfRelativeWithT1D4_1	Char	6	$6.	Sex of Relative
31	AgeOfRelativeWithT1D4_1	Num	8		Current Age of Relative
32	AgeOfOnsetInRelative4_1	Num	8		Age of T1D Onset in relative
33	AgeRelativeStartedInsulin4_1	Num	8		Age relative started insulin
34	RelativeComments4_1	Char	8	$8.	Relative Comments
35	RelativeWithT1D5_1	Char	13	$13.	Relative with type 1 diabetes
36	SexOfRelativeWithT1D5_1	Char	4	$4.	Sex of Relative

Num	Variable	Type	Len	Format	Label
37	AgeOfRelativeWithT1D5_1	Num	8		Current Age of Relative
38	AgeOfOnsetInRelative5_1	Num	8		Age of T1D Onset in relative
39	AgeRelativeStartedInsulin5_1	Num	8		Age relative started insulin
40	RelativeComments5_1	Char	1	$1.	Relative Comments
41	RelativeWithT1D6_1	Char	1	$1.	Relative with type 1 diabetes
42	SexOfRelativeWithT1D6_1	Char	1	$1.	Sex of Relative
43	AgeOfRelativeWithT1D6_1	Num	8		Current Age of Relative
44	AgeOfOnsetInRelative6_1	Num	8		Age of T1D Onset in relative
45	AgeRelativeStartedInsulin6_1	Num	8		Age relative started insulin
46	RelativeComments6_1	Char	1	$1.	Relative Comments
47	RelativeWithT1D7_1	Char	1	$1.	Relative with type 1 diabetes
48	SexOfRelativeWithT1D7_1	Char	1	$1.	Sex of Relative
49	AgeOfRelativeWithT1D7_1	Num	8		Current Age of Relative
50	AgeOfOnsetInRelative7_1	Num	8		Age of T1D Onset in relative
51	AgeRelativeStartedInsulin7_1	Num	8		Age relative started insulin
52	RelativeComments7_1	Char	1	$1.	Relative Comments
53	RelativeWithT1D8_1	Char	1	$1.	Relative with type 1 diabetes
54	SexOfRelativeWithT1D8_1	Char	1	$1.	Sex of Relative
55	AgeOfRelativeWithT1D8_1	Num	8		Current Age of Relative
56	AgeOfOnsetInRelative8_1	Num	8		Age of T1D Onset in relative
57	AgeRelativeStartedInsulin8_1	Num	8		Age relative started insulin
58	RelativeComments8_1	Char	1	$1.	Relative Comments
59	AnyoneInFamilyEverDiagnosedWit	Char	3	$3.	Has anyone in family ever been diagnosed with an autoimmune disease
60	CodeCorrespondingWithDiagno1_1	Char	50	$50.	If YES Record the code that corresponds with the daignosis
61	SpecifyOthersCorrespondingT1_1	Char	53	$53.	If others specify that corresponds with diagnosis
62	CodeCorrespondingWithDiagno2_1	Char	50	$50.	If YES Record the code that corresponds with the daignosis
63	SpecifyOthersCorrespondingT2_1	Char	45	$45.	If others specify that corresponds with diagnosis
64	CodeCorrespondingWithDiagno3_1	Char	36	$36.	If YES Record the code that corresponds with the daignosis
65	SpecifyOthersCorrespondingT3_1	Char	37	$37.	If others specify that corresponds with diagnosis
66	CodeCorrespondingWithDiagno4_1	Char	27	$27.	If YES Record the code that corresponds with the daignosis
67	SpecifyOthersCorrespondingT4_1	Char	38	$38.	If others specify that corresponds with diagnosis
68	CodeCorrespondingWithDiagno5_1	Char	27	$27.	If YES Record the code that corresponds with the daignosis
69	SpecifyOthersCorrespondingT5_1	Char	24	$24.	If others specify that corresponds with diagnosis
70	CodeCorrespondingWithDiagno6_1	Char	27	$27.	If YES Record the code that corresponds with the daignosis
71	SpecifyOthersCorrespondingT6_1	Char	31	$31.	If others specify that corresponds with diagnosis
72	EverDiagnosedWithAutoimmuneDis	Char	3	$3.	Have you ever been diagnosed with an autoimmune diasease
73	EverDiagnosedWithAutoimmune1_1	Char	50	$50.	If YES Record the code that corresponds with the diagnosis
74	OthersCorrespondingToDiagno1_1	Char	27	$27.	Others corresponding with the diagnosis
75	EverDiagnosedWithAutoimmune2_1	Char	25	$25.	If YES Record the code that corresponds with the diagnosis

