

## Data Set Name: ae.sas7bdat

Variable Number 1 Variable TreatmentDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 2 Variable RxDesc Type Character Length 7 Format \$7. Label Treatment Description

Variable Number 3 Variable Eventabateafterstoppingdrug Type Character Length 14 Format \$14. Label Did the eventreaction abate after stopping drug

Variable Number 4 Variable AECategory Type Character Length 35 Format \$35. Label Category

Variable Number 5 Variable AECausalityByReporter Type Character Length 22 Format \$22. Label Causality by reporter

Variable Number 6 Variable AESerious Type Character Length 3 Format \$3. Label Serious

Variable Number 7 Variable AEInitialAEID Type Numeric Length 8 Format NONE Label AE Initial AEID

Variable Number 8 Variable AESelectTerm Type Numeric Length 8 Format NONE Label AE Select Term

Variable Number 9 Variable AESupraOrdinateTerm Type Numeric Length 8 Format NONE Label Adverse Event SupraOrdinate Term sub category

Variable Number 10 Variable AEAssociations\_Death Type Numeric Length 8 Format NONE Label AEAssociations: Death

Variable Number 11 Variable severity\_index Type Numeric Length 8 Format NONE Label Severity Index

Variable Number 12 Variable AEPatientOutcome Type Character Length 100 Format NONE Label AE Patient Outcome

Variable Number 13 Variable AEexpected Type Character Length 100 Format NONE Label AE Expected?

Variable Number 14 Variable AEPrimarySecondary Type Character Length 100 Format NONE Label Is this event a primary or secondary event

Variable Number 15 Variable AESelectTermstr Type Character Length 250 Format NONE Label AE Select Term

Variable Number 16 Variable seriousae Type Numeric Length 8 Format NONE Label Serious AE?

Variable Number 17 Variable ae\_eval\_id Type Numeric Length 8 Format NONE Label AE\_EVAL\_ID

Variable Number 18 Variable AECausalityByReviewer Type Character Length 22 Format \$22. Label Causality by reviewer

Variable Number 19 Variable CTCAE\_VERSION Type Numeric Length 8 Format NONE Label CTCAE\_VERSION

Variable Number 20 Variable AETerm Type Character Length 100 Format NONE Label Term

Variable Number 21 Variable AE\_Submitted Type Numeric Length 8 Format NONE Label Date AE Initially Submitted

Variable Number 22 Variable severity Type Numeric Length 8 Format NONE Label Severity Index

Variable Number 23 Variable dtfollow Type Numeric Length 8 Format MMDDYY10. Label Date at Follow-Up

Variable Number 24 Variable dtreported Type Numeric Length 8 Format MMDDYY10. Label Date at Report

Variable Number 25 Variable dtresolved Type Numeric Length 8 Format MMDDYY10. Label Date Resolved

Variable Number 26 Variable dte Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 27 Variable dtae Type Numeric Length 8 Format MMDDYY10. Label Date at Occurrence

Variable Number 28 Variable aedetails\_abbrev Type Character Length 400 Format NONE Label Adverse Event Details

Variable Number 29 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

### Data Set Name: autoab.sas7bdat

Variable Number 1 Variable TreatmentDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 2 Variable RxDesc Type Character Length 7 Format \$7. Label Treatment Description

Variable Number 3 Variable DRAW\_DATE Type Numeric Length 8 Format MMDDYY10. Label Draw Date

Variable Number 4 Variable GAD65 Type Numeric Length 8 Format NONE Label Anti-GAD65 autoantibody (TrialNet Standard/Local Assay)

Variable Number 5 Variable GAD65H Type Numeric Length 8 Format NONE Label Anti-GAD65 autoantibody (NIDDK Harmonized Assay)

Variable Number 6 Variable IA2H Type Numeric Length 8 Format NONE Label Anti-IA-2 autoantibody (NIDDK Harmonized Assay)

Variable Number 7 Variable ICA Type Numeric Length 8 Format NONE Label Islet Cell Antigen

Variable Number 8 Variable ICA512 Type Numeric Length 8 Format NONE Label Anti-ICA512 (IA-2) autoantibody (TrialNet Standard/Local Assay)

Variable Number 9 Variable MIAA Type Numeric Length 8 Format NONE Label Micro Insulin autoantibody

Variable Number 10 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

## Data Set Name: bmi.sas7bdat

Variable Number 1 Variable TreatmentDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 2 Variable RxDesc Type Character Length 7 Format \$7. Label Treatment Description

Variable Number 3 Variable HeightCM Type Numeric Length 8 Format NONE Label Collection Of physical Assesments height in cm

Variable Number 4 Variable WeightKG Type Numeric Length 8 Format NONE Label Collection Of physical Assesments weight in kg

Variable Number 5 Variable dtexam Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 6 Variable time\_point Type Character Length 48 Format NONE Label Time Point

Variable Number 7 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

## Data Set Name: cpepm.sas7bdat

Variable Number 1 Variable PEP0 Type Numeric Length 8 Format NONE Label 0 minute C-Peptide

Variable Number 2 Variable PEP15 Type Numeric Length 8 Format NONE Label 15 minute C-Peptide

Variable Number 3 Variable PEP30 Type Numeric Length 8 Format NONE Label 30 minute C-Peptide

Variable Number 4 Variable PEP60 Type Numeric Length 8 Format NONE Label 60 minute C-Peptide

Variable Number 5 Variable PEP90 Type Numeric Length 8 Format NONE Label 90 minute C-Peptide

Variable Number 6 Variable PEP120 Type Numeric Length 8 Format NONE Label 120 minute C-Peptide

Variable Number 7 Variable DRAW\_DATE Type Numeric Length 8 Format MMDDYY10. Label Draw Date

Variable Number 8 Variable TreatmentDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 9 Variable RxDesc Type Character Length 7 Format \$7. Label Treatment Description

Variable Number 10 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

## Data Set Name: cpepo.sas7bdat

Variable Number 1 Variable PEP0 Type Numeric Length 8 Format NONE Label 0 minute C-Peptide

Variable Number 2 Variable PEP15 Type Numeric Length 8 Format NONE Label 15 minute C-Peptide

Variable Number 3 Variable PEP30 Type Numeric Length 8 Format NONE Label 30 minute C-Peptide

Variable Number 4 Variable PEP60 Type Numeric Length 8 Format NONE Label 60 minute C-Peptide

Variable Number 5 Variable PEP90 Type Numeric Length 8 Format NONE Label 90 minute C-Peptide

Variable Number 6 Variable PEP120 Type Numeric Length 8 Format NONE Label 120 minute C-Peptide

Variable Number 7 Variable DRAW\_DATE Type Numeric Length 8 Format MMDDYY10. Label Draw Date

Variable Number 8 Variable TreatmentDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 9 Variable RxDesc Type Character Length 7 Format \$7. Label Treatment Description

Variable Number 10 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

### Data Set Name: gtt.sas7bdat

Variable Number 1 Variable TreatmentDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 2 Variable RxDesc Type Character Length 7 Format \$7. Label Treatment Description

Variable Number 3 Variable DRAW\_DATE Type Numeric Length 8 Format MMDDYY10. Label Draw Date

Variable Number 4 Variable GLUM10 Type Numeric Length 8 Format NONE Label Glucose level at -10 min

Variable Number 5 Variable GLU0 Type Numeric Length 8 Format NONE Label Glucose level at 0 min

Variable Number 6 Variable GLU30 Type Numeric Length 8 Format NONE Label Glucose level at 30 min

Variable Number 7 Variable GLU60 Type Numeric Length 8 Format NONE Label Glucose level at 60 min

Variable Number 8 Variable GLU90 Type Numeric Length 8 Format NONE Label Glucose level at 90 min

Variable Number 9 Variable GLU120 Type Numeric Length 8 Format NONE Label Glucose level at 120 min

Variable Number 10 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

### Data Set Name: hba1c.sas7bdat

Variable Number 1 Variable TreatmentDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 2 Variable RxDesc Type Character Length 7 Format \$7. Label Treatment Description

Variable Number 3 Variable DRAW\_DATE Type Numeric Length 8 Format MMDDYY10. Label Draw Date

Variable Number 4 Variable hba1c Type Numeric Length 8 Format NONE Label HbA1c Result

Variable Number 5 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

### Data Set Name: hla.sas7bdat

Variable Number 1 Variable TreatmentDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 2 Variable RxDesc Type Character Length 7 Format \$7. Label Treatment Description

Variable Number 3 Variable DRAW\_DATE Type Numeric Length 8 Format MMDDYY10. Label Draw Date

Variable Number 4 Variable DR3 Type Character Length 20 Format NONE Label Absence/Presence of DRB1\*0301, DQA1\*0501, DQB1\*0201

Variable Number 5 Variable DR4 Type Character Length 20 Format NONE Label Absence/Presence of DRB1\*04###, DQA1\*0301 or 0303, DQB1\*0302

Variable Number 6 Variable HLA Type Character Length 20 Format NONE Label Absence/Presence of DQA1\*0102, DQB1\*0602

Variable Number 7 Variable HLAA Type Character Length 30 Format NONE Label HLA Haplotype  $\alpha$  (DRB1, DQA1, DQB1)

Variable Number 8 Variable HLAB Type Character Length 30 Format NONE Label HLA Haplotype  $\beta$  (DRB1, DQA1, DQB1)

Variable Number 9 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

### Data Set Name: [insulin.sas7bdat](#)

Variable Number 1 Variable INS1 Type Numeric Length 8 Format NONE Label Insulin level at 1 min (RIA)

Variable Number 2 Variable INS3 Type Numeric Length 8 Format NONE Label Insulin level at 3 min (RIA)

Variable Number 3 Variable INST1 Type Numeric Length 8 Format NONE Label Insulin level at 1 min (TOSOH)

Variable Number 4 Variable INST3 Type Numeric Length 8 Format NONE Label Insulin level at 3 min (TOSOH)

Variable Number 5 Variable DRAW\_DATE Type Numeric Length 8 Format MMDDYY10. Label Draw Date

Variable Number 6 Variable TreatmentDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 7 Variable RxDesc Type Character Length 7 Format \$7. Label Treatment Description

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

### Data Set Name: [mastable.sas7bdat](#)

Variable Number 1 Variable PROTOCOL\_ID Type Numeric Length 8 Format NONE Label PROTOCOL\_ID

Variable Number 2 Variable REG Type Numeric Length 8 Format NONE Label Current Status: Registered

Variable Number 3 Variable ELIG Type Numeric Length 8 Format NONE Label Current Status: Eligible

Variable Number 4 Variable DTREG Type Numeric Length 8 Format MMDDYY10. Label Registration Date

Variable Number 5 Variable FIRSTORSECONDDEGREERELATIVEDIA Type Character Length 3 Format \$3. Label Have any of your first or second degree been diagnosed with T1D since the completion of Natural History Family History FormNH01F

Variable Number 6 Variable WEIGHINKG Type Numeric Length 8 Format NONE Label Collection Of physical Assessments weight in kg

Variable Number 7 Variable SEX Type Character Length 6 Format \$6. Label Participant Sex

Variable Number 8 Variable RACE Type Character Length 15 Format NONE Label Race

Variable Number 9 Variable ETHNIC Type Character Length 15 Format NONE Label Ethnicity

Variable Number 10 Variable STRATUM2 Type Character Length 11 Format NONE Label Stratum

Variable Number 11 Variable TREATMENTDATE Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 12 Variable RXDESC Type Character Length 7 Format \$7. Label Treatment Description

Variable Number 13 Variable REASONFORWITHDRAWAL Type Character Length 45 Format \$45. Label Record the primary reason for withdrawal

Variable Number 14 Variable DTWITHDRAWAL Type Numeric Length 8 Format MMDDYY10. Label Withdrawal Date

Variable Number 15 Variable DTREACTIVATE Type Numeric Length 8 Format MMDDYY10. Label Reactivation Date

Variable Number 16 Variable DTSTATUSCHANGE Type Numeric Length 8 Format MMDDYY10. Label Change of Status Date

Variable Number 17 Variable CHANGESTATUS Type Character Length 98 Format NONE Label Change of Status

Variable Number 18 Variable DRUG\_STOPPED Type Character Length 14 Format \$14. Label Change in Study Drug Status

Variable Number 19 Variable DTDRUGSTOPPED Type Numeric Length 8 Format MMDDYY10. Label Date of Change in Study Drug Status

Variable Number 20 Variable LAST\_IVGTT Type Numeric Length 8 Format MMDDYY10. Label Date of Last IVGTT

Variable Number 21 Variable LAST\_OGTT Type Numeric Length 8 Format MMDDYY10. Label Date of Last OGTT

Variable Number 22 Variable LAST\_PHYSICAL\_EXAM Type Numeric Length 8 Format MMDDYY10. Label Date of Last Physical Exam

Variable Number 23 Variable DTFOLLOWUP Type Numeric Length 8 Format MMDDYY10. Label Date of Last Follow-up Visit

Variable Number 24 Variable DTIDDM Type Numeric Length 8 Format MMDDYY10. Label Type 1 Diabetes Date of Diagnosis

Variable Number 25 Variable DTFULAB Type Numeric Length 8 Format MMDDYY10. Label Date of Last Sample

Variable Number 26 Variable MASKID Type Numeric Length 8 Format NONE Label Participant Mask ID#

Variable Number 27 Variable AGEREG Type Numeric Length 8 Format NONE Label Age at Registration

### Data Set Name: rel.sas7bdat

Variable Number 1 Variable TreatmentDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 2 Variable RxDesc Type Character Length 7 Format \$7. Label Treatment Description

Variable Number 3 Variable PROTOCOL\_ID Type Numeric Length 8 Format NONE Label Protocol ID

Variable Number 4 Variable relation Type Character Length 21 Format NONE Label Proband

Variable Number 5 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

### Data Set Name: rx.sas7bdat

Variable Number 1 Variable CapsulesDispensed Type Numeric Length 8 Format NONE Label Number of capsules dispensed

Variable Number 2 Variable CapsulesReturned Type Numeric Length 8 Format NONE Label Number of capsules returned

Variable Number 3 Variable dtdispensed Type Numeric Length 8 Format MMDDYY10. Label Date Capsules were Dispensed

Variable Number 4 Variable dtreturned Type Numeric Length 8 Format MMDDYY10. Label Date Capsules were Returned

Variable Number 5 Variable dttmp Type Numeric Length 8 Format MMDDYY10. Label Date of Visit

Variable Number 6 Variable MaskID Type Numeric Length 8 Format NONE Label Participant Mask ID#

### Data Set Name: tn07\_3monthvisit.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 VisitAtSiteOtherThanPrimaryStu Type Character Length 3 Format \$3. Label Dis the visit occur at a site other than at the primary study site

Variable Number 5 Variable VisitAtSiteOtherThanPrimaryStu2 Type Numeric Length 8 Format NONE Label If yes record site number for reimbursement

Variable Number 6 Variable AnyChangesInHealthSinceLastSch Type Character Length 3 Format \$3. Label Have there been any changes in health since the last scheduled visit

Variable Number 7 Variable AnyChangesInConcomitantMedicat Type Character Length 3 Format \$3. Label Have there been any changes in concomitant medications since last scheduled visit

Variable Number 8 Variable SeatedArmBPSystolic Type Numeric Length 8 Format NONE Label Physical Assessments Seated aremBP systolic

Variable Number 9 Variable SeatedArmBPDiastolic Type Numeric Length 8 Format NONE Label Physical Assessments Seated aremBP Diastolic

Variable Number 10 Variable WeightinKg Type Numeric Length 8 Format NONE Label Physical Assessments weight

Variable Number 11 Variable Weightinlbs Type Numeric Length 8 Format NONE Label Physical Assessments weight in lbs

Variable Number 12 Variable HeightinCm Type Numeric Length 8 Format NONE Label Physical Assessments Height in cm

Variable Number 13 Variable HeightinIn Type Numeric Length 8 Format NONE Label Physical Assessments Height in in

Variable Number 14 Variable ParticipantHasReproductivePote Type Character Length 3 Format \$3. Label If FEMALE does the participant have reproductive potential

Variable Number 15 Variable FemalePAricipantSexuallyActiv Type Character Length 3 Format \$3. Label Is the female participant sexually active

Variable Number 16 Variable CurrentlyUsingFormOfBirthContr Type Character Length 3 Format \$3. Label If yes to question D1 above Does she currently use a form of birth control

Variable Number 17 Variable PlanOfBecomingPregnantInNext6M Type Character Length 2 Format \$2. Label If yes to question D1 above Does she plan on becoming pregnant in the next 6 months

Variable Number 18 Variable UrinePregnancyTestCompletedAtT Type Character Length 3 Format \$3. Label If yes to question D1 above Was urine pregnancy test completed at this visit

Variable Number 19 Variable UrinePregnancyTestPositive Type Character Length 2 Format \$2. Label If yes was the test result positive

Variable Number 20 Variable InitialDoseOfStudyDrugDay Type Numeric Length 8 Format NONE Label Record the day that participant took hisher initial dose of study drug

Variable Number 21 Variable InitialDoseOfStudyDrugMonth Type Character Length 3 Format \$3. Label Record the month that participant took hisher initial dose of study drug

Variable Number 22 Variable InitialDoseOfStudyDrugYear Type Numeric Length 8 Format NONE Label Record the year that participant took hisher initial dose of study drug

Variable Number 23 Variable ParticipantCurrentlyTakingStud Type Character Length 3 Format \$3. Label Is the participant currently taking study drug



Variable Number 24 Variable HbA1cCompletedVisitDate Type Character Length 3 Format \$3. Label The specimens drawn during this visit HbA1c completed on this visit date

Variable Number 25 Variable HbA1cSpecifyCompletedDay Type Numeric Length 8 Format NONE Label The specimens drawn during this visit HbA1c If not done at this visit specify day completed day

Variable Number 26 Variable HbA1cSpecifyCompletedmonth Type Character Length 3 Format \$3. Label The specimens drawn during this visit HbA1c If not done at this visit specify day completed month

Variable Number 27 Variable HbA1cSpecifyCompletedYear Type Numeric Length 8 Format NONE Label The specimens drawn during this visit HbA1c If not done at this visit specify day completed year

