

## **Longitudinal Study of Genetic Causes of Intrahepatic Cholestasis (LOGIC)**

The LOGIC study investigated the natural history and progression of four genetic causes of intrahepatic cholestasis of childhood, including alpha-1 antitrypsin (AAT) deficiency, Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and bile acid synthesis defects. The LOGIC study utilized a collection of diagnostic, clinical, and outcome data at defined intervals from multiple centers. By comparing outcome measures between the four liver diseases (i.e., using each disorder as a disease-control for the other disorders), the full impact of each disorder was assessed in comparison to the other liver diseases.

The LOGIC data archive contains related descriptive documentation, data collection forms, study data, and dataset integrity checks for this study. Additionally, the LOGIC data archive contains descriptive documentation and data collection forms for the PROBE study for datasets that utilized combined study data from LOGIC and PROBE.

Archive files are organized into the following directories:

- Data
- Documents
- Dataset Integrity Check (DSIC)
- Forms
- SAS Programs

### **Data**

The Data directory contains the following files:

- a1atbaseline.sas7bdat
- algsbl.sas7bdat
- algsformats.sas7bdat
- algsfu.sas7bdat
- child\_univariate.sas7bdat
- demographics.sas7bdat
- dxadata.sas7bdat
- parent\_univariate.sas7bdat
- pedsq1\_child\_dis.sas7bdat
- pedsq1\_parent\_dis.sas7bdat
- pfic.sas7bdat
- pficgenetics.sas7bdat

### **Data/Formats**

- a1atlongv4\_formats.sas7bcats
- algsformats.sas7bcats
- ALGS\_NHControls\_formats.sas7bcats
- dxafomats.sas7bcats
- manuscript\_formats\_03oct19.sas7bcats
- pficformats.sas7bcats

### Data/Leung\_ALGS\_Neurodevelopment

- manuscript\_data\_03oct19.sas7bdat

### Data/Shneider\_ALGS\_Natural\_History\_Controls

- algsnhcontrolsbl.sas7bdat
- algsnhcontrolsfu.sas7bdat
- algsnhcontrolsselect.sas7bdat

### Data/Teckman\_A1AT\_Longitudinal

- a1atlongv4.sas7bdat

## **Documents**

The LOGIC Documents directory contains:

- A7 LOGIC Protocol 190919.pdf
- EDITED\_MOO LOGIC\_V3.1 August\_2018.pdf
- Eligibility LOGIC.pdf
- LOGIC Amendment 5.pdf
- LOGIC Amendment 6\_v4 CLEAN COPY 07142017. docx.pdf
- LOGIC Amendment 7 for memo changes 04282020 clean (3) final E&I approved.pdf
- LOGIC Protocol Amendment 7 20200428.pdf
- LOGIC\_Memo\_To\_File\_20190919.pdf
- LOGIC\_MITOHEP\_Sentinel.pdf
- MOO LOGIC V3.pdf
- Participant Demographics LOGIC.pdf

### Documents/Contents

- A1AT Longitudinal Manuscript Codebook.pdf
- ALGSBLDataDictionary.csv
- ALGSFuDataDictionary.csv
- ALGSNHControlsBLDataDictionary.csv
- ALGSNHControlsFuDataDictionary.csv
- ALGSNHControlsSelectDataDictionary.csv
- Codebook\_ALGS\_QOL\_Archive.pdf
- Codebook\_final.pdf
- DXADataDictionary.xlsx
- Leung ALGS Neuro Manuscript Codebook.pdf
- PFICDataDictionary.csv
- PFICGeneticsDataDictionary.csv

### Documents/PROBE

- Final\_MOO PROBE V2.2 Clean Copy .pdf
- probe\_amend6.pdf
- PROBE\_Version 9 Amendment 8 final E and I changes.pdf

## **DSIC**

The LOGIC Dataset Integrity Check (DSIC) directory contains:

- LOGIC-Kamath.DSIC.pdf
- LOGIC\_Leung\_ALGS\_Neurodevelopmental\_DSIC.pdf
- LOGIC\_Loomes\_DXA\_DSIC\_V1.pdf
- LOGIC\_PedsQL\_DSIC.pdf
- LOGIC\_Shneider\_ALGS\_Nat\_Hist\_Controls\_DSIC.pdf
- LOGIC\_Shneider\_Hertel\_PFIC\_DSIC.pdf
- LOGIC\_Techman\_DSIC\_V1.pdf
- PROBE\_LOGIC\_Teckman\_A1AT\_Long\_DSIC.pdf

## **Forms**

The LOGIC Forms directory contains:

