

DPPOS Data Archive

The Diabetes Prevention Program Outcome Study (DPPOS) is the long-term follow-up of the original DPP cohort. This report describes the public release of Phase 1 and Phase 2 of the DPPOS dataset. Phase 1 is based on all DPPOS data collected after the final DPP Bridge visits in 2002 and prior to the Phase 1 data lock in August, 2008. Phase 2 is based on all DPPOS data collected after the DPPOS Phase 1 data lock in 2008 and prior to the Phase 2 data lock in January 2014.

This DPPOS Archive contains the study summary, protocol, study data, forms, and dataset integrity check.

In addition, this data archive contains the bridge period, which was the time period following the main DPP (Diabetes Prevention Program) trial beginning in August 2001 and ending with the start of the DPPOS. This DPP bridge period dataset is based on all data collected after the main DPP visits ended in July 2001 and prior to the DPPOS Phase 1 period which started in the fall of 2002.

Archive files are organized into the following directories:

- Documentation
- Forms
- Data
- Dataset Integrity Check (DSIC)

Documentation

The DPPOS Documents directory contains:

- DPPOS_Protocol.pdf – Study protocol
- Documentation for Phase 1 DPPOS data release.pdf – Description of the DPPOS Phase 1 data
- Documentation for DPPOS Phase 2 data release – FINAL.pdf – Description of the DPPOS Phase 2 data
- DPP_BRIDGE_Documentation.pdf – Description of the DPP Bridge data

Forms

The DPPOS Forms directory contains:

- DPP_BRIDGE_Forms – All forms used during the DPP Bridge period
 - E04.pdf – Pregnancy Confirmation Report
 - E05.pdf – Pregnancy Outcome Report

- F01.2.pdf – Standard Follow-Up Visit Inventory
 - F01.3.pdf – Bridge Period – Standard Follow-Up Visit Inventory
 - F02.2.pdf – Major Follow-Up Visit Inventory
 - F02.3.pdf – Bridge Period – Major Follow-Up Visit Inventory
 - F03.pdf – Interim Follow-Up Visit Inventory
 - F04.pdf – Missed Follow-Up Visit Report
 - F05.pdf – Medication Adherence Interview
 - L03.pdf – Lifestyle Contact – In Person
 - L04.1.pdf – Lifestyle Physical Activity Log
 - L04.2.pdf – Bridge Period – Help Physical Activity Log
 - L05.1.pdf – Lifestyle Group Session Log
 - L05.2.pdf – Bridge Period – Help Group Session Log
 - L06.pdf – Bridge Period – Intensive Lifestyle Contact - Only
 - Q03.pdf – Modifiable Activity Questionnaire
 - Q04.pdf – Low Level Physical Activity Recall
 - Q06.pdf – Retention and Treatment Monitoring Measures
 - Q08.pdf – Interval History Questionnaire
 - Q10.pdf – DPP-Specific Support Measure – Follow-Up Visits
 - Q13.pdf – Urinary Incontinence Questionnaire
 - R04.pdf – Coronary Heart Disease (CHD) Risk Status Report
 - TR1.pdf – Participants Randomized to Troglitazone Follow-Up Visit Inventory
- DPPOS_PHASE1_Forms – All forms using during Phase 1 of the DPPOS Study
 - E04.pdf – Pregnancy Confirmation Report
 - E05.pdf – Pregnancy Outcome Report
 - F01.pdf – Mid-Year Visit Inventory
 - F02.pdf – Annual Visit Inventory
 - F03.pdf – Interim Visit Inventory
 - F04.pdf – Missed Visit Report
 - F06.pdf – Non-Clinic Visit Inventory
 - F07.pdf – Metformin Discontinuation Form
 - L07.pdf – Lifestyle Session Log
 - P06.pdf – Fundus Photography Procedure Log
 - P07.pdf – Blood Draw Procedure
 - Q03.pdf – Modifiable Activity Questionnaire
 - Q13.pdf – Urinary Incontinence Questionnaire
 - Q16.pdf – Economic Evaluation Questionnaire
 - QWB.pdf – Quality of Well-Being
 - R04.pdf – Coronary Heart Disease (CHD) Risk Status Report

