The following are data handling instructions for the Public Use Dataset of the STOP-ALF clinical trial. The dataset is comprised of patients enrolled into the clinical trial from November 12, 2012 through June 9, 2016.

General Notes

- Files
  - ReadMe PDF file
  - 21 dataset SAS files
  - Data dictionary excel file
  - Case Report Forms PDF file
- Datasets
  - A complete listing of all variables, their description and their codes may be found in the data dictionary excel file.
  - There is a separate dataset for each included form.
  - Forms that were collected only once during the study will have one row per subject. Forms collected at multiple visits will have more than one row per subject.
  - Forms that contain logs (Form 04) will have sas files that contain more than one row per subject to account for the repeated measurements.
  - Form 14 is separated into two child table logs and is presented as two sas files (Form 14C1 and Form 14C2). This is reflective of different number of rows per subject in each child table on the form.
  - A complete listing of which forms were collected at each study visit can be found in the data dictionary in the sheet called “Data Collection Schedule”. Forms 17 and 21 captured medications prior to and during the treatment period. These data were never used for data analysis or reporting and were not ‘cleaned’ prior to the database lock. For these reasons, the study team refrained from including these data in the STOPALF public use dataset.
- Subject and Site IDs
  - Subject and Site IDs are unique identifiers for each subject and are not the original ID used by the study team.
    - One subject was enrolled into STOP ALF trial and not into the ALFSG registry (2380) and the Registry data for this patients includes data confirmed by the site
- Variable names
  - Raw data are named in the format F##Q##, where F## is the form number and Q## is the question number. Some variables are renamed for ease of interpretation.
  - Derived variables are included in some datasets, indicated below in Dataset Specific Notes.
- Dates and times
  - All dates and times are replaced with calculated time from enrollment. These variables are expressed as the number of days from enrollment.
  - Negative days indicate the event occurred before enrollment.
- Text fields, including clinical narratives and general comments, are not included in the public use dataset in order to avoid releasing potential identifying patient information.

Dataset Specific Notes

- Form 00: Eligibility Form
- Form 01: Demographics
- Form 02: Medical History
- Form 03: Labs
  - the database was locked with a data entry error in F03Q01 - the site mistakenly entered an incorrect year so the days from enrollment is 362 days
- Form 04: Ammonia Collection Log

- Form 07: Vital Signs
- Form 08: Physical Exam
- Form 09: Glasgow Coma Scale
- Form 10: West Haven Scale for Hepatic Encephalopathy
- Form 11: The Orientation Log (O-Log)
- Form 12: Neurological Exam
- Form 13: Electrocardiogram
- Form 14C1: Study Drug Infusion Log
- Form14C2: Study drug monitoring log
- Form 15: End of Treatment Form
- Form 16: Urinalysis
- Form 18: Adverse Events
- Form 19: End of Study
- Form 20: Day 30 Ammonia
- PK: Pharmacokinetic data was read at a central laboratory and steady state values were calculated by a central reader
- Registry Data— Etiology and indication of liver injury or liver failure are derived from the ALFSG registry database

NOTE: These SAS data files are based on the STOP ALF study database lock on February 27, 2017 and the ALFSG registry database freeze on February 2, 2017. All potential identifying fields have been removed.