Num	Variable	Type	Len	Format	Label
76	OthersCorrespondingToDiagno2_1	Char	1	$1.	Others corresponding with the diagnosis
77	EverDiagnosedWithAutoimmune3_1	Char	1	$1.	If YES Record the code that corresponds with the diagnosis
78	OthersCorrespondingToDiagno3_1	Char	1	$1.	Others corresponding with the diagnosis
79	AsthmaOrSeasonalAllergies	Char	3	$3.	Ever had asthma or seasonal allergies
80	IfFemaleDoesParticipantHasPote	Char	3	$3.	If FEMALE does the participant have reproductive potential
81	IfFemaleIsParticipantSexuallyA	Char	3	$3.	If FEMALE is the participant sexually active
82	IsSheUsingFormOfBirthControl	Char	3	$3.	Does she currently use a form of birth control
83	PlanOfBecomingPregnantNextYear	Char	2	$2.	Does she plan on becoming pregnant in the next year
84	UrinePregnancyTestCompletedThi	Char	3	$3.	Was a urine pregnancy test completed at this visit
85	UrinePregnancyTestPositive	Char	2	$2.	If YES was the test result positive
86	TookOtTakingImmunosuppressiveO	Char	3	$3.	Have you taken in the past or are you currently taking immunosuppressive or steroid drugs
87	TookOtTakingInsulinOrOtherDrug	Char	3	$3.	Have you taken in the past or are you currently taking insulin or other drugs to treat glucose
88	TookOtTakingGrowthHarmoneACPSD	Char	3	$3.	Have you taken in the past or are you currently taking growth harmone anticonvulsants thiazide or potassiumsparing diuretics betablockers or niacin
89	TookOtTakingNonPrescriptionalI	Char	3	$3.	Have you taken in the past or are you currently taking any nonprescription medications including vitamin or herbal supplements
90	PhysicalExamPerformedInInitial	Char	3	$3.	Was a phsical exam performed at this initial visit
91	PerformedDay	Num	8		If NO day performed
92	PerformedMonth	Char	3	$3.	If NO performed month
93	PerformedYear	Num	8		If NO performed year
94	SeatedArmBPSystolic	Num	8		Collection Of physical Assesments seated arm blood pressure systolic
95	SeatedArmBPDiastolic	Num	8		Collection Of physical Assesments seated arm blood pressure diastolic
96	WeighInKg	Num	8		Collection Of physical Assesments weight in kg
97	WeighInlbs	Num	8		Collection Of physical Assesments weight in lbs
98	HeightInCm	Num	8		Collection Of physical Assesments height in cm
99	HeightInIn	Num	8		Collection Of physical Assesments height in inches
100	AbdominalcircumferenceInCm	Num	8		Collection Of physical Assesments Abdominal circumference
101	AbdominalcircumferenceInIn	Num	8		Collection Of physical Assesments Abdominal circumference in Inches
102	HEENTReportedNormal	Char	3	$3.	Record of systemsHEENTparticipant reported normal
103	HEENTNormalOnExam	Char	3	$3.	Record of systemsHEENTNormal on Exam
104	HEENTAbnormalSpecify	Char	184	$184.	Record of systemsHEENTIf either abnormal explain
105	NeckReportedNormal	Char	3	$3.	Record of systemsNeckparticipant reported normal
106	NeckNormalOnExam	Char	3	$3.	Record of systemsNeckNormal on exam
107	NeckAbnormalSpecify	Char	111	$111.	Record of systemsNeckIf abnormal specify
108	ThyroidReportedNormal	Char	3	$3.	Record of systemsThyroidparticipant reported normal
109	ThyroidNormalOnExam	Char	3	$3.	Record of systemsThyroidNormal on Exam
110	ThyroidAbnormalExplain	Char	86	$86.	Record of systemsThyroidIf abnormal explain
111	LungsReportedNormal	Char	3	$3.	Record of systemsLungsparticipant reported normal
112	LungsNormalOnExam	Char	3	$3.	Record of systemsLungsNormal on exam

Num	Variable	Type	Len	Format	Label
113	LungsAbnormalSpecify	Char	105	$105.	Record of systemsLungsIf abnormal explain
114	ChestBreastReportedNormal	Char	3	$3.	Record of systemschestBreasts
115	ChestBreastNormalOnExam	Char	3	$3.	Record of systemschestBreastsnormal on exam
116	ChestBreastAbnormalSpecify	Char	63	$63.	Record of systemschestBreastsif abnormal specify
117	HeartCirculatoryReportedNormal	Char	3	$3.	Record of systemsheartcirculatoryparticipant reported normal
118	HeartCirculatoryNormalOnExam	Char	3	$3.	Record of systemsheartcirculatoryNormal on exam
119	HeartCirculatoryAbnormalExplai	Char	121	$121.	Record of systemsheartcirculatoryif abnormal explain
120	AbdomenReportedNormal	Char	3	$3.	Record the systemAbdomenparticipant reported normal
121	AbdomenNormalOnExam	Char	3	$3.	Record the systemAbdomennormal on exam
122	AbdomenAbnormalExplain	Char	232	$232.	Record the systemAbdomenif abnormal explain
123	MusculoskeletalReportedNormal	Char	3	$3.	Record the systemMusculoskeletal participant reported normal
124	MusculoskeletalNormalOnExam	Char	3	$3.	Record the systemMusculoskeletal Normal on exam
125	MusculoskeletalAbnormalExplain	Char	96	$96.	Record the systemMusculoskeletal If abnormal explain
126	NeurologicreportedNormal	Char	3	$3.	Record the systemNeurologicparticipant reported normal
127	NeurologicNormalOnExam	Char	3	$3.	Record the systemNeurologicNormal on exam
128	NeurologicAbnormalExplain	Char	80	$80.	Record the systemNeurologicId abnormal explain
129	GenitourinaryReportedNormal	Char	3	$3.	Record the systemGenitourinaryTestesparticipant reported normal
130	GenitourinaryNormalOnExam	Char	3	$3.	Record the systemGenitourinaryTestesNormal on exam
131	GenitourinaryAbnormalExplain	Char	134	$134.	Record the systemGenitourinaryTestesIf abnormal explain
132	SkinOrNailsReportedNormal	Char	3	$3.	Record the systemSkinNailsparticipant reported normal
133	SkinOrNailsNormalOnExam	Char	3	$3.	Record the systemSkinNailsNormal on exam
134	SkinOrNailsAbnormalExplain	Char	164	$164.	Record the systemSkinNailsIf abnormal explain
135	LymphNodesreportedNormal	Char	3	$3.	Record the systemLymph nodesparticipant reported normal
136	LymphNodesNormalOnExam	Char	3	$3.	Record the systemLymph nodesNormal on exam
137	LymphNodesAbnormalExplain	Char	87	$87.	Record the systemLymph nodesIf abnormal explain
138	OtherReportedNormal	Char	3	$3.	Record the systemOtherparticipant reported normal
139	OtherNormalOnExam	Char	3	$3.	Record the systemOtherNormal on exam
140	OtherAbnormalExplain	Char	76	$76.	Record the systemOtherIf abnormal explain
141	OthersSpecify	Char	161	$161.	Record the systemIf Other Specify
142	TannerStageBreastFemale	Char	3	$3.	For subjects less than 18 yrs of age record the participants sexual development using the Tanner scale Breastfemale
143	TannerStageGenitaliaMale	Char	3	$3.	For subjects less than 18 yrs of age record the participants sexual development using the Tanner scale Genitaliamale
144	TannerStagePublicHair	Char	3	$3.	For subjects less than 18 yrs of age record the participants sexual development using the Tanner scale Public haitboth
145	IVGTTOnVisitDate	Char	3	$3.	Specimens drawn during the visitIVGTTperformed on visit date
146	IVGTTPerformedDay	Num	8		Specimens drawn during the visitIVGTTIf not performed at this visit specify day
147	IVGTTPerformedMonth	Char	3	$3.	Specimens drawn during the visitIVGTTIf not performed at this visit specify month
148	IVGTTPerformedYear	Num	8		Specimens drawn during the visitIVGTTIf not performed at this visit specify Year
149	SerumForAutoantibodiesPerforme	Char	3	$3.	Specimens drawn during the visitSerum for autoantibodies performed on this visit date

