

## DPT-1 Data Archive

The DPT-1 Data Archive contains the study protocol and other descriptive documentation, study forms, and data collected by the study. The archive is organized into the following directories:

- Documentation
- Forms
- Data
- Dataset\_Integrity\_Check

This new version of the data archive includes an ancillary study of genotyping data for DPT-1 study subjects.

### 1. Documentation

This directory contains the DPT-1 Study Protocol and the Manual of Operations.

### 2. Forms

This directory contains the forms used for data collection. The forms are listed in Table 1.

### 3. Data

This directory contains DPT-1 Study data.

#### 3.1 Main\_Study

This directory contains data in SAS format in 31 data files that are listed in Tables 1 and 2.

This directory also contains 3 subdirectories:

- Documentation contains two files as described below:
  - DPT-1 DB Release.doc: a description of the data release, including a list and description of the tables for which data has been provided in this release.
  - Proc\_Content.rtf: a content listing of each table which provides the number of observations, a complete list of the variables, and a description of each variable for each table included in the file.
- ASCII - This directory contains the same 31 data files in ASCII format.
- SAS Transport - This directory contains a SAS Transport Data File for each of the 31 SAS data files. The transport files were created by SAS V9 PROC CPORT.

**Table 1: Data collected by Study Forms**

| File Name | Description   | SAS Files        |
|-----------|---|------------------|
| AE        | Adverse Reporting Form  | ae.sas7bdat      |
| BM        | Baseline Medical History Form                                 | bm.sas7bdat      |
| DC        | Dispensation and Collection of Oral Medication Form           | dc.sas7bdat      |
| DM        | Study Event Form – Diagnosis of Diabetes                      | dm.sas7bdat      |
| DN        | Death Notice  | dn.sas7bdat      |
| EI        | Encounter Form  | ei.sas7bdat      |
| FH        | Family History Form   | fh.sas7bdat      |
| GENFORM   | Table that collects general completion data for the following | genform.sas7bdat |
| GP        | Home Glucose Monitoring Form                                  | gp.sas7bdat      |
| HY        | Hypoglycemia Reporting Form                                   | hy.sas7bdat      |

| <b>File Name</b> | <b>Description</b>                      | <b>SAS Files</b> |
|------------------|---|------------------|
| IF               | Insulin Infusion Flow-Sheet             | if.sas7bdat      |
| II               | Treatment/Visit Non-Compliance          | ii.sas7bdat      |
| LF               | Lost To Follow-up                       | lf.sas7bdat      |
| MH               | Medical History                         | mh.sas7bdat      |
| OT               | Off-Therapy Follow-Up Form              | ot.sas7bdat      |
| PE               | Physical Examination Form               | pe.sas7bdat      |
| PO               | Pregnancy Outcome Form                  | po.sas7bdat      |
| PQ               | Performance Questionnaire               | pq.sas7bdat      |
| PY               | Pregnancy Form                          | py.sas7bdat      |
| RO               | Request for Replacement Oral Medication | ro.sas7bdat      |
| WR               | Wide Range Achievement Test             | wr.sas7bdat      |

**Table 2: Data files not collected by Study Forms**

| <b>File Name</b> | <b>Description</b>  | <b>SAS Files</b>   |
|------------------|---|--------------------|
| ANCTEST          | Test Table for results related to Dr. Eisenbarth's Ancillary Study (contains all autoantibody results aliquoted from the ICA tests) | anctest.sas7bdat   |
| AV               | Review of Adverse Events by Safety Monitoring Group (SMG) to determine whether event Study Related                                  | av.sas7bdat        |
| CODETABLE        | Look-up table for coded variables in various tables. See Content Listing of each table for indication of which 'Code Group' to use. | codetable.sas7bdat |
| DMREV            | Outcome Review of Study Events by External Review Committee   | dmrev.sas7bdat     |
| EV               | Review of Insulin Infusions to determine acceptability.   | ev.sas7bdat        |
| FOLLOWUP         | Table related to the Follow-Up Questionnaire administered by the DMU  | followup.sas7bdat  |
| HW               | Supplemental table of Heights and Weights extracted from the Specimen Transmittal Forms (STFs) of Glucose Tolerance Tests           | hw.sas7bdat        |
| RELATIVE         | Relative Table (contains information related to the subject's probands)   | relative.sas7bdat  |
| SUBJECT          | Subject Table (contains Race, Gender, Treatment Assignment, Stratum, Age At IDDM Diagnosis, etc.)                                   | subject.sas7bdat   |
| TEST             | Test Table (contains all results for all tests performed related to the DPT-1)  | test.sas7bdat      |

### 3.2 Ancillary\_Genotype

This directory contains genotype data generated in an ancillary study as described in the paper by Butty, et al [1]. The genotype data includes one Excel file, DPT1-Cohort-SNPgenotypes.xls, with the following 3 data sheets:

- Data – it contains some basic phenotype data and the SNP data for 708 DPT-1 subjects
- Data dictionary – it contains the data dictionary describing the variables and the data values
- Primers and probes – it contains all primers and probes used in the genotyping assays

#### **4. Dataset\_Integrity\_Check**

The DPT-1 Dataset Integrity Check directory contains reports of examination of the repository by statisticians and quality control specialists at the Repository. Datasets were checked for completeness, consistency, and usability. The published data from the DPT-1 study were compared to values recalculated from the DPT-1 data in the NIDDK repository.

The “IntegrityMemo\_Article1\_Version1.0.pdf” report is an analysis by repository statisticians using this distribution against the study data published in Skyler et al [2].

The “IntegrityMemo\_Article2\_Version1.0.pdf” report is an analysis by repository statisticians using this distribution against the study data published in Skyler et al [3].

#### **References:**

[1] Butty V, Campbell C, Mathis D, Benoist C; DPT-1 Study Group. Impact of diabetes susceptibility loci on progression from pre-diabetes to diabetes in at-risk individuals of the diabetes prevention trial-type 1 (DPT-1). *Diabetes*. 2008 Sep;57(9):2348-59.

[2] Skyler JS, Diabetes Prevention Trial--Type 1 Diabetes Study Group. Effects of insulin in relatives of patients with type 1 diabetes mellitus. *N Engl J Med*. 2002 May 30;346(22):1685-91.

[3] Skyler JS, Krischer JP, Wolfsdorf J, Cowie C, Palmer JP, Greenbaum C, Cuthbertson D, Rafkin-Mervis LE, Chase HP, Leschek E. Effects of oral insulin in relatives of patients with type 1 diabetes: The Diabetes Prevention Trial--Type 1. *Diabetes Care*. 2005 May;28(5):1068-76.