Variable Number 28 Variable SerumForAutoantibodiesComplete Type Character Length 3 Format \$3. Label The specimens drawn during this visit Serum for autoantibodies completed on visit date

Variable Number 29 Variable SerumForAutoantibodiesSpecifyC Type Numeric Length 8 Format NONE Label The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed day

Variable Number 30 Variable SerumForAutoantibodiesSpecifyC2 Type Character Length 3 Format \$3. Label The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed month

Variable Number 31 Variable SerumForAutoantibodiesSpecifyC3 Type Numeric Length 8 Format NONE Label The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed year

Variable Number 32 Variable SamplesForStorageCompletedVisi Type Character Length 3 Format \$3. Label The specimens drawn during this visit Samples for storage completed on this visit date

Variable Number 33 Variable SamplesForStorageSpecifyComple Type Numeric Length 8 Format NONE Label The specimens drawn during this visit Samples for storage If not done at this visit specify day completed day

Variable Number 34 Variable SamplesForStorageSpecifyComple2 Type Character Length 3 Format \$3. Label The specimens drawn during this visit Samples for storage If not done at this visit specify day completed month

Variable Number 35 Variable SamplesForStorageSpecifyComple3 Type Numeric Length 8 Format NONE Label The specimens drawn during this visit Samples for storage If not done at this visit specify day completed year

Variable Number 36 Variable DispensationOfStudyDrugComple Type Character Length 3 Format \$3. Label Dispensationreturn of study drug completed on this visit date

Variable Number 37 Variable DispensationOfStudyDrugSpecify3 Type Numeric Length 8 Format NONE Label Dispensationreturn of study drug If not done at this visit specify day completed day

Variable Number 38 Variable DispensationOfStudyDrugSpecify Type Character Length 3 Format \$3. Label Dispensationreturn of study drug If not done at this visit specify day completed month

Variable Number 39 Variable DispensationOfStudyDrugSpecify2 Type Numeric Length 8 Format NONE  
Label Dispensationreturn of study drug If not done at this visit specify day completed year

### Data Set Name: tn07\_6monthvisit.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 VisitAtSiteOtherThanPrimaryStu Type Character Length 3 Format \$3. Label  
Dis the visit occur at a site other than at the primary study site

Variable Number 5 Variable VisitAtSiteOtherThanPrimaryStu2 Type Numeric Length 8 Format NONE  
Label If yes record site number for reimbursement

Variable Number 6 Variable AnyChangesInHealthSinceLastSch Type Character Length 3 Format \$3. Label  
Have there been any changes in health since the last scheduled visit

Variable Number 7 Variable AnyChangesInConcomitantMedicat Type Character Length 3 Format \$3.  
Label Have there been any changes in concomitant medications since last scheduled visit

Variable Number 8 Variable SeatedArmBPSystolic Type Numeric Length 8 Format NONE Label Physical  
Assessments Seated aremBP systolic

Variable Number 9 Variable SeatedArmBPDiaStolic Type Numeric Length 8 Format NONE Label Physical  
Assessments Seated aremBP Diastolic

Variable Number 10 Variable WeightinKg Type Numeric Length 8 Format NONE Label Physical  
Assessments weight

Variable Number 11 Variable Weightinlbs Type Numeric Length 8 Format NONE Label Physical  
Assessments weight in lbs

Variable Number 12 Variable HeightinCm Type Numeric Length 8 Format NONE Label Physical  
Assessments Height in cm

Variable Number 13 Variable HeightinIn Type Numeric Length 8 Format NONE Label Physical  
Assessments Height in in

Variable Number 14 Variable AbdominalCircumferenceinCm Type Numeric Length 8 Format NONE Label  
Physical Assessments Abdominal Circumference in cm

Variable Number 15 Variable AbdominalCircumferenceinIn Type Numeric Length 8 Format NONE Label  
Physical Assessments Abdominal Circumference in Inches

Variable Number 16 Variable ParticipantHasReproductivePote Type Character Length 3 Format \$3. Label  
If FEMALE does the participant have reproductive potential

Variable Number 17 Variable FemalePARTicipantSexuallyActiv Type Character Length 3 Format \$3. Label  
Is the female participant sexually active

Variable Number 18 Variable CurrentlyUsingFormOfBirthContr Type Character Length 3 Format \$3. Label If yes to question D1 above Does she currently use a form of birth control

Variable Number 19 Variable PlanOfBecomingPregnantInNext6M Type Character Length 2 Format \$2. Label If yes to question D1 above Does she plan on becoming pregnant in the next 6 months

Variable Number 20 Variable UrinePregnancyTestCompletedAtT Type Character Length 3 Format \$3. Label If yes to question D1 above Was urine pregnancy test completed at this visit

Variable Number 21 Variable UrinePregnancyTestPositive Type Character Length 3 Format \$3. Label If yes was the test result positive

Variable Number 22 Variable DosesMissedSinceLastStudyVisit Type Numeric Length 8 Format NONE Label How many doses has the participant missed since the last study visit

Variable Number 23 Variable ParticipantCurrentlyTakingStud Type Character Length 3 Format \$3. Label Is the participant currently taking study drug

Variable Number 24 Variable HbA1cCompletedVisitDate Type Character Length 3 Format \$3. Label The specimens drawn during this visit HbA1c completed on this visit date

Variable Number 25 Variable HbA1cSpecifyCompletedDay Type Numeric Length 8 Format NONE Label The specimens drawn during this visit HbA1c If not done at this visit specify day completed day

Variable Number 26 Variable HbA1cSpecifyCompletedmonth Type Character Length 3 Format \$3. Label The specimens drawn during this visit HbA1c If not done at this visit specify day completed month

Variable Number 27 Variable HbA1cSpecifyCompletedYear Type Numeric Length 8 Format NONE Label The specimens drawn during this visit HbA1c If not done at this visit specify day completed year

Variable Number 28 Variable OGTTPerformedOnVisitDate Type Character Length 3 Format \$3. Label The specimens drawn during this visit OGTT performed on this visit date

Variable Number 29 Variable OGTTSpecifyPerformedDay Type Numeric Length 8 Format NONE Label The specimens drawn during this visit OGTT If NOT performed at this visit specify date performed

Variable Number 30 Variable OGTTSpecifyPerformedMonth Type Character Length 3 Format \$3. Label The specimens drawn during this visit OGTT If NOT performed at this visit specify month performed

Variable Number 31 Variable OGTTSpecifyPerformedYear Type Numeric Length 8 Format NONE Label The specimens drawn during this visit OGTT If NOT performed at this visit specify year performed

Variable Number 32 Variable SerumForAutoantibodiesComplete Type Character Length 3 Format \$3. Label The specimens drawn during this visit Serum for autoantibodies completed on visit date

Variable Number 33 Variable SerumForAutoantibodiesSpecifyC Type Numeric Length 8 Format NONE Label The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed day

Variable Number 34 Variable SerumForAutoantibodiesSpecifyC2 Type Character Length 3 Format \$3.  
Label The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed month

Variable Number 35 Variable SerumForAutoantibodiesSpecifyC3 Type Numeric Length 8 Format NONE  
Label The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed year

Variable Number 36 Variable SamplesForStorageCompletedVisi Type Character Length 3 Format \$3.  
Label The specimens drawn during this visit Samples for storage completed on this visit date

Variable Number 37 Variable SamplesForStorageSpecifyComple Type Numeric Length 8 Format NONE  
Label The specimens drawn during this visit Samples for storage If not done at this visit specify day completed day

Variable Number 38 Variable SamplesForStorageSpecifyComple2 Type Character Length 3 Format \$3.  
Label The specimens drawn during this visit Samples for storage If not done at this visit specify day completed month

Variable Number 39 Variable SamplesForStorageSpecifyComple3 Type Numeric Length 8 Format NONE  
Label The specimens drawn during this visit Samples for storage If not done at this visit specify day completed year

Variable Number 40 Variable DispensationOfStudyDrugComple Type Character Length 3 Format \$3.  
Label Dispensationreturn of study drug completed on this visit date

Variable Number 41 Variable DispensationOfStudyDrugSpecify Type Numeric Length 8 Format NONE  
Label Dispensationreturn of study drug If not done at this visit specify day completed day

Variable Number 42 Variable DispensationOfStudyDrugSpecify2 Type Character Length 3 Format \$3.  
Label Dispensationreturn of study drug If not done at this visit specify day completed month

Variable Number 43 Variable DispensationOfStudyDrugSpecify3 Type Numeric Length 8 Format NONE  
Label Dispensationreturn of study drug If not done at this visit specify day completed year

## Data Set Name: tn07\_additionalconsent.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 InformedConsentObtainedDay Type Numeric Length 8 Format NONE Label  
Date written informed consent obtained day

Variable Number 5 Variable InformedConsentObtainedMonth Type Character Length 3 Format \$3. Label  
Date written informed consent obtained month

Variable Number 6 Variable InformedConsentObtainedYear Type Numeric Length 8 Format NONE Label  
Date written informed consent obtained year

Variable Number 7 Variable ParticipantPermissionOnOnsetFo Type Character Length 68 Format \$68. Label On the consent form did the participant give permission to store samples for future testing

### Data Set Name: tn07\_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 Date of Visit

Variable Number 3 Variable AdverseEventID Type Numeric Length 8 Format NONE Label Adverse Event ID

Variable Number 4 Variable AETerm Type Character Length 100 Format NONE Label AE Term

Variable Number 5 Variable severity Type Numeric Length 8 Format NONE Label Severity Index

Variable Number 6 Variable AEReportType Type Character Length 9 Format \$9. Label AE Report Type

Variable Number 7 Variable AEReportDtDay Type Numeric Length 8 Format NONE Label Adverse Event Report Date Day

Variable Number 8 Variable AEReportDtMonth Type Numeric Length 8 Format NONE Label Adverse Event Report Date Month

Variable Number 9 Variable AEReportDtYear Type Numeric Length 8 Format NONE Label Adverse Event Report Date Year

Variable Number 10 Variable AEOccurDtDay Type Numeric Length 8 Format NONE Label Date of Adverse Event Occurrence Day

Variable Number 11 Variable AEOccurDtMonth Type Numeric Length 8 Format NONE Label Date of Adverse Event Occurrence Month

Variable Number 12 Variable AEOccurDtYear Type Numeric Length 8 Format NONE Label Date of Adverse Event Occurrence Year

Variable Number 13 Variable AEPrimarySecondary1\_1 Type Character Length 9 Format \$9. Label Is this event a primary or secondary event

Variable Number 14 Variable AECategory Type Character Length 35 Format \$35. Label Category

Variable Number 15 Variable AEDetails Type Character Length 3999 Format \$3999. Label Adverse Event Details

Variable Number 16 Variable AETreatLocation Type Character Length 14 Format \$14. Label Adverse Event Treatment Location

Variable Number 17 Variable AETreatLocationOther Type Character Length 108 Format \$108. Label AE Treatment Location Other

Variable Number 18 Variable AEEExpected1\_1 Type Character Length 3 Format \$3. Label Expected

Variable Number 19 Variable AECausalityByReporter Type Character Length 22 Format \$22. Label Causality by reporter

Variable Number 20 Variable AEAssociations\_Developmentofacon Type Numeric Length 8 Format NONE Label AEAssociations: Development of a congenital anomaly or birth defect

Variable Number 21 Variable AEAssociations\_Developmentofaper Type Numeric Length 8 Format NONE Label AEAssociations: Development of a permanent/ serious/ disabling /incapacitating condition

Variable Number 22 Variable AEAssociations\_Death Type Numeric Length 8 Format NONE Label AEAssociations: Death

Variable Number 23 Variable AEAssociations\_Hospitalizationor Type Numeric Length 8 Format NONE Label AEAssociations: Hospitalization or prolonged hospitalization

Variable Number 24 Variable AEAssociations\_Lifethreatening Type Numeric Length 8 Format NONE Label AEAssociations: Life threatening

Variable Number 25 Variable AEAssociations\_Isanotherconditio Type Numeric Length 8 Format NONE Label AEAssociations: Is another condition which investigators judge to represent significant hazards

Variable Number 26 Variable AEPatientOutcome1\_1 Type Character Length 35 Format \$35. Label Patient Outcome

Variable Number 27 Variable AEResolveDtDay Type Numeric Length 8 Format NONE Label Adverse Event Resolved Date Day

Variable Number 28 Variable AEResolveDtMonth Type Numeric Length 8 Format NONE Label Adverse Event Resolved Date Month

Variable Number 29 Variable AEResolveDtYear Type Numeric Length 8 Format NONE Label Adverse Event Resolved Date Year

Variable Number 30 Variable AEDateDeathDay Type Numeric Length 8 Format NONE Label AE Date of Death Day

Variable Number 31 Variable AEDateDeathMonth Type Numeric Length 8 Format NONE Label AE Date of Death Month

Variable Number 32 Variable AEDateDeathYear Type Numeric Length 8 Format NONE Label AE Date of Death Year

Variable Number 33 Variable Comments Type Character Length 3025 Format \$3025. Label Comments

Variable Number 34 Variable StudyDrugStartDateDay1\_1 Type Numeric Length 8 Format NONE Label Study Drug Start Date Day

Variable Number 35 Variable StudyDrugStartDateMonth1\_1 Type Character Length 3 Format \$3. Label Study Drug Start Date Month

Variable Number 36 Variable StudyDrugStartDateYear1\_1 Type Numeric Length 8 Format NONE Label Study Drug Start Date Year

Variable Number 37 Variable StudyDrugStopDateDay1\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Stop Date Day

Variable Number 38 Variable StudyDrugStopDateMonth1\_1 Type Character Length 3 Format \$3. Label  
Study Drug Stop Date Month

Variable Number 39 Variable StudyDrugStopDateYear1\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Stop Date Year

Variable Number 40 Variable StudyDrugStartDateDay2\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Start Date Day

Variable Number 41 Variable StudyDrugStartDateMonth2\_1 Type Character Length 3 Format \$3. Label  
Study Drug Start Date Month

Variable Number 42 Variable StudyDrugStartDateYear2\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Start Date Year

Variable Number 43 Variable StudyDrugStopDateDay2\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Stop Date Day

Variable Number 44 Variable StudyDrugStopDateMonth2\_1 Type Character Length 3 Format \$3. Label  
Study Drug Stop Date Month

Variable Number 45 Variable StudyDrugStopDateYear2\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Stop Date Year

Variable Number 46 Variable StudyDrugStartDateDay3\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Start Date Day

Variable Number 47 Variable StudyDrugStartDateMonth3\_1 Type Character Length 3 Format \$3. Label  
Study Drug Start Date Month

Variable Number 48 Variable StudyDrugStartDateYear3\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Start Date Year

Variable Number 49 Variable StudyDrugStopDateDay3\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Stop Date Day

Variable Number 50 Variable StudyDrugStopDateMonth3\_1 Type Character Length 3 Format \$3. Label  
Study Drug Stop Date Month

Variable Number 51 Variable StudyDrugStopDateYear3\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Stop Date Year

Variable Number 52 Variable StudyDrugStartDateDay4\_1 Type Numeric Length 8 Format NONE Label  
Study Drug Start Date Day

Variable Number 53 Variable StudyDrugStartDateMonth4\_1 Type Character Length 3 Format \$3. Label  
Study Drug Start Date Month

Variable Number 54 Variable StudyDrugStartDateYear4\_1 Type Numeric Length 8 Format NONE Label Study Drug Start Date Year

Variable Number 55 Variable StudyDrugStopDateDay4\_1 Type Numeric Length 8 Format NONE Label Study Drug Stop Date Day

Variable Number 56 Variable StudyDrugStopDateMonth4\_1 Type Character Length 3 Format \$3. Label Study Drug Stop Date Month

Variable Number 57 Variable StudyDrugStopDateYear4\_1 Type Numeric Length 8 Format NONE Label Study Drug Stop Date Year

Variable Number 58 Variable StudyDrugStartDateDay5\_1 Type Numeric Length 8 Format NONE Label Study Drug Start Date Day

Variable Number 59 Variable StudyDrugStartDateMonth5\_1 Type Character Length 3 Format \$3. Label Study Drug Start Date Month

Variable Number 60 Variable StudyDrugStartDateYear5\_1 Type Numeric Length 8 Format NONE Label Study Drug Start Date Year

Variable Number 61 Variable StudyDrugStopDateDay5\_1 Type Numeric Length 8 Format NONE Label Study Drug Stop Date Day

Variable Number 62 Variable StudyDrugStopDateMonth5\_1 Type Character Length 1 Format \$1. Label Study Drug Stop Date Month

Variable Number 63 Variable StudyDrugStopDateYear5\_1 Type Numeric Length 8 Format NONE Label Study Drug Stop Date Year

Variable Number 64 Variable Eventabateafterstoppingdrug Type Character Length 14 Format \$14. Label Did the eventreaction abate after stopping drug

Variable Number 65 Variable Eventreappearafterreintroducti Type Character Length 14 Format \$14. Label Did the eventreaction reappear after reintroduction

Variable Number 66 Variable AEFollowupDateDay Type Numeric Length 8 Format NONE Label AE Followup Date Day

Variable Number 67 Variable AEFollowupDateMonth Type Numeric Length 8 Format NONE Label AE Followup Date Month

Variable Number 68 Variable AEFollowupDateYear Type Numeric Length 8 Format NONE Label AE Followup Date Year

Variable Number 69 Variable AEReasonForFollowup Type Character Length 55 Format \$55. Label AE Reason for followup

Variable Number 70 Variable AEFollowupNumber Type Numeric Length 8 Format NONE Label AE Followup instance number

Variable Number 71 Variable AESelectTerm Type Numeric Length 8 Format NONE Label AE Select Term



## Data Set Name: tn07\_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 AECausalityByReviewer Type Character Length 22 Format \$22. Label Causality by reviewer

Variable Number 4 Variable RecommendProtocolChange Type Character Length 2 Format \$2. Label Recommend changes to the protocol

Variable Number 5 Variable RecommendConsentChange Type Character Length 3 Format \$3. Label Recommend changes to the consent form

Variable Number 6 Variable AEReviewFormComments Type Character Length 341 Format \$341. Label Review form comments

Variable Number 7 Variable AEAdditionalInfoRequested Type Character Length 3 Format \$3. Label Additional information requested

