

The TrialNet 10 Study Data Archive

TrialNet 10 (TN10) 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. TN10 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.

Archive files are organized into the following directories:

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

Data

The TN10 Data directory contains the following files:

- 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

- TN10_Xtrial_PrimaryAnalysisData.csv

Data\Analysis\Secondary Outcomes

- AE.csv
- ae.sas7bdat
- AUTOAB.csv
- autoab.sas7bdat
- BMI.csv
- bmi.sas7bdat
- CBC.csv
- cbc.sas7bdat
- CMV.csv
- cmv.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
- OGTT_INS.csv
- ogtt_ins.sas7bdat
- RELATION.csv
- relation.sas7bdat
- STATUS.csv
- status.sas7bdat
- TREATMENT.csv
- treatment.sas7bdat

Data\Analysis\Secondary Outcomes\Contents

- TrialNet-TN10 Data Dictionary_Analytic Datasets.pdf

- TrialNet-TN10 Data Dictionary_Central Laboratory Results_Secondary Manuscript.pdf

Data\Analysis\Secondary Outcomes\Exhausted_TCell

- Trialnet-TN10 Data Dictionary_ Exhausted T-Cell Data.pdf
- XTRIAL.csv
- xtrial.sas7bdat

Data\Analysis\Secondary Outcomes\Proinsulin

- PROINSULIN.csv
- proinsulin.sas7bdat
- TrialNet-TN10 Data Dictionary_Proinsulin Data.pdf

Data\Contents

- TrialNet TN10 Data Dictionary_Analysis.pdf
- TrialNet TN10 Data Dictionary_Central Laboratory Results_Analysis.pdf
- TrialNet TN10 Data Dictionary_Flow Cytometry.pdf

Documents

The TN10 Documents directory contains:

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

DSIC

The TN10 Dataset Integrity Check (DSIC) directory contains:

- TrialNet_10_DSIC_V1.pdf
- TrialNet_10_Secondary_Outcomes_DSIC.pdf

Forms

The TN10 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