Num	Variable	Type	Len	Format	Label
150	SerumForAutoantibodiesPerforme2	Num	8		Specimens drawn during the visitSerum for autoantibodies If not performed on visit datespecify performed day
151	SerumForAutoantibodiesPerforme3	Char	3	$3.	Specimens drawn during the visitSerum for autoantibodies If not performed on visit datespecify performed month
152	SerumForAutoantibodiesPerforme4	Num	8		Specimens drawn during the visitSerum for autoantibodies If not performed on visit datespecify performed year
153	SamplesForStoragePerformedOnVi	Char	3	$3.	Specimens drawn during the visitsamples for storage performed on this visit date
154	SamplesForStoragePerformedDay	Num	8		Specimens drawn during the visitsamples for storage If not performed at this visit specift performed day
155	SamplesForStoragePerformedMont	Char	3	$3.	Specimens drawn during the visitsamples for storage If not performed at this visit specift performed month
156	SamplesForStoragePerformedYear	Num	8		Specimens drawn during the visitsamples for storage If not performed at this visit specift performed Year
157	VolunteerUnderstandingAssessme	Char	3	$3.	Volunmteer Understanding Assessment
158	VolunteerUnderstandingAssessme2	Num	8		If VUA VUA VUA not performed at this visit specify perfoemed day
159	VolunteerUnderstandingAssessme3	Char	3	$3.	If VUA VUA not performed at this visit specify month performed
160	VolunteerUnderstandingAssessme4	Num	8		The apecimens frwawm during this visit Volunteer Understanding Assessment If not performed at this visit specift performed year
161	LifestyleQuestionnairePerforme	Char	3	$3.	Lifestyle Questionnaire performed at this visit
162	LifestyleQuestionnairePerforme2	Num	8		If questionnaire not performed at this visit specify day performed
163	LifestyleQuestionnairePerforme3	Char	3	$3.	If questionnaire not performed at this visit specify month performed
164	LifestyleQuestionnairePerforme4	Num	8		If questionnaire not performed at this visit specify year performed

Data Set Name: tn07_permanentsitetransfer.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Effective date for transfer
3	Visit	Char	8	$8.	Visit
4	Old_Site_Number	Char	91		Old Primary Site Number
5	Current_Site_Number	Char	91		Current Site Number
6	Reason_for_Transfer	Char	100	$100.	Reason for Transfer
7	Other_Specify	Char	2000		If Other, specify

Data Set Name: tn07_phonecontact.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	GatheredInformationContact	Char	23	$23.	Information gathered from
5	AnyChangesInHealthSinceLastSch	Char	3	$3.	Have there been any changes in health since the last scheduled visit
6	AnyChangesInConcomitantMedicat	Char	3	$3.	Have there been any changes in concomitant medications since last scheduled visit
7	ParticipantHasReproductivePote	Char	3	$3.	If FEMALE does the participant have reproductive potential
8	CurrentlyUsingFormOfBirthContr	Char	3	$3.	If yes to question D1 above Does she currently use a form of birth control
9	PlanOfBecomingPregnantInNext6M	Char	2	$2.	If yes to question D1 above Does she plan on becoming pregnant in the next 6 months
10	DosesMissedSinceLastStudyVisit	Num	8		How many doses has the participant missed since the last study visit
11	ParticipantCurrentlyTakingStud	Char	3	$3.	Is the participant currently taking study drug

