

EFFECTS OF RITUXIMAB ON THE PROGRESSION OF TYPE 1 DIABETES IN NEW ONSET SUBJECTS

TrialNet-05 (TN-05) Rituximab Anti-CD20 Data Archive

The TN-05 Rituximab Data archive contains data collected at screening, baseline, and follow-up for participants in the TrialNet Rituximab 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 two-arm, multicenter, double-masked, placebo-controlled clinical trial were randomly assigned to Rituximab treatment. The archive includes the study protocol and related descriptive documentation, data collection forms, study data, and the data integrity check for the TN-05 study.

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-05 Documentation Directory contains:

- a brief summary of the study protocol for the entire study, **RTI_61TN05FINALProtocolVersion30Aug09.pdf**
- **RTI_8aAnti-CD20ProtocolSynopsisSpecimen CollectionSchedule.pdf**, a tabulated summary of the study protocol and schedule of laboratory assessments across the study period
- **TrialNet Lab Value Labels-TN01_TN02_TN05 20120202.xlsx**, documents the specimens and tests conducted by the laboratory
- **TNpapers by study.docx**, lists the publications conducted to date by the TN-05 (and TN-01 and TN-02) study groups

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/Rituximab/>

2. Forms Directory

The TN-05 Forms Directory contains 27 data collection forms used in the TN-05 study. A brief description of each form is provided below in Table 1.

3. Data Directory

The TN-05 Data Directory contains:

- A data dictionary, **“Protocol_5.Data Dictionary”** that provides an alphabetical listing of variable names and labels for each study data file. The file is current for data collected as of July 31, 2011.
- 31 SAS data files (*.sas7bdat) corresponding to data collection forms

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

Table 1. Study data and forms

Form	Form Name (.doc or .pdf)	SAS File Name (.sas7bdat)
Screening	RIT01 – Screening031506	Screening_form
Pre-randomization Exit	RIT01E – PreRand031506	Prerand_exit_form
Baseline	RIT02 – Baseline030107	Baseline_med_hist
BaselinePE	RIT03 – BaselinePE072706N EW	Baseline_phys_exam
Family History	RIT04 – Family031506	Family_history
Eligibility	RIT05 – Eligibility050107	Eligibility_form
Randomization	RIT06 – Rand031506	Na
Study Drug Administration	RIT07 – Admin071006NEW	Study_drug_admin
Dosing Vital Sign Monitoring	RIT08 – VitalSigns031506	Dosing_vital_sign_monitoring
Diabetes Management	RIT09 – DM031506	Diabetes_management
Concomitant Medications	RIT10 – ConMeds031506	Concomitant_meds
Physical Exam	RIT11 – PE031506	Phys_exam
Follow-Up	RIT12 – FollowUp090506NE W	Followup_visit_form
Adverse Event	RIT13 – AE081006NEW	AdverseEvent
Mortality	RIT13M – Mort031506	Na

Form	Form Name (.doc or .pdf)	SAS File Name (.sas7bdat)
Pregnancy Confirmation	RIT14 – PregCon031056	Pregnancy_confirmation
Pregnancy Outcome	RIT14R – PregOut031506	Pregnancy_outcome
Change of Status	RIT15 – ChangeStatus031506	Nh07_changeofstatus
Missed Visit	RIT16 – MissedVisit031506	Nh09_followupmissedvisit
Tetanus	RIT17 – Tetanus031506	Na
Hepatitis A	RIT18 – HepA072706NEW	Na
PhiX	RIT19 – PhiX174031506	Phix_admin
Permanent Participant Site Transfer	RIT20 – Transfer080706	Nh20_permparticipantsitetr nsfr
Prot Dev	RIT21 – ProtDev051007	Nh13_protdeviationproced urelerr
Neurologic Assessment	RIT22 – NA070107	Neurologic_assessment
Results Transmittal CBC w/ Differential	RIT99CB	Cbc_wdiff_results
AE MRO Review	Na	Aereview
Diabetes and Health Information	Na	Diabetes_health_info
H1N1 Vaccination	Na	H1n1_vacc_form
Long-Term Follow-up Phase Authorization	Na	Longterm_followup_phase _auth
Parent Survey	Na	Parent_survey
Participant Survey	Na	Participant_survey
Registration	Na	Registration
Research Lab	Na	Research_labs
Treatment Table	Na	Treatment_table

Note: na Form or data not made available to the repository;

4.Dataset Integrity Check

The TN-05 DSIC 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 year one of the study (Prescovitz et al for the Type 1 Diabetes TrialNet MMF/DZB Study Group, 2009, in the *New England Journal of Medicine*) were compared to values recalculated from the TN-05 data in the NIDDK repository.