

HBRN Adult Immune Tolerant Study

The Hepatitis B Research Network (HBRN) Adult 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 Adult IT Data directory contains:

- adult_IT_formats.sas
- AEIT.CSV
- aeit.sas7bdat
- BC.CSV
- bc.sas7bdat
- BEIT.CSV
- beit.sas7bdat
- BP.CSV
- bp.sas7bdat
- CDIT.CSV
- cdit.sas7bdat
- CMIT.CSV
- cmit.sas7bdat
- DCIT.CSV
- dcit.sas7bdat
- DSIT.CSV
- dsit.sas7bdat
- ECIT.CSV
- ecit.sas7bdat
- FQIT.CSV
- fqit.sas7bdat
- FRIT.CSV
- frit.sas7bdat
- LBIT.CSV
- lbit.sas7bdat
- LEIT.CSV
- leit.sas7bdat
- MWIT.CSV
- mwit.sas7bdat
- OPIT.CSV
- opit.sas7bdat

- QLIT.CSV
- qlit.sas7bdat
- RFIT.CSV
- rfit.sas7bdat
- SAIT.CSV
- sait.sas7bdat
- SCREEN_INFO_ADULT_IT.CSV
- screen_info_adult_it.sas7bdat
- SDIT.CSV
- sdit.sas7bdat
- SEIT.CSV
- seit.sas7bdat
- VEIT.CSV
- veit.sas7bdat

Data/Analytic Datasets

- IT_AE_LONG.CSV
- it_ae_long.sas7bdat
- IT_DCIT.CSV
- it_dcit.sas7bdat
- IT_DSIT.CSV
- it_dsit.sas7bdat
- IT_ENRCRIT.CSV
- it_enrcrit.sas7bdat
- IT_LONG.CSV
- it_long.sas7bdat

Data/Analytic Datasets/Contents

- HBRN_AE_LONG_proc contents.pdf
- HBRN_DCIT_proc contents.pdf
- HBRN_DSIT_proc contents.pdf
- HBRN_ENRCRIT_proc contents.rtf.pdf
- HBRN_IT_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/Bioactive Lipids/FA

- 4745_Patel_FA_report_100217.pdf
- 4745_results_092817.xlsx

Data/Ancillary Datasets/Bioactive Lipids/Oxylipin

- 4745 Oxylipin Report.pdf
- Data_Dictionary_Oxylipin_Targets.xlsx
- formats_oxylipin.sas
- HBRNAnc_oxylipin_proc contents.pdf
- oxylipin_result.csv
- oxylipin_result.sas7bdat

Data/Ancillary Datasets/Bioactive Lipids/p400HR

- 4745 FIA p400 Data.xlsx
- 4745 FIA QC p400 Data.xlsx
- 4745 p400HR Sample Analysis Summary.pdf
- 4745 UPLC p400 Data.xlsx
- 4745 UPLC p400 QC Data.xlsx

Data/Central Results Adult Immune Tolerant

- HBRN_BCP_PC_IT_RESULTS.CSV
- hbrn_bcp_pc_it_results.sas7bdat
- HBRN_CDC_IT_RESULTS.CSV
- hbrn_cdc_it_results.sas7bdat
- HBRN_CENTRAL_IT_RESULTS.CSV
- hbrn_central_it_results.sas7bdat
- hbrn_central_results_formats.sas
- HBRN_DRUG_RESISTANCE_IT_RESULTS.CSV
- hbrn_drug_resistance_it_results.sas7bdat
- HBRN_EVENT_ADJ_IT.CSV
- hbrn_event_adj_it.sas7bdat
- HBRN_PATHOLOGY_IT_RESULTS.CSV
- hbrn_pathology_it_results.sas7bdat

Data/Central Results Adult Immune Tolerant/Contents

- HBRN_BCP_PC_Adult IT_proc contents.pdf
- HBRN_CDC_Adult IT_proc contents.pdf
- HBRN_central_Adult IT_proc contents.pdf
- HBRN_Drug_Resistance_Adult IT_proc contents.pdf
- HBRN_event_adj_Adult IT_proc contents.pdf

