

**Data Set Name: tn16\_adverseevents.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Visit Date
3	Visit	Char	48		Visit
4	AdverseEventID	Num	8		Adverse event ID
5	AETerm	Char	100		adverse event supra ordinate term
6	severity	Num	8		Severity
7	AEReportType	Char	9		Adverse event report type
8	AEReportDtDay	Num	8		Adverse event report day
9	AEReportDtMonth	Num	8		Adverse event report month
10	AEReportDtYear	Num	8		Adverse event report year
11	AEOccurDtDay	Num	8		Adverse event occurrence day
12	AEOccurDtMonth	Num	8		Adverse event occurrence month
13	AEOccurDtYear	Num	8		Adverse event occurrence year
14	AEPrimarySecondary1_1	Char	9		Adverse event is primary or secondary
15	AECategory	Char	35		Adverse event category
16	AEDetails	Char	3999		Event details description
17	AETreatLocation	Char	14		Location of event treatment
18	AETreatLocationOther	Char	108		Location of event treatment if other
19	AEExpected1_1	Char	3		Adverse event expected (per the IB or package insert with the exception of observational studies)
20	AECausalityByReporter	Char	22		Causality by reported relative
21	AEAssociations_Developmentofacon	Num	8		Development of a congenital anomaly or birth defect
22	AEAssociations_Developmentofaper	Num	8		Development of a permanent, serious, disabling or incapacitating condition
23	AEAssociations_Death	Num	8		Death
24	AEAssociations_Hospitalizationor	Num	8		Hospitalization or prolonged hospitalization
25	AEAssociations_Lifethreatening	Num	8		Life threatening
26	AEAssociations_Isanotherconditio	Num	8		Another condition which investigators judge to represent significant hazards
27	AEPatientOutcome1_1	Char	35		Patient status
28	AEResolveDtDay	Num	8		Adverse event resolved day
29	AEResolveDtMonth	Num	8		Adverse event resolved month
30	AEResolveDtYear	Num	8		Adverse event resolved year
31	AEDateDeathDay	Num	8		Adverse event death day
32	AEDateDeathMonth	Num	8		Adverse event death month
33	AEDateDeathYear	Num	8		Adverse event death year
34	Comments	Char	3025		Additional comments
35	StudyDrugStartDateDay1_1	Num	8		Study drug start day

Num	Variable	Type	Len	Format	Label
36	StudyDrugStartDateMonth1_1	Char	3		Study drug start month
37	StudyDrugStartDateYear1_1	Num	8		Study drug start year
38	StudyDrugStopDateDay1_1	Num	8		Study drug stop day
39	StudyDrugStopDateMonth1_1	Char	3		Study drug stop month
40	StudyDrugStopDateYear1_1	Num	8		Study drug stop year
41	StudyDrugStartDateDay2_1	Num	8		Study drug start day
42	StudyDrugStartDateMonth2_1	Char	3		Study drug start month
43	StudyDrugStartDateYear2_1	Num	8		Study drug start year
44	StudyDrugStopDateDay2_1	Num	8		Study drug stop day
45	StudyDrugStopDateMonth2_1	Char	3		Study drug stop month
46	StudyDrugStopDateYear2_1	Num	8		Study drug stop year
47	StudyDrugStartDateDay3_1	Num	8		Study drug start day
48	StudyDrugStartDateMonth3_1	Char	3		Study drug start month
49	StudyDrugStartDateYear3_1	Num	8		Study drug start year
50	StudyDrugStopDateDay3_1	Num	8		Study drug stop day
51	StudyDrugStopDateMonth3_1	Char	3		Study drug stop month
52	StudyDrugStopDateYear3_1	Num	8		Study drug stop year
53	StudyDrugStartDateDay4_1	Num	8		Study drug start day
54	StudyDrugStartDateMonth4_1	Char	3		Study drug start month
55	StudyDrugStartDateYear4_1	Num	8		Study drug start year
56	StudyDrugStopDateDay4_1	Num	8		Study drug stop day
57	StudyDrugStopDateMonth4_1	Char	3		Study drug stop month
58	StudyDrugStopDateYear4_1	Num	8		Study drug stop year
59	StudyDrugStartDateDay5_1	Num	8		Study drug start day
60	StudyDrugStartDateMonth5_1	Char	3		Study drug start month
61	StudyDrugStartDateYear5_1	Num	8		Study drug start year
62	StudyDrugStopDateDay5_1	Num	8		Study drug stop day
63	StudyDrugStopDateMonth5_1	Char	1		Study drug stop month
64	StudyDrugStopDateYear5_1	Num	8		Study drug stop year
65	Eventabateafterstoppingdrug	Char	14		Event abated after stopping drug
66	Eventreappearafterreintroducti	Char	14		Event appeared after introducing drug
67	AEFollowupDateDay	Num	8		Adverse event follow-up day
68	AEFollowupDateMonth	Num	8		Adverse event follow-up month
69	AEFollowupDateYear	Num	8		Adverse event follow-up year
70	AEReasonForFollowup	Char	55		Adverse event reason for followup
71	CentralIRBOrlocalIRB	Char	11		Central IRB or local IRB used for this protocol
72	AEFollowupNumber	Num	8		Adverse event follow-up number
73	AEOther	Num	8		Adverse event other
74	AEReporterStaffCode	Num	8		Adverse event reporter staff code

