

## Data Set Name: tn16\_adverseevents.sas7bdat

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Visit date

Variable Number 3 Variable Visit Type Character Length 48 Format NONE Label Visit type

Variable Number 4 Variable AdverseEventID Type Numeric Length 8 Format NONE Label Adverse event ID

Variable Number 5 Variable AETerm Type Character Length 100 Format NONE Label AE Term

Variable Number 6 Variable severity Type Numeric Length 8 Format NONE Label Severity Index

Variable Number 7 Variable AEReportType Type Character Length 9 Format NONE Label Adverse event report type

Variable Number 8 Variable AEReportDtDay Type Numeric Length 8 Format NONE Label Adverse event report day

Variable Number 9 Variable AEReportDtMonth Type Numeric Length 8 Format NONE Label Adverse event report month

Variable Number 10 Variable AEReportDtYear Type Numeric Length 8 Format NONE Label Adverse event report year

Variable Number 11 Variable AEOccurDtDay Type Numeric Length 8 Format NONE Label Adverse event occurrence day

Variable Number 12 Variable AEOccurDtMonth Type Numeric Length 8 Format NONE Label Adverse event occurrence month

Variable Number 13 Variable AEOccurDtYear Type Numeric Length 8 Format NONE Label Adverse event occurrence year

Variable Number 14 Variable AEPrimarySecondary1\_1 Type Character Length 9 Format NONE Label Adverse event is primary or secondary

Variable Number 15 Variable AECategory Type Character Length 35 Format NONE Label Adverse event category

Variable Number 16 Variable AEDetails Type Character Length 3999 Format NONE Label Event details description

Variable Number 17 Variable AETreatLocation Type Character Length 14 Format NONE Label Location of event treatment

Variable Number 18 Variable AETreatLocationOther Type Character Length 108 Format NONE Label Location of event treatment if other

Variable Number 19 Variable AEEExpected1\_1 Type Character Length 3 Format NONE Label Adverse event expected (per the IB or package insert with the exception of observational studies)

Variable Number 20 Variable AECausalityByReporter Type Character Length 22 Format NONE Label Causality by reported relative

Variable Number 21 Variable AEAssociations\_Developmentofacon Type Numeric Length 8 Format NONE Label Development of a congenital anomaly or birth defect

Variable Number 22 Variable AEAssociations\_Developmentofaper Type Numeric Length 8 Format NONE Label Development of a permanent, serious, disabling or incapacitating condition

Variable Number 23 Variable AEAssociations\_Death Type Numeric Length 8 Format NONE Label Death

Variable Number 24 Variable AEAssociations\_Hospitalizationor Type Numeric Length 8 Format NONE Label Hospitalization or prolonged hospitalization

Variable Number 25 Variable AEAssociations\_Lifethreatening Type Numeric Length 8 Format NONE Label Life threatening

Variable Number 26 Variable AEAssociations\_Isanotherconditio Type Numeric Length 8 Format NONE Label Is another condition which investigators judge to represent significant hazards

Variable Number 27 Variable AEPatientOutcome1\_1 Type Character Length 35 Format NONE Label Patient status

Variable Number 28 Variable AEResolveDtDay Type Numeric Length 8 Format NONE Label Adverse event resolved day

Variable Number 29 Variable AEResolveDtMonth Type Numeric Length 8 Format NONE Label Adverse event resolved month

Variable Number 30 Variable AEResolveDtYear Type Numeric Length 8 Format NONE Label Adverse event resolved year

Variable Number 31 Variable AEDateDeathDay Type Numeric Length 8 Format NONE Label Adverse event death day

Variable Number 32 Variable AEDateDeathMonth Type Numeric Length 8 Format NONE Label Adverse event death month

Variable Number 33 Variable AEDateDeathYear Type Numeric Length 8 Format NONE Label Adverse event death year

Variable Number 34 Variable Comments Type Character Length 3025 Format NONE Label Additional comments

Variable Number 35 Variable Eventabateafterstoppingdrug Type Character Length 14 Format NONE Label Event abated after stopping drug

Variable Number 36 Variable Eventreappearafterreintroducti Type Character Length 14 Format NONE Label Event appeared after drug reintroduction

Variable Number 37 Variable AEFollowupDateDay Type Numeric Length 8 Format NONE Label Adverse event followup day

Variable Number 38 Variable AEFollowupDateMonth Type Numeric Length 8 Format NONE Label Adverse event followup month

Variable Number 39 Variable AEFollowupDateYear Type Numeric Length 8 Format NONE Label Adverse event followup year

Variable Number 40 Variable AEReasonForFollowup Type Character Length 55 Format NONE Label Adverse event reason for followup

Variable Number 41 Variable CentralIRBORlocalIRB Type Character Length 11 Format NONE Label Central IRB or local IRB used for this protocol

Variable Number 42 Variable AEFollowupNumber Type Numeric Length 8 Format NONE Label Adverse event followup number

Variable Number 43 Variable AEOther Type Numeric Length 8 Format NONE Label Adverse event other

Variable Number 44 Variable AEReporterStaffCode Type Numeric Length 8 Format NONE Label Adverse event reporter staff code

Variable Number 45 Variable AESelectTerm Type Numeric Length 8 Format NONE Label Adverse event select term

Variable Number 46 Variable centralIRBscriteria Type Character Length 50 Format NONE Label Central IRB criteria

### Data Set Name: [tn16\\_adverseeventsreview.sas7bdat](#)

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Visit Date

Variable Number 3 Variable Visit Type Character Length 48 Format NONE Label Visit

Variable Number 4 Variable AdverseEventID Type Numeric Length 8 Format NONE Label Adverse Event ID

Variable Number 5 Variable AEReviewTreatmentUnblindedForC Type Character Length 2 Format NONE Label Does treatment need to be unblinded for determination of causality