Data Set Name: tn07_pregnancyconfirmation.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	DoPTMonth	Char	3	$3.	Date of positive pregnancy test Month
5	DoPTDay	Num	8		Date of positive pregnancy test Day
6	DoPTYear	Num	8		Date of positive pregnancy test Year
7	DoLMCMonth	Char	3	$3.	Date of last menstrual cycle Month
8	DoLMCDay	Num	8		Date of last menstrual cycle Day
9	DoLMCYear	Num	8		Date of last menstrual cycle Year
10	DoDeliveryMonth	Char	3	$3.	Estimated date of delivery Month
11	DoDeliveryDay	Num	8		Estimated date of delivery Day
12	DoDeliveryYear	Num	8		Estimated date of delivery Year
13	ParticipantCarryingPregnancyTo	Char	7	$7.	Is the participant planning on carrying the pregnancy to term
14	WillingToContinueFUVisits	Char	7	$7.	Is the participant willing to continue with future followup visits
15	ParticpantsObCareProviderInfor	Char	7	$7.	Has the participants obstetric care provider been informed of her participation in this study
16	PriorPregnancyNumberUnknown	Num	8		record total number of prior pregnancies unknown
17	TotalNumOfPregNotIncluThisOne	Num	8		Indicate the total number of prior pregnancies not including this one
18	HadComplicationOfPreg	Char	7	$7.	Has the participant ever experienced a complication of pregnancy
19	Spontaneousmiscarriage	Char	3		Has the participant ever experienced a spontaneous miscarriage
20	StillBirth	Char	2	$2.	Has the participant ever experienced a pregnancy that resulted in a still birth
21	NeonatalDeath	Char	2	$2.	Has the participant ever experienced a pregnancy that resulted in neonatal death
22	PostTermDelivryGT37GWeeks	Char	2	$2.	Has the participant ever experienced a postterm delivery 37 gestational weeks
23	PostTermDelivryLT42GWeeks	Char	2	$2.	Has the participant ever experienced a postterm delivery 42 gestational weeks
24	CodedMedStopped	Char	1	$1.	Has the coded medication been stopped
25	LastAttendedVisit	Char	8	$8.	Last attended study visit prior to the confirmed pregnancy
26	OtherDoVMonth	Char	1	$1.	If OTHER specify date of visit Month
27	DateDeliveryUnknown	Num	8		Estimated date of delivery unknown
28	DateMenCycleUnknown	Num	8		Date of last menstrual cycle unknown
29	DatePregTestUnknown	Num	8		Date of positive pregnancy test unknown
30	OtherDoVDay	Num	8		If OTHER specify date of visit Day
31	OtherDoVYear	Num	8		If OTHER specify date of visit Year

Data Set Name: tn07_pregnancyoutcome.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	OutcomeUKNDueToLossOfParticpan	Char	2	$2.	Is the outcome of the pregnancy unknown due to loss of participant to followup
5	DOPEDay	Num	8		Date Pregnancy ended Day
6	DOPEMonth	Char	3	$3.	Date Pregnancy ended Month
7	DOPEYear	Num	8		Date Pregnancy ended Year
8	PregnancyAbortion	Char	3	$3.	Was the pregnancy terminated as a result of an induced abortion
9	ReasonForAbortionMedicallyIndi2	Char	1	$1.	Specify reason
10	Miscarriage	Char	3	$3.	Did the pregnancy result in a miscarriage
11	LiveBirths	Char	3	$3.	Did the pregnancy result in a live birth or multiple live births
12	StillBirth	Char	2	$2.	Did the pregnancy result in a stillbirth
13	StillBirthHaveMalformations	Char	1	$1.	Did the stillbirth have any congenital malformationsDid the stillbirth have any congenital malformations
14	StillBirthHaveMalformationsSpe	Char	1	$1.	If YES Specify
15	StillBirthHaveAnyOtherComplica	Char	1	$1.	Did the stillbirth have any other complications
16	StillBirthHaveAnyOtherComplica2	Char	1	$1.	If YES Specify
17	NumberOfInfants	Num	8		Record number of infants both living and deceased the birth resulted in
18	NumberOfinfantsUnknown	Num	8		Record number of infants the birth resulted in Unknown
19	ComplicationsInDelivery	Char	7	$7.	Were there any complications during the delivery
20	HbA1cMeasure	Char	7	$7.	Was an HbA1c measured at any time during the pregnancy
21	HbA1cMeasure2	Num	8		Indicate HbA1c
22	RecordHbA1cUnknown	Num	8		Record HbA1c unknown
23	HbA1cMeasureDay	Num	8		Date Measured Day
24	HbA1cMeasureMonth	Char	1	$1.	Date Measured Month
25	HbA1cMeasureYear	Num	8		Date Measured Year
26	BreastFeeding	Char	7	$7.	Is the participant currently breastfeeding
27	Sex1_1	Char	6	$6.	Sex
28	GestationalAge1_1	Num	8		Gestational age
29	GestationalAgeUnknown1_1	Num	8		Gestational age unknown
30	BirthWeight1_1	Num	8		Birth weight gm
31	BirthWeightGMUnknown1_1	Num	8		Birth weight gm unknown
32	BirthWeightLbs1_1	Num	8		Birth weight lbs
33	BirthWeightOz1_1	Num	8		Birth weight oz
34	BirthWeightLBUnknown1_1	Num	8		Birth weight lb unknown
35	_1MinAPGARScore1_1	Num	8		One minute APGAR score
36	OneMinuteAPGARScoreUnknown1_1	Num	8		One minute APGAR score unknown
37	_5MinAPGARScore1_1	Num	8		Five minute APGAR score