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
75	AESelectTerm	Num	8		Adverse event select term
76	centralIRBscriteria	Char	50		Central IRB criteria
77	ElectronicSignature	Char	1		Adverse event electronic signature
78	AESerious	Char	3		Serious adverse event

**Data Set Name: tn16\_adverseeventsreview.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Visit Date
3	Visit	Char	48		Visit
4	AdverseEventID	Num	8		Adverse event ID
5	AECausalityByReviewer	Char	22		Adverse event causality reviewer
6	RecommendProtocolChange	Char	2		Adverse event recommend change
7	RecommendConsentChange	Char	3		Recommend consent change
8	AEReviewFormComments	Char	341		Review form comments
9	AEAdditionalInfoRequested	Char	3		Additional information requested
10	AEAdditionalInfoRequestedDetail	Char	499		Adverse event additional information requested details
11	AEReviewRequireDSMBReview	Num	8		Requires urgent and immediate review by full DSMB committee
12	AEReviewDSMBReviewComments	Char	1		Review requires DSMB review comments
13	AEReviewPriorSimilarSAEs	Char	3		Have there been prior occurrences of similar reported in this study
14	AEReviewReportingTimeframe	Char	27		Reporting time frame to regulatory authorities
15	AEReviewTreatmentUnblindedForC	Char	2		Does treatment need to be unblinded for determination of causality
16	AEReviewPriorSimilarSAEsSummar	Char	280		If prior occurrences of similar serious adverse events provide a brief summary
17	AEPatientOutcome	Char	1		Patient outcome

**Data Set Name: tn16\_changeofstatus.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Visit Date
3	Visit	Char	48		Visit
4	DateCompletionDD	Num	8		Date form completed day
5	DateCompletionMM	Char	3		Date form completed month
6	DateCompletionYYYY	Num	8		Date form completed year
7	DateStatusChangeDay	Num	8		Date status change day
8	DateStatusChangeMonth	Char	3		Date status change month
9	DateStatusChangeYear	Num	8		Date status change year
10	DoRDay	Num	8		Date of reactivation Day
11	DoRMonth	Char	3		Date of reactivation Month
12	DoRYear	Num	8		Date of reactivation Year
13	ChangeOfStatusOccuring	Char	98		Change of status occurring
14	DoWDay	Num	8		Date of withdrawal Day
15	DoWMonth	Char	3		Date of withdrawal Month
16	DoWYear	Num	8		Date of withdrawal Year
17	ReasonForWithdrawal	Char	45		Reason for withdrawal
18	IsParticipantWillingBeContacte	Char	7		Is participant willing to be contacted
19	ParticipantCompletedEntireStud	Char	3		Participant completed entire study
20	WillingToBeContacted	Char	3		Willing to be contacted
21	WillingToContinueAfterPregnanc	Char	3		Is the participant willing to continue participation as a Control after completion of pregnancy
22	WithdrewConsentWhy	Char	68		If withdrew consent selected record the reason why
23	ReasonAdverseEventSpecify	Char	106		Adverse event reason specify
24	ReasonForWithdrawalOTHER	Char	789		If other withdrawal reason specify
25	ReasonWithdrewConsentSpecify	Char	770		Specify reason for withdrawing consent
26	WithdrewConsentWhyIfOther	Char	189		If withdrew consent selected record the reason why other selected specify
27	LastAttendedVisitMonth	Char	3		If other selected specify date of visit month
28	PregnancyCompletionMonth	Char	3		If pregnant what is the estimated date of completion of pregnancy month
29	PregnancyCompletionDay	Num	8		If pregnant what is the estimated date of completion of pregnancy day
30	PregnancyCompletionYear	Num	8		If pregnant what is the estimated date of completion of pregnancy year
31	LastAttendedVisitDay	Num	8		If other selected specify date of visit day
32	LastAttendedVisitYear	Num	8		If other selected specify date of visit year
33	PhiX174VisitNumber	Num	8		Record week number if PhiX174 visit only