Variable Number 6 Variable AECausalityByReviewer Type Character Length 22 Format NONE Label Causality by reviewer

Variable Number 7 Variable RecommendProtocolChange Type Character Length 2 Format NONE Label Recommend changes to the protocol

Variable Number 8 Variable RecommendConsentChange Type Character Length 3 Format NONE Label Recommend changes to the consent form

Variable Number 9 Variable AEReviewFormComments Type Character Length 341 Format NONE Label Review form comments

Variable Number 10 Variable AEAdditionalInfoRequested Type Character Length 3 Format NONE Label Additional information requested

Variable Number 11 Variable AEAdditionalInfoRequestedDetail Type Character Length 499 Format NONE Label Adverse event additional information requested details

Variable Number 12 Variable AEReviewRequireDSMBReview Type Character Length 6 Format NONE Label Requires urgent and immediate review by full DSMB committee

Variable Number 13 Variable AEReviewDSMBReviewComments Type Character Length 1 Format NONE Label Review requires DSMB review comments

Variable Number 14 Variable AEReviewPriorSimilarSAEs Type Character Length 3 Format NONE Label Have there been prior occurrences of similar reported in this study

Variable Number 15 Variable AEReviewReportingTimeframe Type Character Length 27 Format NONE Label Reporting time frame to regulatory authorities

Variable Number 16 Variable AEReviewPriorSimilarSAEsSummary Type Character Length 280 Format NONE Label If prior occurrences of similar serious adverse events provide a brief summary

Variable Number 17 Variable AEPatientOutcome Type Character Length 1 Format NONE Label Patient outcome

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

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 3 Variable Visit Type Character Length 48 Format NONE Label Visit

Variable Number 4 Variable DateStatusChangeDay Type Numeric Length 8 Format NONE Label Date change in status became effective Day

Variable Number 5 Variable DateStatusChangeMonth Type Character Length 3 Format NONE Label DateStatusChangeMonth

Variable Number 6 Variable DateStatusChangeYear Type Numeric Length 8 Format NONE Label DateStatusChangeYear

Variable Number 7 Variable ChangeOfStatusOccuring Type Character Length 98 Format NONE Label Change in status that has occurred

Variable Number 8 Variable DoWDay Type Numeric Length 8 Format NONE Label DoWDay

Variable Number 9 Variable DoWMonth Type Character Length 3 Format NONE Label Date of withdrawal Month

Variable Number 10 Variable DoWYear Type Numeric Length 8 Format NONE Label Date of withdrawal Year

Variable Number 11 Variable ReasonForWithdrawal Type Character Length 45 Format NONE Label Record the primary reason for withdrawal

Variable Number 12 Variable ReasonAdverseEventSpecify Type Character Length 106 Format NONE Label Adverse event reason specify

Variable Number 13 Variable ReasonWithdrewConsentSpecify Type Character Length 770 Format NONE Label Specify reason for withdrawing consent

Variable Number 14 Variable ReasonForWithdrawalOTHER Type Character Length 789 Format NONE Label If other withdrawal reason specify

Variable Number 15 Variable WillingToBeContacted Type Character Length 3 Format NONE Label Is the subject still willing to be contacted

Variable Number 16 Variable DoRDay Type Numeric Length 8 Format NONE Label Date of reactivation Day

Variable Number 17 Variable DoRMonth Type Character Length 3 Format NONE Label Date of reactivation Month

Variable Number 18 Variable DoRYear Type Numeric Length 8 Format NONE Label Date of reactivation Year

Variable Number 19 Variable DateCompletionDD Type Numeric Length 8 Format NONE Label Date form completed day

Variable Number 20 Variable DateCompletionMM Type Character Length 3 Format NONE Label Date form completed month

Variable Number 21 Variable DateCompletionYYYY Type Numeric Length 8 Format NONE Label Date form completed year

Variable Number 22 Variable IsParticipantWillingBeContacte Type Character Length 7 Format NONE Label Is the participant still willing to be contacted

Variable Number 23 Variable ParticipantCompletedEntireStud Type Character Length 3 Format NONE Label Participant completed entire study

Variable Number 24 Variable WillingToContinueAfterPregnanc Type Character Length 3 Format NONE Label Is the participant willing to continue participation as a Control after completion of pregnancy

Variable Number 25 Variable WithdrewConsentWhy Type Character Length 68 Format NONE Label If withdrew consent selected record the reason why

Variable Number 26 Variable WithdrewConsentWhyIfOther Type Character Length 189 Format NONE Label If withdrew consent selected record the reason why other selected specify

Variable Number 27 Variable LastAttendedVisitMonth Type Character Length 3 Format NONE Label If other selected specify date of visit month

Variable Number 28 Variable PregnancyCompletionMonth Type Character Length 3 Format NONE Label If pregnant what is the estimated date of completion of pregnancy month

Variable Number 29 Variable PregnancyCompletionDay Type Numeric Length 8 Format NONE Label If pregnant what is the estimated date of completion of pregnancy day

Variable Number 30 Variable PregnancyCompletionYear Type Numeric Length 8 Format NONE Label If pregnant what is the estimated date of completion of pregnancy year

Variable Number 31 Variable LastAttendedVisitDay Type Numeric Length 8 Format NONE Label If other selected specify date of visit day

Variable Number 32 Variable LastAttendedVisitYear Type Numeric Length 8 Format NONE Label If other selected specify date of visit year

Variable Number 33 Variable PhiX174VisitNumber Type Numeric Length 8 Format NONE Label Record week number if PhiX174 visit only

### Data Set Name: [tn16\\_concomitantmeds.sas7bdat](#)

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 3 Variable Visit Type Character Length 48 Format NONE Label Visit

Variable Number 4 Variable AssessDateDay Type Numeric Length 8 Format NONE Label Assessment date day