Num	Variable	Type	Len	Format	Label
38	FiveMinuteAPGARScoreUnknown1_1	Num	8		Five minute APGAR score unknown
39	InfantBornCongenitalMalform1_1	Char	7	$7.	Was the infant born with any congenital malformations
40	InfantBornCongenitalMalform1_2	Char	1	$1.	Was the infant born with any congenital malformations Specify
41	InfantBornOtherComplication1_1	Char	7	$7.	Was the infant born with other complications
42	InfantBornOtherComplication1_2	Char	27	$27.	Was the infant born with other complications Specify
43	InfantInNICU1_1	Char	7	$7.	Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time
44	DoDInfantDay1_1	Num	8		If NO Date of death Day
45	DoDInfantMonth1_1	Char	3	$3.	If NO Date of death Month
46	DoDInfantYear1_1	Num	8		If NO Date of death Year
47	InfantDeathCause1_1	Char	28	$28.	Specify cause of death
48	InfantDischargedFromHopsita1_1	Char	3	$3.	Was the infant discharged from the hospital alive
49	InfantDischargedFromHopsita1_2	Num	8		If YES Date Discharged DAY
50	InfantDischargedFromHopsita1_3	Char	3	$3.	If YES Date Discharged Month
51	InfantDischargedFromHopsita1_4	Num	8		If YES Date Discharged Year
52	Sex2_1	Char	1	$1.	Sex
53	GestationalAge2_1	Num	8		Gestational age
54	GestationalAgeUnknown2_1	Num	8		Gestational age unknown
55	BirthWeight2_1	Num	8		Birth weight gm
56	BirthWeightGMUnknown2_1	Num	8		Birth weight gm unknown
57	BirthWeightLbs2_1	Num	8		Birth weight lbs
58	BirthWeightOz2_1	Num	8		Birth weight oz
59	BirthWeightLBUnknown2_1	Num	8		Birth weight lb unknown
60	_1MinAPGARScore2_1	Num	8		One minute APGAR score
61	OneMinuteAPGARScoreUnknown2_1	Num	8		One minute APGAR score unknown
62	_5MinAPGARScore2_1	Num	8		Five minute APGAR score
63	FiveMinuteAPGARScoreUnknown2_1	Num	8		Five minute APGAR score unknown
64	InfantBornCongenitalMalform2_1	Char	1	$1.	Was the infant born with any congenital malformations
65	InfantBornCongenitalMalform2_2	Char	1	$1.	Was the infant born with any congenital malformations Specify
66	InfantBornOtherComplication2_1	Char	1	$1.	Was the infant born with other complications
67	InfantBornOtherComplication2_2	Char	1	$1.	Was the infant born with other complications Specify
68	InfantInNICU2_1	Char	1	$1.	Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time
69	DoDInfantDay2_1	Num	8		If NO Date of death Day
70	DoDInfantMonth2_1	Char	1	$1.	If NO Date of death Month
71	DoDInfantYear2_1	Num	8		If NO Date of death Year
72	InfantDeathCause2_1	Char	1	$1.	Specify cause of death
73	InfantDischargedFromHopsita2_1	Char	1	$1.	Was the infant discharged from the hospital alive
74	InfantDischargedFromHopsita2_2	Num	8		If YES Date Discharged DAY
75	InfantDischargedFromHopsita2_3	Char	1	$1.	If YES Date Discharged Month
76	InfantDischargedFromHopsita2_4	Num	8		If YES Date Discharged Year

Num	Variable	Type	Len	Format	Label
77	Sex3_1	Char	1	$1.	Sex
78	GestationalAge3_1	Num	8		Gestational age
79	GestationalAgeUnknown3_1	Num	8		Gestational age unknown
80	BirthWeight3_1	Num	8		Birth weight gm
81	BirthWeightGMUnknown3_1	Num	8		Birth weight gm unknown
82	BirthWeightLbs3_1	Num	8		Birth weight lbs
83	BirthWeightOz3_1	Num	8		Birth weight oz
84	BirthWeightLBUnknown3_1	Num	8		Birth weight lb unknown
85	BirthWeightLBS	Num	8		Birth Weight lbs oz
86	_1MinAPGARScore3_1	Num	8		One minute APGAR score
87	OneMinuteAPGARScoreUnknown3_1	Num	8		One minute APGAR score unknown
88	_5MinAPGARScore3_1	Num	8		Five minute APGAR score
89	FiveMinuteAPGARScoreUnknown3_1	Num	8		Five minute APGAR score unknown
90	InfantBornCongenitalMalform3_1	Char	1	$1.	Was the infant born with any congenital malformations
91	InfantBornCongenitalMalform3_2	Char	1	$1.	Was the infant born with any congenital malformations Specify
92	InfantBornOtherComplication3_1	Char	1	$1.	Was the infant born with other complications
93	InfantBornOtherComplication3_2	Char	1	$1.	Was the infant born with other complications Specify
94	InfantInNICU3_1	Char	1	$1.	Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time
95	DoDInfantDay3_1	Num	8		If NO Date of death Day
96	DoDInfantMonth3_1	Char	1	$1.	If NO Date of death Month
97	DoDInfantYear3_1	Num	8		If NO Date of death Year
98	InfantDeathCause3_1	Char	1	$1.	Specify cause of death
99	InfantDischargedFromHopsita3_1	Char	1	$1.	Was the infant discharged from the hospital alive
100	InfantDischargedFromHopsita3_2	Num	8		If YES Date Discharged DAY
101	InfantDischargedFromHopsita3_3	Char	1	$1.	If YES Date Discharged Month
102	InfantDischargedFromHopsita3_4	Num	8		If YES Date Discharged Year
103	deliverymethod	Char	1	$1.	9 Delivery Method
104	PregnancyIDNumber	Num	8		Record the Pregnancy Identification Number
105	ReasonForAbortionMedicallyIndi	Char	2	$2.	Was the reason for the abortion medically indicated

