

A Phase I/IIa Trial of Intravenous Immunoglobulin (IVIG) Therapy Following Portoenterostomy in Infants with Biliary Atresia (PRIME)

The PRIME study was a multicenter prospective phase 1/2A open label trial, aimed at assessing the feasibility, tolerability, and safety of intravenous immunoglobulin (IVIG) therapy following hepatic portoenterostomy (HPE) in infants with biliary atresia (BA). After enrollment, participants received three intravenous doses of IVIG at designated intervals over the first 60 days following HPE and were followed for 360 days. All infants in this trial were also treated with standardized doses of other routine standard-of-care treatments for BA and this routine clinical care was not modified by participation in this study.

Archive files are organized into the following directories:

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

Data

The PRIME Data directory contains:

- ADDVARS.CSV
- addvars.sas7bdat
- DD_AE.CSV
- dd_ae.sas7bdat
- DD_P007.CSV
- dd_p007.sas7bdat
- DOSING_DERIVED_DATA.CSV
- dosing_derived_data.sas7bdat
- LABS.CSV
- labs.sas7bdat
- LAB_AE.CSV
- lab_ae.sas7bdat
- LISTING2.CSV
- listing2.sas7bdat
- PATIENT.CSV
- patient.sas7bdat
- PRIME001_ELIGIBILITY.CSV
- prime001_eligibility.sas7bdat
- PRIME005DIET.CSV
- prime005diet.sas7bdat
- PRIME007PHYSICALEXAM.CSV
- prime007physicalexam.sas7bdat
- PRIME009IV.CSV
- prime009iv.sas7bdat

- PRIME009LOGIV.CSV
- prime009logiv.sas7bdat
- PRIME011INFUSION.CSV
- prime011infusion.sas7bdat
- PRIME011INFUSION2.CSV
- prime011infusion2.sas7bdat
- PRIME020ADVERSE_EVENT_LOG.CSV
- prime020adverse_event_log.sas7bdat
- PRIME020ADVERSE_EVENT_LOGAE.CSV
- prime020adverse_event_logae.sas7bdat
- PRIME025TRANSPLANT.CSV
- prime025transplant.sas7bdat
- PRIME035FINAL_STATUS.CSV
- prime035final_status.sas7bdat
- PRIME040PROTOCOLDEVIATION_LOG.CSV
- prime040protocoldeviation_log.sas7bdat
- PRIME050RESEARCH_LAB_BLOOD.CSV
- prime050research_lab_blood.sas7bdat
- PRIME051RESEARCH_LAB_PLASMA.CSV
- prime051research_lab_plasma.sas7bdat
- PRIME_000_PROBE_LINK.CSV
- prime_000_probe_link.sas7bdat
- PRIME_008_LABS.CSV
- prime_008_labs.sas7bdat
- PRIME_DERIVED_DATA.CSV
- prime_derived_data.sas7bdat
- START_FINAL_DD.CSV
- start_final_dd.sas7bdat
- START_FINAL_DD2.CSV
- start_final_dd2.sas7bdat

Data/Contents

- PRIME Codebook.xlsx

Documents

The PRIME Documents directory contains:

- Bibliography.pdf
- P007 PRIME Protocol v2 Amend 1 FINAL 10July2013.pdf
- PRIME_MOO.pdf

DSIC

The PRIME DSIC directory contains:

- PRIME_DSIC.pdf

Forms

The PRIME Forms directory contains:

- PRIME_Annotated_Forms.xlsx
- PRIME_Casebook.pdf