Variable Number 5 Variable AssessDateMonth Type Character Length 3 Format NONE Label Assessment date month

Variable Number 6 Variable AssessDateYear Type Numeric Length 8 Format NONE Label Assessment date year

Variable Number 7 Variable Medication Type Character Length 154 Format NONE Label Medication

Variable Number 8 Variable Dose Type Numeric Length 8 Format NONE Label Dose

Variable Number 9 Variable Units Type Character Length 11 Format NONE Label Units

Variable Number 10 Variable UnitIfOtherSpecify Type Character Length 73 Format NONE Label Units specify detail if OTHER is selected

Variable Number 11 Variable ConMedsFrequencyChoices Type Character Length 5 Format NONE Label Frequency Choices

Variable Number 12 Variable ConMedsFrequencyOtherDetail Type Character Length 390 Format NONE Label Frequency specify detail if OTHER is selected

Variable Number 13 Variable ConMedsIntervalChoices Type Character Length 5 Format NONE Label Interval Choices

Variable Number 14 Variable ConMedsIntervalOtherDetails Type Character Length 142 Format NONE Label Interval specify details if OTHER is selected

Variable Number 15 Variable ConMedsRoute Type Character Length 26 Format NONE Label Route

Variable Number 16 Variable ConMedsRouteOtherDetails Type Character Length 24 Format NONE Label Route specify detail if OTHER is selected

Variable Number 17 Variable Indication Type Character Length 354 Format NONE Label Indication

Variable Number 18 Variable StartDateDay Type Numeric Length 8 Format NONE Label Start date day

Variable Number 19 Variable StartDateMonth Type Character Length 3 Format NONE Label Start date month

Variable Number 20 Variable StartDateYear Type Numeric Length 8 Format NONE Label Start date year

Variable Number 21 Variable IsContinuing Type Character Length 3 Format NONE Label Is Continuing

Variable Number 22 Variable StopDateDay Type Numeric Length 8 Format NONE Label Stop date day

Variable Number 23 Variable StopDateMonth Type Character Length 3 Format NONE Label Stop date month

Variable Number 24 Variable StopDateYear Type Numeric Length 8 Format NONE Label Stop date year

### Data Set Name: [tn16\\_diabeteshealthinfo.sas7bdat](#)

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 3 Variable Visit Type Character Length 48 Format NONE Label Visit

Variable Number 4 Variable HospitalizedSinceLastVisit Type Character Length 7 Format \$7. Label Have you been hospitalized for any reason since your last visitcontact

Variable Number 5 Variable HospitalizedReason Type Character Length 341 Format \$341. Label If yes what was the reason

Variable Number 6 Variable OtherChronicDiseases Type Character Length 7 Format \$7. Label Have you been diagnosed with any new chronic diseases other than diabetes

Variable Number 7 Variable AnyNewChronicDisease\_Autoimmuned Type Numeric Length 8 Format NONE Label AnyNewChronicDisease: Autoimmune disease

Variable Number 8 Variable AnyNewChronicDisease\_Cancer Type Numeric Length 8 Format NONE Label AnyNewChronicDisease: Cancer

Variable Number 9 Variable AnyNewChronicDisease\_Neurologica Type Numeric Length 8 Format NONE Label AnyNewChronicDisease: Neurological

Variable Number 10 Variable AnyNewChronicDisease\_Other Type Numeric Length 8 Format NONE Label AnyNewChronicDisease: Other

Variable Number 11 Variable OtherChronicDiseasesOtherSpeci Type Character Length 108 Format \$108. Label Other

Variable Number 12 Variable HaveHadComplicationsFromYourDi Type Character Length 7 Format \$7. Label Have you ever been told that you have had complications from your diabetes that have affected the following areas

Variable Number 13 Variable HaveHadComplications\_Eyes Type Numeric Length 8 Format NONE Label HaveHadComplications: Eyes

Variable Number 14 Variable HaveHadComplications\_Kidneys Type Numeric Length 8 Format NONE Label HaveHadComplications: Kidneys

Variable Number 15 Variable HaveHadComplications\_Nerves Type Numeric Length 8 Format NONE Label HaveHadComplications: Nerves

Variable Number 16 Variable HaveHadComplications\_Heart Type Numeric Length 8 Format NONE Label HaveHadComplications: Heart

Variable Number 17 Variable HaveHadComplications\_Other Type Numeric Length 8 Format NONE Label HaveHadComplications: Other

Variable Number 18 Variable HaveHadComplicationsFromYourDi3 Type Character Length 37 Format \$37. Label Have you ever been told that you have had complications from your diabetes that have affected the following areas If Yes Other

Variable Number 19 Variable WeightKg Type Numeric Length 8 Format NONE Label Weight kg

Variable Number 20 Variable HowIsWeightObtained Type Character Length 13 Format \$13. Label How is weight obtained

Variable Number 21 Variable HeightCm Type Numeric Length 8 Format NONE Label Height cm

Variable Number 22 Variable HowIsHeightObtained Type Character Length 13 Format \$13. Label How is height obtained

Variable Number 23 Variable SubjectUsingCGMS Type Character Length 3 Format \$3. Label Is the person using a Continuous Glucose Monitoring System CGMS

Variable Number 24 Variable AreThere3GlucoseValuesAvailabl Type Character Length 3 Format \$3. Label Are there atleast three glucose values available for atleast three days

Variable Number 25 Variable InsulDoseInfoAvailableFor3Days Type Character Length 3 Format \$3. Label Is the insulin dose information available for atleast three days

Variable Number 26 Variable DateRecordedDD1 Type Numeric Length 8 Format NONE Label Dates glucoseinsulin recorded DD1



Variable Number 27 Variable DateRecordedMM1 Type Character Length 3 Format \$3. Label Dates  
glucoseinsulin recorded MM1

