

NATURAL HISTORY STUDY OF THE DEVELOPMENT OF TYPE 1 DIABETES
TrialNet-01 (TN-01) Natural History Data Archive (through 2016)

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 2016. 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
4. Dataset Integrity Check

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, "Protocol_1.Data Dictionary.rtf," that provides an alphabetical listing of variable names and labels for each study data file
- A total of 22 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 **	Adverseevent
2.	NA	Adverse Event Review	aereview
3.	NA	Follow-up	followup_eligible_participant
4.	01252011_4767_NH01 with variables 20101007	NH01 - Screening Form	NH01_screeningform
5.	01252011_4767_NH01F with variables 20101007	NH01F - Family History Form	NH01F_familyhistoryform
6.	01252011_4767_NH04 with variables 20101008	NH04 - Baseline Risk Assessment	NH04_baselineriskassessment
7.	01252011_4767_NH05 with variables 20101008	NH05 - Follow-Up Risk Assessment Phase 3	NH05_followupriskassessphase3
8.	01252011_4767_NH05C 071006 WITH VARIABLES 20101008	NH05C - Follow-Up Risk Assessment	NH05C_followupriskassessment
9.	01252011_4767_NH07 with variables 20101008	NH07 - Change of Status	NH07_changeofstatus
10.	01252011_4767_NH08 with variables 20101008	NH08 - Diabetes Onset	tn_210416_diabetesons
11.	01252011_4767_NH09 with variables 20101008	NH09 - Follow-Up Missed Visit	NH09_followupmissedvisit
12.	01252011_4767_NH10 with variables 20101008	NH10 - DPT-1 Entry	NH10_dpt1entry
13.	01252011_4767_NH12 090107 WITH VARIABLES 20101008	NH12 - Control Entry	NH12_controlentry
14.	NA	Protocol Deviation	protocol_deviation
15.	NA	Registration **	Registration
16.	NA	Research Lab Forms **	research_labs_baa and research_labs_other

17.	01252011_4767_NH20 NHCH with variables 20101008	Change and Site Transfer Form	NA
18.	NA	Follow-up of Eligible Participant Form	tn_212619_followupofe
19.	NA	Additional Consent Form	tn01_211746_additiona
20.	NA	Autoantibody Positive Follow-up Form	tn01_211857_autoantib
21.	NA	Change of Monitoring Schedule Form	tn01_211858_changeofm
22.	NA	Control Change in Monitoring Form	tn01_212440_nh14ccont

*Note: NA Not Available; ** Study form not included in the repository.*

4. Dataset Integrity Check

The TrialNet Natural History Dataset Integrity Check directory contains a report based on an examination of the data in the repository by statisticians and quality control specialists at the Repository. Datasets were checked for completeness, consistency, and usability. The published data in Mahon et al (2009) in *Pediatric Diabetes* were compared to values recalculated from the Natural History data in the NIDDK Repository.