**Data Set Name: tn16\_concomitantmeds.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Visit Date
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	ConMedsFrequencyChoices	Char	5		Conmeds Frequency
11	ConMedsFrequencyOtherDetail	Char	390		Conmeds frequency other detail
12	ConMedsIntervalChoices	Char	5		Conmeds interval choices
13	ConMedsIntervalOtherDetails	Char	142		Conmeds Interval other details
14	ConMedsRoute	Char	26		Conmeds route
15	Indication	Char	354		Indication
16	StartDateDay	Num	8		Start date day
17	StartDateMonth	Char	3		Start date month
18	StartDateYear	Num	8		Start date year
19	IsContinuing	Char	3		Continuing medication use
20	StopDateDay	Num	8		Stop date day
21	StopDateMonth	Char	3		Stop date month
22	StopDateYear	Num	8		Stop date year

**Data Set Name: tn16\_diabeteshealthinfo.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	HospitalizedSinceLastVisit	Char	7		Have you been hospitalized for any reason since your last visit/contact
5	HospitalizedReason	Char	341		Hospitalization reason
6	OtherChronicDiseases	Char	7		Have you been diagnosed with any new chronic diseases other than diabetes
7	AnyNewChronicDisease_Autoimmuned	Num	8		Newly diagnosed chronic disease: Autoimmune disease
8	AnyNewChronicDisease_Cancer	Num	8		Newly diagnosed chronic disease: Cancer
9	AnyNewChronicDisease_Neurologica	Num	8		Newly diagnosed chronic disease: Neurological
10	AnyNewChronicDisease_Other	Num	8		Newly diagnosed chronic disease: Other
11	OtherChronicDiseasesOtherSpeci	Char	86		Newly diagnosed chronic disease: Other specify
12	HaveHadComplications_Eyes	Num	8		Have you ever been told that you have had complications from your diabetes that have affected the eyes
13	HaveHadComplications_Heart	Num	8		Have you ever been told that you have had complications from your diabetes that have affected the heart
14	HaveHadComplications_Kidneys	Num	8		Have you ever been told that you have had complications from your diabetes that have affected the kidney
15	HaveHadComplications_Nerves	Num	8		Have you ever been told that you have had complications from your diabetes that have affected the nerves
16	HaveHadComplications_Other	Num	8		Have you ever been told that you have had complications from your diabetes that have affected other areas
17	HaveHadComplicationsFromYourDi3	Char	37		Have you ever been told that you have had complications from your diabetes if other specify
18	WeightKg	Num	8		Weight in kilograms
19	HowIsWeightObtained	Char	13		how is weight obtained
20	HeightCm	Num	8		Height in centimeters
21	HowIsHeightObtained	Char	13		how is height obtained
22	SubjectUsingCGMS	Char	3		Is the person using a Continuous Glucose Monitoring System (CGMS)
23	AreThere3GlucoseValuesAvailabl	Char	3		Are there at least three glucose values available for at least three days
24	InsulDoseInfoAvailableFor3Days	Char	3		Is the insulin dose information available for at least three days (same 3-day period as above)
25	DateRecordedDD1	Num	8		Date glucose/insulin recorded day
26	DateRecordedMM1	Char	3		Date glucose/insulin recorded month
27	DateRecordedYYYY1	Num	8		Date glucose/insulin recorded year
28	DateRecordedDD2	Num	8		Date glucose/insulin recorded day
29	DateRecordedMM2	Char	3		Date glucose/insulin recorded month