Variable Number 8 Variable AEAdditionalInfoRequestedDetail Type Character Length 499 Format \$499. Label Adverse event additional information requested details

Variable Number 9 Variable AEReviewRequireDSMBReview Type Numeric Length 8 Format NONE Label Requires urgent and immediate review by full DSMB committee

Variable Number 10 Variable AEReviewDSMBReviewComments Type Character Length 1 Format \$1. Label Review requires DSMB review comments

Variable Number 11 Variable AEReviewPriorSimilarSAEs Type Character Length 3 Format \$3. Label Have there been prior occurrences of similar reported in this study

Variable Number 12 Variable AEReviewReportingTimeframe Type Character Length 27 Format \$27. Label Reporting time frame to regulatory authorities

Variable Number 13 Variable AEReviewTreatmentUnblindedForC Type Character Length 2 Format \$2. Label Does treatment need to be unblinded for determination of causality

Variable Number 14 Variable AEReviewPriorSimilarSAEsSummary Type Character Length 280 Format \$280. Label If prior occurrences of similar serious adverse events provide a brief summary

Variable Number 15 Variable AdverseEventID Type Numeric Length 8 Format NONE Label Adverse Event ID

## Data Set Name: tn07\_annualvisit.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 VisitAtSiteOtherThanPrimaryStu Type Character Length 3 Format \$3. Label Dis the visit occur at a site other than at the primary study site

Variable Number 5 Variable VisitAtSiteOtherThanPrimaryStu2 Type Numeric Length 8 Format NONE Label If yes record site number for reimbursement

Variable Number 6 Variable AnyChangesInHealthSinceLastSch Type Character Length 3 Format \$3. Label Have there been any changes in health since the last scheduled visit

Variable Number 7 Variable AnyChangesInConcomitantMedicat Type Character Length 3 Format \$3. Label Have there been any changes in concomitant medications since last scheduled visit

Variable Number 8 Variable SeatedArmBPSystolic Type Numeric Length 8 Format NONE Label Physical Assessments Seated aremBP systolic

Variable Number 9 Variable SeatedArmBPDiastolic Type Numeric Length 8 Format NONE Label Physical Assessments Seated aremBP Diastolic

Variable Number 10 Variable WeightinKg Type Numeric Length 8 Format NONE Label Physical Assessments weight

Variable Number 11 Variable Weightinlbs Type Numeric Length 8 Format NONE Label Physical Assessments weight in lbs

Variable Number 12 Variable HeightinCm Type Numeric Length 8 Format NONE Label Physical Assessments Height in cm

Variable Number 13 Variable HeightinIn Type Numeric Length 8 Format NONE Label Physical Assessments Height in in

Variable Number 14 Variable AbdominalCircumferenceinCm Type Numeric Length 8 Format NONE Label Physical Assessments Abdominal Circumference in cm

Variable Number 15 Variable AbdominalCircumferenceinIn Type Numeric Length 8 Format NONE Label Physical Assessments Abdominal Circumference in Inches

Variable Number 16 Variable HeentNormalOnExam Type Character Length 3 Format \$3. Label Review of systems Heent Normal on exam

Variable Number 17 Variable HeentReportedNormal Type Character Length 3 Format \$3. Label Review of systems Heent Participant reported normal

Variable Number 18 Variable HeentAbnormalExplain Type Character Length 275 Format \$275. Label Review of systems Heent Either abnormal Explain

Variable Number 19 Variable NeckNormalOnExam Type Character Length 3 Format \$3. Label Review of systems Neck Normal on exam

Variable Number 20 Variable NeckReportedNormal Type Character Length 3 Format \$3. Label Review of systems Neck Participant reported normal

Variable Number 21 Variable NeckAbnormalExplain Type Character Length 113 Format \$113. Label Review of systems Neck If Either Abnormal Expalin

Variable Number 22 Variable ThyroidNormalOnExam Type Character Length 3 Format \$3. Label Review of systems Thyroid Normal on exam

Variable Number 23 Variable ThyroidreportedNormal Type Character Length 3 Format \$3. Label Review of systems Thyroid Participant reported normal

Variable Number 24 Variable ThyroidAbnormalExplain Type Character Length 90 Format \$90. Label Review of systems Thyroid If either abnormal explain

Variable Number 25 Variable LungsNormalOnExam Type Character Length 3 Format \$3. Label Review of systems Lungs Normal on exam

Variable Number 26 Variable LungsReportedNormal Type Character Length 3 Format \$3. Label Review of systems Lungs Participant reported normal

Variable Number 27 Variable LungsAbnormalExplain Type Character Length 158 Format \$158. Label Review of systems Lungs If either abnormal explain

Variable Number 28 Variable ChestNormalOnExam Type Character Length 3 Format \$3. Label Review of systems ChestBreasts Normal on exam

Variable Number 29 Variable ChestReportedNormal Type Character Length 3 Format \$3. Label Review of systems ChestBreastsParticipant reported normal

Variable Number 30 Variable ChestAbnormalExplain Type Character Length 107 Format \$107. Label Review of systems ChestBreasts If either abnormal explain

Variable Number 31 Variable HeartNormalOnExam Type Character Length 3 Format \$3. Label Review of systems HeartCirculatory Normal on exam

Variable Number 32 Variable HeartReportedNormal Type Character Length 3 Format \$3. Label Review of systems HeartCirculatoryParticipant reported normal

Variable Number 33 Variable HeartAbnormalExplain Type Character Length 182 Format \$182. Label Review of systems HeartCirculatory If either abnormal explain

Variable Number 34 Variable MusculoskeletalNormalOnExam Type Character Length 3 Format \$3. Label Review of systems Musculoskeletal Normal on exam

Variable Number 35 Variable MusculoskeletalReportedNormal Type Character Length 3 Format \$3. Label Review of systems Musculoskeletal Participant reported normal

Variable Number 36 Variable MusculoskeletalAbnormalExpalin Type Character Length 261 Format \$261. Label Review of systems Musculoskeletal If either abnormal explain

Variable Number 37 Variable NeurologicNormalOnExam Type Character Length 3 Format \$3. Label Review of systems Neurologic Normal on exam

Variable Number 38 Variable NeurologicReportedNormal Type Character Length 3 Format \$3. Label Review of systems Neurologic Participant reported normal

Variable Number 39 Variable NeurologicAbnormalExplain Type Character Length 235 Format \$235. Label Review of systems Neurologic If either abnormal explain

Variable Number 40 Variable GenitourinaryOrTestesNormalOnE Type Character Length 3 Format \$3. Label Review of systems GenitourinaryTestes Normal on exam

Variable Number 41 Variable GenitourinaryOrTestesreportedN Type Character Length 3 Format \$3. Label Review of systems GenitourinaryTestes Participant reported normal

Variable Number 42 Variable GenitourinaryAbnormalExplain Type Character Length 169 Format \$169. Label Review of systems GenitourinaryTestes If either abnormal explain

Variable Number 43 Variable SkinOrNailsNormalOnExam Type Character Length 3 Format \$3. Label Review of systems SkinNails Normal on Exam

Variable Number 44 Variable sSkinOrNailsReportedNormal Type Character Length 3 Format \$3. Label Review of systems SkinNails Participant Reported Normal

Variable Number 45 Variable SkinOrNailsAbnormalExplain Type Character Length 324 Format \$324. Label Review of systems SkinNails If either abnormal explain

Variable Number 46 Variable LymphNodesNormalOnExam Type Character Length 3 Format \$3. Label Review of systems Lymph nodes normal on exam

Variable Number 47 Variable LymphNodesReportedNormal Type Character Length 3 Format \$3. Label Review of systems Lymph nodes Participant Reported Normal

Variable Number 48 Variable LymphNodesEitherAbnormalExplai Type Character Length 89 Format \$89. Label Review of systems Lymph nodes If either abnormal explain

Variable Number 49 Variable OtherNormalOnExam Type Character Length 3 Format \$3. Label Review of systems Other Normal on Exam

Variable Number 50 Variable OtherReportedNormal Type Character Length 3 Format \$3. Label Review of systems Other Participant Reported Normal

Variable Number 51 Variable OtherSpecify Type Character Length 172 Format \$172. Label Review of systems Other Specify

Variable Number 52 Variable PtherAbnormalExplain Type Character Length 172 Format \$172. Label Review of systems Other If either abnormal explain

Variable Number 53 Variable TannerStageBreast Type Character Length 18 Format \$18. Label Tanner Stage Breast Female

Variable Number 54 Variable TannerStageGenitalia Type Character Length 18 Format \$18. Label Tanner Stage Genitalia Male

Variable Number 55 Variable TannerStagePublicHair Type Character Length 18 Format \$18. Label Tanner Stage Public Hair both

Variable Number 56 Variable ParticipantHasReproductivePote Type Character Length 3 Format \$3. Label If FEMALE does the participant have reproductive potential

Variable Number 57 Variable FemalePARTicipantSexuallyActiv Type Character Length 3 Format \$3. Label Is the female participant sexually active

Variable Number 58 Variable CurrentlyUsingFormOfBirthContr Type Character Length 3 Format \$3. Label If yes to question D1 above Does she currently use a form of birth control

Variable Number 59 Variable PlanOfBecomingPregnantInNext6M Type Character Length 2 Format \$2. Label If yes to question D1 above Does she plan on becoming pregnant in the next 6 months

Variable Number 60 Variable UrinePregnancyTestCompletedAtT Type Character Length 3 Format \$3. Label If yes to question D1 above Was urine pregnancy test completed at this visit

Variable Number 61 Variable UrinePregnancyTestPositive Type Character Length 2 Format \$2. Label If yes was the test result positive

Variable Number 62 Variable DosesMissedSinceLastStudyVisit Type Numeric Length 8 Format NONE Label How many doses has the participant missed since the last study visit

Variable Number 63 Variable ParticipantCurrentlyTakingStud Type Character Length 3 Format \$3. Label Is the participant currently taking study drug

Variable Number 64 Variable HbA1cCompletedVisitDate Type Character Length 3 Format \$3. Label The specimens drawn during this visit HbA1c completed on this visit date

Variable Number 65 Variable HbA1cSpecifyCompletedDay Type Numeric Length 8 Format NONE Label The specimens drawn during this visit HbA1c If not done at this visit specify day completed day

Variable Number 66 Variable HbA1cSpecifyCompletedmonth Type Character Length 3 Format \$3. Label The specimens drawn during this visit HbA1c If not done at this visit specify day completed month

Variable Number 67 Variable HbA1cSpecifyCompletedYear Type Numeric Length 8 Format NONE Label The specimens drawn during this visit HbA1c If not done at this visit specify day completed year

Variable Number 68 Variable OGTTPerformedOnVisitDate Type Character Length 3 Format \$3. Label The specimens drawn during this visit OGTT performed on this visit date

Variable Number 69 Variable OGTTSpecifyPerformedDay Type Numeric Length 8 Format NONE Label The specimens drawn during this visit OGTT If NOT performed at this visit specify date performed

Variable Number 70 Variable OGTTSpecifyPerformedMonth Type Character Length 3 Format \$3. Label The specimens drawn during this visit OGTT If NOT performed at this visit specify month performed

Variable Number 71 Variable OGTTSpecifyPerformedYear Type Numeric Length 8 Format NONE Label The specimens drawn during this visit OGTT If NOT performed at this visit specify year performed

Variable Number 72 Variable SerumForAutoantibodiesComplete Type Character Length 3 Format \$3.  
Label The specimens drawn during this visit Serum for autoantibodies completed on visit date

Variable Number 73 Variable SerumForAutoantibodiesSpecifyC Type Numeric Length 8 Format NONE  
Label The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed day

Variable Number 74 Variable SerumForAutoantibodiesSpecifyC2 Type Character Length 3 Format \$3.  
Label The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed month

Variable Number 75 Variable SerumForAutoantibodiesSpecifyC3 Type Numeric Length 8 Format NONE  
Label The specimens drawn during this visit Serum for autoantibodies If not done at this visit specify day completed year

Variable Number 76 Variable SamplesForStorageCompletedVisi Type Character Length 3 Format \$3.  
Label The specimens drawn during this visit Samples for storage completed on this visit date

Variable Number 77 Variable SamplesForStorageSpecifyComple Type Numeric Length 8 Format NONE  
Label The specimens drawn during this visit Samples for storage If not done at this visit specify day completed day

Variable Number 78 Variable SamplesForStorageSpecifyComple2 Type Character Length 3 Format \$3.  
Label The specimens drawn during this visit Samples for storage If not done at this visit specify day completed month

Variable Number 79 Variable SamplesForStorageSpecifyComple3 Type Numeric Length 8 Format NONE  
Label The specimens drawn during this visit Samples for storage If not done at this visit specify day completed year

Variable Number 80 Variable LifeStylePerformedOnVisitDate Type Character Length 3 Format \$3. Label  
Lifestyle Questionnaire Performed on this visit date

Variable Number 81 Variable LifeStylePerformedDay Type Numeric Length 8 Format NONE Label  
Lifestyle Questionnaire If NOT performed at this visit specify performed day

Variable Number 82 Variable LifeStylePerformedMonth Type Character Length 3 Format \$3. Label  
Lifestyle Questionnaire If NOT performed at this visit specify performed month

Variable Number 83 Variable LifeStylePerformedYear Type Numeric Length 8 Format NONE Label  
Lifestyle Questionnaire If NOT performed at this visit specify performed year

Variable Number 84 Variable DispensationOfStudyDrugComple Type Character Length 3 Format \$3.  
Label Dispensationreturn of study drug completed on this visit date

Variable Number 85 Variable DispensationOfStudyDrugSpecify Type Numeric Length 8 Format NONE  
Label Dispensationreturn of study drug If not done at this visit specify day completed day

Variable Number 86 Variable DispensationOfStudyDrugSpecify2 Type Character Length 3 Format \$3.  
Label Dispensationreturn of study drug If not done at this visit specify day completed month

Variable Number 87 Variable DispensationOfStudyDrugSpecify3 Type Numeric Length 8 Format NONE  
Label Dispensationreturn of study drug If not done at this visit specify day completed year

Variable Number 88 Variable AbdomenNormalOnExam Type Character Length 3 Format \$3. Label  
Review of systems Abdomen Normal on exam

Variable Number 89 Variable AbdomenreportedNormal Type Character Length 3 Format \$3. Label  
Review of systems Abdomen Participant reported normal

Variable Number 90 Variable AbdomenEitherAbnormalExplain Type Character Length 302 Format \$302.  
Label Review of systems Abdomen If Either Abnormal Explain

### Data Set Name: tn07\_changeinstatus.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 DateStatusChangeYear Type Numeric Length 8 Format NONE Label Date  
change in status became effective Year

Variable Number 6 Variable DateStatusChangeMonth Type Character Length 3 Format \$3. Label Date  
change in status became effective Month

Variable Number 7 Variable ChangeOfStatusOccuring Type Character Length 98 Format \$98. Label  
Change in status that has occurred

Variable Number 8 Variable DoWDay Type Numeric Length 8 Format NONE Label Date of withdrawal  
Day

Variable Number 9 Variable DoWMonth Type Character Length 3 Format \$3. 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 \$45. Label Record  
the primary reason for withdrawal

Variable Number 12 Variable ReasonForWithdrawalOTHER Type Character Length 789 Format \$789.  
Label If OTHER Specify

Variable Number 13 Variable ReasonWithdrewConsentSpecify Type Character Length 770 Format \$770.  
Label Reason Withdrew Consent specify

Variable Number 14 Variable ReasonAdverseEventSpecify Type Character Length 106 Format \$106.  
Label Reason Adverse Event specify

Variable Number 15 Variable WillingToBeContacted Type Character Length 3 Format \$3. 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 \$3. 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 PregnancyCompletionDay Type Numeric Length 8 Format NONE Label If YES what is the estimated date of completion of pregnancy Day

Variable Number 20 Variable PregnancyCompletionMonth Type Character Length 3 Format \$3. Label If YES what is the estimated date of completion of pregnancy Month

Variable Number 21 Variable PregnancyCompletionYear Type Numeric Length 8 Format NONE Label If YES what is the estimated date of completion of pregnancy Year

### Data Set Name: [tn07\\_changeinstudydrug.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 StudyStatusDiscontinuing Type Character Length 29 Format \$29. Label Change in study status Discontinuing

Variable Number 4 Variable StudyDrugStatusEffectiveDay Type Numeric Length 8 Format NONE Label Change in study drug status effective day

Variable Number 5 Variable StudyDrugStatusEffectiveMonth Type Character Length 3 Format \$3. Label Change in study drug status effective month

Variable Number 6 Variable StudyDrugStatusEffectiveYear Type Numeric Length 8 Format NONE Label Change in study drug status effective year

Variable Number 7 Variable StudyDrugStoppedReas\_Selfdiscont Type Numeric Length 8 Format NONE Label StudyDrugStoppedReas: Self-discontinued by participant

Variable Number 8 Variable StudyDrugStoppedReas\_Development Type Numeric Length 8 Format NONE Label StudyDrugStoppedReas: Development of T1D

Variable Number 9 Variable StudyDrugStoppedReas\_AdverseEven Type Numeric Length 8 Format NONE Label StudyDrugStoppedReas: Adverse Event

Variable Number 10 Variable StudyDrugStoppedReas\_Pregnancy Type Numeric Length 8 Format NONE Label StudyDrugStoppedReas: Pregnancy



Variable Number 11 Variable StudyDrugStoppedReas\_Studydiscon Type Numeric Length 8 Format NONE Label StudyDrugStoppedReas: Study discontinuation

Variable Number 12 Variable StudyDrugStoppedReas\_Other Type Numeric Length 8 Format NONE Label StudyDrugStoppedReas: Other

Variable Number 13 Variable StudyDrugStoppedReasonSpecify Type Character Length 337 Format \$337. Label If OTHER specify

Variable Number 14 Variable ParticipantInformedOfTreatment Type Character Length 3 Format \$3. Label Was the participant informed of hisher treatment group assignment

Variable Number 15 Variable ReturnOfRemainingStudyDrug Type Character Length 3 Format \$3. Label Did the participant return the remaining study drug