- DPPOS_PHASE2_Forms – All forms used during Phase 2 of the DPPOS Study
 - E04.pdf – Pregnancy Confirmation Report
 - E05.pdf – Pregnancy Outcome Report
 - E11.pdf – Gastric Reduction Surgery Event
 - F01.pdf – Mid-Year Visit Inventory
 - F02.pdf – Annual Visit Inventory
 - F03.pdf – Interim Visit Inventory
 - F04.pdf – Missed Visit Report
 - F06.pdf – Non-Clinic Visit Inventory
 - F07.pdf – Metformin Discontinuation Form
 - F08.pdf – Metformin Safety & Adherence Form
 - L07.pdf – Lifestyle Session Log
 - P07.pdf – Blood Draw Procedure
 - P09.pdf – Physical Functional Assessments
 - Q03.pdf – Modifiable Activity Questionnaire
 - Q11-QWB original.pdf – Quality of Well-Being Scale, Self-Administered
 - Q13.pdf – Urinary Incontinence Questionnaire
 - Q15.pdf – Neuropathy Questionnaire
 - Q16.pdf – Economic Evaluation Questionnaire
 - Q17.pdf – Cognitive Assessments Questionnaire
 - Q19.pdf – Behavioral, Diet, and Activity Questionnaire
 - R04.pdf – Coronary Heart Disease (CHD) Risk Status Report

Data

The DPPOS Data directory contains the following files, and the following raw datasets in Windows-based SAS, v. 7-8-9 format:

- DPP_Bridge – The DPP Bridge data directory contains data corresponding to the DPP Bridge period, and is organized into the following sub-directories:
 - Form_Based – Contains the following datasets, corresponding to the form of the same name (note that the forms corresponding to q01.sas7bdat, Beck Depression Inventory, and q02.sas7bdat, Health Survey Questionnaire, were removed due to copyright):

▪ e04.sas7bdat	▪ f03.sas7bdat
▪ e05.sas7bdat	▪ f04.sas7bdat
▪ f01.sas7bdat	▪ f05.sas7bdat
▪ f02.sas7bdat	▪ i03.sas7bdat

- l04.sas7bdat
 - l05.sas7bdat
 - l06.sas7bdat
 - q01.sas7bdat
 - q02.sas7bdat
 - q03.sas7bdat
 - q04.sas7bdat
 - q06.sas7bdat
 - q08.sas7bdat
 - q10.sas7bdat
 - q13.sas7bdat
 - r04.sas7bdat
 - tr1.sas7bdat
- Non_Form_Based – Contains the following analysis datasets:
 - demographic.sas7bdat – Includes one record for each participant in the released database. Data in this file is identical to the BASELINE data included in the DPP Full Scale data release, but includes only those participants with consent for the bridge data release.
 - events.sas7bdat – A file includes summary event variables for diabetes as well as times to events and censoring data. This file has one record for each participant.
 - lab.sas7bdat – Includes the laboratory results from all regularly scheduled visits.
 - qwbs.sas7bdat – Includes annual (Y02, Y03 and Y04) data based on a self-administered quality of well-being questionnaire.
 - washout.sas7bdat – Includes the glucose results from all washout visits on nondiabetic metformin and placebo participants.
- DPPOS_Phase1 – The DPPOS Phase 1 data directory contains data corresponding to the DPPOS Phase 1 period, and is organized into the following sub-directories:
 - Form_Based – Contains the following datasets, corresponding to the form of the same name (note that the forms corresponding to q01.sas7bdat, Beck Depression Inventory, and q02.sas7bdat, Health Survey Questionnaire, were removed due to copyright):
 - e04.sas7bdat
 - e05.sas7bdat
 - f01.sas7bdat
 - f02.sas7bdat
 - f03.sas7bdat
 - f04.sas7bdat
 - f06.sas7bdat
 - f07.sas7bdat
 - l07.sas7bdat
 - q01.sas7bdat
 - q02.sas7bdat
 - q03.sas7bdat
 - q13.sas7bdat
 - q16.sas7bdat
 - r04.sas7bdat
 - Non_Form_Based – Contains the following analysis datasets:

- demographic.sas7bdat – A file with one record for each participant which includes treatment assignment, baseline age group, baseline BMI group, sex, and race-ethnicity. This file is identical to the data released with the DPP Full Scale Release dataset but includes only participants in the DPPOS Phase 1 release.
 - events.sas7bdat – A file that includes summary event variables for diabetes as well as times to events and censoring data. This file has one record for each participant.
 - fundus.sas7bdat – Two records (one for each eye) of analyzed fundus photo data for all diabetics and a sample of non-diabetics during DPPOS Year 1.
 - laboratory.sas7bdat – One record for each participant for each visit where laboratory measurements were completed.
 - nutrition.sas7bdat – One record of analyzed nutrition data for each participant at DPPOS Years 1, 2 and 5.
 - qwb.sas7bdat – A self-administered Quality of Well Being (QWB) Questionnaire was completed at annual visits during DPPOS Phase 1. One record is included of analyzed QWB data for each participant visit where the QWB was administered.
- DPPOS_Phase2 – The DPPOS Phase 2 data directory contains data corresponding to the DPPOS Phase 2 period, and is organized into the following sub-directories:
 - Form_Based – Contains the following datasets, corresponding to the form of the same name (note that the forms corresponding to q01.sas7bdat, Beck Depression Inventory, and q02.sas7bdat, Health Survey Questionnaire, were removed due to copyright):

▪ e04.sas7bdat	▪ p07.sas7bdat
▪ e05.sas7bdat	▪ p09.sas7bdat
▪ e11.sas7bdat	▪ q01.sas7bdat
▪ f01.sas7bdat	▪ q02.sas7bdat
▪ f02.sas7bdat	▪ q03.sas7bdat
▪ f03.sas7bdat	▪ q13.sas7bdat
▪ f04.sas7bdat	▪ q15.sas7bdat
▪ f06.sas7bdat	▪ q16.sas7bdat
▪ f07.sas7bdat	▪ q17.sas7bdat
▪ f08.sas7bdat	▪ q19.sas7bdat
▪ l07.sas7bdat	▪ r04.sas7bdat
 - Non_Form_Based – Contains the following analysis datasets:

- demographic.sas7bdat – A file with one record for each participant which includes treatment assignment, baseline age group, baseline BMI group, sex, and race-ethnicity. This file is identical to the data released with the DPP Full Scale Release dataset but includes only participants in the DPPOS Phase 2 release.
 - events.sas7bdat – A file that includes summary event variables for diabetes as well as times to events and censoring data. This file has one record for each participant.
 - fundus.sas7bdat – Two records (one for each eye) of analyzed fundus photo data for all participants during DPPOS Years 5 and 11. Data for visits during DPPOS Phase 1 is included.
 - laboratory.sas7bdat – One record for each participant for each visit where laboratory measurements were completed.
 - nutrition.sas7bdat – One record of analyzed nutrition data for each participant at DPPOS Year 11.
 - qwb.sas7bdat – A self-administered Quality of Well Being (QWB) Questionnaire was completed at annual visits during DPPOS Phase 2. One record is included of analyzed QWB data for each participant visit where the QWB was administered.
 - microvascular.sas7bdat – Includes summary event variables for each microvascular based on the DPPOS protocol. This file has one record for each participant.
 - cac.sas7bdat – One record of Coronary Artery Calcification (CAC) CT scans for each participant during DPPOS Year 10.
- Documentation – The Documentation directory contains contents and coding for all datasets, organized by study phase

DSIC

The DPPOS Dataset Integrity Check (DSIC) folder contains:

- DSIC_DPPBridge_IJofO2008.pdf – A report of an examination of the repository for completeness by statisticians and quality control specialists at the Repository. The published data from the DPP BRIDGE study were compared to values recalculated from the DPP BRIDGE data in the NIDDK repository to check for dataset completeness.
- DSIC_DPPOS_Lancet2009_v1.pdf – A report of an examination of the repository for completeness by statisticians and quality control specialists at the Repository. The published data from the DPPOS Phase 1 study were compared to values recalculated from the DPPOS Phase 1 data in the NIDDK repository to check for dataset completeness.
- DPPOS_Phase2_DSIC.pdf – A report of an examination of the DPPOS Phase 2 datasets for completeness by statisticians and quality control specialists at the Repository. These

datasets were used to replicate Table 1 from the paper “Long-term effects of lifestyle intervention or metformin on diabetes development and microvascular complications over 15-year follow-up: the Diabetes Prevention Program Outcomes Study” by Nathan et al. Published results from the DPPOS Phase 2 data were compared to values recalculated from DPPOS raw datasets in the NIDDK repository.