Data Set Name: tn07_protocoldeviation.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	ProtcolDeviationDay	Num	8		Date protocol deviation occurred day
5	ProtcolDeviationMonth	Char	3	$3.	Date protocol deviation occurred month
6	ProtcolDeviationYear	Num	8		Date protocol deviation occurred year
7	ProtocolDeviationOtherSubcateg	Char	89	$89.	Protocol Deviation Other subcategory
8	DeviationOccurenceSpecify	Char	1	$1.	IF OTHER Specify Deviation
9	IfMiscellaneousSpecify	Char	292	$292.	If Miscellaneous specify
10	SubjectRandomizedInelgibilityA	Char	3	$3.	If Ineligible subject randomized checked approved by Eligibility Committee
11	DeviationCircumstances	Char	3445	$3445.	Describe deviation and circumstances
12	DescribeCorrectionAction	Char	175	$175.	Describe corrective action taken if necessary depending on circumstances
13	PInotified	Char	3	$3.	Was PI notified
14	Deviation	Char	1	$1.	Protocol Deviation
15	DeviationError	Char	49	$49.	Protocol deviationprocedural error
16	ProtocolDeviation	Char	87	$87.	Protocol Deviation
17	CorrectiveActionTaken	Char	1698	$1698.	Corrective action taken if necessary depending on circumstances
18	DescribeDeviation	Char	204	$204.	Describe Deviation procedural error and circumstances
19	OtherSpecify	Char	116	$116.	Other Specify
20	StudyVisitCompletedFor	Char	13	$13.	Study visit this form being completed for
21	DeviationDay	Num	8		Date protocol deviation procedural error occurred Day
22	DeviationMonth	Char	3	$3.	Date protocol deviation procedural error occurred Month
23	DeviationYear	Num	8		Date protocol deviation procedural error occurred Year

Data Set Name: tn07_registration.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Date_of_Registration	Num	8	MMDDYY10.	Date of Registration
3	Visit	Char	8		Baseline
4	Status	Char	20		Status

Data Set Name: tn07_researchlabs.sas7bdat

Num	Variable	Type	Len	Format	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		Test Name
7	Result	Char	1000		Result
8	Result_Type	Char	6		Result Type
9	Visit	Char	48		Visit
10	Date_at_Test_Results_Reported	Num	8	MMDDYY10.	Date at Test Results Reported
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		Numeric code to identify testing Lab

Data Set Name: tn07_studydrug.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	StudyDrugReturned	Char	3	$3.	Was study drug returned
5	StudyDrugReturnedDay	Num	8		study drug returned day
6	StudyDrugReturnedMonth	Char	3	$3.	study drug returned month
7	StudyDrugReturnedYear	Num	8		study drug returned year
8	CapsulesReturned	Num	8		Number of capsules returned
9	StudyDrugDispensed	Char	3	$3.	Was study drug dispensed
10	StudyDrugDispensedDay	Num	8		Study drug dispensed day
11	StudyDrugDispensedMonth	Char	3	$3.	Study drug dispensed month
12	StudyDrugDispensedYear	Num	8		Study drug dispensed year
13	CapsulesDispensed	Num	8		Number of capsules dispensed
14	StudyDrugReceiving	Char	18	$18.	How did the participant receive the study drug
15	RandomizationNumber	Char	9	$9.	Record the Randomization Number used for study drug dispensation
16	SecondPartofBottleLabel1_1	Char	49	$49.	study drugbottles dispensed to the participant Bottle Number
17	BottleDispensedDay1_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
18	BottleDispensedMonth1_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
19	BottleDispensedYear1_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
20	BottleDispenseDrugID1_1	Char	19	$19.	study drugbottles dispensed to the participant Drug ID
21	BottleDispenseRandomization1_1	Char	10	$10.	study drugbottles dispensed to the participant Randomization number
22	BottleDispensePkgLot1_1	Char	25	$25.	study drug bottles dispensed to the participant Pkg Lot
23	SecondPartofBottleLabel2_1	Char	49	$49.	study drugbottles dispensed to the participant Bottle Number
24	BottleDispensedDay2_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
25	BottleDispensedMonth2_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
26	BottleDispensedYear2_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
27	BottleDispenseDrugID2_1	Char	19	$19.	study drugbottles dispensed to the participant Drug ID
28	BottleDispenseRandomization2_1	Char	10	$10.	study drugbottles dispensed to the participant Randomization number
29	BottleDispensePkgLot2_1	Char	25	$25.	study drug bottles dispensed to the participant Pkg Lot
30	SecondPartofBottleLabel3_1	Char	216	$216.	study drugbottles dispensed to the participant Bottle Number
31	BottleDispensedDay3_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
32	BottleDispensedMonth3_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
33	BottleDispensedYear3_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
34	BottleDispenseDrugID3_1	Char	19	$19.	study drugbottles dispensed to the participant Drug ID
35	BottleDispenseRandomization3_1	Char	10	$10.	study drugbottles dispensed to the participant Randomization number
36	BottleDispensePkgLot3_1	Char	25	$25.	study drug bottles dispensed to the participant Pkg Lot
37	SecondPartofBottleLabel4_1	Char	42	$42.	study drugbottles dispensed to the participant Bottle Number

