

NATURAL HISTORY STUDY OF THE DEVELOPMENT OF TYPE 1 DIABETES

TrialNet-01 (TN-01) Natural History Data Archive

The TN-01 Natural History Data archive contains data collected at screening (Phase 1), baseline (Phase 2) and repeated follow-up (Phase 3) for participants in the TrialNet Natural History prospective cohort study. The Natural History study is part of the TrialNet Type 1 Diabetes studies. Recruitment for the study is ongoing; the data in this archive include patients recruited through 2018. The archive includes the study protocol and related descriptive documentation, data collection forms and study data, and a dataset integrity check.

The files in the archive are organized into the following directories:

1. Documentation
2. Forms
3. Data

1. Documentation Directory

The TN-01 Documentation Directory contains:

- a brief summary of the study protocol and specimen collection schedule for all three phases of the study, NHS ProtocolSynopsisSpecimenCollectionSchedule.pdf
- A folder, Consents, which includes copies of adult consent and minor assent forms for all three phases of the study and for Phase 1 control sample
- A listing of publications generated from the TN-01 data, TN-01 publications.doc

Details on the study design, eligibility and the baseline and follow-up assessments can be found on the study website, <http://www.diabetestrialnet.org/PathwayToPrevention/>

2. Forms Directory

The TN-01 Forms Directory contains copies of 11 data collection forms used in the TN-01 study. A brief description of each form is provided below.

NH01, Screening Form: Eligibility, participant information

NH01F, Family History: Family History of Type 1 Diabetes

NH04, Baseline Risk Assessment: Eligibility, Medical history, medications, anthropometry, lab tests

NH05, Follow-up Risk Assessment: Eligibility, Medical history, medications, anthropometry, lab tests

NH05C, Control Follow-up: Non T1 Diabetes Patients: Medical history, medications, anthropometry, lab tests

[Note: A small number of patients who screened negative for autoantibodies in Phase 1 were randomly selected and asked to be retested for autoantibodies once per year for 5 years or the end of the study]

NH07, Change of Status: To be completed if patient develops diabetes, becomes ineligible, or unable to continue

NH08, Diabetes Onset: Hospitalization, signs and symptoms, glucose and other lab values

NH09, Follow-up Missed Visit: Missed visit information

NH10, DPT-1 Entry Form: For patients previously enrolled in DPT-1 (to be completed at follow-up 1)
Medical history, medications, anthropometry, lab tests

NH12, Control Entry: Eligibility, medical history, medications, anthropometry, lab tests for study controls (non T1 diabetes)

NH20, Participant Contact Change and Site Transfer: Participant contact information, change and site transfer information

3. Data Directory

The TN-01 Data Directory contains:

- A data dictionary, “TrialNet TN01 Data Dictionary.rtf” that provides an alphabetical listing of variable names and labels for each study data file
- A codebook, “Protocol_1.Data Dictionary_ResearchLabs.docx”, for the research labs datasets
- A total of 29 SAS data files (*.sas7bdat) that correspond to 10 of the 11 data collection forms (form NH20, Change and Site Transfer Form, is not associated with a data file) plus an adverse event file, a patient registration file, a laboratory data file, and additional analysis datasets.

Table 1 provides a listing of study forms (.pdf) and the corresponding study data files (.sas7bdat).

Table 1. Study forms and data

	Study Form (.pdf)	Form Name	Data File Name (*.sas7bdat)
1.	NA	Adverse Event **	tn01_adverseeventsreview.sas7bdat
2.	NA	Adverse Event Review	tn01_adverseevents.sas7bdat
3.	NA	Follow-up of Eligible Participant Form	tn01_followupeligparticipant.sas7bdat and tn01_followupeligparticipant2.sas7bdat
4.	01252011_4767_NH01 with variables 20101007	NH01 - Screening Form	tn01_nh01_screening.sas7bdat
5.	01252011_4767_NH01F with variables 20101007	NH01F - Family History Form	tn01_nh01f_familyhistory.sas7bdat
6.	01252011_4767_NH04 with variables 20101008	NH04 - Baseline Risk Assessment	tn01_nh04_baselineriskassess.sas7bdat
7.	01252011_4767_NH05 with variables 20101008	NH05 - Follow-Up Risk Assessment Phase 3	tn01_nh05_followupriskassess.sas7bdat
8.	01252011_4767_NH05C 071006 WITH VARIABLES 20101008	NH05C - Follow-Up Risk Assessment	tn01_nh05c_followupriskassess.sas7bdat
9.	01252011_4767_NH07 with variables 20101008	NH07 - Change of Status	tn01_nh07_changeofstatus.sas7bdat
10.	01252011_4767_NH08 with variables 20101008	NH08 - Diabetes Onset	tn01_nh08_diabetesonset_old.sas7bdat and tn01_nh08_diabonset_current.sas7bdat
11.	01252011_4767_NH09 with variables 20101008	NH09 - Follow-Up Missed Visit	tn01_nh09_followupmissedvisit.sas7bdat
12.	01252011_4767_NH10 with variables 20101008	NH10 - DPT-1 Entry	tn01_nh10_dtp1entry.sas7bdat
13.	01252011_4767_NH12 090107 WITH VARIABLES 20101008	NH12 - Control Entry	tn01_nh12_controlentry.sas7bdat
14.	NA	NH14c – Control Change In Monitoring Form	tn01_nh14c_contchangemonitor.sas7bdat

	Study Form (.pdf)	Form Name	Data File Name (*.sas7bdat)
15.	NA	Protocol Deviation	tn01_protocoldeviation.sas7bdat
16.	NA	Registration **	tn01_registration.sas7bdat
17.	NA	Research Lab Forms **	tn01_researchlabsbaa_cy2004_2012.sas7bdat, tn01_researchlabsbaa_cy2013_2018.sas7bdat, and tn01_researchlabs_other.sas7bdat
18.	01252011_4767_NH20 NHCH with variables 20101008	Change and Site Transfer Form	tn01_permanentsitetransfer.sas7bdat
19.	NA	Protocol Version	tn01_protocolversion.sas7bdat
20.	NA	Additional Consent Form	tn01_additionalconsent.sas7bdat
21.	NA	Autoantibody Positive Follow-up Form	tn01_autoantibody_posfollowup.sas7bdat
22.	NA	Change of Monitoring Schedule Form	tn01_changemonitoringschedule.sas7bdat
23.	NA	Autoantibody Positive Participant Status	tn01_autoantibodypositivept.sas7bdat
24.	NA	CBC Differential Form	tn01_cbcdifferential.sas7bdat
25.	NA	Pathway to Prevention Visit Assessment Form	tn01_pathwaytoprevention.sas7bdat