

## The TrialNet 10 Study Data Archive

TrialNet 10 was a phase 2 prevention trial of TrialNet, studying the effect of teplizumab on insulin production in the relatives of type 1 diabetics that were at high risk of developing the disease. TrialNet 10 assessed if teplizumab helped prevent or delay the onset of type 1 diabetes by prohibiting the immune process that causes the destruction of insulin secreting beta cells in the pancreas during the "pre-diabetic" state. The TrialNet 10 Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

Archive files are organized into the following directories:

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

### **Data**

The TrialNet10 Data directory contains the following files and datasets in Windows-based SAS and CSV formats. Each dataset corresponds to the form of the same name:

- ae.csv
- ae.sas7bdat
- autoab.csv
- autoab.sas7bdat
- bmi.csv
- bmi.sas7bdat
- cbc.csv
- cbc.sas7bdat
- cmv.csv
- cmv.sas7bdat
- cmvebv.csv
- cmvebv.sas7bdat
- ebv.csv
- ebv.sas7bdat
- hba1c.csv
- hba1c.sas7bdat
- hla.csv
- hla.sas7bdat
- mastable.csv
- mastable.sas7bdat
- ogtt\_cpep.csv
- ogtt\_cpep.sas7bdat
- ogtt\_glu.csv
- ogtt\_glu.sas7bdat

- relation.csv
- relation.sas7bdat
- status.csv
- status.sas7bdat
- treatment.csv
- treatment.sas7bdat

### Data\Analysis

This subdirectory contains an analysis dataset for the TrialNet 10 study:

- TN10\_Xtrial\_PrimaryAnalysisData.csv

### Data\Contents

- TrialNet TN10 Data Dictionary\_Analysis.rtf
- TrialNet TN10 Data Dictionary\_Central Laboratory Results\_Analysis.docx
- TrialNet TN10 Data Dictionary\_Flow Cytometry.docx

### Documents

The TrialNet 10 Documents directory contains:

- 206 TN10 Anti-CD3 Prevention Protocol Version 25JUN14 – CLEAN.doc
- TN10 ANTI-CD3 MOO V 3.0 20130913 FINAL.pdf
- Dataset Preparation Documentation TrialNet 20210901.docx

### DSIC

The TrialNet 10 Data Integrity Check (DSIC) directory contains:

- TrialNet\_10\_DSIC\_V1.pdf - A report of an examination of the analysis and form datasets for completeness by statisticians and quality control specialists at the Repository. Published results from the TrialNet 10 data were compared to values recalculated from TrialNet 10 archived analysis datasets in the NIDDK Central Repository.

### Forms

The TrialNet 10 Forms directory contains:

- Adverse Event Form.pdf
- CBC with Differential Form.pdf
- Change In Study Drug Form.pdf
- Change Of Status Form.pdf
- Concomitant Medications Form.pdf

- Diabetes Onset Form V. 1.pdf
- Diabetes Onset Form V. 2.pdf
- EKG Results Form.pdf
- Eligibility Form V. 2.pdf
- Eligibility Form V. 1.pdf
- Infusion Period Local Lab Results Form.pdf
- Interim Medical History Form.pdf
- Mortality Event Form.pdf
- Phone Contact Form.pdf
- Physical Exam Form.pdf
- Pregnancy Confirmation Form.pdf
- Pregnancy Monitoring Form.pdf
- Pregnancy Outcome Form.pdf
- PreRandomization Exit Form.pdf
- Protocol Deviation Form.pdf
- Screening Medical History.pdf
- Site Transfer Form.pdf
- Study Drug Administration and Monitoring Form.pdf
- Treatment Start Date Form.pdf