

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 type
4	AdverseEventID	Num	8		Adverse event ID
5	AETerm	Char	100		AE Term
6	severity	Num	8		Severity Index
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	AEEExpected1_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		Is 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	Eventabateafterstoppingdrug	Char	14		Event abated after stopping drug
36	Eventreappearafterreintroducti	Char	14		Event appeared after drug reintroduction
37	AEFollowupDateDay	Num	8		Adverse event followup day

Num	Variable	Type	Len	Format	Label
38	AEFollowupDateMonth	Num	8		Adverse event followup month
39	AEFollowupDateYear	Num	8		Adverse event followup year
40	AEReasonForFollowup	Char	55		Adverse event reason for followup
41	CentralIRBORlocalIRB	Char	11		Central IRB or local IRB used for this protocol
42	AEFollowupNumber	Num	8		Adverse event followup number
43	AEOther	Num	8		Adverse event other
44	AEReporterStaffCode	Num	8		Adverse event reporter staff code
45	AESelectTerm	Num	8		Adverse event select term
46	centralIRBscriteria	Char	50		Central IRB criteria

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	AEReviewTreatmentUnblindedForC	Char	2		Does treatment need to be unblinded for determination of causality
6	AECausalityByReviewer	Char	22		Causality by reviewer
7	RecommendProtocolChange	Char	2		Recommend changes to the protocol
8	RecommendConsentChange	Char	3		Recommend changes to the consent form
9	AEReviewFormComments	Char	341		Review form comments
10	AEAdditionalInfoRequested	Char	3		Additional information requested
11	AEAdditionalInfoRequestedDetail	Char	499		Adverse event additional information requested details
12	AEReviewRequireDSMBReview	Char	6		Requires urgent and immediate review by full DSMB committee
13	AEReviewDSMBReviewComments	Char	1		Review requires DSMB review comments
14	AEReviewPriorSimilarSAEs	Char	3		Have there been prior occurrences of similar reported in this study
15	AEReviewReportingTimeframe	Char	27		Reporting time frame to regulatory authorities
16	AEReviewPriorSimilarSAEsSummary	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.	Date of Visit
3	Visit	Char	48		Visit
4	DateStatusChangeDay	Num	8		Date change in status became effective Day
5	DateStatusChangeMonth	Char	3		DateStatusChangeMonth
6	DateStatusChangeYear	Num	8		DateStatusChangeYear
7	ChangeOfStatusOccuring	Char	98		Change in status that has occurred
8	DoWDay	Num	8		DoWDay
9	DoWMonth	Char	3		Date of withdrawal Month
10	DoWYear	Num	8		Date of withdrawal Year
11	ReasonForWithdrawal	Char	45		Record the primary reason for withdrawal
12	ReasonAdverseEventSpecify	Char	106		Adverse event reason specify
13	ReasonWithdrewConsentSpecify	Char	770		Specify reason for withdrawing consent
14	ReasonForWithdrawalOTHER	Char	789		If other withdrawal reason specify
15	WillingToBeContacted	Char	3		Is the subject still willing to be contacted
16	DoRDay	Num	8		Date of reactivation Day
17	DoRMonth	Char	3		Date of reactivation Month
18	DoRYear	Num	8		Date of reactivation Year
19	DateCompletionDD	Num	8		Date form completed day
20	DateCompletionMM	Char	3		Date form completed month
21	DateCompletionYYYY	Num	8		Date form completed year
22	IsParticipantWillingBeContacte	Char	7		Is the participant still willing to be contacted
23	ParticipantCompletedEntireStud	Char	3		Participant completed entire study
24	WillingToContinueAfterPregnanc	Char	3		Is the participant willing to continue participation as a Control after completion of pregnancy
25	WithdrewConsentWhy	Char	68		If withdrew consent selected record the reason why
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

