

FibroScan™ in Pediatric Cholestatic Liver Disease (FORCE) Study Data Archive

The FORCE study was a cross-sectional and longitudinal assessment of the utility of liver stiffness measurements (LSM) in children with chronic cholestatic liver disease. Study participants were from 13 Childhood Liver Disease Research Network (ChiLDRn) sites in the U.S. and Canada, and were also enrolled in the PROBE, BASIC, or LOGIC studies. FORCE participants were evaluated for a period of up to 24 months to assess the non-invasive ultrasound tool (FibroScan™) to detect and quantify global liver fibrosis in children with biliary atresia (BA), alpha-1 antitrypsin deficiency (A1ATD), and Alagille syndrome (ALGS). The participants were non-fasted and non-sedated during data collection. There were three visits in the study: baseline, 12-month follow-up, and 24-month follow-up. Clinical data and specimens were collected at each visit along with repeated FibroScan measurements such as LSM to quantify liver fibrosis, and controlled attenuation parameter (CAP) to quantify liver steatosis.

Archive files are organized into the following directories:

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

Data

The FORCE Data directory contains the following datasets and files:

Data/Baseline

- FORCEBL.CSV
- forcebl.sas7bdat
- forceformats.sas7bcats
- FORCE_FORMATS.CSV
- force_formats.sas7bdat

Data/Baseline/Contents

- FORCE_Data_Dictionary.pdf
- ForceBLDataDictionary.xlsx

Data/Biomarker

- forcebiomarker.csv
- forcebiomarker.sas7bdat
- ForceBiomarkerDataDictionary.csv
- formats.sas7bcats

Documents

The FORCE Documents directory contains:

- Fig1TemplateSampleSelectionV2.pdf
- FORCE MOO V1.53 02282018.pdf
- FORCE Protocol V1.2 07102018_FINAL.pdf

Documents/Key Publications

- FORCE Publications.pdf
- FORCE Study Bibliography.pdf
- Leung_22_Hepatology_Serum Biomarkers for Liver Stiffness.pdf
- Shneider_20_HepComm_FORCE Baseline.pdf

DSIC

The FORCE Dataset Integrity Check (DSIC) directory contains:

- FORCE_Biomarkers_Leung_DSIC.pdf
- FORCE_DSIC_V1.1.pdf

Forms

The FORCE Forms directory contains:

- ALGS_Anomalies_2020.pdf
- Eligibility FORCE.pdf
- Eligibility PROBE.pdf
- Endoscopy2020.pdf
- Form 03C Anomalies PROBE.pdf
- Form 07 Physical Exam LOGIC G2 G5.pdf
- Form 07 Physical Exam PROBE.pdf
- Form 08 Labs Initial Presentation PROBE.pdf
- Form 08.2 08.5 Labs LOGIC G2 G5.pdf
- Form 11 Surgery PROBE.pdf
- Form 11 Surgery Procedure LOGIC.pdf
- Form 13 Current Medications LOGIC.pdf
- Form 20 Physical Exam FU PROBE.pdf
- Form 22 FU Diet_Meds PROBE.pdf
- Form 25F GI Bleed.pdf
- Form 26 FU Surgery.pdf
- Form 35 Final Status FORCE.pdf
- Form 35 Final Status PROBE.pdf
- Initial_History_2020.pdf
- Interval_History_2020.pdf
- Labs_2020.pdf
- Liver Stiffness Measurement FORCE.pdf

- Participant Demographics LOGIC.pdf
- Participant Demographics PROBE.pdf
- Participant_Demographics2020.pdf
- Physical_Exam_2020.pdf
- Sentinel Events GI Bleed.pdf

SAS Programs

- AnalysisForceBiomarkerForRepository.pdf
- ForceAnalysisCodeForRepo.pdf