Num	Variable	Type	Len	Format	Label
38	BottleDispensedDay4_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
39	BottleDispensedMonth4_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
40	BottleDispensedYear4_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
41	BottleDispenseDrugID4_1	Char	19	$19.	study drugbottles dispensed to the participant Drug ID
42	BottleDispenseRandomization4_1	Char	10	$10.	study drugbottles dispensed to the participant Randomization number
43	BottleDispensePkgLot4_1	Char	32	$32.	study drug bottles dispensed to the participant Pkg Lot
44	SecondPartofBottleLabel5_1	Char	42	$42.	study drugbottles dispensed to the participant Bottle Number
45	BottleDispensedDay5_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
46	BottleDispensedMonth5_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
47	BottleDispensedYear5_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
48	BottleDispenseDrugID5_1	Char	19	$19.	study drugbottles dispensed to the participant Drug ID
49	BottleDispenseRandomization5_1	Char	10	$10.	study drugbottles dispensed to the participant Randomization number
50	BottleDispensePkgLot5_1	Char	14	$14.	study drug bottles dispensed to the participant Pkg Lot
51	SecondPartofBottleLabel6_1	Char	45	$45.	study drugbottles dispensed to the participant Bottle Number
52	BottleDispensedDay6_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
53	BottleDispensedMonth6_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
54	BottleDispensedYear6_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
55	BottleDispenseDrugID6_1	Char	19	$19.	study drugbottles dispensed to the participant Drug ID
56	BottleDispenseRandomization6_1	Char	10	$10.	study drugbottles dispensed to the participant Randomization number
57	BottleDispensePkgLot6_1	Char	14	$14.	study drug bottles dispensed to the participant Pkg Lot
58	SecondPartofBottleLabel7_1	Char	42	$42.	study drugbottles dispensed to the participant Bottle Number
59	BottleDispensedDay7_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
60	BottleDispensedMonth7_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
61	BottleDispensedYear7_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
62	BottleDispenseDrugID7_1	Char	19	$19.	study drugbottles dispensed to the participant Drug ID
63	BottleDispenseRandomization7_1	Char	10	$10.	study drugbottles dispensed to the participant Randomization number
64	BottleDispensePkgLot7_1	Char	14	$14.	study drug bottles dispensed to the participant Pkg Lot
65	SecondPartofBottleLabel8_1	Char	32	$32.	study drugbottles dispensed to the participant Bottle Number
66	BottleDispensedDay8_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
67	BottleDispensedMonth8_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
68	BottleDispensedYear8_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
69	BottleDispenseDrugID8_1	Char	4	$4.	study drugbottles dispensed to the participant Drug ID
70	BottleDispenseRandomization8_1	Char	7	$7.	study drugbottles dispensed to the participant Randomization number
71	BottleDispensePkgLot8_1	Char	10	$10.	study drug bottles dispensed to the participant Pkg Lot
72	SecondPartofBottleLabel9_1	Char	2	$2.	study drugbottles dispensed to the participant Bottle Number
73	BottleDispensedDay9_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
74	BottleDispensedMonth9_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
75	BottleDispensedYear9_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
76	BottleDispenseDrugID9_1	Char	4	$4.	study drugbottles dispensed to the participant Drug ID

Num	Variable	Type	Len	Format	Label
77	BottleDispenseRandomization9_1	Char	7	$7.	study drugbottles dispensed to the participant Randomization number
78	BottleDispensePkgLot9_1	Char	10	$10.	study drug bottles dispensed to the participant Pkg Lot
79	SecondPartofBottleLabel10_1	Char	2	$2.	study drugbottles dispensed to the participant Bottle Number
80	BottleDispensedDay10_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
81	BottleDispensedMonth10_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
82	BottleDispensedYear10_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
83	BottleDispenseDrugID10_1	Char	4	$4.	study drugbottles dispensed to the participant Drug ID
84	BottleDispenseRandomization10_1	Char	7	$7.	study drugbottles dispensed to the participant Randomization number
85	BottleDispensePkgLot10_1	Char	10	$10.	study drug bottles dispensed to the participant Pkg Lot
86	SecondPartofBottleLabel11_1	Char	2	$2.	study drugbottles dispensed to the participant Bottle Number
87	BottleDispensedDay11_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
88	BottleDispensedMonth11_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
89	BottleDispensedYear11_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
90	BottleDispenseDrugID11_1	Char	4	$4.	study drugbottles dispensed to the participant Drug ID
91	BottleDispenseRandomization11_1	Char	5	$5.	study drugbottles dispensed to the participant Randomization number
92	BottleDispensePkgLot11_1	Char	10	$10.	study drug bottles dispensed to the participant Pkg Lot
93	SecondPartofBottleLabel12_1	Char	2	$2.	study drugbottles dispensed to the participant Bottle Number
94	BottleDispensedDay12_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
95	BottleDispensedMonth12_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
96	BottleDispensedYear12_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
97	BottleDispenseDrugID12_1	Char	1	$1.	study drugbottles dispensed to the participant Drug ID
98	BottleDispenseRandomization12_1	Char	5	$5.	study drugbottles dispensed to the participant Randomization number
99	BottleDispensePkgLot12_1	Char	10	$10.	study drug bottles dispensed to the participant Pkg Lot
100	SecondPartofBottleLabel13_1	Char	2	$2.	study drugbottles dispensed to the participant Bottle Number
101	BottleDispensedDay13_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
102	BottleDispensedMonth13_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
103	BottleDispensedYear13_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
104	BottleDispenseDrugID13_1	Char	1	$1.	study drugbottles dispensed to the participant Drug ID
105	BottleDispenseRandomization13_1	Char	5	$5.	study drugbottles dispensed to the participant Randomization number
106	BottleDispensePkgLot13_1	Char	10	$10.	study drug bottles dispensed to the participant Pkg Lot
107	SecondPartofBottleLabel14_1	Char	2	$2.	study drugbottles dispensed to the participant Bottle Number
108	BottleDispensedDay14_1	Num	8		study drugbottles dispensed to the participant Day bottle dispensed
109	BottleDispensedMonth14_1	Char	3	$3.	study drugbottles dispensed to the participant Month bottle dispensed
110	BottleDispensedYear14_1	Num	8		study drugbottles dispensed to the participant Year bottle dispensed
111	BottleDispenseDrugID14_1	Char	1	$1.	study drugbottles dispensed to the participant Drug ID
112	BottleDispenseRandomization14_1	Char	5	$5.	study drugbottles dispensed to the participant Randomization number
113	BottleDispensePkgLot14_1	Char	10	$10.	study drug bottles dispensed to the participant Pkg Lot
114	UnusualCircumstances	Char	3	$3.	Were there any unusual circumstances
115	UnusualCircumstancesDescribe	Char	1255	$1255.	Were there any unusual circumstances If YES Describe

