HBRN Pediatric Immune Tolerant Study

The Hepatitis B Research Network (HBRN) Pediatric Immune Tolerant (IT) Study archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Checks.

Archive files are organized into the following directories:
- Data
- Documents
- Dataset Integrity Check (DSIC)
- Forms

Data

The HBRN Pediatric IT Data directory contains:
- AEPIT.CSV
- aepit.sas7bdat
- BCP.CSV
- bcp.sas7bdat
- BEPIT.CSV
- bepit.sas7bdat
- BPP.CSV
- bpp.sas7bdat
- CCPIT.CSV
- ccpit.sas7bdat
- CDPIT.CSV
- cdpit.sas7bdat
- CIPIT.CSV
- cipit.sas7bdat
- CMPIT.CSV
- cmpit.sas7bdat
- CPPIT.CSV
- cppit.sas7bdat
- DCPIT.CSV
- dcpit.sas7bdat
- DSPIT.CSV
- dspit.sas7bdat
- ECPIT.CSV
- ecpit.sas7bdat
- FRPIT.CSV
- frpit.sas7bdat
- LEPIT.CSV
- lepit.sas7bdat
- MWPIT.CSV
- mwpit.sas7bdat
- OPPIT.CSV

- oppit.sas7bdat
- pediatric_IT_formats.sas
- RFPIT.CSV
- rfpit.sas7bdat
- SAPIT.CSV
- sapit.sas7bdat
- SCREEN_INFO_PEDIATRIC_IT.CSV
- screen_info_pediatric_it.sas7bdat
- SDPIT.CSV
- sdpit.sas7bdat
- SEPIT.CSV
- sepit.sas7bdat
- VEPIT.CSV
- vepit.sas7bdat

Data/Analytic Datasets
- ITP_AE_LONG.CSV
- itp_ae_long.sas7bdat
- ITP_DCPIT.CSV
- itp_dcpit.sas7bdat
- ITP_DSPIT.CSV
- itp_dspit.sas7bdat
- ITP_ENRCRIT.CSV
- itp_enrcrit.sas7bdat
- ITP_LONG.CSV
- itp_long.sas7bdat

Data/Analytic Datasets/Contents
- HBRN_AE_LONG_proc contents.pdf
- HBRN_DCPIT_proc contents.pdf
- HBRN_DSPIT_proc contents.pdf
- HBRN_ENRCRIT_proc contents.pdf
- HBRN_ITP_LONG_proc contents.pdf

Data/Ancillary Datasets/ALT Flares IT Trials
- CYTOKINE_RESULTS.CSV
- cytokine_results.sas7bdat
- formats_ITflares.sas
- HBRNAnc_Cytokine Results_proc contents.pdf
- HBRNAnc_IFN Antibody_proc contents.pdf
- HBRNAnc_IFN Fold Change_proc contents.pdf
- HBRNAnc_IL28B Results_proc contents.pdf
- IFN_ANTIBODY.CSV
- ifn_antibody.sas7bdat

- IFN_FOLD_CHANGE.CSV
- ifn_fold_change.sas7bdat
- IL28B_RESULTS.CSV
- il28b_results.sas7bdat

Data/Ancillary Datasets/Liver Biopsy Complications
- biopsy_complication_review.csv
- biopsy_complication_review.sas7bdat
- HBRNAnc_Liver biopsy_proc contents.pdf

Data/Central Results Pediatric Immune Tolerant
- HBRN_BCP_PC_ITP_RESULTS.CSV
- hbrn_bcp_pc_itp_results.sas7bdat
- HBRN_CDC_ITP_RESULTS.CSV
- hbrn_cdc_itp_results.sas7bdat
- HBRN_CENTRAL_ITP_RESULTS.CSV
- hbrn_central_itp_results.sas7bdat
- hbrn_central_results_formats.sas
- HBRN_DRUG_RESISTANCE_ITP_RESULTS.CSV
- hbrn_drug_resistance_itp_results.sas7bdat
- HBRN_EVENT_ADJ_ITP.CSV
- hbrn_event_adj_itp.sas7bdat
- HBRN_PATHOLOGY_ITP_RESULTS.CSV
- hbrn_pathology_itp_results.sas7bdat

Data/Central Results Pediatric Immune Tolerant/Contents
- HBRN_BCP_PC_Pediatric IT_proc contents.pdf
- HBRN_CDC_Pediatric IT_proc contents.pdf
- HBRN_central_Pediatric IT_proc contents.pdf
- HBRN_Drug_Resistance_Pediatric IT_proc contents.pdf
- HBRN_event_adj_Pediatric IT_proc contents.pdf
- HBRN_pathology_Pediatric IT_proc contents.pdf

Data/Contents
- HBRN_AEPIT_proc contents.pdf
- HBRN_BCP_proc contents.pdf
- HBRN_BEPIT_proc contents.pdf
- HBRN_BPP_proc contents.pdf
- HBRN_CCPIT_proc contents.pdf
- HBRN_CDPIT_proc contents.pdf
- HBRN_CIPIT_proc contents.pdf
- HBRN_CMPIT_proc contents.pdf
- HBRN_CPPIT_proc contents.pdf
- HBRN_DCPIT_proc contents.pdf
- HBRN_DSPIT_proc contents.pdf

