DPT-1 Database Release

The following document is to accompany the release of the de-identified DPT-1 Database.

The data included in this release is HIPAA compliant. All subject identifiers have been removed. All date fields have been converted to variables related to the age of the subject at the time of the event (in days). The data is limited to eligible subjects that had a usable ICA screening (N=97272) on or before October 31, 2002. All data is current as of as of April 30, 2003, except the autoantibody data (in the ANCTEST table) that is current as of November 1, 2004.

A masked ID (MaskID) has been created to identify each subject. This ID is composed of a two-letter prefix (randomly chosen from the letters: A, D, E, F, H, J, K, L, M, N, P, R, T, W, X, Y) and a random 4-digit number suffix. The ID for each subject is consistent across all tables.

The data are available in three formats: 1) SAS V9, 2) SAS V6 Transport Data Files and 3) ASCII comma delimited. The SAS files are located in the subdirectory "SAS Data Files", the SAS Transport Data files are located in the subdirectory "SAS Transport Data Files" and the ASCII files are located in the subdirectory "ASCII Data Files".

A content listing of each Table is provided in the file "DPT1.ContentListing.rtf". This listing provides for each Table the number of observations, a complete list of the variables, as well as description of each variable. Additionally, the DPT-1 Protocol, as updated in October 2000, is provided in the file "DPT-1 Protocol as Updated October 2000 Final".

Please note that the table SUBJECT contains the variable Age_At_IDDM_Diagnosis. Based on the status of the subject, this variable was determined by one of three methods:

1) For randomized subjects, this variable was based on the occurrence of confirmed diabetes according to the protocol.
2) For events occurring during staging, this variable is based on the first occurrence of a diabetic event and/or the self-reported date of symptoms.
3) For subjects who were involved in the Follow-up Questionnaire Study who do not fall into categories 1) or 2), this variable was based on self-reported information. To be considered an IDDM diagnosis the subject had to have been diagnosed as having Type 1 diabetes and had to have autoantibodies present from their ICA screening(s).

All subjects with a missing value for the variable Age_At_IDDM_Diagnosis had no indication of diabetes as of April 30, 2003.

To aid in determining a subject's date of last follow-up, three variables are included in the SUBJECT table. These include: Age_At_Last_DPT1_Test (age at last DPT-1 test performed), Age_At_Last_Contact_From_Forms (age at last visit based on the On-Study

Forms), and Age_Of_Last_Contact_Questionnair (age at last contact based on the Follow-Up Questionnaire).

The Tables included in this release are the following:

Table Name	Description
SUBJECT	Subject Table (contains Race, Gender, Treatment Assignment, Stratum, Age At IDDM Diagnosis, etc.)
RELATIVE	Relative Table (contains information related to the subject's probands)
TEST	Test Table (contains all results for all tests performed related to the DPT-1)
ANCTEST	Test Table for results related to Dr. Eisenbarth's Ancillary Study (contains all autoantibody results aliquoted from the ICA tests)
FOLLOWUP	Table related to the Follow-Up Questionnaire administered by the DMU
HW	Supplemental table of Heights and Weights extracted from the Specimen Transmittal Forms (STFs) of Glucose Tolerance Tests
CODETABLE	Look-up table for coded variables in various tables. See Content Listing of each table for indication of which 'Code Group' to use.

Additionally, a table has been provided for each of the On-Study Forms. Data within each of these tables is generally limited to that obtained after a subject was randomized on to the Parenteral or Oral Arm of the DPT-1. The exception to this is the DM Table, which contains additional Study Event data for diabetic events reported from the follow-up of High Risk subjects, the follow-up of Parenteral Subjects after the close of the trial, as well as that obtained from physicians as part of the Follow-Up Questionnaire. A PDF copy of the actual On-Study Form is located in the subdirectory "PDFs Of On-Study Forms".

Table Name	Description
AE	Adverse Reporting Form
BM	Baseline Medical History Form
DC	Dispensation and Collection of Oral Medication Form
DM	Study Event Form – Diagnosis of Diabetes
DN	Death Notice
EI	Encounter Form
FH	Family History Form
GENFORM	Table that collects general completion data for the following forms: DS (Diabetes Clinical Data System (DCDS) Consent) EC (Eligibility Checklist) FU (Family/Friend's Understanding and Expectations Interview) IB (Volunteer's Performance on In-clinic Tasks) PA (Volunteer's Pre-randomization Study Quiz) VA (Volunteer's Availability Interview) VU (Volunteer's Understanding & Expectations)
GP	Home Glucose Monitoring Form

HY	Hypoglycemia Reporting Form
IF	Insulin Infusion Flow-Sheet
II	Treatment/Visit Non-Compliance
LF	Lost To Follow-up
MH	Medical History
OT	Off-Therapy Follow-Up Form
PE	Physical Examination Form
PO	Pregnancy Outcome Form
PQ	Performance Questionnaire
PY	Pregnancy Form
RO	Request for Replacement Oral Medication
WR	Wide Range Achievement Test

Lastly, the following tables contain information related to the review of adverse events, insulin infusions, and study events. Again the data in these tables are limited to those subjects who were randomized on to either the Parenteral or Oral Arms. The exception to this is the DMREV Table, which contains additional reviews of Study Event data for diabetic events reported from the follow-up of High Risk subjects, the follow-up of Parenteral Subjects after the close of the trial, as well as that obtained from physicians as part of the Follow-Up Questionnaire.

Table	Description
AV	Review of Adverse Events by Safety Monitoring Group (SMG) to determine whether event Study Related
EV	Review of Insulin Infusions to determine acceptability.
DMREV	Outcome Review of Study Events by External Review Committee