Data Set Name: tn07_studyendpointvisit.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	Participantwascontac_AffiliateS1	Num	8		Participantwascontac: Affiliate Site Coordinator
5	Participantwascontac_AffiliateS2	Num	8		Participantwascontac: Affiliate Site PI
6	Participantwascontac_ClinicalCe1	Num	8		Participantwascontac: Clinical Center Coordinator
7	Participantwascontac_ClinicalCe2	Num	8		Participantwascontac: Clinical Center PI
8	Participantwascontac_Other	Num	8		Participantwascontac: Other
9	MethodofContact	Char	12	$12.	Method of Contact
10	MethodofContactOther	Char	106	$106.	Method of Contact Other
11	Wastheparticipantabletobereach	Char	3	$3.	Was the participant able to be reached
12	Hastheparticipantscheduledastu	Char	3	$3.	Has the participant scheduled a Study Endpoint Visit
13	indicateiftheparticipantiswill	Char	3	$3.	If responding No to Question 4 please indicate if the participant is willing to visit an outside physician or local lab for specimen collection
14	Iftheparticipanthasdeclinedthe	Char	3	$3.	If the participant has declined the Study Endpoint Visit and a local lab or outside physician specimen collection did the site ascertain the participants diabetes status
15	DateofVisitDay	Num	8		Date of Visit Day
16	DateofVisitMonth	Char	3	$3.	Date of Visit Month
17	DateofVisitYear	Num	8		Date of Visit Year
18	OutsideLaboratoryResultsRandom	Num	8		Outside Laboratory Results Random Glucose
19	OutsideLaboratoryResultsRandom2	Char	1	$1.	Outside Laboratory Results Random Glucose Unit
20	OutsideLaboratoryResultsRandom3	Num	8		Outside Laboratory Results Random Glucose Reference Range Low
21	OutsideLaboratoryResultsRandom4	Num	8		Outside Laboratory Results Random Glucose Reference Range High
22	OutsideLaboratoryResultsRandom5	Num	8		Outside Laboratory Results Random Glucose Date Day
23	OutsideLaboratoryResultsRandom6	Char	1	$1.	Outside Laboratory Results Random Glucose Date Month
24	OutsideLaboratoryResultsRandom7	Num	8		Outside Laboratory Results Random Glucose Date Year
25	Pleaseselectwhichsam_HbA1csentto	Num	8		Pleaseselectwhichsam: HbA1c sent to TrialNet Laboratory for processing
26	Pleaseselectwhichsam_RandomPlas1	Num	8		Pleaseselectwhichsam: Random Plasma Glucose sent to TrialNet Laboratory for processing (collect time of last meal)
27	Pleaseselectwhichsam_HbA1crunbyl	Num	8		Pleaseselectwhichsam: HbA1c run by local lab, result reported to TrialNet
28	Pleaseselectwhichsam_RandomPlas2	Num	8		Pleaseselectwhichsam: Random Plasma Glucose run by local lab, results reported to TrialNet (collect time of last meal)
29	OutsideLaboratoryRes_OutsideLa1	Num	8		OutsideLaboratoryRes: Outside Lab
30	OutsideLaboratoryRes_OutsidePhy1	Num	8		OutsideLaboratoryRes: Outside Physician
31	OutsideLaboratoryRes_OutsideLa2	Num	8		OutsideLaboratoryRes: Outside Lab
32	OutsideLaboratoryRes_OutsidePhy2	Num	8		OutsideLaboratoryRes: Outside Physician
33	OutsideLaboratoryResultsHbA1c	Num	8		Outside Laboratory Results HbA1c
34	OutsideLaboratoryResultsHbA1cR	Num	8		Outside Laboratory Results HbA1c Reference Range Low
35	OutsideLaboratoryResultsHbA1cR2	Num	8		Outside Laboratory Results HbA1c Reference Range High

Num	Variable	Type	Len	Format	Label
36	OutsideLaboratoryResultsHbA1cD	Num	8		Outside Laboratory Results HbA1c Date Day
37	OutsideLaboratoryResultsHbA1cD2	Char	3	$3.	Outside Laboratory Results HbA1c Date Month
38	OutsideLaboratoryResultsHbA1cD3	Num	8		Outside Laboratory Results HbA1c Date Year
39	Timeoflastmealhour	Num	8		Time of last meal hour
40	Timeoflastmealminute	Num	8		Time of last meal minute
41	AdditionalCommentsdescribingpa	Char	758	$758.	Additional Comments describing participants situation
42	Participantwascontactedbyother	Char	1	$1.	Participant was contacted by other

Data Set Name: tn07_treatmentstartdate.sas7bdat

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	TreatmentAssignDate	Num	8	MMDDYY10.	Treatment Assign Date
3	Visit	Char	8		Visit
4	TreatmentStartedDate	Num	8	MMDDYY10.	Treatment Started Date
5	TreatmentDesc	Char	500		Treatment Description

1	MaskID	Num	8		Participant Mask ID#
2	TreatmentAssignDate	Num	8	MMDDYY10.	Treatment Assign Date