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: 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	\$7.	Have you been hospitalized for any reason since your last visitcontact
5	HospitalizedReason	Char	341	\$341.	If yes what was the reason
6	OtherChronicDiseases	Char	7	\$7.	Have you been diagnosed with any new chronic diseases other than diabetes
7	AnyNewChronicDisease_Autoimmuned	Num	8		AnyNewChronicDisease: Autoimmune disease
8	AnyNewChronicDisease_Cancer	Num	8		AnyNewChronicDisease: Cancer
9	AnyNewChronicDisease_Neurologica	Num	8		AnyNewChronicDisease: Neurological
10	AnyNewChronicDisease_Other	Num	8		AnyNewChronicDisease: Other
11	OtherChronicDiseasesOtherSpeci	Char	108	\$108.	Other
12	HaveHadComplicationsFromYourDi	Char	7	\$7.	Have you ever been told that you have had complications from your diabetes that have affected the following areas
13	HaveHadComplications_Eyes	Num	8		HaveHadComplications: Eyes
14	HaveHadComplications_Kidneys	Num	8		HaveHadComplications: Kidneys
15	HaveHadComplications_Nerves	Num	8		HaveHadComplications: Nerves
16	HaveHadComplications_Heart	Num	8		HaveHadComplications: Heart
17	HaveHadComplications_Other	Num	8		HaveHadComplications: Other
18	HaveHadComplicationsFromYourDi3	Char	37	\$37.	Have you ever been told that you have had complications from your diabetes that have affected the following areas If Yes Other
19	WeightKg	Num	8		Weight kg
20	HowIsWeightObtained	Char	13	\$13.	How is weight obtained
21	HeightCm	Num	8		Height cm
22	HowIsHeightObtained	Char	13	\$13.	How is height obtained
23	SubjectUsingCGMS	Char	3	\$3.	Is the person using a Continuous Glucose Monitoring System CGMS
24	AreThere3GlucoseValuesAvailabl	Char	3	\$3.	Are there atleast three glucose values available for atleast three days
25	InsulDoseInfoAvailableFor3Days	Char	3	\$3.	Is the insulin dose information available for atleast three days
26	DateRecordedDD1	Num	8		Dates glucoseinsulin recorded DD1
27	DateRecordedMM1	Char	3	\$3.	Dates glucoseinsulin recorded MM1
28	DateRecordedYYYY1	Num	8		Dates glucoseinsulin recorded YYYY1
29	DateRecordedDD2	Num	8		Dates glucoseinsulin recorded DD2
30	DateRecordedMM2	Char	3	\$3.	Dates glucoseinsulin recorded MM2
31	DateRecordedYYYY2	Num	8		Dates glucoseinsulin recorded YYYY2
32	DateRecordedDD3	Num	8		Dates glucoseinsulin recorded DD3
33	DateRecordedMM3	Char	3	\$3.	Dates glucoseinsulin recorded MM3
34	DateRecordedYYYY3	Num	8		Dates glucoseinsulin recorded YYYY3
35	TotalOfHomeBloodGlucoseOver3Da	Num	8		Total number of home blood glucose monitorings over three days
36	TotalOfHBGMonitoringsLessThan6	Num	8		Number of home blood glucose monitorings over three days that were less than 65mgdl