- HBRN_ECPIT_proc contents.pdf
- HBRN_FRPIT_proc contents.pdf
- HBRN_LEPIT_proc contents.pdf
- HBRN_MWPIT_proc contents.pdf
- HBRN_OPPIT_proc contents.pdf
- HBRN_RFPIT_proc contents.pdf
- HBRN_SAPIT_proc contents.pdf
- HBRN_Screen_info_proc contents.pdf
- HBRN_SDPIT_proc contents.pdf
- HBRN_SEPIT_proc contents.pdf
- HBRN_VEPIT_proc contents.pdf

Documents

The HBRN Pediatric IT Documents directory contains:
- 01_Rosenthal_et_al-2019-Hepatology.pdf
- Adjudication materials and process_v1.8.pdf
- HBRN Ancillary studies README.pdf
- HBRN Pediatric Immune Tolerant Protocol Amendment V4.pdf
- HBRN Pediatric IT Trial_DataArchive_ReadMe_042423.pdf
- Pediatric Immune Tolerant Trial Read Me file_20230424.pdf
- Pediatric IT Bibliography.pdf

Documents/Manual of Operations
- AEPIT_Adverse_Event_MOP_v1.0.pdf
- BCP_Baseline_Evaluation_Coordinator_MOP_v1.4.pdf
- BEPIT_Baseline_Evaluation_MOP_v1.1.pdf
- BPP_Baseline_Evaluation_Patient_MOP_v1.0.pdf
- CCPIT_CHQ_Patient_MOP_v1.0.pdf
- CDPIT_CES-D_MOP_v1.0.pdf
- CIPIT_CDI_MOP_v1.0.pdf
- CMPIT_Concomitant_Medication_MOP_v1.0.pdf
- CPPIT_CHQ_Parent_MOP_v1.0.pdf
- DCPIT_Dose_Change_MOP_v1.1.pdf
- DSPIT_Discontinuation_of_Tmt or Study_MOP_v1.3.pdf
- ECPIT_Enrollment_Criteria_MOP_v1.4.pdf
- FRP_Flare_Resolution_MOP_v1.2.pdf
- HBPIT_Health_Behavior_Questionnaire_MOP_v1.0.pdf
- LBPIT_Liver_Biopsy_MOP_v1.1.pdf
- LEPIT_Laboratory_Evaluation_MOP_v1.2.pdf
- MW_MedWatch_MOP.pdf
- OPPIT_Off_Protocol__MOP_v1.2.pdf
- SAPIT_Symptom_Assessment_MOP_v1.0.pdf
- SDPIT_Study_Drug_Log_MOP_v1.0_.pdf

- SEPIT_Screening_Evaluation_MOP_v1.0.pdf
- TFPIT_Tanner_Female_MOP_v1.0.pdf
- TMPIT_Tanner_Male_MOP_v1.0.pdf
- VEPIT_Visit_Evaluation_MOP_v1.0.pdf

DSIC

The HBRN Pediatric IT Dataset Integrity Check (DSIC) directory contains:
- HBRN_Pediatric_IT_DSIC.pdf
- HBRN_ALT_Flares_IT_Trials_Ancillary_DSIC

Forms

The HBRN Pediatric IT Forms directory contains:
- AEPIT_Adverse Event_v1.0_codebook.pdf
- BCP_Baseline_Evaluation_Coordinator_v1.4_Codebook.pdf
- BEPIT_Baseline Evaluation_v1.1_codebook.pdf
- BPP_Baseline_Evaluation_Patient_v1.0_Codebook.pdf
- CCPIT_CHQ_patient_v1.0_codebook.pdf
- CDPIT_CES-D_v1.0_codebook.pdf
- CIPIT_CDI_v1.0_codebook.pdf
- CMPIT_Concomitant Medication Log_v1.0_codebook.pdf
- CPPIT_CHQ_parent_v1.0_codebook.pdf
- DCPIT_Dose Change_v1.1_codebook.pdf
- DSPIT_Discontinuation of Tmt or Study_v1.3_codebook.pdf
- ECPIT_Enrollment Criteria_v1.4_codebook.pdf
- FRP_Ped_Flare_Resolution_v1.0_codebook.pdf
- HBPIT_Ped_Health_behavior_questionnaire_v1.0_codebook.pdf
- LBPIT_Ped_Liver biopsy v1.1_codebook.pdf
- LEPIT_Lab Evaluation_v1.2_codebook.pdf
- MW_codebook.pdf
- OPPIT_Off Protocol_v1.2_codebook.pdf
- SAPIT_Symptom Assessment_v1.0_codebook.pdf
- SDPIT_Study Drug Log_v1.0_codebook.pdf
- SEPIT_Screening Evaluation_v1.0_codebook.pdf
- TFPIT_Tanner_Staging_Questionnaire_Female_v1.0.pdf
- TMPIT_Tanner_Staging_Questionnaire_Male_v1.0.pdf
- VEPIT_Visit Evaluation_v1.1_codebook.pdf