

The LOGIC Study Data Archive

The Longitudinal Study of Genetic Causes of Intrahepatic Cholestasis Study (LOGIC) Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

The LOGIC study investigated the natural history and progression of four genetic causes of intrahepatic cholestasis of childhood, including alpha-1 antitrypsin deficiency (a1-AT), Alagille Syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC) or benign recurrent intrahepatic cholestasis (BRIC), and bile acid synthesis defects (BAD). In this study, defined data elements were collected in a uniform fashion at fixed intervals for up to twenty years over a relatively large number of patients with these rare disorders. A biobank of patient specimens and DNA samples was established for use in ancillary studies to be performed in addition to this study. 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 could be determined in comparison to the other liver diseases. This was a multi-center study utilizing collection of diagnostic, clinical, and outcome data at defined intervals.

Archive files are organized into the following directories:

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

Documents

The LOGIC Documents directory contains:

- EDITED_MOO LOGIC_V3.1August_2018.pdf – version 3.1 of the Manual of Operations for the LOGIC study
- LOGIC Amendment 5.pdf – version 5 of the amended protocol for the LOGIC study
- LOGIC Amendment 6_v4 CLEAN COPY 07142017. docx.pdf – version 6 v4 of the amended protocol for the LOGIC study
- MOO LOGIC V3.pdf – version 3 of the Manual of Operations for the LOGIC study
- MOO PROBE V2.1.pdf – version 2.1 of the Manual of Operations for the LOGIC study
- probe_amend6.pdf – version 7 amendment 6 of the Protocol for the LOGIC study
- ChildrenALGSCoDeForNIDDKRepository.sas.pdf
- Eligibility LOGIC.pdf
- LOGIC_Memo_To_File_20190919.pdf
- LOGIC_MITOHEP_Sentinel.pdf
- Participant Demographics LOGIC.pdf

Forms

The LOGIC Forms directory contains:

- Sentinel Events Bones.pdf

- QL13P_ParentReportTeens.pdf
- QL13C_TeenReport.pdf
- QL8C_ChildReport.pdf
- QL5P_ParentReportChild.pdf
- QL5C_YoungChildReport.pdf
- QL2P_ParentToddlerReport.pdf
- P004 Form S23.2WK.V04 FU Labs.doc
- P003 Form 23.V04 FU Labs.doc
- Poo3 Form 21B.V04 PedsQL Ages 5 to 7.doc
- P003 Form 21A.V04 PedsQL Ages 2 to 4.doc
- P003 Form 20.V04 FU Physical.doc
- P003 Form 08.V04 Initial Lab.doc
- P003 Form 02.V04 Demographic.doc
- P003 Form 07.V04 Physical Exam.doc
- Form 35 Final Status LOGIC G4.pdf
- Form 35 Final Status LOGIC G3.pdf
- Form 35 Final Status LOGIC G2 G5.pdf
- Form 35 Final Status LOGIC G1.pdf
- Form 14 Diagnosis LOGIC G5.pdf
- Form 14 Diagnosis LOGIC G1 G2 G3.pdf
- Form 25N and 25 Liver Tranplant LOGIC.pdf
- Form 31 Audiology LOGIC.pdf
- Form 11 Surgery Procedure LOGIC.pdf
- Form 08.2 08.5 Labs LOGIC G2 G5.pdf
- Form 08.1 08.3 Labs LOGIC G1 G3.pdf
- Form 07 Physical Exam LOGIC G4.pdf
- Form 07 Physical Exam LOGIC G2 G5.pdf
- Form 07 Physical Exam LOGIC G1.pdf
- Form 03 Initial History LOGIC G5.pdf
- Form 03 Initial History LOGIC G4.pdf
- Form 03 Initial History LOGIC G1 G2 G3.pdf
- Family Demographics LOGIC G2 G3 G5.pdf
- Family Demographics LOGIC G1.pdf
- Eligibility LOGIC.pdf
- 24.2_IntervalHistory_v2.5.pdf
- 24.1_IntervalHistory.doc
- 14A.5_v1.1_Change in Diagnosis.doc
- 14A.1_v1.1_Change in Diagnosis.doc
- 14.5_v1.2_Diagnosis.doc
- 14.1_v1.4_Diagnosis.doc

- 13_Discharge Medications_v05_2008_06_02_Annotated.doc
- 11_v1.1_Surgery Procedure_2009_08_20_Annotated.doc
- 11_Surgery_v05_2010_11_11_Annotated.doc
- 09_Initial Imaging_v04_2008_06_02_Annotated.doc
- 09_ImagingForm ANNOTATED.doc
- 08_Initial Lab_v05.1_2010_03_16_Annotated.doc
- 08.5_v2.3_Labs_2001_01_20_Annotated.doc
- 08.2_v2.3_Labs_2011_01_20_Annotated.doc
- 07_Physical Exam_v05_2008_06_02_Annotated.doc
- 07.5_PhysicalExam_v3.0_2012_03_30_Annotated.doc
- 07.5_PhysicalExam_v3.0.doc
- 07.4_v1.4_PhysicalExam.doc
- 03.2_V1.2_InitialHistory.doc
- 03.1_V1.2_InitialHistory_06_23_2009_Annotated.doc
- 02A_Subject Demographics_v05_2008_02_06_Annotated.doc
- 02A.5_v1.1_Subject Demographics_2009_03_12_Annotated .doc
- 02A.5_v1.1_Subject Demographics.doc
- 02A.3_v2.0_Subject Demographics.doc
- 02A.2_v2.0_Subject Demographics.doc
- 01.5_v2.6_Eligibility.doc
- 01.4_v2.4_Eligibility.doc
- 01.3_v2.5_Eligibility.doc
- 01.2_v2.5_Eligibility.doc
- 01.1_v2.7_Eligibility_2010_06_02_Annotated.doc
- 01.1_v2.7_Elgibility.doc

Data

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

- child_univariate.sas7bdat
- demographics.sas7bdat
- parent_univariate.sas7bdat
- pedsq1_child_dis_sas7bdat
- pedsq1_parent_dis.sas7bdat
- algsbl.sas7bdat
- algsformats.sas7bdat
- algsfu.sas7bdat

Analysis_Data subfolder:

DXA subfolder:

- dxadata.sas7bdat
- dxaformats.sas7bcat
- DXADictionary.xlsx

Teckman subfolder:

- a1atbaseline.sas7bdat
- Codebook_final.docx

Contents subfolder:

The Contents subfolder contains codebooks and data dictionaries for the LOGIC files in the main Data folder. These codebooks are:

- Codebook_final.docx
- DXADictionary.xlsx
- ALGSBLDataDictionary.csv
- ALGSFuDataDictionary.csv
- Codebook_ALGS_QOL_Archive.docx
- Codebook_final.docx

SAS Program

- Table1MacroV3.sas.pdf

DSIC

The LOGIC Data Integrity Check (DSIC) directory contains:

- LOGIC_Loomes_DXA_DSIC_V1.pdf - A report of an examination of the analysis and form datasets (Loomes paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the LOGIC data were compared to values recalculated from LOGIC archived analysis datasets in the NIDDK repository.
- LOGIC_Teckman_DSIC_V1.pdf – A report of an examination of the analysis and form datasets (Teckman paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the LOGIC data were compared to values recalculated from LOGIC archived analysis datasets in the NIDDK repository.
- LOGIC-Kamath.DSIC.pdf