

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 biosamples 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.

Only baseline data are available in the data package. 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 baseline dataset in Windows-based SAS and SAS format files:

- forcebl.sas7bdat
- force_formats.sas7bdat
- forceformats.sas7bcat

Data/Contents

- FORCE_Data_Dictionary.pdf

Documents

The FORCE Documents directory contains:

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

DSIC

The FORCE Data Integrity Check (DSIC) directory contains:

- FORCE_DSIC_V1.1.pdf - A report of an examination of the baseline dataset for completeness by statisticians and quality control specialists at the Repository. Reported results from the FORCE data were compared to values recalculated from the FORCE baseline data in the NIDDK repository.

Forms

The FORCE Forms directory contains:

- Eligibility FORCE.pdf
- Eligibility PROBE.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
- Liver Stiffness Measurement FORCE.pdf
- Participant Demographics LOGIC.pdf
- Participant Demographics PROBE.pdf
- Sentinel Events GI Bleed.pdf

SAS Programs

The FORCE SAS Programs directory contains:

- ForceAnalysisCodeForRepo.pdf