Variable Number 28 Variable DateRecordedYYYY1 Type Numeric Length 8 Format NONE Label Dates  
glucoseinsulin recorded YYYY1

Variable Number 29 Variable DateRecordedDD2 Type Numeric Length 8 Format NONE Label Dates  
glucoseinsulin recorded DD2

Variable Number 30 Variable DateRecordedMM2 Type Character Length 3 Format \$3. Label Dates  
glucoseinsulin recorded MM2

Variable Number 31 Variable DateRecordedYYYY2 Type Numeric Length 8 Format NONE Label Dates  
glucoseinsulin recorded YYYY2

Variable Number 32 Variable DateRecordedDD3 Type Numeric Length 8 Format NONE Label Dates  
glucoseinsulin recorded DD3

Variable Number 33 Variable DateRecordedMM3 Type Character Length 3 Format \$3. Label Dates  
glucoseinsulin recorded MM3

Variable Number 34 Variable DateRecordedYYYY3 Type Numeric Length 8 Format NONE Label Dates  
glucoseinsulin recorded YYYY3

Variable Number 35 Variable TotalOfHomeBloodGlucoseOver3Da Type Numeric Length 8 Format NONE  
Label Total number of home blood glucose monitorings over three days

Variable Number 36 Variable TotalOfHBGMonitoringsLessThan6 Type Numeric Length 8 Format NONE  
Label Number of home blood glucose monitorings over three days that were less than 65mgdl

Variable Number 37 Variable AvgRecordedFastingGlucosesmmol Type Character Length 6 Format \$6.  
Label Average of recorded fasting glucoses over three days units

Variable Number 38 Variable AvgRecordedFastingGlucosesmgdl Type Numeric Length 8 Format NONE  
Label Average of recorded fasting glucoses over three days

Variable Number 39 Variable AvgAllRecordedGlucosesMmol Type Character Length 6 Format \$6. Label  
Average of all recorded glucoses over three days units

Variable Number 40 Variable AvgAllRecordedGlucosesMgDL Type Numeric Length 8 Format NONE Label  
Average of all recorded glucoses over three days

Variable Number 41 Variable LowestGlucosemgdl Type Numeric Length 8 Format NONE Label Lowest  
recorded glucose over three days

Variable Number 42 Variable LowestGlucosemmol Type Character Length 6 Format \$6. Label Lowest  
recorded glucose over three days units

Variable Number 43 Variable HighestGlucosemgdl Type Numeric Length 8 Format NONE Label Highest  
recorded glucose over three days

Variable Number 44 Variable HighestGlucosemmol Type Character Length 6 Format \$6. Label Highest recorded glucose over three days units

Variable Number 45 Variable InsulinRoutineDaily Type Character Length 27 Format \$27. Label Daily insulin routines check one

Variable Number 46 Variable AvgUnitsShortActingInsulin Type Numeric Length 8 Format NONE Label Average unitsday of short acting insulin

Variable Number 47 Variable AverageUnitsOfIntermediateInsul Type Numeric Length 8 Format NONE Label Average unitsday of intermediatelong acting insulin average over 3 day period

Variable Number 48 Variable RememberDateOfMostRecentHbA1c Type Character Length 3 Format \$3. Label Do you remember the date of the most recent HbA1c

Variable Number 49 Variable LastHbA1cDay Type Numeric Length 8 Format NONE Label Last HbA1c day

Variable Number 50 Variable LastHbA1cMonth Type Character Length 3 Format \$3. Label Last HbA1c month

Variable Number 51 Variable LastHbA1cYear Type Numeric Length 8 Format NONE Label Last HbA1c year

Variable Number 52 Variable RememberValueOfMostRecentHbA1c Type Character Length 3 Format \$3. Label Do you remember the most recent HbA1c value

Variable Number 53 Variable LastHbA1cValue Type Numeric Length 8 Format NONE Label Last HbA1c value

Variable Number 54 Variable SeizuresFaintingLowBloodGlucos Type Character Length 7 Format \$7. Label Any episodes of seizures or loss of consciousness from low blood glucose

Variable Number 55 Variable HospitalizationsForHighGlucose Type Character Length 7 Format \$7. Label Any emergency room visits or hospitalizations for high blood glucose or DKA

Variable Number 56 Variable RequiredSpecimensCollected Type Character Length 3 Format \$3. Label Were all required specimens collected for this visit

Variable Number 57 Variable IfSpecimensNotCollec\_Participant Type Numeric Length 8 Format NONE Label IfSpecimensNotCollec: Participant declined collection of specimen(s)

Variable Number 58 Variable IfSpecimensNotCollec\_Reachedmaxi Type Numeric Length 8 Format NONE Label IfSpecimensNotCollec: Reached maximum blood volume limit

Variable Number 59 Variable IfSpecimensNotCollec\_Illnesssurg Type Numeric Length 8 Format NONE Label IfSpecimensNotCollec: Illness, surgery, or hospitalization

Variable Number 60 Variable IfSpecimensNotCollec\_Unabletoobt Type Numeric Length 8 Format NONE Label IfSpecimensNotCollec: Unable to obtain venous access

Variable Number 61 Variable IfSpecimensNotCollec\_Forgottocol Type Numeric Length 8 Format NONE Label IfSpecimensNotCollec: Forgot to collect specimen(s)

Variable Number 62 Variable IfSpecimensNotCollec\_RemoteVisit Type Numeric Length 8 Format NONE Label IfSpecimensNotCollec: Remote Visit (PBMC only)

Variable Number 63 Variable IfSpecimensNotCollec\_Other Type Numeric Length 8 Format NONE Label IfSpecimensNotCollec: Other

Variable Number 64 Variable OtherReason Type Character Length 237 Format \$237. Label If other provide reason