Num	Variable	Type	Len	Format	Label
30	DateRecordedYYYY2	Num	8		Date glucose/insulin recorded year
31	DateRecordedDD3	Num	8		Date glucose/insulin recorded day
32	DateRecordedMM3	Char	3		Date glucose/insulin recorded month
33	DateRecordedYYYY3	Num	8		Date glucose/insulin recorded year
34	TotalOfHomeBloodGlucoseOver3Da	Num	8		Total number of home blood glucose monitoring values over 3 days
35	TotalOfHBGMonitoringsLessThan6	Num	8		Number of home blood glucose monitoring values over 3 days that were less than 65 mg/dL
36	AvgRecordedFastingGlucosesmgdl	Num	8		Average of recorded fasting glucoses (Average of fasting glucose is total value of glucose divided by total of number of readings collected in the 3-day period) in mg/dL
37	AvgAllRecordedGlucosesMmol	Char	6		Average of all recorded glucoses (Average of recorded glucose is total value of glucose divided by total of number of readings collected in the 3-day period) in mmol/L
38	LowestGlucosemgdl	Num	8		Lowest recorded glucose (over 3 days) in mg/dL
39	LowestGlucosemmol	Char	6		Lowest recorded glucose (over 3 days) in mmol/L
40	HighestGlucosemgdl	Num	8		Highest recorded glucose (over 3 days) in mg/dL
41	HighestGlucosemmol	Char	6		Highest recorded glucose (over 3 days) in mmol/L
42	InsulinRoutineDaily	Char	27		Daily insulin routine
43	AvgUnitsShortActingInsulin	Num	8		Average units/day of short acting insulin (average over 3-day period)
44	AverageUnitsOfIntermediateInsul	Num	8		Average units/day of intermediate/long acting insulin (average over 3-day period)
45	RememberDateOfMostRecentHbA1c	Char	3		Do you remember the date of most recent hba1c
46	LastHbA1cDay	Num	8		Last hba1c day
47	LastHbA1cMonth	Char	3		Last hba1c month
48	LastHbA1cYear	Num	8		Last hba1c year
49	RememberValueOfMostRecentHbA1c	Char	3		Do you remember the value of most recent hba1c
50	LastHbA1cValue	Num	8		Last hba1c value
51	SeizuresFaintingLowBloodGlucos	Char	7		Any episodes of seizures or loss of consciousness from low blood glucose since your last visit
52	HospitalizationsForHighGlucose	Char	7		Any emergency room visits or hospitalizations for high blood glucose or DKA since your last visit
53	RequiredSpecimensCollected	Char	3		Were all required specimens collected for this visit
54	IfSpecimensNotCollec_Participant	Num	8		Required specimens not collected: Participant declined collection of specimens
55	IfSpecimensNotCollec_Reachedmaxi	Num	8		Required specimens not collected: Reached maximum blood volume limit
56	IfSpecimensNotCollec_Illnessurg	Num	8		Required specimens not collected: Illness, injury, or hospitalization
57	IfSpecimensNotCollec_Unabletoobt	Num	8		Required specimens not collected: Unable to obtain venous access
58	IfSpecimensNotCollec_Forgottocol	Num	8		Required specimens not collected: Forgot to collect specimens

