

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	AETreatLocation	Char	14		Location of event treatment
17	AEEExpected1_1	Char	3		Adverse event expected (per the IB or package insert with the exception of observational studies)
18	AECausalityByReporter	Char	22		Causality by reported relative
19	AEAssociations_Death	Num	8		Death
20	AEAssociations_Hospitalizationor	Num	8		Hospitalization or prolonged hospitalization
21	AEAssociations_Lifethreatening	Num	8		Life threatening
22	AEAssociations_Isanotherconditio	Num	8		Is another condition which investigators judge to represent significant hazards
23	AEPatientOutcome1_1	Char	35		Patient status
24	AEResolveDtDay	Num	8		Adverse event resolved day
25	AEResolveDtMonth	Num	8		Adverse event resolved month
26	AEResolveDtYear	Num	8		Adverse event resolved year
27	AEDateDeathDay	Num	8		Adverse event death day
28	AEDateDeathMonth	Num	8		Adverse event death month
29	AEDateDeathYear	Num	8		Adverse event death year
30	Eventabateafterstoppingdrug	Char	14		Event abated after stopping drug
31	Eventreappearafterreintroducti	Char	14		Event appeared after drug reintroduction
32	AEFollowupDateDay	Num	8		Adverse event followup day
33	AEFollowupDateMonth	Num	8		Adverse event followup month
34	AEFollowupDateYear	Num	8		Adverse event followup year
35	AEReasonForFollowup	Char	55		Adverse event reason for followup
36	AEFollowupNumber	Num	8		Adverse event followup number

Num	Variable	Type	Len	Format	Label
37	AEReporterStaffCode	Num	8		Adverse event reporter staff code
38	AESelectTerm	Num	8		Adverse event select term

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	AEReviewPriorSimilarSAEs	Char	3		Have there been prior occurrences of similar reported in this study
8	AEReviewReportingTimeframe	Char	27		Reporting time frame to regulatory authorities

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	WillingToBeContacted	Char	3		Is the subject still willing to be contacted
13	DoRDay	Num	8		Date of reactivation Day
14	DoRMonth	Char	3		Date of reactivation Month
15	DoRYear	Num	8		Date of reactivation Year

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

Num	Variable	Type	Len	Format	Label
37	AvgAllRecordedGlucosesMmol	Char	6	\$6.	Average of all recorded glucoses over three days units
38	AvgAllRecordedGlucosesMgDL	Num	8		Average of all recorded glucoses over three days
39	LowestGlucosemgdl	Num	8		Lowest recorded glucose over three days
40	LowestGlucosemmol	Char	6	\$6.	Lowest recorded glucose over three days units
41	HighestGlucosemgdl	Num	8		Highest recorded glucose over three days
42	HighestGlucosemmol	Char	6	\$6.	Highest recorded glucose over three days units
43	InsulinRoutineDaily	Char	27	\$27.	Daily insulin routines check one
44	AvgUnitsShortActingInsulin	Num	8		Average unitsday of short acting insulin
45	AverageUnitsOfIntermediateInsul	Num	8		Average unitsday of intermediatelong acting insulin average over 3 day period
46	RememberDateOfMostRecentHbA1c	Char	3	\$3.	Do you remember the date of the most recent HbA1c
47	LastHbA1cDay	Num	8		Last HbA1c day
48	LastHbA1cMonth	Char	3	\$3.	Last HbA1c month
49	LastHbA1cYear	Num	8		Last HbA1c year
50	RememberValueOfMostRecentHbA1c	Char	3	\$3.	Do you remember the most recent HbA1c value
51	LastHbA1cValue	Num	8		Last HbA1c value
52	SeizuresFaintingLowBloodGlucos	Char	7	\$7.	Any episodes of seizures or loss of consciousness from low blood glucose
53	HospitalizationsForHighGlucose	Char	7	\$7.	Any emergency room visits or hospitalizations for high blood glucose or DKA
54	RequiredSpecimensCollected	Char	3	\$3.	Were all required specimens collected for this visit
55	IfSpecimensNotCollec_Participant	Num	8		IfSpecimensNotCollec: Participant declined collection of specimen(s)
56	IfSpecimensNotCollec_Reachedmaxi	Num	8		IfSpecimensNotCollec: Reached maximum blood volume limit
57	IfSpecimensNotCollec_Unabletoobt	Num	8		IfSpecimensNotCollec: Unable to obtain venous access
58	IfSpecimensNotCollec_Forgottocol	Num	8		IfSpecimensNotCollec: Forgot to collect specimen(s)
59	IfSpecimensNotCollec_RemoteVisit	Num	8		IfSpecimensNotCollec: Remote Visit (PBMC only)
60	IfSpecimensNotCollec_Other	Num	8		IfSpecimensNotCollec: Other
61	OGTTCollected	Char	3	\$3.	Was OGTT collected
62	OGTTTestStartTimeHrs	Num	8		OGTT Start Time of Tolerance Test Hrs
63	OGTTTestStartTimeMins	Num	8		OGTT Start Time of Tolerance Test Mins
64	OGTTAmountConsumed	Num	8		OGTT What was the amount consumed
65	OGTTTimeToConsumeGlucola	Num	8		OGTT How long did it take for the participant to consume the Glucola
66	MMTTCollected	Char	3	\$3.	Was MMTT collected
67	MMTTTestStartTimeHrs	Num	8		MMTT Start Time of Tolerance Test Hrs
68	MMTTTestStartTimeMins	Num	8		MMTT Start Time of Tolerance Test Mins
69	MMTTAmountConsumed	Num	8		MMTT What was the amount consumed
70	MMTTTimeToConsumeBoost	Num	8		MMTT How long did it take for the participant to consume the Boost
71	AreYouUsingInjections	Char	7	\$7.	Are you using injections
72	InsulinPump	Char	7	\$7.	Are you using an insulin pump
73	InsulinDoseLast24Hrs	Num	8		What is your average total insulin dose in 24 hours
74	AvgTotalInsulinUnknown	Num	8		Average Total Insulin Unknown
75	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 consentassent as applicable
6	InformedConsentDay	Num	8		If yes date consentassent was obtained Day
7	InformedConsentMonth	Char	3	\$3.	If yes date consentassent was obtained Month
8	InformedConsentYear	Num	8		If yes date consentassent 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	HowDoYouFeelAboutBeingInTrialN	Char	20	\$20.	Overall how do you feel about being in the TrialNet study