Variable Number 65 Variable OGTTCollected Type Character Length 3 Format \$3. Label Was OGTT collected

Variable Number 66 Variable OGTTTestStartTimeHrs Type Numeric Length 8 Format NONE Label OGTT Start Time of Tolerance Test Hrs

Variable Number 67 Variable OGTTTestStartTimeMins Type Numeric Length 8 Format NONE Label OGTT Start Time of Tolerance Test Mins

Variable Number 68 Variable OGTTAmountConsumed Type Numeric Length 8 Format NONE Label OGTT What was the amount consumed

Variable Number 69 Variable OGTTTimeToConsumeGlucola Type Numeric Length 8 Format NONE Label OGTT How long did it take for the participant to consume the Glucola

Variable Number 70 Variable MMTTCollected Type Character Length 3 Format \$3. Label Was MMTT collected

Variable Number 71 Variable MMTTTestStartTimeHrs Type Numeric Length 8 Format NONE Label MMTT Start Time of Tolerance Test Hrs

Variable Number 72 Variable MMTTTestStartTimeMins Type Numeric Length 8 Format NONE Label MMTT Start Time of Tolerance Test Mins

Variable Number 73 Variable MMTTAmountConsumed Type Numeric Length 8 Format NONE Label MMTT What was the amount consumed

Variable Number 74 Variable MMTTTimeToConsumeBoost Type Numeric Length 8 Format NONE Label MMTT How long did it take for the participant to consume the Boost

Variable Number 75 Variable AreYouUsingInjections Type Character Length 7 Format \$7. Label Are you using injections

Variable Number 76 Variable InsulinPump Type Character Length 7 Format \$7. Label Are you using an insulin pump

Variable Number 77 Variable InsulinDoseLast24Hrs Type Numeric Length 8 Format NONE Label What is your average total insulin dose in 24 hours

Variable Number 78 Variable AvgTotalInsulinUnknown Type Numeric Length 8 Format NONE Label Average Total Insulin Unknown

Variable Number 79 Variable ProtocolVersion Type Character Length 3 Format \$3. Label Protocol Version

### Data Set Name: tn16\_eligibility.sas7bdat

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 3 Variable Visit Type Character Length 48 Format NONE Label Visit

Variable Number 4 Variable SelectTheTrialNetStudyInWhichT Type Character Length 35 Format \$35. Label Select the TrialNet Study in which the subject last participated

Variable Number 5 Variable SubjectHasSignedWrittenInforme Type Character Length 3 Format \$3. Label Subject or Authorized Legal Representative has signed written informed consentassent as applicable

Variable Number 6 Variable InformedConsentDay Type Numeric Length 8 Format NONE Label If yes date consentassent was obtained Day

Variable Number 7 Variable InformedConsentMonth Type Character Length 3 Format \$3. Label If yes date consentassent was obtained Month

Variable Number 8 Variable InformedConsentYear Type Numeric Length 8 Format NONE Label If yes date consentassent was obtained Year

Variable Number 9 Variable AllowToPutAnyRemainingBloodSam Type Character Length 3 Format \$3. Label Is subject willing to allow TrialNet to put any remaining blood samples in the NIDDK repository

Variable Number 10 Variable Date\_of\_Diagnosis Type Numeric Length 8 Format MMDDYY10. Label Date of Diagnosis

### Data Set Name: tn16\_healthstatusquest.sas7bdat

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 3 Variable Visit Type Character Length 48 Format NONE Label Visit

Variable Number 4 Variable CurrentHeightText Type Numeric Length 8 Format NONE Label What is your current height text

Variable Number 5 Variable CurrentHeightSelection Type Character Length 9 Format \$9. Label What is your current height selection

Variable Number 6 Variable CurrentWeightText Type Numeric Length 8 Format NONE Label What is your current weight text

Variable Number 7 Variable CurrentWeightSelection Type Character Length 3 Format \$3. Label What is your current weight selection

Variable Number 8 Variable MostRecentHbA1cText Type Character Length 7 Format \$7. Label What was your most recent HbA1c text

Variable Number 9 Variable MostRecentHbA1cMonth Type Character Length 3 Format \$3. Label What was your most recent HbA1c Month

Variable Number 10 Variable MostRecentHbA1cYear Type Numeric Length 8 Format NONE Label What was your most recent HbA1c Year

Variable Number 11 Variable HowDoYouTakeInsulin Type Character Length 16 Format \$16. Label How do you usually take insulin

Variable Number 12 Variable TotalLongActingInsulinDose Type Character Length 8 Format \$8. Label If you use insulin injections or pens on a typical day what is your Total longacting insulin dose

Variable Number 13 Variable TotalShortActingInsulinDose Type Character Length 8 Format \$8. Label If you use insulin injections or pens on a typical day what is your Total shortacting insulin dose

Variable Number 14 Variable DailyInsulinDosePump Type Character Length 6 Format \$6. Label If you use an insulin pump what is your total daily insulin dose

Variable Number 15 Variable PercentDailyInsulinDoseBasal Type Character Length 4 Format \$4. Label What percentage of your total daily insulin dose is from basal insulin

Variable Number 16 Variable PercentDailyInsulinDoseBolus Type Character Length 4 Format \$4. Label What percentage of your total daily insulin dose is from bolus insulin

Variable Number 17 Variable CurrentlyUsingCGM Type Character Length 3 Format \$3. Label Are you currently using a continuous glucose monitor CGM

Variable Number 18 Variable AvgBloodGlucoseValueForWeek Type Numeric Length 8 Format NONE Label From your CGM or blood glucose meter please provide your average blood glucose value for the week

Variable Number 19 Variable AvgBloodGlucoseValue\_CGM Type Numeric Length 8 Format NONE Label AvgBloodGlucoseValue: CGM

