

## **The NASH TONIC Study Data Archive**

The NASH TONIC 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 TONIC Documents directory contains:

- TONIC\_Protocol.pdf – NASH TONIC Protocol
- NASHCRN\_Bibliography.pdf – NASH CRN Published Manuscripts
- NASHCRN\_Bibliography\_V2.pdf – Updated NASH CRN Published Manuscripts, as of April 20, 2015
- TONIC\_Consents.pdf – NASH TONIC consent statement
- TONIC\_SOPs.pdf – NASH TONIC Standard Operations Manual

### **Forms**

The NASH TONIC Forms directory contains:

- TONIC\_JAMA\_FORMS.pdf – Blood Collection for DNA form.
- TONIC\_forms.pdf – Includes multiple forms for the TONIC study, including:
  - Alcohol Use Disorders Identification Test
  - Baseline History, Central Histology Review
  - Death Report
  - DEXA Scan for Body Fat
  - Followup Medical History
  - Interim Event Report, Symptoms of Liver Disease (Children)
  - Laboratory Results-Tests Done at Visit s1 and During Followup
  - Laboratory Results-Tests Done Only During Screening
  - Laboratory Results-Tests Required at Visit s2
  - Modifiable Activity Questionnaire
  - MRI Report
  - Physical Examination
  - Focused Physical Examination

- Study Drug Dispensing and Return
- Registration

## **Data**

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

- ad1.sas7bdat – This dataset contains 173 observations from the Alcohol Use Disorders Identification Test form. It contains information about the subjects’ drinking habits.
- bg2.sas7bdat – This dataset includes 173 observations from the Baseline History dataset. Data includes family history of liver disease, NAFLD history, weight history, and other medical and medication history.
- cr1.sas7bdat – This dataset includes 322 observations from the Central Histology Review form. It contains information regarding liver biopsy slides.
- dr1.sas7bdat – This dataset includes 1 observation from the death report form, which is a record used to report a patient’s death. It includes cause of death.
- dx1.sas7bdat – This dataset contains 321 observations from the DEXA Scan for Body Fat form, which records information and results from the scan.
- hi1.sas7bdat – This dataset contains 1490 observations from the Followup Medical History form. This form was completed at several follow-up visits and includes information about changes in the patient’s alcohol consumption, NAFLD, smoking habits, medication use and health.
- ie1.sas7bdat – This dataset contains 103 observations 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.
- lp1.sas7bdat – This dataset contains 610 observations from the Symptoms of Liver Disease (Children) form, which records the patient’s liver disease symptoms, their severity, level of tiredness, and overall well-being.
- lr1.sas7bdat – This dataset contains 1629 observations from the Laboratory Results-Tests Done at Visit s1 and During Followup form. Data includes laboratory results for ALT, hematology, metabolic panel, hepatic panel, prothrombin time, GGT, HbA1c, fasting lipid profile, fasting glucose, oral glucose tolerance test, vitamin B12, free fatty acid, leptin, and C-reactive protein, and other tests.
- ls1.sas7bdat – This dataset contains 173 observations from the Laboratory Results-Tests Done Only During Screening form, including screening etiologic tests, autoantibody studies, ceruloplasmin, A1AT, and iron.
- lu1.sas7bdat – This dataset contains 172 observations from the Laboratory Results-Tests Required at Visit s2 form, including a hepatic panel, vitamin B12, free fatty acid, leptin, C-reactive protein, prothrombin time, GGT, HbA1c, oral glucose tolerance test, and a pregnancy test.
- ma1.sas7bdat – This dataset includes 610 observations from the Modifiable Activity Questionnaire. This includes information about time spent doing different leisure-time physical activities, and exercise habits.

- mr1.sas7bdat – This dataset contains 82 observations from the MRI report form, which includes results from the upper abdominal MRI.
- pe1.sas7bdat – This dataset contains 610 observations from the Physical Examination form, which has detailed physical exam findings from various visits, including measurements and examination findings.
- pf1.sas7bdat – This dataset contains 1014 observations from the Focused Physical Examination form. . The data includes measurements and liver signs from focused physical exams.
- pq1.sas7bdat – This dataset contains 413 observations from the Pediatric Quality of Life: Parent Report for Teens (ages 13-17) form. Data includes information about the teen’s daily activities, mood, and overall behavior, as determined by the parent.
- pr1.sas7bdat – This dataset contains 190 observations from the Pediatric Quality of Life: Parent Report for Children (ages 8-12) form. Data includes information about the child’s daily activities, mood, and overall behavior, as determined by the parent.
- pw1.sas7bdat – This dataset contains 190 observations from the Pediatric Quality of Life: Child Report (ages 8-12). Data includes patient-reported information about their daily activities, mood, and behavior.
- py1.sas7bdat – This dataset contains 419 observations from the Pediatric Quality of Life: Teen Report (ages 13-17) form. Data includes patient-reported information about their daily activities, mood, and behavior.
- rd1.sas7bdat – This dataset contains 1610 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.
- rg1.sas7bdat – This dataset contains 173 observations from the Registration form, which registers patients for enrollment and includes demographic information such as race, education, parents’ education and income, and if they had been previously enrolled in a NASH CRN study.
- treatment.sas7bdat – This dataset contains 173 observations and contains the treatment given to each patient.
- table1.sas7bdat– This analysis dataset contains 173 records. This data set used for the table 1 in Lavine’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 173 records. This data set used for the table 2 in Lavine’s paper. Data include treatment group and ALT measurements at different time points.
- table3.sas7bdat– This analysis dataset contains 173 records. This data set used for the table 3 in Lavine’s paper. Data include treatment group and variables regarding fibrosis, steatosis, inflammation, ballooning, and activity score.
- table4.sas7bdat– This analysis dataset contains 173 records. This data set used for the table 4 in Lavine’s paper. Data include treatment group and variables regarding Serum Biochemistry Test Results, Lipid Levels, Metabolic Characteristics, and Quality of Life by Treatment.

## Data\Contents

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

## **DSIC**

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

- A report of an examination of the table1, table2, table3, and table 4 datasets (Lavine paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the NASH TONIC data were compared to values recalculated from NASH TONIC archived analysis datasets in the NIDDK repository.

## **SAS Programs**

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