Variable Number 16 Variable ChangeInStudyStatus Type Character Length 3 Format \$3. Label Is there a change in study status at this time

### Data Set Name: tn07\_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: [tn07\\_diabetesonset.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 DiagnosisDay Type Numeric Length 8 Format NONE Label Diagnosis day

Variable Number 4 Variable DiagnosisMonth Type Character Length 3 Format \$3. Label Diagnosis month

Variable Number 5 Variable DiagnosisYear Type Numeric Length 8 Format NONE Label Diagnosis year

Variable Number 6 Variable DiagnosisBy Type Character Length 19 Format \$19. Label Diagnosis made by

Variable Number 7 Variable DiagnosisByOthersSpecify Type Character Length 97 Format \$97. Label If other facility specify

Variable Number 8 Variable InsulinTreatmentStartedDay Type Numeric Length 8 Format NONE Label Day insulin treatment started

Variable Number 9 Variable InsulinTreatmentStartedMonth Type Character Length 3 Format \$3. Label Month insulin treatment started

Variable Number 10 Variable InsulinTreatmentStartedYear Type Numeric Length 8 Format NONE Label Year insulin treatment started

Variable Number 11 Variable DateInsulinTreatmentStartedUnk Type Numeric Length 8 Format NONE Label Date Insulin treatment started Unknown

Variable Number 12 Variable HospitalizedAtDiagnosisTime Type Character Length 3 Format \$3. Label Was the participant hospitalized at the time of diagnosis

Variable Number 13 Variable AdmissionDay Type Numeric Length 8 Format NONE Label Day of admission

Variable Number 14 Variable AdmissionMonth Type Character Length 3 Format \$3. Label Month of admission

Variable Number 15 Variable AdmissionYear Type Numeric Length 8 Format NONE Label Year of admission

Variable Number 16 Variable DischargeDay Type Numeric Length 8 Format NONE Label Day of discharge

Variable Number 17 Variable DischargeMonth Type Character Length 3 Format \$3. Label Month of discharge

Variable Number 18 Variable DischargeYear Type Numeric Length 8 Format NONE Label Year of discharge

Variable Number 19 Variable Polyuria Type Character Length 3 Format \$3. Label Did the participant experience Polyuria

Variable Number 20 Variable PolyuriaMonth Type Character Length 3 Format \$3. Label Month polyuria experienced

Variable Number 21 Variable PolyuriaYear Type Numeric Length 8 Format NONE Label Year polyuria experienced

Variable Number 22 Variable Polydipsia Type Character Length 3 Format \$3. Label Did the participant experience Polydipsia

Variable Number 23 Variable PolydipsiaMonth Type Character Length 3 Format \$3. Label Month polydipsia experienced

Variable Number 24 Variable Polydipsiayear Type Numeric Length 8 Format NONE Label Year polydipsia experienced

Variable Number 25 Variable Polyphagia Type Character Length 3 Format \$3. Label Did the participant experience Polyphagia

Variable Number 26 Variable PolyphagiaMonth Type Character Length 3 Format \$3. Label Month polyphagia experienced

Variable Number 27 Variable PolyphagiaYear Type Numeric Length 8 Format NONE Label Year polyphagia experienced

Variable Number 28 Variable Fatigue Type Character Length 3 Format \$3. Label Did the participant experience fatigue

Variable Number 29 Variable FatigueMonth Type Character Length 3 Format \$3. Label Month fatigue experienced

Variable Number 30 Variable FatigueYear Type Numeric Length 8 Format NONE Label Year fatigue experienced

Variable Number 31 Variable UnexplainedWeightLoss Type Character Length 3 Format NONE Label Did the participant experience unexplained weight loss

Variable Number 32 Variable UnexplainedWeightLossMonth Type Character Length 3 Format NONE Label Month of unexplained weight loss

Variable Number 33 Variable UnexplainedWeightLossYear Type Numeric Length 8 Format NONE Label Year of unexplained weight loss

Variable Number 34 Variable WeightLostInKgs Type Numeric Length 8 Format NONE Label Amount of weight loss in kgs

Variable Number 35 Variable WeightLostInLbs Type Numeric Length 8 Format NONE Label Amount of weight loss in lbs

Variable Number 36 Variable Ketoacidosis Type Character Length 3 Format \$3. Label Did the participant experience ketoacidosis

Variable Number 37 Variable KetoacidosisMonth23 Type Character Length 3 Format \$3. Label Did the participant experience Ketoacidosismonth

Variable Number 38 Variable KetoacidosisYear23 Type Numeric Length 8 Format NONE Label Did the participant experience Ketoacidosisyear

Variable Number 39 Variable PlasmaGlucoseResult Type Numeric Length 8 Format NONE Label Plasma glucose result

Variable Number 40 Variable PlasmaGlucoseUnits Type Character Length 6 Format \$6. Label Plasma glucose units

Variable Number 41 Variable PlasmaGlucoseRefRangeLow Type Numeric Length 8 Format NONE Label Plasma glucose low reference range

Variable Number 42 Variable PlasmaGlucoseRefRangeHigh Type Numeric Length 8 Format NONE Label Plasma glucose high reference range

Variable Number 43 Variable PlasmaGlucoseday Type Numeric Length 8 Format NONE Label Plasma glucose day

Variable Number 44 Variable PlasmaGlucoseMonth Type Character Length 3 Format \$3. Label Plasma glucose month

Variable Number 45 Variable PlasmaGlucoseYear Type Numeric Length 8 Format NONE Label Plasma glucose year

Variable Number 46 Variable pHResult Type Numeric Length 8 Format NONE Label pH(serum) result

Variable Number 47 Variable pHUnits Type Character Length 7 Format \$7. Label pH(serum) units

Variable Number 48 Variable pHReferenceRangeLow Type Numeric Length 8 Format NONE Label pH(serum) low reference range

Variable Number 49 Variable pHReferenceRangeHigh Type Numeric Length 8 Format NONE Label pH(serum) high reference range

Variable Number 50 Variable pHday Type Numeric Length 8 Format NONE Label pH(serum) day

Variable Number 51 Variable pHMonth Type Character Length 3 Format \$3. Label pH(serum) month

Variable Number 52 Variable pHYear Type Numeric Length 8 Format NONE Label pH(serum) year

Variable Number 53 Variable SerumKetonesResult Type Numeric Length 8 Format NONE Label Serum ketones result

Variable Number 54 Variable SerumKetonesUnits Type Character Length 7 Format \$7. Label Serum ketones units

Variable Number 55 Variable SerumKetonesRefRangeLow Type Numeric Length 8 Format NONE Label Serum ketones low reference range

Variable Number 56 Variable SerumKetonesRefRangeHigh Type Numeric Length 8 Format NONE Label Serum ketones high reference range

Variable Number 57 Variable SerumKetonesday Type Numeric Length 8 Format NONE Label Serum ketones day

Variable Number 58 Variable SerumKetonesMonth Type Character Length 3 Format \$3. Label Serum ketones month

Variable Number 59 Variable SerumKetonesYear Type Numeric Length 8 Format NONE Label Serum ketones year

Variable Number 60 Variable AnionGapResult Type Numeric Length 8 Format NONE Label Anion gap result

Variable Number 61 Variable AnionGapUnits Type Character Length 22 Format \$22. Label Anion gap units

Variable Number 62 Variable AnionGapRefRangeLow Type Numeric Length 8 Format NONE Label Anion gap low reference range

Variable Number 63 Variable AnionGapRefRangeHigh Type Numeric Length 8 Format NONE Label Anion gap high reference range

Variable Number 64 Variable AnionGapDay Type Numeric Length 8 Format NONE Label Anion gap day

Variable Number 65 Variable AnionGapMonth Type Character Length 3 Format \$3. Label Anion gap month

Variable Number 66 Variable AnionGapYear Type Numeric Length 8 Format NONE Label Anion gap year

Variable Number 67 Variable BicarbonateResult Type Numeric Length 8 Format NONE Label Bicarbonate result

Variable Number 68 Variable BicarbonateUnits Type Character Length 22 Format \$22. Label Bicarbonate units

Variable Number 69 Variable BicarbonateRefRangeLow Type Numeric Length 8 Format NONE Label Bicarbonate low reference range

Variable Number 70 Variable BicarbonateRefRangeHigh Type Numeric Length 8 Format NONE Label Bicarbonate high reference range

Variable Number 71 Variable BicarbonateDay Type Numeric Length 8 Format NONE Label bicarbonate day

Variable Number 72 Variable BicarbonateMonth Type Character Length 3 Format \$3. Label Bicarbonate month

Variable Number 73 Variable BicarbonateYear Type Numeric Length 8 Format NONE Label Bicarbonate year

Variable Number 74 Variable UrineKetonesResult Type Numeric Length 8 Format NONE Label Urine ketones result

Variable Number 75 Variable UrineKetonesUnits Type Character Length 7 Format \$7. Label Urine ketones units

Variable Number 76 Variable UrineKetonesRefRangeLow Type Numeric Length 8 Format NONE Label Urine ketones low reference range

Variable Number 77 Variable UrineKetonesRefRangeHigh Type Numeric Length 8 Format NONE Label Urine ketones high reference range

Variable Number 78 Variable UrineKetonesDay Type Numeric Length 8 Format NONE Label Urine ketones day

Variable Number 79 Variable UrineKetonesMonth Type Character Length 3 Format \$3. Label Urine ketones month

Variable Number 80 Variable UrineKetonesYear Type Numeric Length 8 Format NONE Label Urine ketones year

Variable Number 81 Variable Result1\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 82 Variable Units1\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 83 Variable LowerReferenceRange1\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range

Variable Number 84 Variable HigherReferenceRange1\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 85 Variable GlucoseDay1\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 86 Variable GlucoseMonth1\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 87 Variable GlucoseYear1\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 88 Variable GlucoseType1\_1 Type Character Length 9 Format \$9. Label Glucose type

Variable Number 89 Variable MeasuredBy1\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 90 Variable Result2\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 91 Variable Units2\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 92 Variable LowerReferenceRange2\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range

Variable Number 93 Variable HigherReferenceRange2\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 94 Variable GlucoseDay2\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 95 Variable GlucoseMonth2\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 96 Variable GlucoseYear2\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 97 Variable GlucoseType2\_1 Type Character Length 9 Format \$9. Label Glucose type

Variable Number 98 Variable MeasuredBy2\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 99 Variable Result3\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 100 Variable Units3\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 101 Variable LowerReferenceRange3\_1 Type Numeric Length 8 Format NONE Label Glucose level lower reference range

Variable Number 102 Variable HigherReferenceRange3\_1 Type Numeric Length 8 Format NONE Label Glucose level higher reference range

Variable Number 103 Variable GlucoseDay3\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 104 Variable GlucoseMonth3\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 105 Variable GlucoseYear3\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 106 Variable GlucoseType3\_1 Type Character Length 9 Format \$9. Label Glucose type

Variable Number 107 Variable MeasuredBy3\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 108 Variable Result4\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 109 Variable Units4\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 110 Variable LowerReferenceRange4\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range

Variable Number 111 Variable HigherReferenceRange4\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 112 Variable GlucoseDay4\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 113 Variable GlucoseMonth4\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 114 Variable GlucoseYear4\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 115 Variable GlucoseType4\_1 Type Character Length 9 Format \$9. Label Glucose type

Variable Number 116 Variable MeasuredBy4\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 117 Variable Result5\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 118 Variable Units5\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 119 Variable LowerReferenceRange5\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range

Variable Number 120 Variable HigherReferenceRange5\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 121 Variable GlucoseDay5\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 122 Variable GlucoseMonth5\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 123 Variable GlucoseYear5\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 124 Variable GlucoseType5\_1 Type Character Length 9 Format \$9. Label Glucose type

Variable Number 125 Variable MeasuredBy5\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 126 Variable Result6\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 127 Variable Units6\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 128 Variable LowerReferenceRange6\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range



Variable Number 129 Variable HigherReferenceRange6\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 130 Variable GlucoseDay6\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 131 Variable GlucoseMonth6\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 132 Variable GlucoseYear6\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 133 Variable GlucoseType6\_1 Type Character Length 9 Format \$9. Label Glucose type

Variable Number 134 Variable MeasuredBy6\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 135 Variable Result7\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 136 Variable Units7\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 137 Variable LowerReferenceRange7\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range

Variable Number 138 Variable HigherReferenceRange7\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 139 Variable GlucoseDay7\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 140 Variable GlucoseMonth7\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 141 Variable GlucoseYear7\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 142 Variable GlucoseType7\_1 Type Character Length 9 Format \$9. Label Glucose type

Variable Number 143 Variable MeasuredBy7\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 144 Variable Result8\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 145 Variable Units8\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 146 Variable LowerReferenceRange8\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range

Variable Number 147 Variable HigherReferenceRange8\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 148 Variable GlucoseDay8\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 149 Variable GlucoseMonth8\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 150 Variable GlucoseYear8\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 151 Variable GlucoseType8\_1 Type Character Length 7 Format \$7. Label Glucose type

Variable Number 152 Variable MeasuredBy8\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 153 Variable Result9\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 154 Variable Units9\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 155 Variable LowerReferenceRange9\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range

Variable Number 156 Variable HigherReferenceRange9\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 157 Variable GlucoseDay9\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 158 Variable GlucoseMonth9\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 159 Variable GlucoseYear9\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 160 Variable GlucoseType9\_1 Type Character Length 6 Format \$6. Label Glucose type

Variable Number 161 Variable MeasuredBy9\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 162 Variable Result10\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 163 Variable Units10\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 164 Variable LowerReferenceRange10\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range

Variable Number 165 Variable HigherReferenceRange10\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 166 Variable GlucoseDay10\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 167 Variable GlucoseMonth10\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 168 Variable GlucoseYear10\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 169 Variable GlucoseType10\_1 Type Character Length 7 Format \$7. Label Glucose type

Variable Number 170 Variable MeasuredBy10\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 171 Variable Result11\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 172 Variable Units11\_1 Type Character Length 6 Format \$6. Label Glucose level units

Variable Number 173 Variable LowerReferenceRange11\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range

Variable Number 174 Variable HigherReferenceRange11\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 175 Variable GlucoseDay11\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 176 Variable GlucoseMonth11\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 177 Variable GlucoseYear11\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 178 Variable GlucoseType11\_1 Type Character Length 6 Format \$6. Label Glucose type

Variable Number 179 Variable MeasuredBy11\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 180 Variable Result12\_1 Type Numeric Length 8 Format NONE Label Glucose level result

Variable Number 181 Variable Units12\_1 Type Character Length 1 Format \$1. Label Glucose level units

Variable Number 182 Variable LowerReferenceRange12\_1 Type Numeric Length 8 Format NONE Label Glucose level low reference range

Variable Number 183 Variable HigherReferenceRange12\_1 Type Numeric Length 8 Format NONE Label Glucose level high reference range

Variable Number 184 Variable GlucoseDay12\_1 Type Numeric Length 8 Format NONE Label Glucose day

Variable Number 185 Variable GlucoseMonth12\_1 Type Character Length 3 Format \$3. Label Glucose month

Variable Number 186 Variable GlucoseYear12\_1 Type Numeric Length 8 Format NONE Label Glucose year

Variable Number 187 Variable GlucoseType12\_1 Type Character Length 6 Format \$6. Label Glucose type

Variable Number 188 Variable MeasuredBy12\_1 Type Character Length 9 Format \$9. Label Glucose levels measured by

Variable Number 189 Variable HbA1cResult Type Numeric Length 8 Format NONE Label Other laboratory values hba1c result

Variable Number 190 Variable HbA1cLowerReferenceRange Type Numeric Length 8 Format NONE Label Other laboratory values hba1c low reference range

Variable Number 191 Variable HbA1chigherrReferenceRange Type Numeric Length 8 Format NONE Label Other laboratory values hba1c high reference range

Variable Number 192 Variable HbA1cDay Type Numeric Length 8 Format NONE Label Other laboratory values hba1c day

Variable Number 193 Variable HbA1cMonth Type Character Length 3 Format \$3. Label Other laboratory values hba1c month

Variable Number 194 Variable HbA1cYear Type Numeric Length 8 Format NONE Label Other laboratory values hba1c year

Variable Number 195 Variable Currentvisitorlastscheduledvis Type Character Length 8 Format \$8. Label Current visit or last scheduled visit preceding diagnosis of diabetes

### Data Set Name: tn07\_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 ParticipantBetween3and45Or3and Type Character Length 3 Format \$3. Label Inclusion Is the participant between 3 and 45 years of age and a sibling offspring or parent of an individual with T1D OR participant between 3 and 20 years of age with another relative with T1D

Variable Number 5 Variable ParticipantWillingToAcceptRand Type Character Length 3 Format \$3. Label Inclusion Is the participant willing to accept random assignments

Variable Number 6 Variable DidParticipantConfirmedPositiv Type Character Length 3 Format \$3. Label Inclusion Does the participant have confirmed positive mIAA with in the past 6 months

Variable Number 7 Variable ParticipantHasAtleastOnesample Type Character Length 3 Format \$3. Label Inclusion Does the participant have at least one other antibody present on two separate samples One of which was drawn with in the past six months

Variable Number 8 Variable ParticipantHasOGTTPast7weeks Type Character Length 3 Format \$3. Label Inclusion Does the participant have a normal OGTT within the past 7 weeks

Variable Number 9 Variable TwoConsecutiveNormalOGTTs Type Character Length 3 Format \$3. Label If yes has the participant had two consecutive normal OGTTs since the abnormal OGTT

Variable Number 10 Variable ParticipantHasT1D Type Character Length 3 Format \$3. Label Exclusion Does the participant have T1D

Variable Number 11 Variable participantPreviouslyEnrolledI Type Character Length 2 Format \$2. Label Exclusion Has the participant previously been enrolled in another clinical trial for T1D prevention

Variable Number 12 Variable participantImmunodeficient Type Character Length 2 Format \$2. Label Exclusion Is the participant immunodeficient

Variable Number 13 Variable ParticipantHaDiseaseWhichPrevent Type Character Length 2 Format \$2. Label Exclusion Does the participant have a disease which would limit his/her ability to participate in the study

Variable Number 14 Variable ParticipantTreatedWithImmunosu Type Character Length 3 Format \$3.  
Label Exclusion Has the participant been treated with immunosuppressive drugs or glucocorticoids within the past 2 years for a period of more than 3 months

