Immune Effects of Oral Insulin in Relatives at Risk for Type 1 Diabetes Mellitus (TN20)

The TN20 study was a two-arm, multi-center, randomized, open-labeled clinical trial designed to assess the effects of varying doses and schedules of oral insulin on immunological and metabolic markers in relatives at risk for type 1 diabetes.

Archive files are organized into the following directories:
- Data
- Documents
- Dataset Integrity Check (DSIC)
- Forms

Data

The TN20 Data directory contains the following datasets in SAS and CSV formats:
- TN20_Ab_RBA_ECL_Aff_Subtyping.csv
- tn20_ab_rba_ecl_aff_subtyping.sas7bdat
- TN20_AdverseEvents.csv
- tn20_adverseevents.sas7bdat
- TN20_CBCDifferential.csv
- tn20_cbcdifferential.sas7bdat
- TN20_ChangeInStatus.csv
- tn20_changeinstatus.sas7bdat
- TN20_ChangeInStudyDrug.csv
- tn20_changeinstudydrug.sas7bdat
- TN20_Class_II_Tetramer.csv
- tn20_class_ii_tetramer.sas7bdat
- TN20_ConcomitantMeds.csv
- tn20_concomitantmeds.sas7bdat
- TN20_CyTOF_CD8_Tmr_Statistics.csv
- tn20_cytof_cd8_tmr_statistics.sas7bdat
- TN20_DiabetesOnset.csv
- tn20_diabetesonset.sas7bdat
- TN20_Eligibility.csv
- tn20_eligibility.sas7bdat
- TN20_FreqPhen_HLA_A1.csv
- tn20_freqphen_hla_a1.sas7bdat
- TN20_FreqPhen_HLA_A1_A3.csv
- tn20_freqphen_hla_a1_a3.sas7bdat
- TN20_FreqPhen_HLA_A1_B7.csv
- tn20_freqphen_hla_a1_b7.sas7bdat
- TN20_FreqPhen_HLA_A2.csv
- tn20_freqphen_hla_a2.sas7bdat
- TN20_FreqPhen_HLA_A24.csv
- tn20_freqphen_hla_a24.sas7bdat

- TN20_FreqPhen_HLA_A2_A3.csv
- tn20_freqphen_hla_a2_a3.sas7bdat
- TN20_FreqPhen_HLA_A3_A24.csv
- tn20_freqphen_hla_a3_a24.sas7bdat
- TN20_FreqPhen_HLA_A3_B7.csv
- tn20_freqphen_hla_a3_b7.sas7bdat
- TN20_FreqPhen_InsBPPIIGRPIAPP.csv
- tn20_freqphen_insbppiigrpiapp.sas7bdat
- TN20_HBsAb.csv
- tn20_hbsab.sas7bdat
- TN20_InitialVisit.csv
- tn20_initialvisit.sas7bdat
- TN20_ParticipantSiteTransfer.csv
- tn20_participantsitetransfer.sas7bdat
- TN20_ProtocolDeviation.csv
- tn20_protocoldeviation.sas7bdat
- TN20_Registration.csv
- tn20_registration.sas7bdat
- TN20_ResearchLabs.csv
- tn20_researchlabs.sas7bdat
- TN20_StudyDrug.csv
- tn20_studydrug.sas7bdat
- TN20_StudyVisit.csv
- tn20_studyvisit.sas7bdat
- TN20_TreatmentStartDate.csv
- tn20_treatmentstartdate.sas7bdat
- TN20_TreatPhasePtContact.csv
- tn20_treatphaseptcontact.sas7bdat

Data/Contents
- TrialNet-20.Data Dictionary_ResearchLabs.docx
- TrialNet-TN20 Data Dictionary.rtf

<u>Documents</u>

The TN20 Documents directory contains:
- Protocol.pdf

Documents/MOO

- Appendix A. Proband Definition.pdf
- Appendix B. Reimbursement.pdf
- Appendix C. Summary of Visit Windows 15Jan16.pdf
- Appendix D. Oral Glucose Tolerance Test (OGTT).pdf
- Appendix E. Participant Drug Information Sheet 500 mg.pdf

- Appendix E. Participant Drug Information Sheet 67.5 mg.pdf
- Appendix F. Protocol Deviation Checklist.pdf
- Appendix G. Definitions.pdf
- Appendix H. Audit Guidelines.pdf
- Appendix I TN10 V TN20 OGTT Eligibility.pdf
- Appendix J TN10 vs. TN20 Autoantibody Eligibility.pdf
- TN20 MOO V2 20160115 Clean.pdf

DSIC

The TN20 Dataset Integrity Check (DSIC) directory contains:
- TN20_DSIC.pdf

Forms

The TN20 Forms directory contains:
- CBC with Differential Results 20151106.pdf
- Concomitant Medications Form 10SEP15.pdf
- IE01 Initial Visit 03Feb16.pdf
- IE01 Initial Visit 10SEP2015.pdf
- IE02 Study Visit Form 01SEP015.pdf
- IE03 Eligibility form 03Feb16.pdf
- IE03 Eligibility form 10SEP2015.pdf
- IE04 Study Drug Form 10SEP15.pdf
- IE04 Study Drug Form 17Feb16.pdf
- IE05 Change in Study Drug Form 10SEP2015.pdf
- IE06 Treatment Phase Participant Contact Form 10SEP15.pdf
- IE07 Change of Status Form 10SEP2015.pdf
- IE08 Diabetes Onset Form 10SEP2015.pdf
- IE09 Participant Transfer 10SEP15.pdf
- IE10 Protocol Deviation Form 10SEP15.pdf
- IE11 Pregnancy Confirmation Form 10SEP15.pdf
- IE12 Pregnancy Outcome Report Form 10SEP15.pdf
- IE13 Mortality Event Form 10SEP15.pdf