

The NASH FLINT Study Data Archive

The NASH FLINT 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 FLINT Documents directory contains:

- NASHCRN_Bibliography.pdf – NASH CRN Published Manuscripts
- FLINTProtocol_May2013.pdf – NASH FLINT Protocol
- FLINT_SOPs.pdf – NASH FLINT Standard Operations Manual
- FLINT_consent.pdf – NASH FLINT consent statement
- FLINT_forms.pdf
- FLINT_genetic_consent.pdf
- FLINT_Lancet_Correction.pdf
- FLINT_Lancet.pdf
- FLINT_memo.pdf
- FLINT_protocol.pdf

Forms

The NASH FLINT Forms directory contains:

- FLINT_Lancet_Forms.pdf – Includes multiple forms for the FLINT study, including:
 - Baseline History (versions 1 and 2)
 - Central Histology Review
 - Followup Medical History (versions 1 and 2)
 - Interim Event Report (versions 1, 2, and 3)
 - Laboratory Results – Tests Done at Screening and Followup Visits

- Missed or Incomplete Visit
- Physical Examination
- Focused Physical Examination
- Registration

Data

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

- table1.sas7bdat – This analysis dataset contains 283 observations, and was used for Table 1 in Lancet’s paper. Data includes treatment group, age, results of baseline laboratory tests including blood pressure, ALT, cholesterol, insulin, platelet count, and uric acid, and inflammation and fibrosis scores.
- table2.sas7bdat – This analysis dataset contains 283 records, and was used for Table 2 in Lancet’s paper. Data includes ballooning score, fibrosis score, NAFLD activity score, steatosis score, and portal inflammation score at baseline and week 72.
- table3.sas7bdat – This analysis dataset contains 258 observations, and was used for Table 3 in Lancet’s paper. Data includes week 72 laboratory results, such as ALT, AST, cholesterol, creatinine, hemoglobin, insulin, blood pressure, platelet count, and uric acid. Changes from baseline to week 72 are also included.
- table4.sas7bdat – This analysis dataset contains 191 observations, and was used for Table 4 in Lancet’s paper. Data includes AE body system, AE category, AE grade, and date of AE.
- table_s1.sas7bdat – This analysis dataset contains 283 observations, and was used for Supplementary Table 1 in Lancet’s paper. Data includes treatment group, changes from baseline to week 72 in weight and ALT, and whether or not the primary outcome was achieved in patients at risk
- table_s2.sas7bdat – This analysis dataset contains 219 observations, and was used for Supplementary Table 2 in Lancet’s paper. Data includes subgroupings for certain variables, such as age (under 55 or over 55), fibrosis stage (stage 0-2 or stage 3-4), vitamin E use (yes or no), and ALT (under 60 or over 60).
- table_s3.sas7bdat – This analysis dataset contains 244 observations, and was used for Supplementary Table 3 in Lancet’s paper. Data includes laboratory test results, such as ALT, AST, cholesterol, creatinine, hemoglobin, insulin, blood pressure, platelet count, and uric acid, from week 96. Changes from baseline to week 96 are also included.
- table_s4.sas7bdat – This analysis dataset contains 200 observations, and was used for Supplementary Table 4 in Lancet’s paper. Data includes detailed histology outcomes, such as ballooning score, fibrosis stage, NAFLD activity score, and steatosis score at baseline and week 72.
- figure1.sas7bdat – This analysis dataset contains 283 observations, and was used for Figure 1 in Lancet’s paper. Data includes reason for not participating in FLINT, reason for missing F72 biopsy, and whether or not the primary outcome was achieved in patients at risk.

- figure2.sas7bdat – This analysis dataset contains 2089 observations and was used for Figure 2 in Lancet’s paper. Data includes treatment group, alkaline phosphatase, ALT, GGT, weight, and visit.
- figure_s1.sas7bdat – This analysis dataset contains 2086 observations and was used for Supplementary Figure 1 in Lancet’s paper. Data includes cholesterol, HDL, LDL, triglycerides, treatment group, and visit.
- figure_s2.sas7bdat – This analysis dataset contains 2086 observations and was used for Supplementary Figure 2 in Lancet’s paper. Data includes treatment group, AST, and visit.
- ad.sas7bdat
- bg.sas7bdat
- cg.sas7bdat
- cr.sas7bdat
- cv.sas7bdat
- dr.sas7bdat
- hi.sas7bdat
- ld.sas7bdat
- lr.sas7bdat
- ls.sas7bdat
- pe.sas7bdat
- pf.sas7bdat
- qf.sas7bdat
- rd.sas7bdat
- rg.sas7bdat
- tx.sas7bdat

Data\Contents

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

DSIC

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

- A report of an examination of the Table1, Table2, Table 3, and Table 4 datasets (Lancet paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the NASH FLINT data were compared to values recalculated from NASH FLINT 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.