Variable Number 15 Variable ParticipantHasHLADQ10102DQB106 Type Character Length 3 Format \$3.  
Label Exclusion Does the participant have the HLA DQA10102 DQB10602 Haplotype

Variable Number 16 Variable ParticipanttakingMedicationsAf Type Character Length 3 Format \$3. Label  
Exclusion is the participant taking any medications that affect glucose homeostasis

Variable Number 17 Variable ParticipantHasTreatmentWithIns Type Character Length 3 Format \$3. Label  
Exclusion Does the participant have a history of treatment with insulin or any oral hypoglycemic agents

Variable Number 18 Variable ParticipantEverHadAbnormalOGTT Type Character Length 3 Format \$3.  
Label Exclusion Has the participant ever had an abnormal OGTT

Variable Number 19 Variable ParticipantPregnantOrPlanningb Type Character Length 2 Format \$2. Label  
Exclusion Is the participant pregnant or planning on becoming pregnant during the course of the study

Variable Number 20 Variable AnyoneInFamilyWholsRandomizedI Type Character Length 3 Format \$3.  
Label Is there anyone in your immediate family or living n your household who is currently randomized in the Oral Insulin Trial

Variable Number 21 Variable HowManyIndivdualsInFamilyWhoAr Type Numeric Length 8 Format NONE  
Label If Yes specify how many individuals

Variable Number 22 Variable FamilyMemberParticipantId1\_1 Type Character Length 9 Format \$9. Label  
Participant ID

Variable Number 23 Variable FamilyMemberParticipantRela1\_1 Type Character Length 17 Format \$17.  
Label Participant Relationship

Variable Number 24 Variable FamilyMemberParticipantId2\_1 Type Character Length 1 Format \$1. Label  
Participant ID

Variable Number 25 Variable FamilyMemberParticipantRela2\_1 Type Character Length 1 Format \$1.  
Label Participant Relationship

Variable Number 26 Variable FamilyMemberParticipantId3\_1 Type Character Length 1 Format \$1. Label  
Participant ID

Variable Number 27 Variable FamilyMemberParticipantRela3\_1 Type Character Length 1 Format \$1.  
Label Participant Relationship

Variable Number 28 Variable FamilyMemberParticipantId4\_1 Type Character Length 1 Format \$1. Label  
Participant ID

Variable Number 29 Variable FamilyMemberParticipantRela4\_1 Type Character Length 1 Format \$1.  
Label Participant Relationship

Variable Number 30 Variable FamilyMemberParticipantId5\_1 Type Character Length 1 Format \$1. Label Participant ID

Variable Number 31 Variable FamilyMemberParticipantRela5\_1 Type Character Length 1 Format \$1. Label Participant Relationship

Variable Number 32 Variable FamilyMemberParticipantId6\_1 Type Character Length 1 Format \$1. Label Participant ID

Variable Number 33 Variable FamilyMemberParticipantRela6\_1 Type Character Length 1 Format \$1. Label Participant Relationship

Variable Number 34 Variable FamilyMemberParticipantId7\_1 Type Character Length 1 Format \$1. Label Participant ID

Variable Number 35 Variable FamilyMemberParticipantRela7\_1 Type Character Length 1 Format \$1. Label Participant Relationship

Variable Number 36 Variable ParticipantRandomized Type Character Length 3 Format \$3. Label Was the participant randomized

Variable Number 37 Variable RandomizationDateDay Type Numeric Length 8 Format NONE Label Date of Randomization day

Variable Number 38 Variable RandomizationDateMonth Type Character Length 3 Format \$3. Label Date of Randomization month

Variable Number 39 Variable RandomizationDateYear Type Numeric Length 8 Format NONE Label Date of Randomization year

Variable Number 40 Variable RandomizationNumber Type Character Length 8 Format \$8. Label Randomization Number

Variable Number 41 Variable NoRandomizationSpecifyWhy Type Character Length 1 Format \$1. Label If NO Explain

Variable Number 42 Variable IVGTTIfneededPerformedOnVisitD Type Character Length 3 Format \$3. Label The specimens that should be drawn during this visit IVGTTif needed performed on this visit date

Variable Number 43 Variable IVGTTIfNotPerformedCollectedDa Type Numeric Length 8 Format NONE Label The specimens that should be drawn during this visit IVGTTif needed If Not performed on this date specify collected day

Variable Number 44 Variable IVGTTIfNotPerformedCollectedMo Type Character Length 3 Format \$3. Label The specimens that should be drawn during this visit IVGTTif needed If Not performed on this date specify collected month

Variable Number 45 Variable IVGTTIfNotPerformedCollectedYe Type Numeric Length 8 Format NONE Label The specimens that should be drawn during this visit IVGTTif needed If Not performed on this date specify collected year

Variable Number 46 Variable DispensationOfStudyDrugPerform Type Character Length 3 Format \$3.  
Label The specimens that should be drawn during this visit Dispensation of study drug performed on this visit date

Variable Number 47 Variable DispensationOfStudyDrugNotPerf Type Numeric Length 8 Format NONE  
Label The specimens that should be drawn during this visit Dispensation of study drug if Not performed on visit date specify collected day

Variable Number 48 Variable DispensationOfStudyDrugNotPerf2 Type Character Length 3 Format \$3.  
Label The specimens that should be drawn during this visit Dispensation of study drug if Not performed on visit date specify collected month

Variable Number 49 Variable DispensationOfStudyDrugNotPerf3 Type Numeric Length 8 Format NONE  
Label The specimens that should be drawn during this visit Dispensation of study drug if Not performed on visit date specify collected year

Variable Number 50 Variable EligibilityCommitteeOverride Type Character Length 3 Format \$3. Label  
Subject is eligible per eligibility committee

### Data Set Name: [tn07\\_followupdrugallocation.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 VisitDateDay Type Numeric Length 8 Format NONE Label Visit Date Day

Variable Number 5 Variable VisitDateMonth Type Character Length 3 Format \$3. Label Visit Date Month

Variable Number 6 Variable VisitDateYear Type Numeric Length 8 Format NONE Label Visit Date Year

Variable Number 7 Variable HaveYouCollectedAllBottlesOfRe Type Character Length 3 Format \$3. Label  
Have you collected all bottles of returned study drug empty partially full and full and determined the number of new bottles that need to be allocated to the participant

Variable Number 8 Variable HaveYouCompletedTheDrugAllocat Type Character Length 3 Format \$3.  
Label Have you completed the Drug Allocation Request Form and faxed it to EMINENT

Variable Number 9 Variable HaveYouReceivedTheDrugAllocati Type Character Length 3 Format \$3. Label  
Have you received the Drug Allocation Assignment Report from EMINENT

Variable Number 10 Variable DateofDrugAllocationAssignment Type Numeric Length 8 Format NONE  
Label Date of Drug Allocation Assignment Day

Variable Number 11 Variable DateofDrugAllocationAssignment2 Type Character Length 3 Format \$3.  
Label Date of Drug Allocation Assignment Month

Variable Number 12 Variable DateofDrugAllocationAssignment3 Type Numeric Length 8 Format NONE  
Label Date of Drug Allocation Assignment Year

Variable Number 13 Variable AllocationID Type Numeric Length 8 Format NONE Label Allocation ID

Variable Number 14 Variable HaveYouPulledFromTheReserveSup Type Character Length 3 Format \$3.  
Label Have you pulled from the reserve supply the bottles indicated on the Drug Allocation Assignment Report from EMINENT

Variable Number 15 Variable HaveYouDispensed7BottlesOfStud Type Character Length 3 Format \$3.  
Label Have you dispensed 7 bottles of study drug to the participant including any full unopened bottles that were redispensed and all newly allocated bottles as listed on the Allocation Assignment Report

Variable Number 16 Variable WereThereAnyUnusualCircumstanc Type Character Length 3 Format \$3.  
Label Were there any unusual circumstances

Variable Number 17 Variable IfYESdescribe Type Character Length 631 Format \$631. Label If YES Describe

### Data Set Name: [tn07\\_h1n1vaccination.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 DidSubjectReceiveH1N1Vaccinati Type Character Length 3 Format \$3. Label H1N1 Vaccination Did subject receive H1N1 Vaccination

Variable Number 5 Variable H1N1VaccinationType Type Character Length 16 Format \$16. Label H1N1 Vaccination Received H1N1 Vaccination If yes type

Variable Number 6 Variable H1N1VaccinationDateDay Type Numeric Length 8 Format NONE Label H1N1 Vaccination Received H1N1 Vaccination If yes vaccination date day

Variable Number 7 Variable H1N1VaccinationDateMonth Type Character Length 3 Format \$3. Label H1N1 Vaccination Received H1N1 Vaccination If yes vaccination date month

Variable Number 8 Variable H1N1VaccinationDateYear Type Numeric Length 8 Format NONE Label H1N1 Vaccination Received H1N1 Vaccination If yes vaccination date year

Variable Number 9 Variable DidSubjectReceiveH1N1Vaccinati2 Type Character Length 3 Format \$3. Label H1N1 Vaccination Did subject receive H1N1 Vaccination booster

Variable Number 10 Variable H1N1VaccinationBoosterType Type Character Length 16 Format \$16. Label H1N1 Vaccination Receive H1N1 Vaccination booster If yes type

Variable Number 11 Variable H1N1VaccinationBoosterDateDay Type Numeric Length 8 Format NONE Label H1N1 Vaccination Receive H1N1 Vaccination booster If yes booster date day

Variable Number 12 Variable H1N1VaccinationBoosterDateMont Type Character Length 3 Format \$3. Label H1N1 Vaccination Receive H1N1 Vaccination booster If yes booster date month



Variable Number 13 Variable H1N1VaccinationBoosterDateYear Type Numeric Length 8 Format NONE  
Label H1N1 Vaccination Receive H1N1 Vaccination booster If yes booster date year

### Data Set Name: tn07\_initialvisit.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 SiteVisitOtherThanPrimaryStudy Type Character Length 3 Format \$3. Label  
Did the visit occur at a site other than at the primary study site

Variable Number 5 Variable SiteVisitOtherThanPrimaryStudy2 Type Character Length 4 Format \$4. Label  
If YES record site number for reimbursement

Variable Number 6 Variable InformedConsentObtainedDay Type Numeric Length 8 Format NONE Label  
Date written informed consent obtained day

Variable Number 7 Variable InformedConsentObtainedMonth Type Character Length 3 Format \$3. Label  
Date written informed consent obtained month

Variable Number 8 Variable InformedConsentObtainedYear Type Numeric Length 8 Format NONE Label  
Date written informed consent obtained year

Variable Number 9 Variable ParticipantPermissionOnOnsetFo Type Character Length 68 Format \$68.  
Label On the consent form did the participant give permission to store samples for future testing

Variable Number 10 Variable FirstOrSecondDegreeRelativeDia Type Character Length 3 Format \$3. Label  
Have any of your first or second degree been diagnosed with T1D since the completion of Natural  
History Family History FormNH01F

Variable Number 11 Variable RelativeWithT1D1\_1 Type Character Length 22 Format \$22. Label Relative  
with type 1 diabetes

Variable Number 12 Variable SexOfRelativeWithT1D1\_1 Type Character Length 6 Format \$6. Label Sex of  
Relative

Variable Number 13 Variable AgeOfRelativeWithT1D1\_1 Type Numeric Length 8 Format NONE Label  
Current Age of Relative

Variable Number 14 Variable AgeOfOnsetInRelative1\_1 Type Numeric Length 8 Format NONE Label Age  
of T1D Onset in relative

Variable Number 15 Variable AgeRelativeStartedInsulin1\_1 Type Numeric Length 8 Format NONE Label  
Age relative started insulin

Variable Number 16 Variable RelativeComments1\_1 Type Character Length 154 Format \$154. Label  
Relative Comments

Variable Number 17 Variable RelativeWithT1D2\_1 Type Character Length 17 Format \$17. Label Relative with type 1 diabetes

Variable Number 18 Variable SexOfRelativeWithT1D2\_1 Type Character Length 6 Format \$6. Label Sex of Relative

Variable Number 19 Variable AgeOfRelativeWithT1D2\_1 Type Numeric Length 8 Format NONE Label Current Age of Relative

Variable Number 20 Variable AgeOfOnsetInRelative2\_1 Type Numeric Length 8 Format NONE Label Age of T1D Onset in relative

Variable Number 21 Variable AgeRelativeStartedInsulin2\_1 Type Numeric Length 8 Format NONE Label Age relative started insulin

Variable Number 22 Variable RelativeComments2\_1 Type Character Length 39 Format \$39. Label Relative Comments

Variable Number 23 Variable RelativeWithT1D3\_1 Type Character Length 17 Format \$17. Label Relative with type 1 diabetes

Variable Number 24 Variable SexOfRelativeWithT1D3\_1 Type Character Length 6 Format \$6. Label Sex of Relative

Variable Number 25 Variable AgeOfRelativeWithT1D3\_1 Type Numeric Length 8 Format NONE Label Current Age of Relative

Variable Number 26 Variable AgeOfOnsetInRelative3\_1 Type Numeric Length 8 Format NONE Label Age of T1D Onset in relative

Variable Number 27 Variable AgeRelativeStartedInsulin3\_1 Type Numeric Length 8 Format NONE Label Age relative started insulin

Variable Number 28 Variable RelativeComments3\_1 Type Character Length 40 Format \$40. Label Relative Comments

Variable Number 29 Variable RelativeWithT1D4\_1 Type Character Length 13 Format \$13. Label Relative with type 1 diabetes

Variable Number 30 Variable SexOfRelativeWithT1D4\_1 Type Character Length 6 Format \$6. Label Sex of Relative

Variable Number 31 Variable AgeOfRelativeWithT1D4\_1 Type Numeric Length 8 Format NONE Label Current Age of Relative

Variable Number 32 Variable AgeOfOnsetInRelative4\_1 Type Numeric Length 8 Format NONE Label Age of T1D Onset in relative

Variable Number 33 Variable AgeRelativeStartedInsulin4\_1 Type Numeric Length 8 Format NONE Label Age relative started insulin

Variable Number 34 Variable RelativeComments4\_1 Type Character Length 8 Format \$8. Label Relative Comments

Variable Number 35 Variable RelativeWithT1D5\_1 Type Character Length 13 Format \$13. Label Relative with type 1 diabetes

Variable Number 36 Variable SexOfRelativeWithT1D5\_1 Type Character Length 4 Format \$4. Label Sex of Relative

Variable Number 37 Variable AgeOfRelativeWithT1D5\_1 Type Numeric Length 8 Format NONE Label Current Age of Relative

Variable Number 38 Variable AgeOfOnsetInRelative5\_1 Type Numeric Length 8 Format NONE Label Age of T1D Onset in relative

Variable Number 39 Variable AgeRelativeStartedInsulin5\_1 Type Numeric Length 8 Format NONE Label Age relative started insulin

Variable Number 40 Variable RelativeComments5\_1 Type Character Length 1 Format \$1. Label Relative Comments

Variable Number 41 Variable RelativeWithT1D6\_1 Type Character Length 1 Format \$1. Label Relative with type 1 diabetes

Variable Number 42 Variable SexOfRelativeWithT1D6\_1 Type Character Length 1 Format \$1. Label Sex of Relative

Variable Number 43 Variable AgeOfRelativeWithT1D6\_1 Type Numeric Length 8 Format NONE Label Current Age of Relative

Variable Number 44 Variable AgeOfOnsetInRelative6\_1 Type Numeric Length 8 Format NONE Label Age of T1D Onset in relative

Variable Number 45 Variable AgeRelativeStartedInsulin6\_1 Type Numeric Length 8 Format NONE Label Age relative started insulin

Variable Number 46 Variable RelativeComments6\_1 Type Character Length 1 Format \$1. Label Relative Comments

Variable Number 47 Variable RelativeWithT1D7\_1 Type Character Length 1 Format \$1. Label Relative with type 1 diabetes

Variable Number 48 Variable SexOfRelativeWithT1D7\_1 Type Character Length 1 Format \$1. Label Sex of Relative

Variable Number 49 Variable AgeOfRelativeWithT1D7\_1 Type Numeric Length 8 Format NONE Label Current Age of Relative

Variable Number 50 Variable AgeOfOnsetInRelative7\_1 Type Numeric Length 8 Format NONE Label Age of T1D Onset in relative

Variable Number 51 Variable AgeRelativeStartedInsulin7\_1 Type Numeric Length 8 Format NONE Label Age relative started insulin

Variable Number 52 Variable RelativeComments7\_1 Type Character Length 1 Format \$1. Label Relative Comments

Variable Number 53 Variable RelativeWithT1D8\_1 Type Character Length 1 Format \$1. Label Relative with type 1 diabetes

Variable Number 54 Variable SexOfRelativeWithT1D8\_1 Type Character Length 1 Format \$1. Label Sex of Relative

Variable Number 55 Variable AgeOfRelativeWithT1D8\_1 Type Numeric Length 8 Format NONE Label Current Age of Relative

Variable Number 56 Variable AgeOfOnsetInRelative8\_1 Type Numeric Length 8 Format NONE Label Age of T1D Onset in relative

Variable Number 57 Variable AgeRelativeStartedInsulin8\_1 Type Numeric Length 8 Format NONE Label Age relative started insulin

Variable Number 58 Variable RelativeComments8\_1 Type Character Length 1 Format \$1. Label Relative Comments

Variable Number 59 Variable AnyoneInFamilyEverDiagnosedWit Type Character Length 3 Format \$3. Label Has anyone in family ever been diagnosed with an autoimmune disease

Variable Number 60 Variable CodeCorrespondingWithDiagno1\_1 Type Character Length 50 Format \$50. Label If YES Record the code that corresponds with the daignosis

Variable Number 61 Variable SpecifyOthersCorrespondingT1\_1 Type Character Length 53 Format \$53. Label If others specify that corresponds with diagnosis

Variable Number 62 Variable CodeCorrespondingWithDiagno2\_1 Type Character Length 50 Format \$50. Label If YES Record the code that corresponds with the daignosis

Variable Number 63 Variable SpecifyOthersCorrespondingT2\_1 Type Character Length 45 Format \$45. Label If others specify that corresponds with diagnosis

