

TrialNet Pathway To Prevention (formerly Natural History Study) (TN01)

TrialNet is a network of 19 clinical centers worldwide that conducts research on the study, prevention, and early treatment of type 1 diabetes (T1D). The TrialNet Pathway To Prevention (TN01) is a screening and monitoring study that was established to provide a source of subjects for enrollment into prevention trials. In addition, the prospectively followed cohort is used to gain new insights into the natural history of pre-type 1 diabetes in patients with increased risk for the disease. The primary aim of the study is to identify subjects for TrialNet prevention and investigation trials, but can also be used for assessing the predictive value of existing and novel risk markers of T1D, and for examining the demographic, immunologic, and metabolic characteristics of individuals at risk for developing T1D.

Archive files are organized into the following directories:

- Data
- Documents
- Dataset Integrity Check (DSIC)
- Forms

Data

The TN01 Data directory contains the following datasets in SAS and CSV formats:

- TN01_ADDITIONALCONSENT.CSV
- tn01_additionalconsent.sas7bdat
- TN01_ADVERSEEVENTS.CSV
- tn01_adverseevents.sas7bdat
- TN01_ADVERSEEVENTSREVIEW.CSV
- tn01_adverseeventsreview.sas7bdat
- TN01_AUTOANTIBODYPOSITIVEPT.CSV
- tn01_autoantibodypositivept.sas7bdat
- TN01_AUTOANTIBODY_POSFOLLOWUP.CSV
- tn01_autoantibody_posfollowup.sas7bdat
- TN01_CBCDIFFERENTIAL.CSV
- tn01_cbcdifferential.sas7bdat
- TN01_CHANGEMONITORINGSCHEDULE.CSV
- tn01_changemonitoringschedule.sas7bdat
- TN01_COVID19PTASSESSMENT.CSV
- tn01_covid19ptassessment.sas7bdat
- TN01_FOLLOWUPELIGPARTICIPANT.CSV
- tn01_followupeligparticipant.sas7bdat
- TN01_FOLLOWUPELIGPARTICIPANT2.CSV
- tn01_followupeligparticipant2.sas7bdat
- TN01_GLYCEMICSTATUSASSESSMENT.CSV
- tn01_glycemicstatusassessment.sas7bdat
- TN01_LOCALLABABRESULTS.CSV
- tn01_locallababresults.sas7bdat

- TN01_NH01F_FAMILYHISTORY.CSV
- tn01_nh01f_familyhistory.sas7bdat
- TN01_NH01_SCREENING.CSV
- tn01_nh01_screening.sas7bdat
- TN01_NH04_BASELINERISKASSESS.CSV
- tn01_nh04_baselineriskassess.sas7bdat
- TN01_NH05C_FOLLOWUPRISKASSESS.CSV
- tn01_nh05c_followupriskassess.sas7bdat
- TN01_NH05_FOLLOWUPRISKASSESS.CSV
- tn01_nh05_followupriskassess.sas7bdat
- TN01_NH07_CHANGEOFSTATUS.CSV
- tn01_nh07_changeofstatus.sas7bdat
- TN01_NH08_DIABETESONSET_OLD.CSV
- tn01_nh08_diabetesonset_old.sas7bdat
- TN01_NH08_DIABONSET_CURRENT.CSV
- tn01_nh08_diabonset_current.sas7bdat
- TN01_NH09_FOLLOWUPMISSEDVISIT.CSV
- tn01_nh09_followupmissedvisit.sas7bdat
- TN01_NH10_DTP1ENTRY.CSV
- tn01_nh10_dtp1entry.sas7bdat
- TN01_NH12_CONTROLENTY.CSV
- tn01_nh12_controlentry.sas7bdat
- TN01_NH14C_CONTCHANGEMONITOR.CSV
- tn01_nh14c_contchangemonitor.sas7bdat
- TN01_PATHWAYTOPREVENTION.CSV
- tn01_pathwaytoprevention.sas7bdat
- TN01_PERMANENTSITETRANSFER.CSV
- tn01_permanentsitetransfer.sas7bdat
- TN01_PROTOCOLDEVIATION.CSV
- tn01_protocoldeviation.sas7bdat
- TN01_PROTOCOLVERSION.CSV
- tn01_protocolversion.sas7bdat
- TN01_REGISTRATION.CSV
- tn01_registration.sas7bdat
- TN01_RESEARCHLABSBAA_CY04_12.CSV
- tn01_researchlabsbaa_cy04_12.sas7bdat
- TN01_RESEARCHLABSBAA_CY13_20.CSV
- tn01_researchlabsbaa_cy13_20.sas7bdat
- TN01_RESEARCHLABS_OTHER.CSV
- tn01_researchlabs_other.sas7bdat

Data/Contents

- TrialNet-01.Data Dictionary_ResearchLabs.docx
- TrialNet-TN01 Data Dictionary.rtf

Documents

The TN01 Documents directory contains:

- CTCAEv3.xls
- NHS ProtocolSynopsisSpecimenCollectionSchedule.pdf
- TN-01 publications.docx

Documents/Consents

- 01252011_4748_37 TN01 Phase 1 Assent Protocol Version 22Jul09.doc
- 01252011_4748_39 TN01 Phase 2 Assent Protocol Version 22Jul09.doc
- 01252011_4748_41 TN01 Phase 3 Assent Protocol Version 22Jul09.doc
- 01252011_4748_43 TN01 Phase 1 Consent with Controls Protocol Version 22Jul09.DOC
- 01252011_4748_45 TN01 Phase 2 Consent Protocol Version 22Jul09.doc
- 01252011_4748_47 TN01 Phase 3 Consent Protocol Version 22Jul09.doc
- 01252011_4748_49 TN01 Phase 3 Controls Protocol Version 22Jul09.doc

DSIC

The TN01 Dataset Integrity Check (DSIC) directory contains:

- tn01_dataset_integrity_check.pdf
- TN01_DSIC.pdf

Forms

The TN01 Forms directory contains:

- 01252011_4767_NH01 with variables 20101007.pdf
- 01252011_4767_NH01F with variables 20101007.pdf
- 01252011_4767_NH04 with variables 20101008.pdf
- 01252011_4767_NH05 with variables 20101008.pdf
- 01252011_4767_NH05C 071006 WITH VARIABLES 20101008.pdf
- 01252011_4767_NH07 with variables 20101008.pdf
- 01252011_4767_NH08 with variables 20101008.pdf
- 01252011_4767_NH09 with variables 20101008.pdf
- 01252011_4767_NH10 with variables 20101008.pdf
- 01252011_4767_NH12 090107 WITH VARIABLES 20101008.pdf
- 01252011_4767_NH20 NHCH with variables 20101008.pdf