Num	Variable	Type	Len	Format	Label
37	AvgRecordedFastingGlucosesmmol	Char	6	\$6.	Average of recorded fasting glucoses over three days units
38	AvgRecordedFastingGlucosesmgdl	Num	8		Average of recorded fasting glucoses over three days
39	AvgAllRecordedGlucosesMmoll	Char	6	\$6.	Average of all recorded glucoses over three days units
40	AvgAllRecordedGlucosesMgDL	Num	8		Average of all recorded glucoses over three days
41	LowestGlucosemgdl	Num	8		Lowest recorded glucose over three days
42	LowestGlucosemmoll	Char	6	\$6.	Lowest recorded glucose over three days units
43	HighestGlucosemgdl	Num	8		Highest recorded glucose over three days
44	HighestGlucosemmol	Char	6	\$6.	Highest recorded glucose over three days units
45	InsulinRoutineDaily	Char	27	\$27.	Daily insulin routines check one
46	AvgUnitsShortActingInsulin	Num	8		Average unitsday of short acting insulin
47	AverageUnitsOfintermediateInsul	Num	8		Average unitsday of intermediatelong acting insulin average over 3 day period
48	RememberDateOfMostRecentHbA1c	Char	3	\$3.	Do you remember the date of the most recent HbA1c
49	LastHbA1cDay	Num	8		Last HbA1c day
50	LastHbA1cMonth	Char	3	\$3.	Last HbA1c month
51	LastHbA1cYear	Num	8		Last HbA1c year
52	RememberValueOfMostRecentHbA1c	Char	3	\$3.	Do you remember the most recent HbA1c value
53	LastHbA1cValue	Num	8		Last HbA1c value
54	SeizuresFaintingLowBloodGlucos	Char	7	\$7.	Any episodes of seizures or loss of consciousness from low blood glucose
55	HospitalizationsForHighGlucose	Char	7	\$7.	Any emergency room visits or hospitalizations for high blood glucose or DKA
56	RequiredSpecimensCollected	Char	3	\$3.	Were all required specimens collected for this visit
57	IfSpecimensNotCollec_Participant	Num	8		IfSpecimensNotCollec: Participant declined collection of specimen(s)
58	IfSpecimensNotCollec_Reachedmaxi	Num	8		IfSpecimensNotCollec: Reached maximum blood volume limit
59	IfSpecimensNotCollec_Illnessurg	Num	8		IfSpecimensNotCollec: Illness, surgery, or hospitalization
60	IfSpecimensNotCollec_Unabletoobt	Num	8		IfSpecimensNotCollec: Unable to obtain venous access
61	IfSpecimensNotCollec_Forgottocol	Num	8		IfSpecimensNotCollec: Forgot to collect specimen(s)
62	IfSpecimensNotCollec_RemoteVisit	Num	8		IfSpecimensNotCollec: Remote Visit (PBMC only)
63	IfSpecimensNotCollec_Other	Num	8		IfSpecimensNotCollec: Other
64	OtherReason	Char	237	\$237.	If other provide reason
65	OGTTCollected	Char	3	\$3.	Was OGTT collected
66	OGTTTestStartTimeHrs	Num	8		OGTT Start Time of Tolerance Test Hrs
67	OGTTTestStartTimeMins	Num	8		OGTT Start Time of Tolerance Test Mins
68	OGTTAmountConsumed	Num	8		OGTT What was the amount consumed
69	OGTTTimeToConsumeGlucola	Num	8		OGTT How long did it take for the participant to consume the Glucola
70	MMTTCollected	Char	3	\$3.	Was MMTT collected
71	MMTTTestStartTimeHrs	Num	8		MMTT Start Time of Tolerance Test Hrs
72	MMTTTestStartTimeMins	Num	8		MMTT Start Time of Tolerance Test Mins
73	MMTTAmountConsumed	Num	8		MMTT What was the amount consumed
74	MMTTTimeToConsumeBoost	Num	8		MMTT How long did it take for the participant to consume the Boost
75	AreYouUsingInjections	Char	7	\$7.	Are you using injections

