

**NEW ONSET OF TYPE 1 DIABETES MYCOPHENOLATE MOFETIL – DACLIZUMAB CLINICAL TRIAL
 TrialNet-02 (TN-02) Mycophenolate mofetil-Daclizumab Data Archive**

The TN-02 Mycophenolate mofetil-Daclizumab Data archive contains data collected at screening, baseline, and follow-up for participants in the TrialNet MMF/DZB clinical trial. The clinical trial is part of the second type of TrialNet Type 1 Diabetes studies: intervention studies for those recently diagnosed with Type 1 Diabetes (within 100 days). Participants in the three-arm, double-blind, placebo-controlled clinical trial were randomized to one of three conditions: MMF with DZB placebo; MMF with active DZB; or MMF placebo with DZB placebo.

The files in the archive are organized into the following directories:

1. Documentation
2. Forms
3. Data
4. Dataset Integrity Check (DSIC)

1. Documentation Directory

The TN-02 Documentation Directory contains:

- the study protocol, **RTI_01TN02ProtocolVersion 2.1 11Feb08.pdf**
- **specimen collection.pdf**, a schedule of laboratory assessments across the study period and the schedule for monitoring of Epstein-Barr Virus and Cytomegalovirus
- a list of study publications, **TrialNet TN-02 Publication list.doc**

Additional details on the study design, eligibility and the baseline and follow-up assessments can be found on the study website, <http://www.diabetestrialnet.org/studies/MMF-DZB.htm>

2. Forms Directory

The TN-02 Forms Directory contains 42 files of data collection forms used in the TN-02 study. A brief description of each form is provided below in **Table 1**.

3. Data Directory

The TN-02 Data Directory contains:

- A data dictionary, "**Protocol_2.Data Dictionary**" that provides an alphabetical listing of variable names and labels for each study data file
- 37 SAS data files (*.sas7bdat) corresponding to 35 of the data collection forms plus a randomization file to indicate subject randomization status (mmf_randlist.sas7bdat) and laboratory results (mmf_labdata.sas7bdat)

Table 1 provides a listing of the study data files and corresponding case report forms.

| TABLE 1 | | SAS File Name (.sas7bdat) |
|--|--|----------------------------------|
| Form Type | Form Name (.pdf) | |
| Screening Form (MMF01) | 01 TNO2 MMF Version 01 06July04 | mmf01 |
| Baseline Form (MMF02) | 01 TN02 Form MMF02 Version 1.2 01Oct05 | mmf02 |
| Eligibility and Randomization Form (MMF03) | 01 TN02 Form MMF 03 1.2 01Oct05 | mmf03 |
| Major Hypoglycemic Events (MMF04) | MMF04.new | mmf04 |
| Family History Form (MMF05) | MMF05.new | mmf05 |
| Family History Form (Children) | MMF05.new | mmf05c |
| Family History Form (Siblings) | MMF05.new | mmf05s |

| TABLE 1 | | SAS File Name (.sas7bdat) |
|--|----------------------------------|----------------------------------|
| Form Type | Form Name (.pdf) | |
| Follow-up Form (MMF06) | MMF06 rev 100105 | mmf06 |
| End of Treatment Contact Form (MMF06E) | MMF06E new | Na |
| Blood Glucose & Insulin Record (MMF06G) | MMF06G rev 080107 | Na |
| Missed Visit Form (MMF06M) | MMF06M new | Na |
| Post-treatment Follow-up Form (MMF06P) | MMF06P rev 1000105 | mmf06p |
| Short Follow-up Form (MMF06S) | MMF06S rev 100105 | mmf06s |
| Adverse Event Report Form (MMF07) | MMF07 rev 100105 | mmf07 |
| Mortality Event Form (MMF07M) | MMF07M new | Na |
| Unexpected Change in Study Medication (MMF08) | MMF08 new | mmf08 |
| Medication Withdrawal Form (MMF08W) | MMF08W new | mmf08w |
| Pregnancy Confirmation Report (MMF09) | MMF09 new | na |
| Pregnancy Outcome Report Form (MMF09R) | MMF09R new | mmf09r |
| Change of Status Form (MMF10) | MMF10 new | mmf10 |
| End of Study Form (MMF10E) | MMF10E 080808 | Na |
| Protocol Deviation Form (MMF11) | MMF 11 rev 100105 | mmf11 |
| Participant Transfer Form (MMF12) | MMF 12 Participant Transfer Form | mmf12 |
| MMF22 Neurologic Assessment | TN02-MMF22_CRF | mmf22 |
| Autoantibodies (STF) | MMF99AA | mmf99aa |
| Results Transmittal Form, CBC w/ Differentials | MMF99CB | mmf99cb |
| Chemistries (STF) | MMF99CH | mmf99ch |
| Baseline C-peptide (STF) | MMF99CP | mmf99cp |
| DNA (STF) | MMF99DN | mmf99dn |
| DNA (STF, international) | MMF99DNi | |
| DZB (STF) | MMF99DZ | mmf99dz |
| ELISPOT (STF) | MMF99EL | mmf99el |
| HbA1c (STF); HbA1c (STF, international) | MMF99HB; MMF99HBi | mmf99hb |
| HLA (STF); HLA (STF, international) | MMF99HL; MMF99HLi | mmf99hl |
| HIV/HEP B/HEP C Screening (STF) | MMF99HV | mmf99hv |
| 2-hour MMTT (STF) | MMF99M2 | mmf99m2 |
| 4-hour MMTT (STF) | MMF99M4 | mmf99m4 |
| MMF Levels (STF) | MMF99MF | mmf99mf |
| EBV/CMV PCR (STF) | MMF99PC | mmf99pc |
| PK Analysis (STF) | MMF99PK | mmf99pk |

| TABLE 1 | | SAS File Name (.sas7bdat) |
|------------------------|---------------------------|----------------------------------|
| Form Type | Form Name (.pdf) | |
| Viral Serology (STF) | MMF99VS | mmf99vs |
| MedWatch Form | TrialNet MedWatch (MMFSA) | mmfsa |
| MMF Randomization List | NA | mmf_randlist |
| MMF Laboratory Results | NA | mmf_labdata |

Note: STF, Specimen Transmittal Form

Na: Case report forms MMF06E new, MMF06G rev 080107, MMF06M new, MMF07M, MMF09 new, MMF10E 080808 have no associated data.

4. Data Integrity Check

The TN-02 Data 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. Data were checked for completeness, consistency, and usability. The published data from the study (Gottlieb et al for the Type 1 Diabetes TrialNet MMF/DZB Study Group, 2010, in *Diabetes Care*) were compared to values recalculated from the TN-02 data in the NIDDK repository.