Variable Number 64 Variable CodeCorrespondingWithDiagno3\_1 Type Character Length 36 Format \$36. Label If YES Record the code that corresponds with the daignosis

Variable Number 65 Variable SpecifyOthersCorrespondingT3\_1 Type Character Length 37 Format \$37. Label If others specify that corresponds with diagnosis

Variable Number 66 Variable CodeCorrespondingWithDiagno4\_1 Type Character Length 27 Format \$27. Label If YES Record the code that corresponds with the daignosis

Variable Number 67 Variable SpecifyOthersCorrespondingT4\_1 Type Character Length 38 Format \$38. Label If others specify that corresponds with diagnosis

Variable Number 68 Variable CodeCorrespondingWithDiagno5\_1 Type Character Length 27 Format \$27.  
Label If YES Record the code that corresponds with the daignosis

Variable Number 69 Variable SpecifyOthersCorrespondingT5\_1 Type Character Length 24 Format \$24.  
Label If others specify that corresponds with diagnosis

Variable Number 70 Variable CodeCorrespondingWithDiagno6\_1 Type Character Length 27 Format \$27.  
Label If YES Record the code that corresponds with the daignosis

Variable Number 71 Variable SpecifyOthersCorrespondingT6\_1 Type Character Length 31 Format \$31.  
Label If others specify that corresponds with diagnosis

Variable Number 72 Variable EverDiagnosedWithAutoimmuneDis Type Character Length 3 Format \$3.  
Label Have you ever been diagnosed with an autoimmune diasease

Variable Number 73 Variable EverDiagnosedWithAutoimmune1\_1 Type Character Length 50 Format \$50.  
Label If YES Record the code that corresponds with the diagnosis

Variable Number 74 Variable OthersCorrespondingToDiagno1\_1 Type Character Length 27 Format \$27.  
Label Others corresponding with the diagnosis

Variable Number 75 Variable EverDiagnosedWithAutoimmune2\_1 Type Character Length 25 Format \$25.  
Label If YES Record the code that corresponds with the diagnosis

Variable Number 76 Variable OthersCorrespondingToDiagno2\_1 Type Character Length 1 Format \$1.  
Label Others corresponding with the diagnosis

Variable Number 77 Variable EverDiagnosedWithAutoimmune3\_1 Type Character Length 1 Format \$1.  
Label If YES Record the code that corresponds with the diagnosis

Variable Number 78 Variable OthersCorrespondingToDiagno3\_1 Type Character Length 1 Format \$1.  
Label Others corresponding with the diagnosis

Variable Number 79 Variable AsthmaOrSeasonalAllergies Type Character Length 3 Format \$3. Label Ever  
had asthma or seasonal allergies

Variable Number 80 Variable IfFemaleDoesParticipantHasPote Type Character Length 3 Format \$3. Label  
If FEMALE does the participant have reproductive potential

Variable Number 81 Variable IfFemaleIsParticipantSexuallyA Type Character Length 3 Format \$3. Label If  
FEMALE is the participant sexually active

Variable Number 82 Variable IsSheUsingFormOfBirthControl Type Character Length 3 Format \$3. Label  
Does she currently use a form of birth control

Variable Number 83 Variable PlanOfBecomingPregnantNextYear Type Character Length 2 Format \$2.  
Label Does she plan on becoming pregnant in the next year

Variable Number 84 Variable UrinePregnancyTestCompletedThi Type Character Length 3 Format \$3.  
Label Was a urine pregnancy test completed at this visit

Variable Number 85 Variable UrinePregnancyTestPositive Type Character Length 2 Format \$2. Label If YES was the test result positive

Variable Number 86 Variable TookOtTakingImmunosuppressiveO Type Character Length 3 Format \$3. Label Have you taken in the past or are you currently taking immunosuppressive or steroid drugs

Variable Number 87 Variable TookOtTakingInsulinOrOtherDrug Type Character Length 3 Format \$3. Label Have you taken in the past or are you currently taking insulin or other drugs to treat glucose

Variable Number 88 Variable TookOtTakingGrowthHormoneACPSD Type Character Length 3 Format \$3. Label Have you taken in the past or are you currently taking growth hormone anticonvulsants thiazide or potassiumsparing diuretics betablockers or niacin

Variable Number 89 Variable TookOtTakingNonPrescriptionalI Type Character Length 3 Format \$3. Label Have you taken in the past or are you currently taking any nonprescription medications including vitamin or herbal supplements

Variable Number 90 Variable PhysicalExamPerformedInInitial Type Character Length 3 Format \$3. Label Was a physical exam performed at this initial visit

Variable Number 91 Variable PerformedDay Type Numeric Length 8 Format NONE Label If NO day performed

Variable Number 92 Variable PerformedMonth Type Character Length 3 Format \$3. Label If NO performed month

Variable Number 93 Variable PerformedYear Type Numeric Length 8 Format NONE Label If NO performed year

Variable Number 94 Variable SeatedArmBPSystolic Type Numeric Length 8 Format NONE Label Collection Of physical Assessments seated arm blood pressure systolic

Variable Number 95 Variable SeatedArmBPDiaStolic Type Numeric Length 8 Format NONE Label Collection Of physical Assessments seated arm blood pressure diastolic

Variable Number 96 Variable WeighInKg Type Numeric Length 8 Format NONE Label Collection Of physical Assessments weight in kg

Variable Number 97 Variable WeighInlbs Type Numeric Length 8 Format NONE Label Collection Of physical Assessments weight in lbs

Variable Number 98 Variable HeightInCm Type Numeric Length 8 Format NONE Label Collection Of physical Assessments height in cm

Variable Number 99 Variable HeightInIn Type Numeric Length 8 Format NONE Label Collection Of physical Assessments height in inches

Variable Number 100 Variable AbdominalCircumferenceInCm Type Numeric Length 8 Format NONE Label Collection Of physical Assessments Abdominal circumference

Variable Number 101 Variable AbdominalCircumferenceIn Type Numeric Length 8 Format NONE Label Collection Of physical Assessments Abdominal circumference in Inches

Variable Number 102 Variable HEENTReportedNormal Type Character Length 3 Format \$3. Label Record of systemsHEENTparticipant reported normal

Variable Number 103 Variable HEENTNormalOnExam Type Character Length 3 Format \$3. Label Record of systemsHEENTNormal on Exam

Variable Number 104 Variable HEENTAbnormalSpecify Type Character Length 184 Format \$184. Label Record of systemsHEENTIf either abnormal explain

Variable Number 105 Variable NeckReportedNormal Type Character Length 3 Format \$3. Label Record of systemsNeckparticipant reported normal

Variable Number 106 Variable NeckNormalOnExam Type Character Length 3 Format \$3. Label Record of systemsNeckNormal on exam

Variable Number 107 Variable NeckAbnormalSpecify Type Character Length 111 Format \$111. Label Record of systemsNeckIf abnormal specify

Variable Number 108 Variable ThyroidReportedNormal Type Character Length 3 Format \$3. Label Record of systemsThyroidparticipant reported normal

Variable Number 109 Variable ThyroidNormalOnExam Type Character Length 3 Format \$3. Label Record of systemsThyroidNormal on Exam

Variable Number 110 Variable ThyroidAbnormalExplain Type Character Length 86 Format \$86. Label Record of systemsThyroidIf abnormal explain

Variable Number 111 Variable LungsReportedNormal Type Character Length 3 Format \$3. Label Record of systemsLungsparticipant reported normal

Variable Number 112 Variable LungsNormalOnExam Type Character Length 3 Format \$3. Label Record of systemsLungsNormal on exam

Variable Number 113 Variable LungsAbnormalSpecify Type Character Length 105 Format \$105. Label Record of systemsLungsIf abnormal explain

Variable Number 114 Variable ChestBreastReportedNormal Type Character Length 3 Format \$3. Label Record of systemschestBreasts

Variable Number 115 Variable ChestBreastNormalOnExam Type Character Length 3 Format \$3. Label Record of systemschestBreastsnormal on exam

Variable Number 116 Variable ChestBreastAbnormalSpecify Type Character Length 63 Format \$63. Label Record of systemschestBreastsif abnormal specify

Variable Number 117 Variable HeartCirculatoryReportedNormal Type Character Length 3 Format \$3. Label Record of systemsheartcirculatoryparticipant reported normal

Variable Number 118 Variable HeartCirculatoryNormalOnExam Type Character Length 3 Format \$3.  
Label Record of systemsheartcirculatoryNormal on exam

Variable Number 119 Variable HeartCirculatoryAbnormalExplai Type Character Length 121 Format \$121.  
Label Record of systemsheartcirculatoryif abnormal explain

Variable Number 120 Variable AbdomenReportedNormal Type Character Length 3 Format \$3. Label  
Record the systemAbdomenparticipant reported normal

Variable Number 121 Variable AbdomenNormalOnExam Type Character Length 3 Format \$3. Label  
Record the systemAbdomennormal on exam

Variable Number 122 Variable AbdomenAbnormalExplain Type Character Length 232 Format \$232.  
Label Record the systemAbdomenif abnormal explain

Variable Number 123 Variable MusculoskeletalReportedNormal Type Character Length 3 Format \$3.  
Label Record the systemMusculoskeletal participant reported normal

Variable Number 124 Variable MusculoskeletalNormalOnExam Type Character Length 3 Format \$3.  
Label Record the systemMusculoskeletal Normal on exam

Variable Number 125 Variable MusculoskeletalAbnormalExplain Type Character Length 96 Format \$96.  
Label Record the systemMusculoskeletal If abnormal explain

Variable Number 126 Variable NeurologicreportedNormal Type Character Length 3 Format \$3. Label  
Record the systemNeurologicparticipant reported normal

Variable Number 127 Variable NeurologicNormalOnExam Type Character Length 3 Format \$3. Label  
Record the systemNeurologicNormal on exam

Variable Number 128 Variable NeurologicAbnormalExplain Type Character Length 80 Format \$80. Label  
Record the systemNeurologicId abnormal explain

Variable Number 129 Variable GenitourinaryReportedNormal Type Character Length 3 Format \$3. Label  
Record the systemGenitourinaryTestesparticipant reported normal

Variable Number 130 Variable GenitourinaryNormalOnExam Type Character Length 3 Format \$3. Label  
Record the systemGenitourinaryTestesNormal on exam

Variable Number 131 Variable GenitourinaryAbnormalExplain Type Character Length 134 Format \$134.  
Label Record the systemGenitourinaryTestesIf abnormal explain

Variable Number 132 Variable SkinOrNailsReportedNormal Type Character Length 3 Format \$3. Label  
Record the systemSkinNailsparticipant reported normal

Variable Number 133 Variable SkinOrNailsNormalOnExam Type Character Length 3 Format \$3. Label  
Record the systemSkinNailsNormal on exam

Variable Number 134 Variable SkinOrNailsAbnormalExplain Type Character Length 164 Format \$164.  
Label Record the systemSkinNailsIf abnormal explain



Variable Number 135 Variable LymphNodesreportedNormal Type Character Length 3 Format \$3. Label Record the systemLymph nodesparticipant reported normal

Variable Number 136 Variable LymphNodesNormalOnExam Type Character Length 3 Format \$3. Label Record the systemLymph nodesNormal on exam

Variable Number 137 Variable LymphNodesAbnormalExplain Type Character Length 87 Format \$87. Label Record the systemLymph nodesIf abnormal explain

Variable Number 138 Variable OtherReportedNormal Type Character Length 3 Format \$3. Label Record the systemOtherparticipant reported normal

Variable Number 139 Variable OtherNormalOnExam Type Character Length 3 Format \$3. Label Record the systemOtherNormal on exam

Variable Number 140 Variable OtherAbnormalExplain Type Character Length 76 Format \$76. Label Record the systemOtherIf abnormal explain

Variable Number 141 Variable OthersSpecify Type Character Length 161 Format \$161. Label Record the systemIf Other Specify

Variable Number 142 Variable TannerStageBreastFemale Type Character Length 3 Format \$3. Label For subjects less than 18 yrs of age record the participants sexual development using the Tanner scale Breastfemale

Variable Number 143 Variable TannerStageGenitaliaMale Type Character Length 3 Format \$3. Label For subjects less than 18 yrs of age record the participants sexual development using the Tanner scale Genitaliamale

Variable Number 144 Variable TannerStagePublicHair Type Character Length 3 Format \$3. Label For subjects less than 18 yrs of age record the participants sexual development using the Tanner scale Public haitboth

Variable Number 145 Variable IVGTTOnVisitDate Type Character Length 3 Format \$3. Label Specimens drawn during the visitIVGTTperformed on visit date

Variable Number 146 Variable IVGTTPerformedDay Type Numeric Length 8 Format NONE Label Specimens drawn during the visitIVGTTIf not performed at this visit specify day

Variable Number 147 Variable IVGTTPerformedMonth Type Character Length 3 Format \$3. Label Specimens drawn during the visitIVGTTIf not performed at this visit specify month

Variable Number 148 Variable IVGTTPerformedYear Type Numeric Length 8 Format NONE Label Specimens drawn during the visitIVGTTIf not performed at this visit specify Year

Variable Number 149 Variable SerumForAutoantibodiesPerforme Type Character Length 3 Format \$3. Label Specimens drawn during the visitSerum for autoantibodies performed on this visit date

Variable Number 150 Variable SerumForAutoantibodiesPerforme2 Type Numeric Length 8 Format NONE Label Specimens drawn during the visitSerum for autoantibodies If not performed on visit datespecify performed day

Variable Number 151 Variable SerumForAutoantibodiesPerforme3 Type Character Length 3 Format \$3.  
Label Specimens drawn during the visitSerum for autoantibodies If not performed on visit datespecify performed month

Variable Number 152 Variable SerumForAutoantibodiesPerforme4 Type Numeric Length 8 Format NONE  
Label Specimens drawn during the visitSerum for autoantibodies If not performed on visit datespecify performed year

Variable Number 153 Variable SamplesForStoragePerformedOnVi Type Character Length 3 Format \$3.  
Label Specimens drawn during the visitsamples for storage performed on this visit date

Variable Number 154 Variable SamplesForStoragePerformedDay Type Numeric Length 8 Format NONE  
Label Specimens drawn during the visitsamples for storage If not performed at this visit specif performed day

Variable Number 155 Variable SamplesForStoragePerformedMont Type Character Length 3 Format \$3.  
Label Specimens drawn during the visitsamples for storage If not performed at this visit specif performed month

Variable Number 156 Variable SamplesForStoragePerformedYear Type Numeric Length 8 Format NONE  
Label Specimens drawn during the visitsamples for storage If not performed at this visit specif performed Year

Variable Number 157 Variable VolunteerUnderstandingAssessme Type Character Length 3 Format \$3.  
Label Volunmteer Understanding Assessment

Variable Number 158 Variable VolunteerUnderstandingAssessme2 Type Numeric Length 8 Format NONE  
Label If VUA VUA VUA not performed at this visit specify perfoemed day

Variable Number 159 Variable VolunteerUnderstandingAssessme3 Type Character Length 3 Format \$3.  
Label If VUA VUA not performed at this visit specify month performed

Variable Number 160 Variable VolunteerUnderstandingAssessme4 Type Numeric Length 8 Format NONE  
Label The apesimens frwawm during this visit Volunteer Understanding Assessment If not performed at this visit specif performed year

Variable Number 161 Variable LifestyleQuestionnairePerforme Type Character Length 3 Format \$3.  
Label Lifestyle Questionnaire performed at this visit

Variable Number 162 Variable LifestyleQuestionnairePerforme2 Type Numeric Length 8 Format NONE  
Label If questionnaire not performed at this visit specify day performed

Variable Number 163 Variable LifestyleQuestionnairePerforme3 Type Character Length 3 Format \$3.  
Label If questionnaire not performed at this visit specify month performed

Variable Number 164 Variable LifestyleQuestionnairePerforme4 Type Numeric Length 8 Format NONE  
Label If questionnaire not performed at this visit specify year performed

**Data Set Name:** tn07\_permanentsitettransfer.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

Variable Number 7 Variable Other\_Specify Type Character Length 2000 Format NONE Label If Other, specify

### Data Set Name: tn07\_phonecontact.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 GatheredInformationContact Type Character Length 23 Format \$23. Label Information gathered from

Variable Number 5 Variable AnyChangesInHealthSinceLastSch Type Character Length 3 Format \$3. Label Have there been any changes in health since the last scheduled visit

Variable Number 6 Variable AnyChangesInConcomitantMedicat Type Character Length 3 Format \$3. Label Have there been any changes in concomitant medications since last scheduled visit

Variable Number 7 Variable ParticipantHasReproductivePote Type Character Length 3 Format \$3. Label If FEMALE does the participant have reproductive potential

Variable Number 8 Variable CurrentlyUsingFormOfBirthContr Type Character Length 3 Format \$3. Label If yes to question D1 above Does she currently use a form of birth control

Variable Number 9 Variable PlanOfBecomingPregnantInNext6M Type Character Length 2 Format \$2. Label If yes to question D1 above Does she plan on becoming pregnant in the next 6 months

Variable Number 10 Variable DosesMissedSinceLastStudyVisit Type Numeric Length 8 Format NONE Label How many doses has the participant missed since the last study visit

Variable Number 11 Variable ParticipantCurrentlyTakingStud Type Character Length 3 Format \$3. Label Is the participant currently taking study drug

### Data Set Name: tn07\_pregnancyconfirmation.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 DoPTMonth Type Character Length 3 Format \$3. Label Date of positive pregnancy test Month

Variable Number 5 Variable DoPTDay Type Numeric Length 8 Format NONE Label Date of positive pregnancy test Day

Variable Number 6 Variable DoPTYear Type Numeric Length 8 Format NONE Label Date of positive pregnancy test Year

Variable Number 7 Variable DoLMCMonth Type Character Length 3 Format \$3. Label Date of last menstrual cycle Month

Variable Number 8 Variable DoLMCDay Type Numeric Length 8 Format NONE Label Date of last menstrual cycle Day

Variable Number 9 Variable DoLMCYear Type Numeric Length 8 Format NONE Label Date of last menstrual cycle Year

