

A Prospective Database of Infants with Cholestasis (PROBE)

This is a multi-center project to establish a prospective database of clinical information and a repository of blood and tissue samples from children with diagnoses of neonatal liver diseases, such as biliary atresia and neonatal hepatitis, in order to perform research in these liver problems. Children were screened and enrolled at presentation at the participating pediatric liver sites. Subjects diagnosed with biliary atresia were followed intensively for the first year, at 18 months of age, and then annually up to 15 years of age. Other subjects diagnosed with cholestasis were followed on the same schedule; if there was complete (clinical and biochemical) resolution of their underlying liver disease off all therapy, there was one follow up visit within one year (preferably scheduled at the time of the next planned follow up visit or at 12 months of age, whichever was later) for data collection and to obtain blood samples. The development of a serum and tissue bank of specimens from children with various neonatal cholestatic disorders are used for future investigations into the etiology and pathogenesis of hepatobiliary injury in the infant.

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

Data/PROBE Analysis Datasets

- ANALYSIS.CSV
- analysis.sas7bdat
- BANEURO_RAW_14MAR19.CSV
- baneuro_raw_14mar19.sas7bdat
- DISCRIMINATE_BA.CSV
- discriminate_ba.sas7bdat
- INH_01JUL19.CSV
- inh_01jul19.sas7bdat
- SURGERY_DATASET.CSV
- surgery_dataset.sas7bdat

Data/PROBE Analysis Datasets/Formats

- baneuro_formats_14mar19.sas7bcat

- inh_formats_09dec21.sas7bcat

Data/PROBE BASIC Analysis Datasets

- BA_VH_18AUG22.CSV
- ba_vh_18aug22.sas7bdat
- MANUSCRIPT_DATA_25JUN19.CSV
- manuscript_data_25jun19.sas7bdat

Data/PROBE BASIC Analysis Datasets/Formats

- manuscript_formats_18aug22.sas7bcat
- manuscript_formats_29apr19.sas7bcat

Data/PROBE LOGIC Analysis Datasets

- A1ATLONGV4.CSV
- a1atlongv4.sas7bdat

Data/PROBE LOGIC Analysis Datasets/Formats

- a1atlongv4_formats.sas7bcat

Documents

The PROBE Documents directory contains:

- BASIC Publications as of 0221.docx
- LOGIC Publications as of 0221.docx
- PROBE and BASIC Bibliography.docx
- PROBE Publications 20220223.docx

Documents/BASIC Documents

- BASIC Manual of Operations V3.2.pdf
- BASIC Protocol V6 .pdf

Documents/Codebooks

- A1AT Longitudinal Manuscript Codebook.docx
- analysis_Data_Derivation.docx
- BA Risk of VH Manuscript Codebook.docx
- BA SNL Manuscript Codebook.docx
- Data Dictionary for SAS Dataset Predictors.docx
- INH Manuscript Codebook.docx
- Older BA Neuro Manuscript Codebook.docx
- Surgery Manuscript Data Specifications.docx

Documents/LOGIC Documents

- EDITED_MOO LOGIC_V3.1 August_2018.pdf
- LOGIC Amendment 7 for memo changes 04282020 clean (3) final E&I approved.pdf

Documents/PROBE Documents

- PROBE MOO V2.2.pdf
- PROBE Protocol V9 Amendment 8.pdf

DSIC

The PROBE Dataset Integrity Check (DSIC) directory contains:

- PROBE_BASIC_Bass_Risk_of_VH_DSIC.pdf
- PROBE_BASIC_Venkat_BA_Nat_Hist_DSIC.pdf
- PROBE_Bilirubin_integrity_check_analysis.doc
- PROBE_Hertel_IHH_DSIC.pdf
- probe_integrity_check_02152017.doc
- PROBE_integrity_check_analysis_JSquires_V3.pdf
- PROBE_integrity_check_analysis_Superina.doc
- PROBE_LOGIC_Teckman_A1AT_Long_DSIC.pdf

Forms

The PROBE Forms directory contains:

Forms/BASIC Forms

- Eligibility BASIC.pdf
- Form 03B Medical History Pre-Tx BASIC.pdf
- Form 03C Anomalies BASIC.pdf
- Form 07 Physical Exam BASIC.pdf
- Form 08 Labs BASIC.pdf
- Form 23 FU Labs BASIC.pdf
- Form 24 FU Medical History BASIC.pdf
- Form 25 Liver Transplant BASIC.pdf
- Form 25L Transplant Listing BASIC.pdf
- Form 35 Final Status BASIC.pdf
- Form 41 GI ENDO Pre-Transplant BASIC.pdf
- Participant Demographics BASIC.pdf

Forms/LOGIC Forms

- Eligibility LOGIC.pdf
- Form 03 Initial History LOGIC G1 G2 G3.pdf
- Form 07 Physical Exam LOGIC G1.pdf
- Form 07 Physical Exam LOGIC G2 G5.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 25.1 Liver Transplant LOGIC G1.pdf
- Form 25N and 25 Liver Transplant LOGIC.pdf
- Form 35 Final Status LOGIC G1.pdf

- Form 35 Final Status LOGIC G2 G5.pdf
- Participant Demographics LOGIC.pdf

Forms/PROBE Forms

- 01 Eligibility.pdf
- 02A Subject Demographics.pdf
- 03 Initial History.pdf
- 07 Physical Exam.pdf
- 08 Labs Initial Pre-lap.pdf
- 11_Surgery.pdf
- 14 Diagnosis.pdf
- 21C_Bayley II_v04_2006_12_01_Annotated.doc
- 25N Liver Transplant.pdf
- 27C Biliary_Ultrasound.pdf
- 29 Change in Diagnosis.pdf
- BSID Bayley III.pdf
- Eligibility PROBE.pdf
- Family Demographics PROBE.pdf
- Form 03 Initial History PROBE.pdf
- Form 03C Anomalies PROBE.pdf
- Form 04 Pregnancy HX PROBE.pdf
- Form 05 Maternal Family History PROBE.pdf
- Form 06 Paternal Family 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 09 Initial Imaging PROBE.pdf
- Form 10 Pathology PROBE.pdf
- Form 11 Surgery PROBE.pdf
- Form 12 Hospital Discharge PROBE.pdf
- Form 13 Discharge Medications PROBE.pdf
- Form 20 Physical Exam FU PROBE.pdf
- Form 22 FU Diet_Meds PROBE.pdf
- Form 23 FU Labs PROBE.pdf
- Form 25C Ascending Cholangitis.pdf
- Form 25D Ascites.pdf
- Form 25F GI Bleed.pdf
- Form 25H Coagulopathy.pdf
- Form 25I Hepatopulmonary Syndrome.pdf
- Form 25L Transplant Listing PROBE.pdf
- Form 25M Other Sentinel Events.pdf
- Form 25N and 25 Liver Transplant PROBE.pdf
- Form 26 FU Surgery.pdf
- Form 35 Final Status PROBE.pdf

- Liver Stiffness Measurement FORCE.pdf
- Participant Demographics PROBE.pdf
- Sentinel Events Coagulopathy.pdf
- Sentinel Events Other.pdf
- Wechsler Intelligence Scale for Children.pdf
- WPPSI Wechsler Preschool and Primary Scale of Intelligence.pdf

SAS Programs

The SAS Programs directory contains:

- SAS_alloutput_16jul2019_NIDDK.pdf
- SAS_Table 1_Bass_BA_Risk_of_VH.pdf
- SAS_Table 1_Hertel_INH.pdf
- SAS_Table1_Venkat_BA_Natural_Hist.pdf