- 01.1\_v2.7\_Eligibility.doc
- 01.1\_v2.7\_Eligibility\_2010\_06\_02\_Annotated.doc
- 01.2\_v2.5\_Eligibility.doc
- 01.3\_v2.5\_Eligibility.doc
- 01.4\_v2.4\_Eligibility.doc
- 01.5\_v2.6\_Eligibility.doc
- 02A.2\_v2.0\_Subject Demographics.doc
- 02A.3\_v2.0\_Subject Demographics.doc
- 02A.5\_v1.1\_Subject Demographics.doc
- 02A.5\_v1.1\_Subject Demographics\_2009\_03\_12\_Annotated .doc
- 02A\_Subject Demographics\_v05\_2008\_02\_06\_Annotated.doc
- 03.1\_V1.2\_InitialHistory\_06\_23\_2009\_Annotated.doc
- 03.2\_V1.2\_InitialHistory.doc
- 07.4\_v1.4\_PhysicalExam.doc
- 07.5\_PhysicalExam\_v3.0.doc
- 07.5\_PhysicalExam\_v3.0\_2012\_03\_30\_Annotated.doc
- 07\_Physical Exam\_v05\_2008\_06\_02\_Annotated.doc
- 08.2\_v2.3\_Labs\_2011\_01\_20\_Annotated.doc
- 08.5\_v2.3\_Labs\_2011\_01\_20\_Annotated.doc
- 08\_Initial Lab\_v05.1\_2010\_03\_16\_Annotated.doc
- 09\_ImagingForm ANNOTATED.doc
- 09\_Initial Imaging\_v04\_2008\_06\_02\_Annotated.doc
- 11\_Surgery\_v05\_2010\_11\_11\_Annotated.doc
- 11\_v1.1\_Surgery Procedure\_2009\_08\_20\_Annotated.doc
- 13\_Discharge Medications\_v05\_2008\_06\_02\_Annotated.doc
- 14.1\_v1.4\_Diagnosis.doc
- 14.5\_v1.2\_Diagnosis.doc
- 14A.1\_v1.1\_Change in Diagnosis.doc
- 14A.5\_v1.1\_Change in Diagnosis.doc

- 24.1\_IntervalHistory.doc
- 24.2\_IntervalHistory\_v2.5.pdf
- Eligibility LOGIC.pdf
- Family Demographics LOGIC G1.pdf
- Family Demographics LOGIC G2 G3 G5.pdf
- Form 03 Initial History LOGIC G1 G2 G3.pdf
- Form 03 Initial History LOGIC G4.pdf
- Form 03 Initial History LOGIC G5.pdf
- Form 04B Genetics Testing Results LOGIC.pdf
- Form 07 Physical Exam LOGIC G1.pdf
- Form 07 Physical Exam LOGIC G2 G5.pdf
- Form 07 Physical Exam LOGIC G4.pdf
- Form 08.1 08.3 Labs LOGIC G1 G3.pdf
- Form 08.2 08.5 Labs LOGIC G2 G5.pdf
- Form 11 Surgery Procedure LOGIC.pdf
- Form 13 Current Medications LOGIC.pdf
- Form 14 Diagnosis LOGIC G1 G2 G3.pdf
- Form 14 Diagnosis LOGIC G5.pdf
- Form 14A Change in Diagnosis LOGIC G1 G2 G3.pdf
- Form 25.1 Liver Transplant LOGIC G1.pdf
- Form 25H Coagulopathy.pdf
- Form 25M Other Sentinel Events.pdf
- Form 25N and 25 Liver Transplant LOGIC.pdf
- Form 31 Audiology LOGIC.pdf
- Form 35 Final Status LOGIC G1.pdf
- Form 35 Final Status LOGIC G2 G5.pdf
- Form 35 Final Status LOGIC G3.pdf
- Form 35 Final Status LOGIC G4.pdf
- Liver Stiffness Measurement FORCE.pdf
- P003 Form 02.V04 Demographics.doc
- P003 Form 07.V04 Physical Exam.doc
- P003 Form 08.V04 Initial Lab.doc
- P003 Form 20.V04 FU Physical.doc
- P003 Form 21A.V04 PedsQL Ages 2 to 4.doc
- P003 Form 21B.V04 PedsQL Ages 5 to 7.doc
- P003 Form 23.V04 FU Labs.doc
- P004 Form S23.2WK.V04 FU Labs.doc
- Participant Demographics LOGIC.pdf
- QL02P English Peds QL Parent Report for Toddlers Ages 2-4.pdf
- QL05P English Peds QL Parent Report for Young Children Ages 5-7.pdf
- QL08P English Peds QL Parent Report for Children Ages 8-12.pdf
- QL13C\_TeenReport.pdf
- QL13P English Peds QL Parent Report for Teens Ages 13-18.pdf
- QL13P\_ParentReportTeens.pdf

- QL2P\_ParentToddlerReport.pdf
- QL5C\_YoungChildReport.pdf
- QL5P\_ParentReportChild.pdf
- QL8C\_ChildReport.pdf
- Sentinel Events Ascites.pdf
- Sentinel Events Bones.pdf
- Sentinel Events Coagulopathy.pdf
- Sentinel Events GI Bleed.pdf
- Sentinel Events Other.pdf
- Sentinel Events Transplant Listing.pdf
- Wechsler Intelligence Scale for Children.pdf
- WPPSI Wechsler Preschool and Primary Scale of Intelligence.pdf

#### Forms/PROBE

- Eligibility PROBE.pdf
- Form 03 Initial History PROBE.pdf
- Form 07 Physical Exam PROBE.pdf
- Form 08 Labs Initial Pre-lap PROBE.pdf
- Form 08 Labs Initial Presentation PROBE.pdf
- Form 11 Surgery PROBE.pdf
- Form 12 Hospital Discharge PROBE.pdf
- Form 13 Discharge Medications PROBE.pdf
- Form 14 Diagnosis PROBE.pdf
- Form 20 Physical Exam FU PROBE.pdf
- Form 23 FU Labs PROBE.pdf
- Form 25N and 25 Liver Transplant PROBE.pdf
- Form 35 Final Status PROBE.pdf
- Participant Demographics PROBE.pdf

#### **SAS Programs**

The SAS Programs directory contains:

- A1AT\_Long\_SAS\_manuscript\_table1\_niddk.pdf
- AnalysisALGSITCHControlsForRepo.pdf
- ChildrenALGSCodeForNIDDKRepository.sas.pdf
- Leung\_ALGS\_Neuro\_SAS\_Table 1\_niddk.pdf
- PFICAnalysisCodeForRepo.pdf
- Sentinel Events Other.pdf
- Table1MacroV3.sas.pdf