Variable Number 20 Variable AvgBloodGlucoseValue\_BloodGlucos Type Numeric Length 8 Format NONE Label AvgBloodGlucoseValue: BloodGlucoseMeter

Variable Number 21 Variable CategoryThatBestDescribesYou Type Character Length 56 Format \$56. Label The category that best describes you

Variable Number 22 Variable HaveYouLostSymptomsThatUsedToO Type Character Length 3 Format \$3. Label Have you lost some of the symptoms that used to occur when your blood sugar was low

Variable Number 23 Variable ModerateHypoglycemiaPastSixMon Type Character Length 28 Format \$28. Label 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

Variable Number 24 Variable SevereHypoglycemiaPastYear Type Character Length 13 Format \$13. Label 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

Variable Number 25 Variable NumberOfReadingsWithSymptomsIn Type Character Length 18 Format \$18. Label How often in the last month have you had readings 70 mgdl with symptoms

Variable Number 26 Variable NumberOfReadingsWithoutSymptom Type Character Length 18 Format \$18. Label How often in the last month have you had readings 70 mgdl without symptoms

Variable Number 27 Variable ScoringQ5AndQ6 Type Character Length 11 Format \$11. Label Scoring Q5 and Q6

Variable Number 28 Variable LowBloodSugarToFeelSymptoms Type Character Length 15 Format \$15. Label How long does your blood sugar go before you feel symptoms

Variable Number 29 Variable ExtentOfLowBloodSugarsBySympto Type Character Length 9 Format \$9. Label To what extent can you tell low blood sugars by your symptoms

Variable Number 30 Variable NumberOfAResponses Type Numeric Length 8 Format NONE Label Number of A Responses

Variable Number 31 Variable NumberOfRResponses Type Numeric Length 8 Format NONE Label Number of R Responses

Variable Number 32 Variable NumberOfUResponses Type Numeric Length 8 Format NONE Label Number of U Responses

Variable Number 33 Variable HaveYouHadEpisodesOfDKASinceLa Type Character Length 7 Format \$7. Label Have you had any episodes of DKA since your last visit

Variable Number 34 Variable HowManyEpisodesOfDKASinceLastV Type Character Length 1 Format \$1. Label Have you had any episodes of DKA since your last visit If Yes how many

Variable Number 35 Variable HowDoYouFeelAboutBeingInTrialN Type Character Length 20 Format \$20. Label Overall how do you feel about being in the TrialNet study

Variable Number 36 Variable WasBeingInTrialNetStudyAGoodDe Type Character Length 16 Format \$16. Label Do you think being in the TrialNet study was a good decision

Variable Number 37 Variable WouldYouRecommendBeingInATrial Type Character Length 5 Format \$5. Label Would you recommend being in a trial to a friend

Variable Number 38 Variable HaveYouExperiencedNewSevereAll Type Character Length 3 Format \$3. Label Have you experienced any new severe allergies or anaphylactic reactions

Variable Number 39 Variable NewSevereAllergiesWhatKind Type Character Length 36 Format \$36. Label Have you experienced any new severe allergies or anaphylactic reactions If Yes what kind

Variable Number 40 Variable HaveYouHadSevereInfections Type Character Length 3 Format \$3. Label Have you had any severe or unusual infections that required hospitalization

Variable Number 41 Variable SevereInfectionsWhatKind Type Character Length 148 Format \$148. Label Have you had any severe or unusual infections that required hospitalization If Yes what kind

Variable Number 42 Variable HaveYouHadRepeatedInfections Type Character Length 3 Format \$3. Label Have you had any repeated infections such as pneumonia cold sore herpes or mono

Variable Number 43 Variable RepeatedInfectionsWhatKind Type Character Length 63 Format \$63. Label Have you had any repeated infections such as pneumonia cold sore herpes or mono If Yes what kind

Variable Number 44 Variable BloodCellCountAbnormalities Type Character Length 3 Format \$3. Label Have you been told that you have any blood cell count abnormalities eg anemia low platelet count

Variable Number 45 Variable BloodCellCountAbnormalitiesWha Type Character Length 8 Format \$8. Label Have you been told that you have any blood cell count abnormalities eg anemia low platelet count If Yes what kind

Variable Number 46 Variable ToldYouHaveNewAutoimmuneDiseas Type Character Length 3 Format \$3. Label Have you been told that you have a new autoimmune disease such as thyroid disease or celiac disease

Variable Number 47 Variable NewAutoimmuneDiseaseWhatKind Type Character Length 10 Format \$10. Label Have you been told that you have a new autoimmune disease such as thyroid disease or celiac disease If Yes what kind

Variable Number 48 Variable DiagnosedWithNewCancer Type Character Length 2 Format \$2. Label Have you been diagnosed with a new cancer including skin cancers

Variable Number 49 Variable DiagnosedWithNewCancerWhatKind Type Character Length 1 Format \$1. Label Have you been diagnosed with a new cancer including skin cancers If Yes what kind

Variable Number 50 Variable HaveYouSeenAnEyeSpecialist Type Character Length 3 Format \$3. Label Have you seen an eye specialist or had your eyes photographed

Variable Number 51 Variable EyeSpecialistWasResultNormal Type Character Length 3 Format \$3. Label Have you seen an eye specialist or had your eyes photographed If Yes was the result normal

Variable Number 52 Variable ProblemsConceivingAChild Type Character Length 2 Format \$2. Label Have you ever had problems conceiving a child

Variable Number 53 Variable HaveYouOrPartnerGottenPregnant Type Character Length 2 Format \$2. Label Since completing the trial have you or your partner gotten pregnant

Variable Number 54 Variable DidPregnancyResultInMiscarriag Type Character Length 14 Format \$14. Label Did the pregnancy result in a miscarriage