Num	Variable	Type	Len	Format	Label
76	InsulinPump	Char	7	\$7.	Are you using an insulin pump
77	InsulinDoseLast24Hrs	Num	8		What is your average total insulin dose in 24 hours
78	AvgTotalInsulinUnknown	Num	8		Average Total Insulin Unknown
79	ProtocolVersion	Char	3	\$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 as applicable
6	InformedConsentDay	Num	8		If yes date consent was obtained Day
7	InformedConsentMonth	Char	3	\$3.	If yes date consent was obtained Month
8	InformedConsentYear	Num	8		If yes date consent 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_healthstatusquest.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	CurrentHeightText	Num	8		What is your current height text
5	CurrentHeightSelection	Char	9	\$9.	What is your current height selection
6	CurrentWeightText	Num	8		What is your current weight text
7	CurrentWeightSelection	Char	3	\$3.	What is your current weight selection
8	MostRecentHbA1cText	Char	7	\$7.	What was your most recent HbA1c text
9	MostRecentHbA1cMonth	Char	3	\$3.	What was your most recent HbA1c Month
10	MostRecentHbA1cYear	Num	8		What was your most recent HbA1c Year
11	HowDoYouTakeInsulin	Char	16	\$16.	How do you usually take insulin
12	TotalLongActingInsulinDose	Char	8	\$8.	If you use insulin injections or pens on a typical day what is your Total longacting insulin dose
13	TotalShortActingInsulinDose	Char	8	\$8.	If you use insulin injections or pens on a typical day what is your Total shortacting insulin dose
14	DailyInsulinDosePump	Char	6	\$6.	If you use an insulin pump what is your total daily insulin dose
15	PercentDailyInsulinDoseBasal	Char	4	\$4.	What percentage of your total daily insulin dose is from basal insulin
16	PercentDailyInsulinDoseBolus	Char	4	\$4.	What percentage of your total daily insulin dose is from bolus insulin
17	CurrentlyUsingCGM	Char	3	\$3.	Are you currently using a continuous glucose monitor CGM
18	AvgBloodGlucoseValueForWeek	Num	8		From your CGM or blood glucose meter please provide your average blood glucose value for the week
19	AvgBloodGlucoseValue_CGM	Num	8		AvgBloodGlucoseValue: CGM
20	AvgBloodGlucoseValue_BloodGlucos	Num	8		AvgBloodGlucoseValue: BloodGlucoseMeter
21	CategoryThatBestDescribesYou	Char	56	\$56.	The category that best describes you
22	HaveYouLostSymptomsThatUsedToO	Char	3	\$3.	Have you lost some of the symptoms that used to occur when your blood sugar was low
23	ModerateHypoglycemiaPastSixMon	Char	28	\$28.	In the past six months how often have you had moderate hypoglycemia episodes where you might have been confused disoriented or lethargic and were unable to treat yourself
24	SevereHypoglycemiaPastYear	Char	13	\$13.	In the past year how often have you had severe hypoglycemia where you were unconscious or had a seizure or needed glucagon or intravenous glucose
25	NumberOfReadingsWithSymptomsIn	Char	18	\$18.	How often in the last month have you had readings 70 mgdl with symptoms
26	NumberOfReadingsWithoutSymptom	Char	18	\$18.	How often in the last month have you had readings 70 mgdl without symptoms
27	ScoringQ5AndQ6	Char	11	\$11.	Scoring Q5 and Q6
28	LowBloodSugarToFeelSymptoms	Char	15	\$15.	How long does your blood sugar go before you feel symptoms
29	ExtentOfLowBloodSugarsBySympto	Char	9	\$9.	To what extent can you tell low blood sugars by your symptoms
30	NumberOfAResponses	Num	8		Number of A Responses
31	NumberOfRResponses	Num	8		Number of R Responses
32	NumberOfUResponses	Num	8		Number of U Responses
33	HaveYouHadEpisodesOfDKASinceLa	Char	7	\$7.	Have you had any episodes of DKA since your last visit
34	HowManyEpisodesOfDKASinceLastV	Char	1	\$1.	Have you had any episodes of DKA since your last visit If Yes how many

