

The NASH PIVENS Study Data Archive

The NASH PIVENS Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

Archive files are organized into the following directories:

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

Documents

The NASH PIVENS Documents directory contains:

- PIVENS_Protocol.pdf – NASH PIVENS Protocol
- NASHCRN_Bibliography.pdf – NASH CRN Published Manuscripts
- NASHCRN_Bibliography_V2.pdf – NASH CRN Published Manuscripts, updated as of April 20, 2015
- PIVENS_consent.pdf – NASH PIVENS consent statement
- PIVENS_genetic_consent.pdf – NASH PIVENS blood sample collection, and genetic research consent statement
- PIVENS_SOPs.pdf – NASH PIVENS Standard Operations Manual

Forms

The NASH PIVENS Forms directory contains:

- PIVENS_NEJM_Forms.pdf – Blood Collection for DNA form.
- PIVENS_Forms.pdf – Includes multiple forms for the PIVENS study, including:
 - Alcohol Use Disorders Identification Test
 - Baseline History
 - Central Histology Review
 - DEXA Scan for Bone Mineral Density
 - Death Report
 - DEXA Scan for Body Fat
 - Followup Medical History
 - Interim Event Report
 - Lifetime Drinking History
 - Symptoms of Liver Disease
 - Laboratory Results - Tests Done at s1 and During Followup,
 - Laboratory Results - Tests Done Only During Screening

- Laboratory Results - Tests Required at Visit s2
- Missed or Incomplete Visit
- Physical Activity
- Physical Examination
- Focused Physical Examination
- MOS 36-Item Short-Form Health Survey
- Study Drug Dispensing and Return
- Registration

Data

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

- ad.sas7bdat – This dataset contains 247 records, and contains information from the Alcohol Use Disorders Identification Test (AUDIT) form. It contains information about the subjects' drinking habits.
- bg.sas7bdat – This dataset contains 247 records from the Baseline History form. Data includes family history of liver disease, NASH history, weight history, and other medical and medication history.
- cr.sas7bdat – This dataset contains 469 records from the Central Histology Review form. It contains information regarding liver biopsy slides.
- dd.sas7bdat – This dataset contains 664 records from the DEXA Scan for Bone Mineral Density form. Data includes results from the DEXA scans, and information about the scan.
- dr.sas7bdat – This dataset contains 1 observation from the Death Report form, which is a record to report a patient's death. It includes cause of death.
- dx.sas7bdat – This dataset contains 666 records from the DEXA Scan for Body Fat form, which records information and results from the scan.
- hi.sas7bdat – This dataset contains 2489 records from the follow-up medical history form. This form was completed at several follow-up visits and includes information about changes in the patient's alcohol consumption, medication use and health.
- ie.sas7bdat – This dataset contains 188 records from the Interim Event Report form, which documents events that impact the patient's treatment/participation in the study, or other adverse events not recorded on another form.
- ld.sas7bdat – This dataset contains 248 records from the Lifetime Drinking History form, which includes information about the patient's alcohol drinking patterns from the time they started drinking.
- lr.sas7bdat – This dataset contains 3807 records from the Laboratory Results-Tests done at s1 and During Followup. Data includes laboratory results for hematology, chemistries (i.e. sodium, potassium, etc.), liver panel, prothrombin time, GGT, HbA1c, fasting lipid profile, fasting glucose, oral glucose tolerance test, microalbuminuria, and other tests.
- lq.sas7bdat – This dataset contains 893 observations from the Symptoms of Liver Disease form. This form records information about the patient's different liver

- disease symptoms, and their severity.
- ls.sas7bdat – This dataset contains 247 observations from the Laboratory Results-Tests Done Only During Screening form, including screening etiologic tests, autoantibody studies, ceruloplasmin, A1AT, and iron.
 - lu.sas7bdat – This dataset contains 247 observations from the Laboratory Results-Tests Required at Visit s2, including prothrombin time, GGT, HbA1c, liver panel, oral glucose tolerance test, and microalbuminuria.
 - pa.sas7bdat – This dataset contains 893 observations from the Physical Activity form, which records information about the patient’s work-related and recreational physical activity.
 - pe.sas7bdat – This dataset contains 920 observations from the Physical Examination form, which has detailed physical exam findings from various visits, including measurements and examination findings.
 - pf.sas7bdat – This dataset contains 1752 observations from the Focused Physical Examination form. The data includes measurements and liver signs from focused physical exams.
 - pivtx.sas7bdat – This dataset contains 247 observations and contains the treatment given to each patient.
 - qf.sas7bdat – This dataset contains 893 observations from the MOS 36-Item Short-Form Health Survey. This records patient’s views of their health, pain, how health affects their daily life, and their emotional health.
 - rd.sas7bdat – This dataset contains 3281 observations from the Study Drug Dispensing and Return form. It records whether or not drugs were either returned or dispensed at that given study visit.
 - rg.sas7bdat – This dataset contains 247 observations from the Registration form, which registers patients for enrollment and includes demographic information such as race, education, occupation, income, marital status, and if they had been previously enrolled in a NASH CRN study.
 - figure2.sas7bdat – This analysis dataset contains 3812 records. Data include treatment group, weight, ALT/AST/HIMA-IR, and visit number.
 - table1.sas7bdat – This analysis dataset contains 247 records. This data set used for the table 1 in Sanyal’s paper. Data include basic demographics, treatment group, age, sex, race, BMI, waist, and medical test scores like HDL/HOMA/NAFLD/Fibrosis/Steatosis.
 - table2.sas7bdat – This analysis dataset contains 247 records. This data set used for the table 2 in Sanyal’s paper. Data include treatment group, and medical test (changes) scores like Fibrosis/Steatosis/Ballooning/Inflammation.
 - table3.sas7bdat – This analysis dataset contains 247 records. This data set used for the table 3 in Sanyal’s paper. Data include treatment group, and medical test scores like HDL/GGT/HOMA/Cholesterol/GGT/BMI/ALT/AST, etc.

Data\Contents

This subdirectory contains contents/frequencies of data sets in the Data directory.

- PIVENS_proc_contenets.pdf – contains contents for the ad.sas7bdat, bg.sas7bdat, cr.sas7bdat, dd.sas7bdat, dr.sas7bdat, dx.sas7bdat, hi.sas7bdat, ie.sas7bdat, ld.sas7bdat, lr.sas7bdat, lq.sas7bdat, ls.sas7bdat, lu.sas7bdat, pa.sas7bdat, pe.sas7bdat, pf.sas7bdat, pivtx.sas7bdat, qf.sas7bdat, rd.sas7bdat, and rg.sas7bdat files.

DSIC

The NASH PIVENS Data Integrity Check (DSIC) directory contains:

- A report of an examination of the table1, table2, table3 datasets (Sanyal paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the NASH PIVENS data were compared to values recalculated from NASH PIVENS archived analysis datasets in the NIDDK repository.

SAS Programs

This subdirectory contains the SAS programs which created the analysis data sets in the Data directory.