Variable Number 55 Variable DidPregnancyResultInStillbirth Type Character Length 14 Format \$14. Label Did the pregnancy result in a stillbirth

Variable Number 56 Variable WasBabyBornWithDefects Type Character Length 14 Format \$14. Label Was the baby born with any birth defects

Variable Number 57 Variable BabyBornWithDefectsWhatKind Type Character Length 1 Format \$1. Label Was the baby born with any birth defects If Yes what kind

Variable Number 58 Variable AddtlVisitNotes Type Character Length 30 Format \$30. Label Additional Visit NotesComments

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

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Effective date for transfer

Variable Number 3 Variable Visit Type Character Length 8 Format \$8. Label Visit

Variable Number 4 Variable Old\_Site\_Number Type Character Length 91 Format NONE Label Old Primary Site Number

Variable Number 5 Variable Current\_Site\_Number Type Character Length 91 Format NONE Label Current Site Number

Variable Number 6 Variable Reason\_for\_Transfer Type Character Length 100 Format \$100. Label Reason for Transfer

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

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 3 Variable Visit Type Character Length 48 Format NONE Label Visit

Variable Number 4 Variable WeightKG Type Numeric Length 8 Format NONE Label WeightKGDoube

Variable Number 5 Variable WeightNotDone Type Numeric Length 8 Format NONE Label weight not done

Variable Number 6 Variable HeightCM Type Numeric Length 8 Format NONE Label Height CM

Variable Number 7 Variable HeightNotDone Type Numeric Length 8 Format NONE Label Height not done

Variable Number 8 Variable BPSystolic Type Numeric Length 8 Format NONE Label Seated arm blood pressure Systolic

Variable Number 9 Variable BPDiatolic Type Numeric Length 8 Format NONE Label Seated arm blood pressure diastolic

Variable Number 10 Variable BloodPressureNotDone Type Numeric Length 8 Format NONE Label BloodPressure not done

Variable Number 11 Variable TemperatureC Type Numeric Length 8 Format NONE Label temperature C



Variable Number 12 Variable TemperatureNotDone Type Numeric Length 8 Format NONE Label temperature not done

Variable Number 13 Variable HeartRateBPM Type Numeric Length 8 Format NONE Label heartRate count

Variable Number 14 Variable HeartRateNotDone Type Numeric Length 8 Format NONE Label heartRate not done

Variable Number 15 Variable RespiratoryRatePerMin Type Numeric Length 8 Format NONE Label respiratory rate per min

Variable Number 16 Variable RespiratoryRateNotDone Type Numeric Length 8 Format NONE Label respiratory rate not done

Variable Number 17 Variable TannerStageBreast Type Character Length 18 Format \$18. Label Tanner Stage Breast

Variable Number 18 Variable TannerGenitalia Type Character Length 18 Format \$18. Label Genitalia male

Variable Number 19 Variable TannerPubicHair Type Character Length 18 Format \$18. Label Pubic Hair both

Variable Number 20 Variable AbnormalitiesOnThePhysicalExam Type Character Length 7 Format \$7. Label Were there any abnormalities on the physical exam

Variable Number 21 Variable SpecifyAbnormalitiesOnThePhysi Type Character Length 312 Format \$312. Label If YES specify

Variable Number 22 Variable AbnormalitiesAtPreviousDrugAdm Type Character Length 7 Format \$7. Label Were there any abnormalities at the previous drug administration site

Variable Number 23 Variable SpecifyPreviousAbnormalities Type Character Length 230 Format \$230. Label If YES specify

Variable Number 24 Variable CompletedNeurologicalAssessmen Type Character Length 7 Format \$7. Label Was a neurological assessment completed at this visit

Variable Number 25 Variable ClinicallySignificantAbnormali Type Character Length 7 Format \$7. Label were there any clinically significant abnormalities

Variable Number 26 Variable SpecifyClinicallySignificantAb Type Character Length 111 Format \$111. Label If YES specify

Variable Number 27 Variable IsFemaleWithReproductivePotent Type Character Length 3 Format \$3. Label If FEMALE does the participant have reproductive or childbearing potential

Variable Number 28 Variable CurrentlyUseBirthControl Type Character Length 3 Format \$3. Label 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

Variable Number 29 Variable PlanOnBecomingPregnant Type Character Length 3 Format \$3. Label Do you plan on becoming pregnant before the study end

Variable Number 30 Variable CurrentlyTakingBirthControlMed Type Character Length 3 Format \$3. Label Are you currently taking birth control medication

Variable Number 31 Variable PregnancyTestAtVisit Type Character Length 3 Format \$3. Label Was a urine pregnancy test completed at this visit

Variable Number 32 Variable UrinePregnancyTestResultPositi Type Character Length 2 Format \$2. Label If YES was the test result positive

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

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 3 Variable Visit Type Character Length 48 Format NONE Label Visit

Variable Number 4 Variable ProtocolDeviationDay Type Numeric Length 8 Format NONE Label Date protocol deviation occurred day

Variable Number 5 Variable ProtocolDeviationMonth Type Character Length 3 Format \$3. Label Date protocol deviation occurred month

Variable Number 6 Variable ProtocolDeviationYear Type Numeric Length 8 Format NONE Label Date protocol deviation occurred year

Variable Number 7 Variable TN16ProtocolDeviation Type Character Length 88 Format \$88. Label TN16 Protocol deviation

Variable Number 8 Variable ProtocolDeviationOtherSubcateg Type Character Length 89 Format \$89. Label Protocol Deviation Other subcategory

Variable Number 9 Variable IfMiscellaneousSpecify Type Character Length 292 Format \$292. Label If Miscellaneous specify

Variable Number 10 Variable SubjectRandomizedIneligibilityA Type Character Length 3 Format \$3. Label If Ineligible subject randomized checked approved by Eligibility Committee

