

## **A Randomized, Double-Blinded, Placebo-Controlled Trial of Corticosteroid Therapy Following Portoenterostomy in Infants with Biliary Atresia (START) Study Data Archive**

The START study participants were recruited from the PROBE study and randomized into either the corticosteroid or placebo group within 72 hours after the portoenterostomy procedure. Participants were given their assigned treatments daily over the course of 13 weeks. After the treatment period, participants underwent follow-up testing and assessments until age 24 months.

Archive files are organized into the following directories:

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

### **Data**

The START Data directory contains the following datasets and files:

#### Data/PROBE\_START\_Bayley\_Ng

- Bayley Manuscript Data Specifications.pdf
- bayley\_ms\_saf.csv
- bayley\_ms\_saf.sas7bdat

#### Data/PROBE\_START\_Growth\_Alonso

- START Growth Manuscript Codebook.pdf
- start\_growth\_25oct18.csv
- start\_growth\_25oct18.sas7bdat
- start\_growth\_formats\_25oct18.sas7bcat

#### Data/START

- dosing\_day\_by\_day.sas7bdat
- DOSING\_DAY\_BY\_DAY.CSV
- start\_final\_dd2.sas7bdat
- START\_FINAL\_DD2.CSV
- study\_medication\_compliance.sas7bdat
- STUDY\_MEDICATION\_COMPLIANCE.CSV

#### Data/Codebook

- Day-by-Day Dosing Derived Dataset Specifications V2 .pdf
- START Efficacy Specifications.pdf
- Study Medication Compliance Derived Dataset Specifications V2 .pdf

## Data/Venkat START VitaminDeficiency

- Codebook\_final.pdf
- zenkat\_archive.csv
- zenkat\_archive.sas7bdat

## Documents

The START Documents directory contains:

- START\_protocol.pdf

## Documents/MOO

- MOO PROBE V2.1 (1).pdf
- MOO\_00\_toc (1).pdf
- MOO\_00\_toc (2).pdf
- MOO\_00\_toc (3).pdf
- MOO\_00\_toc (4).pdf
- MOO\_00\_toc (5).pdf
- MOO\_00\_toc (6).pdf
- MOO\_00\_toc (7).pdf
- MOO\_00\_toc (8).pdf
- START MOO.pdf

## Documents/START PROBE Bayley\_Ng

- MOO PROBE V2.1 (1).pdf
- probe\_amend6.pdf
- Publication for PROBE\_201802s.pdf

## Documents/START PROBE Growth Alonso

- Alonso\_18\_JPediatrics\_(START)Impact of Steroid Therapy on Early Grow...pdf
- Bibliography\_START\_PROBE\_201811.pdf
- START growth manuscript in press.pdf
- start\_growth\_manuscript\_tables\_25oct2018.pdf

## DSIC

The START Dataset Integrity Check (DSIC) directory contains:

- PROBE\_START\_Bayley\_Manuscript\_Ng\_DSIC.pdf
- PROBE\_START\_Growth\_Manuscript\_Alonso\_DSIC.pdf
- START\_DSIC\_Bezerra.pdf
- START\_Venkat\_DSIC.pdf

## **Forms**

The START Forms directory contains:

- 01 Eligibility.pdf
- 02A Subject Demographics.pdf
- 02A\_Subject Demographics\_v05\_2008\_02\_06\_Annotated.pdf
- 07a Anomalies (1).pdf
- 07a Anomalies (2).pdf
- 08 Labs Initial Pre-lap.pdf
- 08\_Initial Lab\_v05.1\_2010\_03\_16\_Annotated.pdf
- 11\_Surgery.pdf
- 13\_Discharge Medications\_v05\_2008\_06\_02\_Annotated.pdf
- 22\_FU Diet Meds\_v05\_2008\_06\_02\_Annotated.pdf
- 23\_FU Labs\_v05.1\_2010\_03\_16\_Annotated.pdf
- 25N Liver Transplant.pdf
- 35 Final Status PROBE.pdf
- P004 Form S11.V03 Eligibility 070105.pdf
- P004 Form S11D.V03 Hypokalemia 12012006.pdf
- P004 Form S11F.V03 070105.pdf
- P004 Form S11G.V04 Pancreatitis 12012006.pdf
- P004 Form S12.V03 Discharge AE Screen 070105.pdf
- P004 Form S12B.V03 Hypertension 070105.pdf
- P004 Form S12C.V03 Hyperglycemia 070105.pdf
- P004 Form S12D.V03 Hypokalemia 070105.pdf
- P004 Form S12E.V03 Wound Healing 070105.pdf
- P004 Form S12F.V03 GI Bleed 070105.pdf
- P004 Form S12G.V03 Pancreatitis 070105.pdf
- P004 Form S12H.V03 Irritability 070105.pdf
- P004 Form S12I.V03 Vaccine Prev Infections 070105.pdf
- P004 Form S12J.V03 Cataracts 070105.pdf
- P004 Form S13B annotated.pdf
- P004 Form S13B.V03 Steroid Placebo 030106.pdf
- P004 Form S13C.V03 Steroid Pulse 070105.pdf
- P004 Form S13D.V03 Ranitidine 030106.pdf
- P004 Form S13E.V03 TMP SMZ 030106.pdf
- P004 Form S13G.V03 ADEK 030106.pdf
- P004 Form S13H.V03 Vitamin K 120106doc.pdf
- P004 Form S20.V03 FU AE Screen 070105.pdf
- P004 Form S20J.V03 Cataracts070105.pdf
- P004 Form S22.2WK.V03 FU Diet Meds 120106.pdf
- P004 Form S22I.V03 Immunization Record 120106.pdf
- P004 Form S22V.V03 Vaccine Titer 120106.pdf
- P004 Form S23.2WK.V03 FU Labs 12012006.pdf

- P004 Form S23a.pdf
- P004 Form S33 Study Drug Reduction Log 070105.pdf
- P004 Form S34C.V03 Treatment Assignment Coordinator 070105.pdf
- P004 Form S34F.V03 Treatment Assignment Father 070105.pdf
- P004 Form S34H.V03 Treatment Assignment Hepatologist 070105.pdf
- P004 Form S34M.V03 Treatment Assignment Mother 070105.pdf
- P004 Form S34S.V03 Treatment Assignment Surgeon 070105.pdf
- P004 Form S35.V04 Final Status 120106.pdf

Forms/START PROBE Bayley Ng

- 01 Eligibility.pdf
- 02A Subject Demographics.pdf
- 07a Anomalies (1).pdf
- 08 Labs Initial Pre-lap.pdf
- 11\_Surgery.pdf
- 25N Liver Transplant.pdf
- BSID.pdf
- Form 35 Final Status PROBE.pdf
- P003 Form 02A.V05 Demographics 020608.pdf
- P003 Form 07.V04 Physical Exam 120106.pdf
- P003 Form 20.V04 FU Physical 120106.pdf
- P003 Form 21C.V04 Bayley 120106.pdf
- P003 Form 22.V04 FU Diet Meds 120106.pdf
- P003 Form 23.V04 FU Labs 120106.pdf
- P003 Form 25C.V03 Ascending Cholangitis 070105.pdf
- P003 Form 25D.V03 Ascites 070105.pdf
- P003 Form 25E.V03 Bacterial Peritonitis 070105.pdf
- P003 Form 25F.V03 GI Bleed 070105.pdf
- P003 Form 25M.V03 Other Events 070105.pdf
- Schedule .pdf

Forms/START PROBE Growth Alonso

- Form 26 FU Surgery.pdf
- PROBE Family Demographics.pdf
- PROBE Form 03C Anomalies.pdf
- PROBE Form 07 Physical Exam.pdf
- PROBE Form 11 Surgery.pdf
- PROBE Form 20 Physical Exam FU.pdf
- PROBE Form 22 FU Diet\_Meds.pdf
- PROBE Form 23 FU Labs.pdf
- PROBE Form 25N and 25 Liver Tranplant.pdf
- PROBE Form 35 End Status.pdf