Num	Variable	Type	Len	Format	Label
35	WasBeingInTrialNetStudyAGoodDe	Char	16	\$16.	Do you think being in the TrialNet study was a good decision
36	WouldYouRecommendBeingInATrial	Char	5	\$5.	Would you recommend being in a trial to a friend
37	HaveYouExperiencedNewSevereAll	Char	3	\$3.	Have you experienced any new severe allergies or anaphylactic reactions
38	NewSevereAllergiesWhatKind	Char	36	\$36.	Have you experienced any new severe allergies or anaphylactic reactions If Yes what kind
39	HaveYouHadSevereInfections	Char	3	\$3.	Have you had any severe or unusual infections that required hospitalization
40	SevereInfectionsWhatKind	Char	148	\$148.	Have you had any severe or unusual infections that required hospitalization If Yes what kind
41	HaveYouHadRepeatedInfections	Char	3	\$3.	Have you had any repeated infections such as pneumonia cold sore herpes or mono
42	RepeatedInfectionsWhatKind	Char	63	\$63.	Have you had any repeated infections such as pneumonia cold sore herpes or mono If Yes what kind
43	BloodCellCountAbnormalities	Char	3	\$3.	Have you been told that you have any blood cell count abnormalities eg anemia low platelet count
44	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
45	ToldYouHaveNewAutoimmuneDiseas	Char	3	\$3.	Have you been told that you have a new autoimmune disease such as thyroid disease or celiac disease
46	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
47	HaveYouSeenAnEyeSpecialist	Char	3	\$3.	Have you seen an eye specialist or had your eyes photographed
48	EyeSpecialistWasResultNormal	Char	3	\$3.	Have you seen an eye specialist or had your eyes photographed If Yes was the result normal
49	ProblemsConceivingAChild	Char	2	\$2.	Have you ever had problems conceiving a child
50	HaveYouOrPartnerGottenPregnant	Char	2	\$2.	Since completing the trial have you or your partner gotten pregnant
51	DidPregnancyResultInMiscarriag	Char	14	\$14.	Did the pregnancy result in a miscarriage
52	DidPregnancyResultInStillbirth	Char	14	\$14.	Did the pregnancy result in a stillbirth
53	WasBabyBornWithDefects	Char	14	\$14.	Was the baby born with any birth defects
54	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	HeightCM	Num	8		Height CM
6	BPSystolic	Num	8		Seated arm blood pressure Systolic
7	BPDiatolic	Num	8		Seated arm blood pressure diastolic
8	BloodPressureNotDone	Num	8		BloodPressure not done
9	IsFemaleWithReproductivePotent	Char	3	\$3.	If FEMALE does the participant have reproductive or childbearing potential
10	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
11	PlanOnBecomingPregnant	Char	3	\$3.	Do you plan on becoming pregnant before the study end
12	CurrentlyTakingBirthControlMed	Char	3	\$3.	Are you currently taking birth control medication
13	PregnancyTestAtVisit	Char	3	\$3.	Was a urine pregnancy test completed at this visit

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	PInotified	Char	3	\$3.	Was PI notified

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