

## 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.

<b>TABLE 1</b>		<b>SAS File Name (.sas7bdat)</b>
<b>Form Type</b>	<b>Form Name (.pdf)</b>	
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

<b>TABLE 1</b>		<b>SAS File Name (.sas7bdat)</b>
<b>Form Type</b>	<b>Form Name (.pdf)</b>	
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

<b>TABLE 1</b>		<b>SAS File Name (.sas7bdat)</b>
<b>Form Type</b>	<b>Form Name (.pdf)</b>	
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.