

## **The TrialNet 19 (TN19) Study Data Archive**

The ATG-GCSF in New Onset Type 1 Diabetes (TN19) archive contains the Documents, Forms, Study Data, and Dataset Integrity Check.

Archive files are organized into the following directories:

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

### **Documents**

The TN19 Documents directory contains:

- Manual\_of\_Operations.pdf – Manual of Operations for the TrialNet 19 study
- Protocol.pdf – Protocol for the TrialNet 19 study

### **Forms**

The TN19 Forms directory contains 22 Forms from the study

### **Data**

The TN19 Data directory contains the following files in SAS format (.sas7bdat):

- ae.sas7bdat – Adverse Events Dataset
- autoab.sas7bdat – Autoantibodies Dataset
- bmi.sas7bdat – Body Mass Index (BMI) Dataset
- cbc.sas7bdat – Complete Blood Count (CBC) Dataset
- cd4cd8.sas7bdat – CD4/CD8 Cell Data
- cd4cd8x.sas7bdat – CD4/CD8 Additional Cell Data
- change.sas7bdat – Change in Status Dataset
- cpeptide.sas7bdat – C-peptide M Dataset
- hba1c.sas7bdat – HBA1C Dataset
- hypo.sas7bdat – Hypoglycemic Events Dataset
- insulin.sas7bdat – Insulin Dataset
- mastable.sas7bdat – Master Table Dataset including key variables
- mmtt.sas7bdat – Mixed Meal Tolerance Test (Glucose) Dataset
- treatment.sas7bdat – Treatment Dataset

### **DSIC**

The TN19 Dataset Integrity Check (DSIC) directory contains:

- DSIC.doc – A report of an examination of the TN19 datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Table 1 from the paper “Low-Dose Anti-Thymocyte Globulin (ATG) Preserves  $\beta$ -Cell Function and

Improves HbA1c in New-Onset Type 1 Diabetes". Published results from the TN19 data were compared to values recalculated from TN19 archived datasets in the NIDDK repository.