Variable Number 11 Variable DeviationCircumstances Type Character Length 3445 Format \$3445. Label Describe deviation and circumstances

Variable Number 12 Variable CorrectiveActionTaken Type Character Length 1698 Format \$1698. Label Corrective action taken if necessary depending on circumstances

Variable Number 13 Variable PInotified Type Character Length 3 Format \$3. Label Was PI notified

Variable Number 14 Variable DeviationDay Type Numeric Length 8 Format NONE Label Date protocol deviationprocedural error occurred Day

Variable Number 15 Variable DeviationMonth Type Character Length 3 Format \$3. Label Date protocol deviationprocedural error occurred Month

Variable Number 16 Variable DeviationYear Type Numeric Length 8 Format NONE Label Date protocol deviationprocedural error occurred Year

Variable Number 17 Variable TestingErrorProcedure Type Character Length 1 Format \$1. Label Testing procedure error

Variable Number 18 Variable RequiredBloodCollectionProcedu Type Character Length 1 Format \$1. Label Required procedureblood collection not completed Specify

Variable Number 19 Variable ProtocolDeviationSpecify Type Character Length 119 Format \$119. Label If OTHER Specify deviation

Variable Number 20 Variable Deviation Type Character Length 1 Format \$1. Label Protocol Deviation

Variable Number 21 Variable DeviationError Type Character Length 49 Format \$49. Label Protocol deviationprocedural error

Variable Number 22 Variable DeviationReportedFor Type Character Length 6 Format \$6. Label Protocol deviation reported for

Variable Number 23 Variable ProtocolDeviation Type Character Length 87 Format \$87. Label Protocol Deviation

Variable Number 24 Variable ProtocolDeviation2 Type Character Length 83 Format \$83. Label Protocol Deviation

Variable Number 25 Variable ProtocolDeviationApprovedByElg Type Character Length 3 Format \$3. Label Was protocol deviation approved by the Eligibility Committee

Variable Number 26 Variable DescribeCorrectionAction Type Character Length 175 Format \$175. Label Describe corrective action taken if necessary depending on circumstances

Variable Number 27 Variable DescribeDeviation Type Character Length 204 Format \$204. Label Describe Deviation procedural error and circumstances

Variable Number 28 Variable DeviationOccurenceSpecify Type Character Length 1 Format \$1. Label IF OTHER Specify Deviation

Variable Number 29 Variable ExlcudedMedicationSpecify Type Character Length 1 Format \$1. Label Excluded Medications Specify

Variable Number 30 Variable ExplanProtocolDeviation Type Character Length 1 Format \$1. Label Explanation for protocol deviation

Variable Number 31 Variable PhiX174WeekNumber Type Numeric Length 8 Format NONE Label If PhiX174 Visit ONLY ie Weeks 6 7 8 13 14 16 53 54 58 59 60 62 Record week number

Variable Number 32 Variable OtherSpecify Type Character Length 116 Format \$116. Label Other Specify

Variable Number 33 Variable OtherSpecify2 Type Character Length 159 Format \$159. Label If Other Specify

Variable Number 34 Variable OtherSpecify3 Type Character Length 1 Format \$1. Label Other Specifiy

Variable Number 35 Variable ProtocolChair Type Character Length 1 Format \$1. Label If yes who was the protocol chair

Variable Number 36 Variable StudyVisitCompletedFor Type Character Length 13 Format \$13. Label Study visit this form being completed for

Variable Number 37 Variable OtheYear Type Numeric Length 8 Format NONE Label If OTHER specify date of visitYear

Variable Number 38 Variable OtheMonth Type Character Length 3 Format \$3. Label If OTHER specify date of visit Month

Variable Number 39 Variable OtherDay Type Numeric Length 8 Format NONE Label If OTHER specify date of visit Day

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

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Visit\_Dt Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 3 Variable Visit Type Character Length 48 Format NONE Label Visit

Variable Number 4 Variable SelectTheVersionOfTN16 Type Character Length 17 Format \$17. Label Select the version of TN16

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

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Date\_of\_Registration Type Numeric Length 8 Format MMDDYY10. Label Date of Registration

Variable Number 3 Variable Status Type Character Length 20 Format NONE Label Status

Variable Number 4 Variable Date\_of\_Study\_Start Type Numeric Length 8 Format MMDDYY10. Label Date of Study Start

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

Variable Number 1 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 2 Variable Date\_of\_Draw Type Numeric Length 8 Format MMDDYY10. Label Date of Draw

Variable Number 3 Variable Event\_Title Type Character Length 100 Format NONE Label Specimen Collection Form

Variable Number 4 Variable Spec\_Name Type Character Length 250 Format NONE Label Specimen Name

Variable Number 5 Variable SampleMaskID Type Character Length 10 Format NONE Label Sample Mask ID#

Variable Number 6 Variable Test\_Name Type Character Length 150 Format NONE Label Test Name

Variable Number 7 Variable Result Type Character Length 1000 Format NONE Label Result

Variable Number 8 Variable Result\_Type Type Character Length 6 Format NONE Label Result Type

Variable Number 9 Variable Visit Type Character Length 48 Format NONE Label Visit

Variable Number 10 Variable Date\_at\_Test\_Results\_Reported Type Numeric Length 8 Format MMDDYY10. Label Date at Test Results Reported

Variable Number 11 Variable Date\_at\_Evaluation Type Numeric Length 8 Format MMDDYY10. Label Date at Sample Evaluation

Variable Number 12 Variable Date\_Received Type Numeric Length 8 Format MMDDYY10. Label Date when Sample Received at Lab

Variable Number 13 Variable Date\_Shipped Type Numeric Length 8 Format MMDDYY10. Label Date when Sample Shipped

Variable Number 14 Variable LabID Type Numeric Length 8 Format NONE Label Numeric code to identify testing Lab