

## **The RISE Adult Medication Study Data Archive**

The RISE Adult Medication Study was a partially double-blind, placebo-controlled, four-arm clinical trial. Study participants were randomized into four groups and received treatment for 12 months. During the treatment period, the first group received Metformin alone; the second group received Glargine for three months, followed by Metformin for the remaining nine months; the third group received Liraglutide in combination with Metformin; and the fourth group was treated with placebo. Following the 12-month treatment period, each group underwent treatment withdrawal for three months. Insulin sensitivity and beta-cell function was evaluated at baseline, the end of the treatment period, and the end of the withdrawal period.

Archive files are organized into the following directories:

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

### **Documents**

The RISE Adult Documents directory contains:

- Documentation for RISE Adult Med data release FINAL.pdf

### **Forms**

The RISE Adult Forms directory contains:

- Adult sleep questionnaires - Data dictionary.pdf
- Adult sleep questionnaires.pdf
- BASELINE\_Baseline Visit Inventory.pdf
- CLAMP\_clamp procedures.pdf
- EXITFORM Participant end-of-study exit interview.pdf
- HISTORY Participant history questionnaire.pdf
- LOCLAB Local lab results.pdf
- OGTT\_OGTT procedures.pdf
- RUNEND Run-in end inventory.pdf
- RUNSTART Run-in start inventory.pdf
- SCREEN Screening Inventory.pdf
- SMBG Self monitoring blood glucose.pdf
- VISIT Post randomization visit inventory.pdf

## **Data**

The RISE Adult data directory contains the following files, and the following datasets in Windows-based *SAS*, v. 7-8-9 format. Each dataset corresponds to the form of the same name:

- riseadult\_basedata\_niddk\_only.sas7bdat
- riseadult\_basedata.sas7bdat
- riseadult\_baseline.sas7bdat
- riseadult\_clampdata.sas7bdat
- riseadult\_clamp.sas7bdat
- riseadult\_exitform.sas7bdat
- riseadult\_history.sas7bdat
- riseadult\_loclab.sas7bdat
- riseadult\_ogttdata.sas7bdat
- riseadult\_ogtt.sas7bdat
- riseadult\_otherlabdata.sas7bdat
- riseadult\_runend.sas7bdat
- riseadult\_runstart.sas7bdat
- riseadult\_screen.sas7bdat
- riseadult\_slpq\_adu.sas7bdat
- riseadult\_smbg.sas7bdat
- riseadult\_status.sas7bdat
- riseadult\_unsched.sas7bdat
- riseadult\_visit.sas7bdat

### Data/Contents

- RISEAdult\_Basedata\_NIDDK\_Only.rtf
- RISEAdult\_basedata.rtf
- RISEAdult\_baseline.rtf
- RISEAdult\_ClampData.rtf
- RISEAdult\_clamp.rtf
- RISEAdult\_exitform.rtf
- RISEAdult\_history.rtf
- RISEAdult\_LOCLAB.rtf
- RISEAdult\_OGTTData.rtf
- RISEAdult\_OGTT.rtf

- RISEAdult\_OtherLabData.rtf
- RISEAdult\_runend.rtf
- RISEAdult\_runstart.rtf
- RISEAdult\_screen.rtf
- RISEAdult\_SLPQ\_ADU.rtf
- RISEAdult\_SMBG.rtf
- RISEAdult\_STATUS.rtf
- RISEAdult\_unsched.rtf
- RISEAdult\_visit.rtf

## **DSIC**

The RISE Adult Data Integrity Check (DSIC) directory contains:

- RISE\_Adult\_DSIC\_V1.pdf - A report of an examination of the analysis and form datasets for completeness by statisticians and quality control specialists at the Repository. Reported results from the RISE Adult data were compared to values recalculated from RISE Adult archived analysis datasets in the NIDDK repository.