Variable Number 10 Variable DoDeliveryMonth Type Character Length 3 Format \$3. Label Estimated date of delivery Month

Variable Number 11 Variable DoDeliveryDay Type Numeric Length 8 Format NONE Label Estimated date of delivery Day

Variable Number 12 Variable DoDeliveryYear Type Numeric Length 8 Format NONE Label Estimated date of delivery Year

Variable Number 13 Variable ParticipantCarryingPregnancyTo Type Character Length 7 Format \$7. Label Is the participant planning on carrying the pregnancy to term

Variable Number 14 Variable WillingToContinueFUVVisits Type Character Length 7 Format \$7. Label Is the participant willing to continue with future followup visits

Variable Number 15 Variable ParticipantsObCareProviderInfor Type Character Length 7 Format \$7. Label Has the participants obstetric care provider been informed of her participation in this study

Variable Number 16 Variable PriorPregnancyNumberUnknown Type Numeric Length 8 Format NONE Label record total number of prior pregnancies unknown

Variable Number 17 Variable TotalNumOfPregNotIncluThisOne Type Numeric Length 8 Format NONE Label Indicate the total number of prior pregnancies not including this one

Variable Number 18 Variable HadComplicationOfPreg Type Character Length 7 Format \$7. Label Has the participant ever experienced a complication of pregnancy

Variable Number 19 Variable Spontaneousmiscarriage Type Character Length 3 Format NONE Label Has the participant ever experienced a spontaneous miscarriage

Variable Number 20 Variable StillBirth Type Character Length 2 Format \$2. Label Has the participant ever experienced a pregnancy that resulted in a still birth

Variable Number 21 Variable NeonatalDeath Type Character Length 2 Format \$2. Label Has the participant ever experienced a pregnancy that resulted in neonatal death

Variable Number 22 Variable PostTermDelivryGT37GWeeks Type Character Length 2 Format \$2. Label Has the participant ever experienced a postterm delivery 37 gestational weeks

Variable Number 23 Variable PostTermDelivryLT42GWeeks Type Character Length 2 Format \$2. Label Has the participant ever experienced a postterm delivery 42 gestational weeks

Variable Number 24 Variable CodedMedStopped Type Character Length 1 Format \$1. Label Has the coded medication been stopped

Variable Number 25 Variable LastAttendedVisit Type Character Length 8 Format \$8. Label Last attended study visit prior to the confirmed pregnancy

Variable Number 26 Variable OtherDoVMonth Type Character Length 1 Format \$1. Label If OTHER specify date of visit Month

Variable Number 27 Variable DateDeliveryUnknown Type Numeric Length 8 Format NONE Label Estimated date of delivery unknown

Variable Number 28 Variable DateMenCycleUnknown Type Numeric Length 8 Format NONE Label Date of last menstrual cycle unknown

Variable Number 29 Variable DatePregTestUnknown Type Numeric Length 8 Format NONE Label Date of positive pregnancy test unknown

Variable Number 30 Variable OtherDoVDay Type Numeric Length 8 Format NONE Label If OTHER specify date of visit Day

Variable Number 31 Variable OtherDoVYear Type Numeric Length 8 Format NONE Label If OTHER specify date of visit Year

### Data Set Name: [tn07\\_pregnancyoutcome.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 OutcomeUKNDueToLossOfParticpan Type Character Length 2 Format \$2. Label Is the outcome of the pregnancy unknown due to loss of participant to followup

Variable Number 5 Variable DOPEDay Type Numeric Length 8 Format NONE Label Date Pregnancy ended Day

Variable Number 6 Variable DOPEMonth Type Character Length 3 Format \$3. Label Date Pregnancy ended Month

Variable Number 7 Variable DOPEYear Type Numeric Length 8 Format NONE Label Date Pregnancy ended Year

Variable Number 8 Variable PregnancyAbortion Type Character Length 3 Format \$3. Label Was the pregnancy terminated as a result of an induced abortion

Variable Number 9 Variable ReasonForAbortionMedicallyIndi2 Type Character Length 1 Format \$1. Label Specify reason

Variable Number 10 Variable Miscarriage Type Character Length 3 Format \$3. Label Did the pregnancy result in a miscarriage

Variable Number 11 Variable LiveBirths Type Character Length 3 Format \$3. Label Did the pregnancy result in a live birth or multiple live births

Variable Number 12 Variable StillBirth Type Character Length 2 Format \$2. Label Did the pregnancy result in a stillbirth

Variable Number 13 Variable StillBirthHaveMalformations Type Character Length 1 Format \$1. Label Did the stillbirth have any congenital malformationsDid the stillbirth have any congenital malformations

Variable Number 14 Variable StillBirthHaveMalformationsSpe Type Character Length 1 Format \$1. Label If YES Specify

Variable Number 15 Variable StillBirthHaveAnyOtherComplica Type Character Length 1 Format \$1. Label Did the stillbirth have any other complications

Variable Number 16 Variable StillBirthHaveAnyOtherComplica2 Type Character Length 1 Format \$1. Label If YES Specify

Variable Number 17 Variable NumberOfInfants Type Numeric Length 8 Format NONE Label Record number of infants both living and deceased the birth resulted in

Variable Number 18 Variable NumberOfinfantsUnknown Type Numeric Length 8 Format NONE Label Record number of infants the birth resulted in Unknown

Variable Number 19 Variable ComplicationsInDelivery Type Character Length 7 Format \$7. Label Were there any complications during the delivery

Variable Number 20 Variable HbA1cMeasure Type Character Length 7 Format \$7. Label Was an HbA1c measured at any time during the pregnancy

Variable Number 21 Variable HbA1cMeasure2 Type Numeric Length 8 Format NONE Label Indicate HbA1c

Variable Number 22 Variable RecordHbA1cUnknown Type Numeric Length 8 Format NONE Label Record HbA1c unknown

Variable Number 23 Variable HbA1cMeasureDay Type Numeric Length 8 Format NONE Label Date Measured Day

Variable Number 24 Variable HbA1cMeasureMonth Type Character Length 1 Format \$1. Label Date Measured Month

Variable Number 25 Variable HbA1cMeasureYear Type Numeric Length 8 Format NONE Label Date Measured Year

Variable Number 26 Variable BreastFeeding Type Character Length 7 Format \$7. Label Is the participant currently breastfeeding

Variable Number 27 Variable Sex1\_1 Type Character Length 6 Format \$6. Label Sex

Variable Number 28 Variable GestationalAge1\_1 Type Numeric Length 8 Format NONE Label Gestational age

Variable Number 29 Variable GestationalAgeUnknown1\_1 Type Numeric Length 8 Format NONE Label Gestational age unknown

Variable Number 30 Variable BirthWeight1\_1 Type Numeric Length 8 Format NONE Label Birth weight gm

Variable Number 31 Variable BirthWeightGMUnknown1\_1 Type Numeric Length 8 Format NONE Label Birth weight gm unknown

Variable Number 32 Variable BirthWeightLbs1\_1 Type Numeric Length 8 Format NONE Label Birth weight lbs

Variable Number 33 Variable BirthWeightOz1\_1 Type Numeric Length 8 Format NONE Label Birth weight oz

Variable Number 34 Variable BirthWeightLBUnknown1\_1 Type Numeric Length 8 Format NONE Label Birth weight lb unknown

Variable Number 35 Variable \_1MinAPGARScore1\_1 Type Numeric Length 8 Format NONE Label One minute APGAR score

Variable Number 36 Variable OneMinuteAPGARScoreUnknown1\_1 Type Numeric Length 8 Format NONE Label One minute APGAR score unknown

Variable Number 37 Variable \_5MinAPGARScore1\_1 Type Numeric Length 8 Format NONE Label Five minute APGAR score

Variable Number 38 Variable FiveMinuteAPGARScoreUnknown1\_1 Type Numeric Length 8 Format NONE Label Five minute APGAR score unknown

Variable Number 39 Variable InfantBornCongenitalMalform1\_1 Type Character Length 7 Format \$7. Label Was the infant born with any congenital malformations

Variable Number 40 Variable InfantBornCongenitalMalform1\_2 Type Character Length 1 Format \$1. Label Was the infant born with any congenital malformations Specify

Variable Number 41 Variable InfantBornOtherComplication1\_1 Type Character Length 7 Format \$7. Label Was the infant born with other complications

Variable Number 42 Variable InfantBornOtherComplication1\_2 Type Character Length 27 Format \$27. Label Was the infant born with other complications Specify

Variable Number 43 Variable InfantInNICU1\_1 Type Character Length 7 Format \$7. Label Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time

Variable Number 44 Variable DoDInfantDay1\_1 Type Numeric Length 8 Format NONE Label If NO Date of death Day

Variable Number 45 Variable DoDInfantMonth1\_1 Type Character Length 3 Format \$3. Label If NO Date of death Month

Variable Number 46 Variable DoDInfantYear1\_1 Type Numeric Length 8 Format NONE Label If NO Date of death Year

Variable Number 47 Variable InfantDeathCause1\_1 Type Character Length 28 Format \$28. Label Specify cause of death

Variable Number 48 Variable InfantDischargedFromHopsita1\_1 Type Character Length 3 Format \$3. Label Was the infant discharged from the hospital alive

Variable Number 49 Variable InfantDischargedFromHopsita1\_2 Type Numeric Length 8 Format NONE Label If YES Date Discharged DAY

Variable Number 50 Variable InfantDischargedFromHopsita1\_3 Type Character Length 3 Format \$3. Label If YES Date Discharged Month

Variable Number 51 Variable InfantDischargedFromHopsita1\_4 Type Numeric Length 8 Format NONE Label If YES Date Discharged Year

Variable Number 52 Variable Sex2\_1 Type Character Length 1 Format \$1. Label Sex

Variable Number 53 Variable GestationalAge2\_1 Type Numeric Length 8 Format NONE Label Gestational age

Variable Number 54 Variable GestationalAgeUnknown2\_1 Type Numeric Length 8 Format NONE Label Gestational age unknown

Variable Number 55 Variable BirthWeight2\_1 Type Numeric Length 8 Format NONE Label Birth weight gm

Variable Number 56 Variable BirthWeightGMUnknown2\_1 Type Numeric Length 8 Format NONE Label Birth weight gm unknown

Variable Number 57 Variable BirthWeightLbs2\_1 Type Numeric Length 8 Format NONE Label Birth weight lbs

Variable Number 58 Variable BirthWeightOz2\_1 Type Numeric Length 8 Format NONE Label Birth weight oz

Variable Number 59 Variable BirthWeightLBUnknown2\_1 Type Numeric Length 8 Format NONE Label Birth weight lb unknown



Variable Number 60 Variable \_1MinAPGARScore2\_1 Type Numeric Length 8 Format NONE Label One minute APGAR score

Variable Number 61 Variable OneMinuteAPGARScoreUnknown2\_1 Type Numeric Length 8 Format NONE Label One minute APGAR score unknown

Variable Number 62 Variable \_5MinAPGARScore2\_1 Type Numeric Length 8 Format NONE Label Five minute APGAR score

Variable Number 63 Variable FiveMinuteAPGARScoreUnknown2\_1 Type Numeric Length 8 Format NONE Label Five minute APGAR score unknown

Variable Number 64 Variable InfantBornCongenitalMalform2\_1 Type Character Length 1 Format \$1. Label Was the infant born with any congenital malformations

Variable Number 65 Variable InfantBornCongenitalMalform2\_2 Type Character Length 1 Format \$1. Label Was the infant born with any congenital malformations Specify

Variable Number 66 Variable InfantBornOtherComplication2\_1 Type Character Length 1 Format \$1. Label Was the infant born with other complications

Variable Number 67 Variable InfantBornOtherComplication2\_2 Type Character Length 1 Format \$1. Label Was the infant born with other complications Specify

Variable Number 68 Variable InfantInNICU2\_1 Type Character Length 1 Format \$1. Label Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time

Variable Number 69 Variable DoDInfantDay2\_1 Type Numeric Length 8 Format NONE Label If NO Date of death Day

Variable Number 70 Variable DoDInfantMonth2\_1 Type Character Length 1 Format \$1. Label If NO Date of death Month

Variable Number 71 Variable DoDInfantYear2\_1 Type Numeric Length 8 Format NONE Label If NO Date of death Year

Variable Number 72 Variable InfantDeathCause2\_1 Type Character Length 1 Format \$1. Label Specify cause of death

Variable Number 73 Variable InfantDischargedFromHopsita2\_1 Type Character Length 1 Format \$1. Label Was the infant discharged from the hospital alive

Variable Number 74 Variable InfantDischargedFromHopsita2\_2 Type Numeric Length 8 Format NONE Label If YES Date Discharged DAY

Variable Number 75 Variable InfantDischargedFromHopsita2\_3 Type Character Length 1 Format \$1. Label If YES Date Discharged Month

Variable Number 76 Variable InfantDischargedFromHopsita2\_4 Type Numeric Length 8 Format NONE Label If YES Date Discharged Year

Variable Number 77 Variable Sex3\_1 Type Character Length 1 Format \$1. Label Sex

Variable Number 78 Variable GestationalAge3\_1 Type Numeric Length 8 Format NONE Label Gestational age

Variable Number 79 Variable GestationalAgeUnknown3\_1 Type Numeric Length 8 Format NONE Label Gestational age unknown

Variable Number 80 Variable BirthWeight3\_1 Type Numeric Length 8 Format NONE Label Birth weight gm

Variable Number 81 Variable BirthWeightGMUnknown3\_1 Type Numeric Length 8 Format NONE Label Birth weight gm unknown

Variable Number 82 Variable BirthWeightLbs3\_1 Type Numeric Length 8 Format NONE Label Birth weight lbs

Variable Number 83 Variable BirthWeightOz3\_1 Type Numeric Length 8 Format NONE Label Birth weight oz

Variable Number 84 Variable BirthWeightLBUnknown3\_1 Type Numeric Length 8 Format NONE Label Birth weight lb unknown

Variable Number 85 Variable BirthWeightLBS Type Numeric Length 8 Format NONE Label Birth Weight lbs oz

Variable Number 86 Variable \_1MinAPGARScore3\_1 Type Numeric Length 8 Format NONE Label One minute APGAR score

Variable Number 87 Variable OneMinuteAPGARScoreUnknown3\_1 Type Numeric Length 8 Format NONE Label One minute APGAR score unknown

Variable Number 88 Variable \_5MinAPGARScore3\_1 Type Numeric Length 8 Format NONE Label Five minute APGAR score

Variable Number 89 Variable FiveMinuteAPGARScoreUnknown3\_1 Type Numeric Length 8 Format NONE Label Five minute APGAR score unknown

Variable Number 90 Variable InfantBornCongenitalMalform3\_1 Type Character Length 1 Format \$1. Label Was the infant born with any congenital malformations

Variable Number 91 Variable InfantBornCongenitalMalform3\_2 Type Character Length 1 Format \$1. Label Was the infant born with any congenital malformations Specify

Variable Number 92 Variable InfantBornOtherComplication3\_1 Type Character Length 1 Format \$1. Label Was the infant born with other complications

Variable Number 93 Variable InfantBornOtherComplication3\_2 Type Character Length 1 Format \$1. Label Was the infant born with other complications Specify

Variable Number 94 Variable InfantInNICU3\_1 Type Character Length 1 Format \$1. Label Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time

Variable Number 95 Variable DoDInfantDay3\_1 Type Numeric Length 8 Format NONE Label If NO Date of death Day

Variable Number 96 Variable DoDInfantMonth3\_1 Type Character Length 1 Format \$1. Label If NO Date of death Month

Variable Number 97 Variable DoDInfantYear3\_1 Type Numeric Length 8 Format NONE Label If NO Date of death Year

Variable Number 98 Variable InfantDeathCause3\_1 Type Character Length 1 Format \$1. Label Specify cause of death

Variable Number 99 Variable InfantDischargedFromHopsita3\_1 Type Character Length 1 Format \$1. Label Was the infant discharged from the hospital alive

Variable Number 100 Variable InfantDischargedFromHopsita3\_2 Type Numeric Length 8 Format NONE Label If YES Date Discharged DAY

Variable Number 101 Variable InfantDischargedFromHopsita3\_3 Type Character Length 1 Format \$1. Label If YES Date Discharged Month

Variable Number 102 Variable InfantDischargedFromHopsita3\_4 Type Numeric Length 8 Format NONE Label If YES Date Discharged Year

Variable Number 103 Variable deliverymethod Type Character Length 1 Format \$1. Label 9 Delivery Method

Variable Number 104 Variable PregnancyIDNumber Type Numeric Length 8 Format NONE Label Record the Pregnancy Identification Number

Variable Number 105 Variable ReasonForAbortionMedicallyIndi Type Character Length 2 Format \$2. Label Was the reason for the abortion medically indicated

### Data Set Name: [tn07\\_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 ProtocolDeviationOtherSubcateg Type Character Length 89 Format \$89. Label Protocol Deviation Other subcategory

Variable Number 8 Variable DeviationOccurrenceSpecify Type Character Length 1 Format \$1. Label IF OTHER Specify Deviation

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 DescribeCorrectionAction Type Character Length 175 Format \$175. Label Describe 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 Deviation Type Character Length 1 Format \$1. Label Protocol Deviation

Variable Number 15 Variable DeviationError Type Character Length 49 Format \$49. Label Protocol deviationprocedural error

Variable Number 16 Variable ProtocolDeviation Type Character Length 87 Format \$87. Label Protocol Deviation

Variable Number 17 Variable CorrectiveActionTaken Type Character Length 1698 Format \$1698. Label Corrective action taken if necessary depending on circumstances

Variable Number 18 Variable DescribeDeviation Type Character Length 204 Format \$204. Label Describe Deviation procedural error and circumstances

Variable Number 19 Variable OtherSpecify Type Character Length 116 Format \$116. Label Other Specify

Variable Number 20 Variable StudyVisitCompletedFor Type Character Length 13 Format \$13. Label Study visit this form being completed for

Variable Number 21 Variable DeviationDay Type Numeric Length 8 Format NONE Label Date protocol deviation procedural error occurred Day

Variable Number 22 Variable DeviationMonth Type Character Length 3 Format \$3. Label Date protocol deviation procedural error occurred Month