Num	Variable	Type	Len	Format	Label
35	HowDoYouFeelAboutBeingInTrialN	Char	20	\$20.	Overall how do you feel about being in the TrialNet study
36	WasBeingInTrialNetStudyAGoodDe	Char	16	\$16.	Do you think being in the TrialNet study was a good decision
37	WouldYouRecommendBeingInATrial	Char	5	\$5.	Would you recommend being in a trial to a friend
38	HaveYouExperiencedNewSevereAll	Char	3	\$3.	Have you experienced any new severe allergies or anaphylactic reactions
39	NewSevereAllergiesWhatKind	Char	36	\$36.	Have you experienced any new severe allergies or anaphylactic reactions If Yes what kind
40	HaveYouHadSevereInfections	Char	3	\$3.	Have you had any severe or unusual infections that required hospitalization
41	SevereInfectionsWhatKind	Char	148	\$148.	Have you had any severe or unusual infections that required hospitalization If Yes what kind
42	HaveYouHadRepeatedInfections	Char	3	\$3.	Have you had any repeated infections such as pneumonia cold sore herpes or mono
43	RepeatedInfectionsWhatKind	Char	63	\$63.	Have you had any repeated infections such as pneumonia cold sore herpes or mono If Yes what kind
44	BloodCellCountAbnormalities	Char	3	\$3.	Have you been told that you have any blood cell count abnormalities eg anemia low platelet count
45	BloodCellCountAbnormalitiesWha	Char	8	\$8.	Have you been told that you have any blood cell count abnormalities eg anemia low platelet count If Yes what kind
46	ToldYouHaveNewAutoimmuneDiseas	Char	3	\$3.	Have you been told that you have a new autoimmune disease such as thyroid disease or celiac disease
47	NewAutoimmuneDiseaseWhatKind	Char	10	\$10.	Have you been told that you have a new autoimmune disease such as thyroid disease or celiac disease If Yes what kind
48	DiagnosedWithNewCancer	Char	2	\$2.	Have you been diagnosed with a new cancer including skin cancers
49	DiagnosedWithNewCancerWhatKind	Char	1	\$1.	Have you been diagnosed with a new cancer including skin cancers If Yes what kind
50	HaveYouSeenAnEyeSpecialist	Char	3	\$3.	Have you seen an eye specialist or had your eyes photographed
51	EyeSpecialistWasResultNormal	Char	3	\$3.	Have you seen an eye specialist or had your eyes photographed If Yes was the result normal
52	ProblemsConceivingAChild	Char	2	\$2.	Have you ever had problems conceiving a child
53	HaveYouOrPartnerGottenPregnant	Char	2	\$2.	Since completing the trial have you or your partner gotten pregnant
54	DidPregnancyResultInMiscarriag	Char	14	\$14.	Did the pregnancy result in a miscarriage
55	DidPregnancyResultInStillbirth	Char	14	\$14.	Did the pregnancy result in a stillbirth
56	WasBabyBornWithDefects	Char	14	\$14.	Was the baby born with any birth defects
57	BabyBornWithDefectsWhatKind	Char	1	\$1.	Was the baby born with any birth defects If Yes what kind
58	AddtlVisitNotes	Char	30	\$30.	Additional Visit NotesComments

