The FSGS Study Data Archive

The FSGS Archive contains the Protocol, Manual of Operations, Forms, Study data, and Dataset Integrity Check.

Archive files are organized into the following directories:
- Data
- Documents
- Dataset Integrity Check (DSIC)
- Forms

FSGS Data

The FSGS study has 138 eligible patients.

The FSGS data directory contains following files, and the following raw dataset in SAS format. Data in Stata format are also available in the "stata_data" folder.
- ae_w00_w26_arch.sas7bdat – This analysis dataset contains 2584 records. Data include events from week 0 to week 26.
- ae_w00_w52_arch.sas7bdat – This analysis dataset contains 3202 records. Data include events from week 0 to week 52.
- bsl_dataset.sas7bdat – This analysis dataset contains 192 records. Data include eligibility, basic demographics, age sex, race, BMI, family/self medical history, Date of biopsy, income, and smoking status.
- central_lab_rslt.sas7bdat – This analysis dataset contains 50344 records. Data include urine/serum lab results.
- f10.sas7bdat – This dataset contains 192 records. Data include screening data.
- f11.sas7bdat – This dataset contains 181 records. Data include baseline visit data.
- f14.sas7bdat – This dataset contains 177 records. Data include disease history data.
- f16.sas7bdat – This dataset contains 1885 records. Data include follow up visit data.
- f30.sas7bdat – This dataset contains 138 records. Data include online randomization data.
- f31.sas7bdat – This dataset contains 54 records. Data include study exit for non-randomized patients data.
- f32.sas7bdat – This dataset contains 1 record. Data include re-enrollment data.
- f36.sas7bdat – This dataset contains 156 records. Data include health information.
- f37_43.sas7bdat – This dataset contains 630 records. Data include pediatric quality of life inventory info.
- f44_notstudy.sas7bdat – This dataset contains 8289 records. Data include medication info.
- f44_study.sas7bdat – This dataset contains 27027 records. Data include medication info
- f45.sas7bdat – This dataset contains 36 records. Data include medication termination info.
- f46.sas7bdat – This dataset contains 1984 records. Data include physical exam info.
- f51.sas7bdat – This dataset contains 4 records. Data include relapse therapy info.
- f52.sas7bdat – This dataset contains 444 records. Data include long term monitoring info.
- f54.sas7bdat – This dataset contains 25 records. Data include closeout vital and dialysis status info.
- f60_61.sas7bdat – This dataset contains 654 records. Data include adverse event info.
- f62.sas7bdat – This dataset contains 118 records. Data include hospitalization info.

- f63.sas7bdat – This dataset contains 3 records. Data include death notification info.
- f64.sas7bdat – This dataset contains 86 records. Data include medication non protocol dosing info.
- f66.sas7bdat – This dataset contains 2 records. Data include MMF GI Toxicity info.
- f71.sas7bdat – This dataset contains 29 records. Data include study exit for randomized patients info.
- f72.sas7bdat – This dataset contains 8 records. Data include medication stop point info.
- f79.sas7bdat – This dataset contains 220 records. Data include local lab info.
- f80.sas7bdat – This dataset contains 2506 records. Data include core lab urine mailing info.
- f83.sas7bdat – This dataset contains 2153 records. Data include core lab urine data report.
- f86.sas7bdat – This dataset contains 182 records. Data include biopsy mailing info.
- f87.sas7bdat – This dataset contains 179 records. Data include biopsy results report.
- f91.sas7bdat – This dataset contains 161 records. Data include local tuberculin skin test results.
- f94.sas7bdat – This dataset contains 165 records. Data include consent for repository info.
- f95.sas7bdat – This dataset contains 321 records. Data include biological specimen mailing info.
- f96.sas7bdat – This dataset contains 97 records. Data include DNA genetics initiative phlebotomy mailing info.
- formats.sas
- fsgs_primary.sas7bdat – This analysis dataset contains 138 records. Data include basic demographics, age, sex, race, death info, eGFR, ESRD, Lisnorril, end study date, outcome, MMF/CAS info.
- FSGS-CT genotypes.csv.

FSGS Data\Contents
- FSGS_baseline.doc – Variable listing from FSGS Clinical Trial Baseline AnalysisDataset bsl_dataset.sas7bdat
- FSGS_primary.doc – Variable listing from FSGS Clinical Trial Primary AnalysisDataset fsgs_primary.sas7bdat
- FSGS_urine_serum_results.doc – Variable listing from Urine/Serum Lab ResultsAnalysis Dataset CENTRAL_LAB_RSLT.sas7bdat

FSGS Documents

The FSGS Documents directory contains:
- FSGS_Protocol.pdf – FSGS protocol
- FormsTOC_arch.pdf – FSGS-CT forms table of contents
- FSGS_Bibliography.doc – FSGS publications and presentations
- MOPsec1_20.pdf – FSGS operations manual
- Ready0915.pdf – FSGS site enrollment info
- AEformats_1.sas – Contains formats for the ae_w00_w26_arch.sas7bdat and the ae_w00_w52_arch.sas7bdat datasets

FSGS DSIC

The FSGS Data Integrity Check (DSIC) directory contains:
- A report of an examination of the FSGS BASELINE, PRIMARY, AE week 0-26, and 0-52 datasets (Gipson paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the FSGS data were compared to values recalculated from FSGS archived analysis datasets in the NIDDK Central Repository.

FSGS Forms

This subdirectory contains the forms for the non-analysis data set in the FSGS Data directory.