Variable Number 23 Variable DeviationYear Type Numeric Length 8 Format NONE Label Date protocol deviation procedural error occurred Year

### Data Set Name: [tn07\\_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 Visit Type Character Length 8 Format NONE Label Baseline

Variable Number 4 Variable Status Type Character Length 20 Format NONE Label Status

### Data Set Name: tn07\_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

### Data Set Name: tn07\_studydrug.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 StudyDrugReturned Type Character Length 3 Format \$3. Label Was study drug returned

Variable Number 5 Variable StudyDrugReturnedDay Type Numeric Length 8 Format NONE Label study drug returned day

Variable Number 6 Variable StudyDrugReturnedMonth Type Character Length 3 Format \$3. Label study drug returned month

Variable Number 7 Variable StudyDrugReturnedYear Type Numeric Length 8 Format NONE Label study drug returned year

Variable Number 8 Variable CapsulesReturned Type Numeric Length 8 Format NONE Label Number of capsules returned

Variable Number 9 Variable StudyDrugDispensed Type Character Length 3 Format \$3. Label Was study drug dispensed

Variable Number 10 Variable StudyDrugDispensedDay Type Numeric Length 8 Format NONE Label Study drug dispensed day

Variable Number 11 Variable StudyDrugDispensedMonth Type Character Length 3 Format \$3. Label Study drug dispensed month

Variable Number 12 Variable StudyDrugDispensedYear Type Numeric Length 8 Format NONE Label Study drug dispensed year

Variable Number 13 Variable CapsulesDispensed Type Numeric Length 8 Format NONE Label Number of capsules dispensed

Variable Number 14 Variable StudyDrugReceiving Type Character Length 18 Format \$18. Label How did the participant receive the study drug

Variable Number 15 Variable RandomizationNumber Type Character Length 9 Format \$9. Label Record the Randomization Number used for study drug dispensation

Variable Number 16 Variable SecondPartofBottleLabel1\_1 Type Character Length 49 Format \$49. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 17 Variable BottleDispensedDay1\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 18 Variable BottleDispensedMonth1\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 19 Variable BottleDispensedYear1\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 20 Variable BottleDispenseDrugID1\_1 Type Character Length 19 Format \$19. Label study drugbottles dispensed to the participant Drug ID

Variable Number 21 Variable BottleDispenseRandomization1\_1 Type Character Length 10 Format \$10. Label study drugbottles dispensed to the participant Randomization number

Variable Number 22 Variable BottleDispensePkgLot1\_1 Type Character Length 25 Format \$25. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 23 Variable SecondPartofBottleLabel2\_1 Type Character Length 49 Format \$49. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 24 Variable BottleDispensedDay2\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 25 Variable BottleDispensedMonth2\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 26 Variable BottleDispensedYear2\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 27 Variable BottleDispenseDrugID2\_1 Type Character Length 19 Format \$19. Label study drugbottles dispensed to the participant Drug ID

Variable Number 28 Variable BottleDispenseRandomization2\_1 Type Character Length 10 Format \$10. Label study drugbottles dispensed to the participant Randomization number

Variable Number 29 Variable BottleDispensePkgLot2\_1 Type Character Length 25 Format \$25. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 30 Variable SecondPartofBottleLabel3\_1 Type Character Length 216 Format \$216. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 31 Variable BottleDispensedDay3\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 32 Variable BottleDispensedMonth3\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 33 Variable BottleDispensedYear3\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 34 Variable BottleDispenseDrugID3\_1 Type Character Length 19 Format \$19. Label study drugbottles dispensed to the participant Drug ID

Variable Number 35 Variable BottleDispenseRandomization3\_1 Type Character Length 10 Format \$10. Label study drugbottles dispensed to the participant Randomization number

Variable Number 36 Variable BottleDispensePkgLot3\_1 Type Character Length 25 Format \$25. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 37 Variable SecondPartofBottleLabel4\_1 Type Character Length 42 Format \$42. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 38 Variable BottleDispensedDay4\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 39 Variable BottleDispensedMonth4\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 40 Variable BottleDispensedYear4\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 41 Variable BottleDispenseDrugID4\_1 Type Character Length 19 Format \$19. Label study drugbottles dispensed to the participant Drug ID

Variable Number 42 Variable BottleDispenseRandomization4\_1 Type Character Length 10 Format \$10. Label study drugbottles dispensed to the participant Randomization number

Variable Number 43 Variable BottleDispensePkgLot4\_1 Type Character Length 32 Format \$32. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 44 Variable SecondPartofBottleLabel5\_1 Type Character Length 42 Format \$42. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 45 Variable BottleDispensedDay5\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 46 Variable BottleDispensedMonth5\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 47 Variable BottleDispensedYear5\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 48 Variable BottleDispenseDrugID5\_1 Type Character Length 19 Format \$19. Label study drugbottles dispensed to the participant Drug ID

Variable Number 49 Variable BottleDispenseRandomization5\_1 Type Character Length 10 Format \$10. Label study drugbottles dispensed to the participant Randomization number

Variable Number 50 Variable BottleDispensePkgLot5\_1 Type Character Length 14 Format \$14. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 51 Variable SecondPartofBottleLabel6\_1 Type Character Length 45 Format \$45. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 52 Variable BottleDispensedDay6\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 53 Variable BottleDispensedMonth6\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 54 Variable BottleDispensedYear6\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 55 Variable BottleDispenseDrugID6\_1 Type Character Length 19 Format \$19. Label study drugbottles dispensed to the participant Drug ID

Variable Number 56 Variable BottleDispenseRandomization6\_1 Type Character Length 10 Format \$10. Label study drugbottles dispensed to the participant Randomization number



Variable Number 57 Variable BottleDispensePkgLot6\_1 Type Character Length 14 Format \$14. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 58 Variable SecondPartofBottleLabel7\_1 Type Character Length 42 Format \$42. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 59 Variable BottleDispensedDay7\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 60 Variable BottleDispensedMonth7\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 61 Variable BottleDispensedYear7\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 62 Variable BottleDispenseDrugID7\_1 Type Character Length 19 Format \$19. Label study drugbottles dispensed to the participant Drug ID

Variable Number 63 Variable BottleDispenseRandomization7\_1 Type Character Length 10 Format \$10. Label study drugbottles dispensed to the participant Randomization number

Variable Number 64 Variable BottleDispensePkgLot7\_1 Type Character Length 14 Format \$14. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 65 Variable SecondPartofBottleLabel8\_1 Type Character Length 32 Format \$32. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 66 Variable BottleDispensedDay8\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 67 Variable BottleDispensedMonth8\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 68 Variable BottleDispensedYear8\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 69 Variable BottleDispenseDrugID8\_1 Type Character Length 4 Format \$4. Label study drugbottles dispensed to the participant Drug ID

Variable Number 70 Variable BottleDispenseRandomization8\_1 Type Character Length 7 Format \$7. Label study drugbottles dispensed to the participant Randomization number

Variable Number 71 Variable BottleDispensePkgLot8\_1 Type Character Length 10 Format \$10. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 72 Variable SecondPartofBottleLabel9\_1 Type Character Length 2 Format \$2. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 73 Variable BottleDispensedDay9\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 74 Variable BottleDispensedMonth9\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 75 Variable BottleDispensedYear9\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 76 Variable BottleDispenseDrugID9\_1 Type Character Length 4 Format \$4. Label study drugbottles dispensed to the participant Drug ID

Variable Number 77 Variable BottleDispenseRandomization9\_1 Type Character Length 7 Format \$7. Label study drugbottles dispensed to the participant Randomization number

Variable Number 78 Variable BottleDispensePkgLot9\_1 Type Character Length 10 Format \$10. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 79 Variable SecondPartofBottleLabel10\_1 Type Character Length 2 Format \$2. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 80 Variable BottleDispensedDay10\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 81 Variable BottleDispensedMonth10\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 82 Variable BottleDispensedYear10\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 83 Variable BottleDispenseDrugID10\_1 Type Character Length 4 Format \$4. Label study drugbottles dispensed to the participant Drug ID

Variable Number 84 Variable BottleDispenseRandomization10\_1 Type Character Length 7 Format \$7. Label study drugbottles dispensed to the participant Randomization number

Variable Number 85 Variable BottleDispensePkgLot10\_1 Type Character Length 10 Format \$10. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 86 Variable SecondPartofBottleLabel11\_1 Type Character Length 2 Format \$2. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 87 Variable BottleDispensedDay11\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 88 Variable BottleDispensedMonth11\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 89 Variable BottleDispensedYear11\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 90 Variable BottleDispenseDrugID11\_1 Type Character Length 4 Format \$4. Label study drugbottles dispensed to the participant Drug ID

Variable Number 91 Variable BottleDispenseRandomization11\_1 Type Character Length 5 Format \$5. Label study drugbottles dispensed to the participant Randomization number

Variable Number 92 Variable BottleDispensePkgLot11\_1 Type Character Length 10 Format \$10. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 93 Variable SecondPartofBottleLabel12\_1 Type Character Length 2 Format \$2. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 94 Variable BottleDispensedDay12\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 95 Variable BottleDispensedMonth12\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 96 Variable BottleDispensedYear12\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 97 Variable BottleDispenseDrugID12\_1 Type Character Length 1 Format \$1. Label study drugbottles dispensed to the participant Drug ID

Variable Number 98 Variable BottleDispenseRandomization12\_1 Type Character Length 5 Format \$5. Label study drugbottles dispensed to the participant Randomization number

Variable Number 99 Variable BottleDispensePkgLot12\_1 Type Character Length 10 Format \$10. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 100 Variable SecondPartofBottleLabel13\_1 Type Character Length 2 Format \$2. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 101 Variable BottleDispensedDay13\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 102 Variable BottleDispensedMonth13\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 103 Variable BottleDispensedYear13\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 104 Variable BottleDispenseDrugID13\_1 Type Character Length 1 Format \$1. Label study drugbottles dispensed to the participant Drug ID

Variable Number 105 Variable BottleDispenseRandomization13\_1 Type Character Length 5 Format \$5. Label study drugbottles dispensed to the participant Randomization number

Variable Number 106 Variable BottleDispensePkgLot13\_1 Type Character Length 10 Format \$10. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 107 Variable SecondPartofBottleLabel14\_1 Type Character Length 2 Format \$2. Label study drugbottles dispensed to the participant Bottle Number

Variable Number 108 Variable BottleDispensedDay14\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Day bottle dispensed

Variable Number 109 Variable BottleDispensedMonth14\_1 Type Character Length 3 Format \$3. Label study drugbottles dispensed to the participant Month bottle dispensed

Variable Number 110 Variable BottleDispensedYear14\_1 Type Numeric Length 8 Format NONE Label study drugbottles dispensed to the participant Year bottle dispensed

Variable Number 111 Variable BottleDispenseDrugID14\_1 Type Character Length 1 Format \$1. Label study drugbottles dispensed to the participant Drug ID

Variable Number 112 Variable BottleDispenseRandomization14\_1 Type Character Length 5 Format \$5. Label study drugbottles dispensed to the participant Randomization number

Variable Number 113 Variable BottleDispensePkgLot14\_1 Type Character Length 10 Format \$10. Label study drug bottles dispensed to the participant Pkg Lot

Variable Number 114 Variable UnusualCircumstances Type Character Length 3 Format \$3. Label Were there any unusual circumstances

Variable Number 115 Variable UnusualCircumstancesDescribe Type Character Length 1255 Format \$1255. Label Were there any unusual circumstances If YES Describe

### Data Set Name: [tn07\\_studyendpointvisit.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 Participantwascontac\_AffiliateS1 Type Numeric Length 8 Format NONE Label Participantwascontac: Affiliate Site Coordinator

Variable Number 5 Variable Participantwascontac\_AffiliateS2 Type Numeric Length 8 Format NONE Label Participantwascontac: Affiliate Site PI

Variable Number 6 Variable Participantwascontac\_ClinicalCe1 Type Numeric Length 8 Format NONE Label Participantwascontac: Clinical Center Coordinator

Variable Number 7 Variable Participantwascontac\_ClinicalCe2 Type Numeric Length 8 Format NONE Label Participantwascontac: Clinical Center PI

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

Variable Number 9 Variable MethodofContact Type Character Length 12 Format \$12. Label Method of Contact

Variable Number 10 Variable MethodofContactOther Type Character Length 106 Format \$106. Label Method of Contact Other

Variable Number 11 Variable Wastheparticipantabletobereach Type Character Length 3 Format \$3.  
Label Was the participant able to be reached

Variable Number 12 Variable HastheparticipantscheduledaStu Type Character Length 3 Format \$3. Label  
Has the participant scheduled a Study Endpoint Visit

Variable Number 13 Variable indicateiftheparticipantiswill Type Character Length 3 Format \$3. Label If  
responding No to Question 4 please indicate if the participant is willing to visit an outside physician or  
local lab for specimen collection

Variable Number 14 Variable Iftheparticipanthasdeclinedthe Type Character Length 3 Format \$3. Label If  
the participant has declined the Study Endpoint Visit and a local lab or outside physician specimen  
collection did the site ascertain the participants diabetes status

Variable Number 15 Variable DateofVisitDay Type Numeric Length 8 Format NONE Label Date of Visit  
Day

Variable Number 16 Variable DateofVisitMonth Type Character Length 3 Format \$3. Label Date of Visit  
Month

Variable Number 17 Variable DateofVisitYear Type Numeric Length 8 Format NONE Label Date of Visit  
Year

Variable Number 18 Variable OutsideLaboratoryResultsRandom Type Numeric Length 8 Format NONE  
Label Outside Laboratory Results Random Glucose

Variable Number 19 Variable OutsideLaboratoryResultsRandom2 Type Character Length 1 Format \$1.  
Label Outside Laboratory Results Random Glucose Unit

Variable Number 20 Variable OutsideLaboratoryResultsRandom3 Type Numeric Length 8 Format NONE  
Label Outside Laboratory Results Random Glucose Reference Range Low

Variable Number 21 Variable OutsideLaboratoryResultsRandom4 Type Numeric Length 8 Format NONE  
Label Outside Laboratory Results Random Glucose Reference Range High

Variable Number 22 Variable OutsideLaboratoryResultsRandom5 Type Numeric Length 8 Format NONE  
Label Outside Laboratory Results Random Glucose Date Day

Variable Number 23 Variable OutsideLaboratoryResultsRandom6 Type Character Length 1 Format \$1.  
Label Outside Laboratory Results Random Glucose Date Month

Variable Number 24 Variable OutsideLaboratoryResultsRandom7 Type Numeric Length 8 Format NONE  
Label Outside Laboratory Results Random Glucose Date Year

Variable Number 25 Variable Pleaseselectwhichsam\_HbA1csentto Type Numeric Length 8 Format NONE  
Label Pleaseselectwhichsam: HbA1c sent to TrialNet Laboratory for processing

Variable Number 26 Variable Pleaseselectwhichsam\_RandomPlas1 Type Numeric Length 8 Format NONE  
Label Pleaseselectwhichsam: Random Plasma Glucose sent to TrialNet Laboratory for processing (collect  
time of last meal)

Variable Number 27 Variable Pleaseselectwhichsam\_HbA1crunbyl Type Numeric Length 8 Format NONE  
Label Pleaseselectwhichsam: HbA1c run by local lab, result reported to TrialNet

Variable Number 28 Variable Pleaseselectwhichsam\_RandomPlas2 Type Numeric Length 8 Format NONE  
Label Pleaseselectwhichsam: Random Plasma Glucose run by local lab, results reported to TrialNet  
(collect time of last meal)

Variable Number 29 Variable OutsideLaboratoryRes\_OutsideLa1 Type Numeric Length 8 Format NONE  
Label OutsideLaboratoryRes: Outside Lab

Variable Number 30 Variable OutsideLaboratoryRes\_OutsidePhy1 Type Numeric Length 8 Format NONE  
Label OutsideLaboratoryRes: Outside Physician

Variable Number 31 Variable OutsideLaboratoryRes\_OutsideLa2 Type Numeric Length 8 Format NONE  
Label OutsideLaboratoryRes: Outside Lab

Variable Number 32 Variable OutsideLaboratoryRes\_OutsidePhy2 Type Numeric Length 8 Format NONE  
Label OutsideLaboratoryRes: Outside Physician

Variable Number 33 Variable OutsideLaboratoryResultsHbA1c Type Numeric Length 8 Format NONE  
Label Outside Laboratory Results HbA1c

Variable Number 34 Variable OutsideLaboratoryResultsHbA1cR Type Numeric Length 8 Format NONE  
Label Outside Laboratory Results HbA1c Reference Range Low

Variable Number 35 Variable OutsideLaboratoryResultsHbA1cR2 Type Numeric Length 8 Format NONE  
Label Outside Laboratory Results HbA1c Reference Range High

Variable Number 36 Variable OutsideLaboratoryResultsHbA1cD Type Numeric Length 8 Format NONE  
Label Outside Laboratory Results HbA1c Date Day

Variable Number 37 Variable OutsideLaboratoryResultsHbA1cD2 Type Character Length 3 Format \$3.  
Label Outside Laboratory Results HbA1c Date Month

Variable Number 38 Variable OutsideLaboratoryResultsHbA1cD3 Type Numeric Length 8 Format NONE  
Label Outside Laboratory Results HbA1c Date Year

Variable Number 39 Variable Timeoflastmealhour Type Numeric Length 8 Format NONE Label Time of  
last meal hour

Variable Number 40 Variable Timeoflastmealminute Type Numeric Length 8 Format NONE Label Time of  
last meal minute

Variable Number 41 Variable AdditionalCommentsdescribingpa Type Character Length 758 Format \$758.  
Label Additional Comments describing participants situation

Variable Number 42 Variable Participantwascontactedbyother Type Character Length 1 Format \$1. Label  
Participant was contacted by other

[Data Set Name: tn07\\_treatmentstartdate.sas7bdat](#)

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

Variable Number 2 Variable TreatmentAssignDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Assign Date

Variable Number 3 Variable Visit Type Character Length 8 Format NONE Label Visit

Variable Number 4 Variable TreatmentStartedDate Type Numeric Length 8 Format MMDDYY10. Label Treatment Started Date

Variable Number 5 Variable TreatmentDesc Type Character Length 500 Format NONE Label Treatment Description