

The ALFSG Study Data Archive

The ALFSG 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)

Documents

The ALFSG Documents directory contains:

- Data Collection Schedule v8.pdf: Contains the schedule of data collection
- ALF ALI ProtocolV6 0_WML04012013_Clean.pdf: Protocol for the ALFSG study
- ALFSG_Publications_04NOV2014.pdf: Contains the list of the publications for the study as of November 4, 2014

Forms

The ALFSG Forms directory contains:

- ALFSG Distinct CRFs v12 19Jun2014.pdf – Contains the following blank forms:
 - Form 00: Patient Enrollment Form
 - Form 01: ALI Admission Form
 - Form 02: ALF Admission Form
 - Form 03: Medical History
 - Form 04: Risk Factors & Past Medication
 - Form 06: The Orientation Log
 - Form 07: Imaging EEG Biopsy v4
 - Form 08: Lab Data
 - Form 09: Bio-sample Collection Log
 - Form 11: Pre-Study Peak Lab Values
 - Form 12: Daily Check-Up
 - Form 13: Vital Signs
 - Form 14: Infections
 - Form 15: Transplant
 - Form 16: Diagnosis
 - Form 17: Discharge Summary
 - Form 18: LTFU Part 1 - Outcome
 - Form 19: LTFU Part 2 - Complications
 - Form 20: LTFU Part 3 - Current Medications
 - Form 21: LTFU Part 4 - Substance Abuse

- Form 22: LTFU Part 5
- Form 23: RBANS Test
- Form 24: SF-36 Health Survey
- Form 25: CDC HRQOL-14 Survey on Health and Well-Being
- Form 26: End of Study
- Form 27: Glasgow Coma Scale
- Form 28: Outcome Lab Data
- Form 29: Serological Exam
- Form 32: Acute Rejection
- Form 34: 21 Day Status
- Form 35: DNA Collection
- Form 36: Follow-Up Contact Log
- Screen Failure Log

Data

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

- The following datasets correspond to the form with the same name (note that forms that contain logs have this information in the SAS files indicated by a 'c', and these files may have more than one row per subject (all other SAS files are in the format of one row per subject per visit). Form 07 was a log that has been split into 5 separate data files.)
 - form00
 - form01
 - form02
 - form03
 - form04
 - form04c
 - form07_abdomen_ct_mri
 - form07_abdomen_ultrasound
 - form07_brain_ct_mri
 - form07_egg
 - form_07_liverbiopsy
 - form08
 - form11
 - form12
 - form13
 - form14
 - form15
 - form16
 - form16c
 - form17
 - form18
 - form19
 - form20

- form21
- form22
- form23
- form24
- form25
- form26
- form27
- form28
- form29
- form32
- form34
- SubjectIds_ALFSG.xls – A listing of the subject IDs used in the Dataset Integrity Check
- /Data/Contents: Contains the following:
 - Contents.pdf: Contains the contents of the SAS data sets listed above
 - data_dictionary.xlsx: Contains the data dictionary (including labels) for the SAS data sets listed above

DSIC

The ALFSG Data Integrity Check (DSIC) directory contains:

- ALFSG_DSIC.pdf – A report of an examination of the ALFSG datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Table 1 and Table 2 from the paper ‘2-year outcomes in Adults with Acute Liver failure: Results from a Prospective, Multicenter Registry Study’ by Fontana et al. Published results from the ALFSG data were compared to values recalculated from ALFSG archived datasets in the NIDDK repository.