Data Set Name: tn16_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

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.	Date of Visit
3	Visit	Char	48		Visit
4	WeightKG	Num	8		WeightKGDoube
5	WeightNotDone	Num	8		weight not done
6	HeightCM	Num	8		Height CM
7	HeightNotDone	Num	8		Height not done
8	BPSystolic	Num	8		Seated arm blood pressure Systolic
9	BPDiatolic	Num	8		Seated arm blood pressure diastolic
10	BloodPressureNotDone	Num	8		BloodPressure not done
11	TemperatureC	Num	8		temperature C
12	TemperatureNotDone	Num	8		temperature not done
13	HeartRateBPM	Num	8		heartRate count
14	HeartRateNotDone	Num	8		heartRate not done
15	RespiratoryRatePerMin	Num	8		respiratory rate per min
16	RespiratoryRateNotDone	Num	8		respiratory rate not done
17	TannerStageBreast	Char	18	\$18.	Tanner Stage Breast
18	TannerGenitalia	Char	18	\$18.	Genitalia male
19	TannerPubicHair	Char	18	\$18.	Pubic Hair both
20	AbnormalitiesOnThePhysicalExam	Char	7	\$7.	Were there any abnormalities on the physical exam
21	SpecifyAbnormalitiesOnThePhysi	Char	312	\$312.	If YES specify
22	AbnormalitiesAtPreviousDrugAdm	Char	7	\$7.	Were there any abnormalities at the previous drug administration site
23	SpecifyPreviousAbnormalities	Char	230	\$230.	If YES specify
24	CompletedNeurologicalAssessmen	Char	7	\$7.	Was a neurological assessment completed at this visit
25	ClinicallySignificantAbnormali	Char	7	\$7.	were there any clinically significant abnormalities
26	SpecifyClinicallySignificantAb	Char	111	\$111.	If YES specify
27	IsFemaleWithReproductivePotent	Char	3	\$3.	If FEMALE does the participant have reproductive or childbearing potential
28	CurrentlyUseBirthControl	Char	3	\$3.	Do you currently use a form of birth control Females of reproductive age are expected to sue a form of birth control or practice abstinence
29	PlanOnBecomingPregnant	Char	3	\$3.	Do you plan on becoming pregnant before the study end
30	CurrentlyTakingBirthControlMed	Char	3	\$3.	Are you currently taking birth control medication
31	PregnancyTestAtVisit	Char	3	\$3.	Was a urine pregnancy test completed at this visit
32	UrinePregnancyTestResultPositi	Char	2	\$2.	If YES was the 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.	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	TN16ProtocolDeviation	Char	88	\$88.	TN16 Protocol deviation
8	ProtocolDeviationOtherSubcateg	Char	89	\$89.	Protocol Deviation Other subcategory
9	IfMiscellaneousSpecify	Char	292	\$292.	If Miscellaneous specify
10	SubjectRandomizedIneligibilityA	Char	3	\$3.	If Ineligible subject randomized checked approved by Eligibility Committee
11	DeviationCircumstances	Char	3445	\$3445.	Describe deviation and circumstances
12	CorrectiveActionTaken	Char	1698	\$1698.	Corrective action taken if necessary depending on circumstances
13	PInotified	Char	3	\$3.	Was PI notified
14	DeviationDay	Num	8		Date protocol deviationprocedural error occurred Day
15	DeviationMonth	Char	3	\$3.	Date protocol deviationprocedural error occurred Month
16	DeviationYear	Num	8		Date protocol deviationprocedural error occurred Year
17	TestingErrorProcedure	Char	1	\$1.	Testing procedure error
18	RequiredBloodCollectionProcedu	Char	1	\$1.	Required procedureblood collection not completed Specify
19	ProtocolDeviationSpecify	Char	119	\$119.	If OTHER Specify deviation
20	Deviation	Char	1	\$1.	Protocol Deviation
21	DeviationError	Char	49	\$49.	Protocol deviationprocedural error
22	DeviationReportedFor	Char	6	\$6.	Protocol deviation reported for
23	ProtocolDeviation	Char	87	\$87.	Protocol Deviation
24	ProtocolDeviation2	Char	83	\$83.	Protocol Deviation
25	ProtocolDeviationApprovedByElg	Char	3	\$3.	Was protocol deviation approved by the Eligibility Committee
26	DescribeCorrectionAction	Char	175	\$175.	Describe corrective action taken if necessary depending on circumstances
27	DescribeDeviation	Char	204	\$204.	Describe Deviation procedural error and circumstances
28	DeviationOccurenceSpecify	Char	1	\$1.	IF OTHER Specify Deviation
29	ExlcudedMedicationSpecify	Char	1	\$1.	Excluded Medications Specify
30	ExplanProtocolDeviation	Char	1	\$1.	Explanation for protocol deviation
31	PhiX174WeekNumber	Num	8		If PhiX174 Visit ONLY ie Weeks 6 7 8 13 14 16 53 54 58 59 60 62 Record week number
32	OtherSpecify	Char	116	\$116.	Other Specify
33	OtherSpecify2	Char	159	\$159.	If Other Specify
34	OtherSpecify3	Char	1	\$1.	Other Specify
35	ProtocolChair	Char	1	\$1.	If yes who was the protocol chair
36	StudyVisitCompletedFor	Char	13	\$13.	Study visit this form being completed for
37	OtheYear	Num	8		If OTHER specify date of visitYear

Num	Variable	Type	Len	Format	Label
38	OtheMonth	Char	3	\$3.	If OTHER specify date of visit Month
39	OtherDay	Num	8		If OTHER specify date of visit Day

Data Set Name: tn16_protocolversion.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	SelectTheVersionOfTN16	Char	17	\$17.	Select the version of TN16

Data Set Name: tn16_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	Status	Char	20		Status
4	Date_of_Study_Start	Num	8	MMDDYY10.	Date of Study Start

Data Set Name: tn16_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