Num	Variable	Type	Len	Format	Label
59	IfSpecimensNotCollec_RemoteVisit	Num	8		Required specimens not collected: Remove visit (PBMC only)
60	IfSpecimensNotCollec_Other	Num	8		Required specimens not collected: Other
61	OtherReason	Char	237		Required specimens not collected: Other reason
62	OGTTCollected	Char	3		OGTT collected
63	OGTTTestStartTimeHrs	Num	8		OGTT test start time hrs
64	OGTTTestStartTimeMins	Num	8		OGTT test start time mins
65	OGTTAmountConsumed	Num	8		OGTT amount consumed
66	OGTTTimeToConsumeGlucola	Num	8		How long did it take for the participant to consume the Glucola
67	MMTTCollected	Char	3		MMTT collected
68	MMTTTestStartTimeHrs	Num	8		MMTT test start time hrs
69	MMTTTestStartTimeMins	Num	8		MMTT test start time mins
70	MMTTAmountConsumed	Num	8		MMTT amount consumed
71	MMTTTimeToConsumeBoost	Num	8		How long did it take for the participant to consume the BOOST
72	AreYouUsingInjections	Char	7		Are you using injections
73	InsulinPump	Char	7		Insulin pump
74	AvgAllRecordedGlucosesMgDL	Num	8		Average of all recorded glucoses (Average of recorded glucose is total value of glucose divided by total of number of readings collected in the 3-day period) in mg/DL
75	AvgRecordedFastingGlucosesmmol	Char	6		Average of recorded fasting glucoses (Average of fasting glucose is total value of glucose divided by total of number of readings collected in the 3-day period) in mmol/L
76	InsulinDoseLast24Hrs	Num	8		Insulin dose in last 24 hours
77	AvgTotalInsulinUnknown	Num	8		Average total insulin unknown
78	HaveHadComplicationsFromYourDi	Char	7		Have you ever been told that you have had complications from your diabetes
79	ProtocolVersion	Char	3		Protocol Version

**Data Set Name: tn16\_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	SelectTheTrialNetStudyInWhichT	Char	35	\$35.	Select the TrialNet Study in which the subject last participated
5	SubjectHasSignedWrittenInforme	Char	3	\$3.	Subject or Authorized Legal Representative has signed written informed consent/assent as applicable
6	InformedConsentDay	Num	8		If yes date consent assent was obtained Day
7	InformedConsentMonth	Char	3	\$3.	If yes date consent assent was obtained Month
8	InformedConsentYear	Num	8		If yes date consent assent was obtained Year
9	AllowToPutAnyRemainingBloodSam	Char	3	\$3.	Is subject willing to allow TrialNet to put any remaining blood samples in the NIDDK repository
10	Date_of_Diagnosis	Num	8	MMDDYY10.	Date of Diagnosis

**Data Set Name: tn16\_permanentsitetransfer.sas7bdat**

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

**Data Set Name: tn16\_physicalexam.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Visit Date
3	Visit	Char	48		Visit
4	WeightKG	Num	8		Weight in kilograms
5	WeightNotDone	Num	8		weight not done
6	HeightCM	Num	8		Height in centimeters
7	HeightNotDone	Num	8		Height not done
8	BPSystolic	Num	8		Blood pressure systolic
9	BPDiatolic	Num	8		blood pressure diastolic
10	BloodPressureNotDone	Num	8		Blood pressure not done
11	TemperatureC	Num	8		Temperature in Celsius
12	TemperatureNotDone	Num	8		Temperature not done
13	HeartRateBPM	Num	8		Heart rate in BPM
14	HeartRateNotDone	Num	8		Heart rate not done
15	RespiratoryRatePerMin	Num	8		Respiratory rate per minute
16	RespiratoryRateNotDone	Num	8		respiratory rate not done
17	TannerStageBreast	Char	18		Tanner Stage Breast
18	TannerGenitalia	Char	18		Tanner Stage genitalia
19	TannerPubicHair	Char	18		Tanner stage pubic hair
20	AbnormalitiesOnThePhysicalExam	Char	7		Abnormalities on the physical exam
21	SpecifyAbnormalitiesOnThePhysi	Char	312		Specify abnormalities on the physical exam
22	AbnormalitiesAtPreviousDrugAdm	Char	7		Abnormalities at previous drug administration
23	SpecifyPreviousAbnormalities	Char	230		Specify previous abnormalities
24	CompletedNeurologicalAssessmen	Char	7		Completed neurological assessment
25	ClinicallySignificantAbnormali	Char	7		Clinically significant abnormality
26	SpecifyClinicallySignificantAb	Char	111		Specify clinically significant abnormality
27	IsFemaleWithReproductivePotent	Char	3		Is this a female with reproductive potential
28	CurrentlyUseBirthControl	Char	3		Currently using birth control
29	PlanOnBecomingPregnant	Char	3		Plan on becoming pregnant
30	CurrentlyTakingBirthControlMed	Char	3		Currently taking birth control medication
31	PregnancyTestAtVisit	Char	3		Pregnancy test done at visit
32	UrinePregnancyTestResultPositi	Char	2		Is urine pregnancy test result positive