- HBRN_pathology_Adult IT_proc contents.pdf

Data/Contents

- HBRN_AEIT_proc contents.pdf
- HBRN_BC_proc contents.pdf
- HBRN_BEIT_proc contents.pdf
- HBRN_BP_proc contents.pdf
- HBRN_CDIT_proc contents.pdf
- HBRN_CMIT_proc contents.pdf
- HBRN_DCIT_proc contents.pdf
- HBRN_DSIT_proc contents.pdf
- HBRN_ECIT_proc contents.pdf
- HBRN_FQIT_proc contents.pdf
- HBRN_FRIT_proc contents.pdf
- HBRN_LBIT_proc contents.pdf
- HBRN_LEIT_proc contents.pdf
- HBRN_MWIT_proc contents.pdf
- HBRN_OPIT_proc contents.pdf
- HBRN_QLIT_proc contents.pdf
- HBRN_RFIT_proc contents.pdf
- HBRN_SAIT_proc contents.pdf
- HBRN_SDIT_proc contents.pdf
- HBRN_SEIT_proc contents.pdf
- HBRN_VEIT_proc contents.pdf

Documents

The HBRN Adult IT Documents directory contains:

- Adjudication materials and process_v1.8.pdf
- Adult Immune Tolerant Trial Read Me File_20230424.pdf
- Adult IT Bibliography.pdf
- Feld_et_al-2019-Hepatology.pdf
- HBRN Adult Immune Tolerant Protocol v7 0.pdf
- HBRN Adult IT Trial_DataArchive_ReadMe_042423.pdf
- HBRN Ancillary studies README.pdf
- HBRN Public Website URL.pdf

Documents/Manual of Operations

- AEIT_Adverse_Event_MOP_1.0.pdf
- BC_Baseline_Evaluation_Coordinator_MOP_v1.4.pdf
- BEIT_Baseline_Evaluation_MOP_v1.1.pdf
- BP_Baseline_Evaluation_Patient_MOP_v1.0.pdf
- CDIT_CES-D_MOP_v1.0.pdf
- CMIT_Concomitant_Medication_MOP_v1.0.pdf
- DCIT_Dose_Change_MOP_v1.0.pdf

- DSIT_Discontinuation_of_Tmt or Study_MOP_v1.3.pdf
- ECIT_Enrollment_Criteria_MOP_v1.3.pdf
- FQIT_Fatigue_Questionnaire_MOP_v1.0.pdf
- FRIT_Flare_Resolution_MOPv_1.2.pdf
- LBIT_Liver_Biopsy_MOP_v1.1.pdf
- LEIT_Laboratory_Evaluation_MOP_v1.2.pdf
- MW_MedWatch_MOP_v1.0.pdf
- OPIT_Off_Protocol_MOP_v1.3.pdf
- QLIT_Quality_of_Life_Questionnaire_MOP_v1.1.pdf
- SAIT_Symptom_Assessment_MOP_v1.0.pdf
- SDIT_Study_Drug_Log_MOP_v1.0.pdf
- SEIT_Screening_Evaluation_MOP_v1.0.pdf
- VEIT_Visit_Evaluation_MOP_v1.1.pdf

DSIC

The HBRN Adult IT Dataset Integrity Check (DSIC) directory contains:

- HBRN_Adult_IT_DSIC.pdf
- HBRN_ALT_Flares_IT_Trials_Ancillary_DSIC

Forms

The HBRN Adult IT Forms directory contains:

- AEIT_Adverse_Event_v1.0_codebook.pdf
- BC_Baseline_Evaluation_Coordinator_v1.4_Codebook.pdf
- BEIT_Baseline_Evaluation_v1.1_codebook.pdf
- BP_Baseline_Evaluation_Patient_v1.0_Codebook.pdf
- CDIT_CES-D_v1.0_codebook.pdf
- CMIT_Concomitant_Medication_Log_v1.0_codebook.pdf
- DCIT_Dose_Change_v1.0_codebook.pdf
- DSIT_Discontinuation_of_Tmt_or_Study_v1.3_codebook.pdf
- ECIT_Enrollment_Criteria_v1.3_codebook.pdf
- FQIT_Fatigue_Questionnaire_v1.0_codebook.pdf
- FRIT_Flare_resolution_v1.2_codebook.pdf
- LBIT_Liver_biopsy_v1.1_codebook.pdf
- LEIT_Lab_Evaluation_v1.2_codebook.pdf
- MW_codebook.pdf
- OPIT_Off_Protocol_v1.3_codebook.pdf
- QLIT_Quality_of_Life_v1.1_codebook.pdf
- SAIT_Symptom_Assessment_v1.0_codebook.pdf
- SDIT_Study_Drug_Log_v1.0_codebook.pdf
- SEIT_Screening_Evaluation_v1.0_codebook.pdf
- VEIT_Visit_Evaluation_v1.1_codebook.pdf

Forms/Previous versions of Enrollment Criteria

- ECIT_Enrollment Criteria_v1.1_codebook.pdf
- ECIT_Enrollment Criteria_v1.2_codebook.pdf