

## The TrialNet 06 Study Data Archive

The TrialNet 06 Archive contains the following directories:

- Documentation
- Data
- DSIC
- Forms

### Documentation

The TrialNet 06 Documentation directory contains:

- Protocol\_6.Data\_Dictionary.rtf – Contains a contents of the TrialNet 06 datasets. Note that variables that included personally identifiable information were removed from the datasets. This includes any month of birth and day of birth fields.
- 01 TN06 MOO VERSION DRAFT.pdf – Manual of Operations
- 06 TN06 FINAL PROTOCOL VERSION 05SEP08.pdf - Protocol

### Data

The TrialNet 06 data directory contains the following 32 files in SAS format:

- aereview.sas7bdat
- registration.sas7bdat
- research\_labs.sas7bdat
- tn\_914\_adverseevent.sas7bdat
- tn\_210416\_diabetesons.sas7bdat
- tn\_210745\_ctl16missed.sas7bdat
- tn\_210746\_protocoldev.sas7bdat
- tn\_210753\_changeofsta.sas7bdat
- tn06\_210729\_npp06infa.sas7bdat
- tn06\_210730\_npp07infa.sas7bdat
- tn06\_210731\_npp08nonn.sas7bdat
- tn06\_210732\_npp09nurs.sas7bdat
- tn06\_210733\_npp10infa.sas7bdat
- tn06\_210734\_npp11.infa.sas7bdat
- tn06\_210735\_npp15stud.sas7bdat
- tn06\_210736\_npp16stud.sas7bdat
- tn06\_210737\_npp20infa.sas7bdat
- tn06\_210739\_npp20eall.sas7bdat
- tn06\_210740\_npp20mpre.sas7bdat

- tn06\_210741\_npp22moth.sas7bdat
- tn06\_210742\_npp25veri.sas7bdat
- tn06\_210743\_npp21food.sas7bdat
- tn06\_210767\_eligelig.sas7bdat
- tn06\_210768\_npp26stud.sas7bdat
- tn06\_210798\_npp01gene.sas7bdat
- tn06\_210799\_npp02preg.sas7bdat
- tn06\_210800\_npp03preg.sas7bdat
- tn06\_210815\_npp04.infa.sas7bdat
- tn06\_210823\_npp05preg.sas7bdat
- tn06\_210953\_npp12ever.sas7bdat
- tn06\_210954\_npp1312mo.sas7bdat
- treatment\_table.sas7bdat

## **DSIC**

The TrialNet 06 DSIC directory contains the following file:

- Trialnet\_06\_DSIC.doc – This file includes a comparison of the TrialNet 06 data to the “Nutritional Intervention to Prevent (NIP) Type 1 Diabetes” manuscript published in the journal Infant, Child, and Adolescent Nutrition.

## **Forms**

The TrialNet 06 Forms directory contains the following 29 Case Report Forms in Microsoft Word format:

- NPP Eligibility Form Site 8 01042008.doc
- NPP01 General Screening Form 05222007 v1.3.doc
- NPP02 Pregnant Woman Screening Form 05222007 v1.2.doc
- NPP03 Pregnant Woman Enrollment Form 09212006 v1.0.doc
- NPP04 Infant Screening Form 03282007 v1.2.doc
- NPP05 Pregnancy History Form 05222007 v1.2.doc
- NPP06 Infant Enrollment Medical History Form 03082007 v1.6.doc
- NPP07 Infant Family History Form 11282006 v1.doc
- NPP08 Entry A Non-Nursing Mother Visit Form 03082007 v1.0.doc
- NPP09 Nursing Mother Visit Form 12062006 v1.3.doc
- NPP10 Follow-Up Visit Form 03082007 v1.3.doc
- NPP11 Infant 6, 12, 18 and Every 6 Months Old Visit Form 3092007 v1.3.doc
- NPP12 6, 18, 30, and Every 6 Months Infant Specimen Collection Form 11282006 v1.doc
- NPP13 12 Months Old Infant Specimen Collection Form 07022007 v1.1.doc

- NPP14 24 Months Old Infant Specimen Collection Form 07022007 v1.1.doc
- NPP15 Study Substance Dispensation Return Form 05222007 v1.2.doc
- NPP16 Study Substance Compliance Form 11282007 v1.2.doc
- NPP17 Missed Visit Form 11152007 v1.2.doc
- NPP18 Participant Status Form 05312007 v1.2.doc
- NPP19 Protocol Deviation 15Nov2007 v1.1.doc
- NPP20 Infant Dietary Supplement15Nov2007 (v1.2).doc
- NPP20E All Mothers Infant Enrollment Dietary Supplement 11152007 v1.1.doc
- NPP20M Pregnant Nursing Dietary Supplement 15Nov2007 v1.1.doc
- NPP21 Food Introduction History Form 11152007 v1.3.doc
- NPP22 Food Frequency Questionnaire 15Nov2007 v1.2.doc
- NPP23 Adverse Event Report Form 15Nov2007 ( v1.3).doc
- NPP24 Type 1 Diabetes Onset Form 11152007 v1.1.doc
- NPP25 Entry A Verification of Infant Eligibility Form 05222007 v1.2.doc
- NPP26 Study Substance Permanent Discontinuation Form 04162007 v1.3.doc