**Data Set Name: tn16\_protocoldeviation.sas7bdat**

Num	Variable	Type	Len	Format	Label
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Visit Date
3	Visit	Char	48		Visit
4	DeviationDay	Num	8		Deviation day
5	DeviationMonth	Char	3		Deviation month
6	DeviationYear	Num	8		Deviation year
7	ProtocolDeviationDay	Num	8		Protocol deviation day
8	ProtocolDeviationMonth	Char	3		Protocol deviation month
9	ProtocolDeviationYear	Num	8		Protocol deviation year
10	SubjectRandomizedIneligibilityA	Char	3		If Ineligible subject randomized checked approved by Eligibility Committee
11	TestingErrorProcedure	Char	1		Testing procedure error
12	RequiredBloodCollectionProcedu	Char	1		Blood collection not completed
13	ProtocolDeviationSpecify	Char	119		Specify other deviation
14	Deviation	Char	1		Protocol deviation
15	DeviationError	Char	49		Deviation error
16	DeviationReportedFor	Char	6		Reason
17	PNotified	Char	3		was the PI notified of deviation
18	ProtocolDeviation	Char	87		Protocol Deviation
19	ProtocolDeviation2	Char	83		Protocol Deviation
20	ProtocolDeviationApprovedByElg	Char	3		Was protocol deviation approved by the Eligibility Committee
21	TN16ProtocolDeviation	Char	88		TN16 Protocol deviation
22	CorrectiveActionTaken	Char	1698		Corrective action taken if necessary depending on circumstances
23	DescribeCorrectionAction	Char	175		Describe corrective action taken
24	DescribeDeviation	Char	204		Describe deviation
25	DeviationCircumstances	Char	3445		Deviation circumstances
26	DeviationOccurenceSpecify	Char	1		Specify deviation occurrence
27	ExlcudedMedicationSpecify	Char	1		Specify excluded medication
28	ExplanProtocolDeviation	Char	1		Explain protocol deviation
29	PhiX174WeekNumber	Num	8		If PhiX174 Visit ONLY (i.e. 6, 7, 8, 13, 14, 16, 53, 54, 58, 59, 60, 62 Record week number)
30	IfMiscellaneousSpecify	Char	292		If Miscellaneous specify
31	OtherSpecify	Char	116		Specify other
32	OtherSpecify2	Char	159		Other specify
33	OtherSpecify3	Char	1		Other specify
34	ProtocolChair	Char	1		If yes who was the protocol chair
35	ProtocolDeviationOtherSubcateg	Char	89		Protocol deviation other subcategory

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
36	StudyVisitCompletedFor	Char	13		Study visit this form being completed for
37	OtheYear	Num	8		Other year
38	OtheMonth	Char	3		Other month
39	OtherDay	Num	8		Other day

**Data Set Name: tn16\_protocolversion.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	MaskID	Num	8		Participant Mask ID#
2	Visit_Dt	Num	8	MMDDYY10.	Date of Visit
3	Visit	Char	48		Visit
4	SelectTheVersionOfTN16	Char	17	\$17.	Select the version of TN16

**Data Set Name: tn16\_registration.sas7bdat**

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

**Data Set Name: tn16\_researchlabs.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Format</b>	<b>Label</b>
1	MaskID	Num	8		Participant Mask ID#
2	Date_of_Draw	Num	8	MMDDYY10.	Date of Draw
3	Event_Title	Char	100		Specimen Collection Form
4	Spec_Name	Char	250		Specimen Name
5	SampleMaskID	Char	10		Sample Mask ID#
6	Test_Name	Char	150		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