HBRN Immune Active Trial

The HBRN Immune Active Trial 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

<u>Data</u>

The HBRN Immune Active Data directory contains:
- adult_ia_formats.sas
- AEIA.CSV
- aeia.sas7bdat
- BEIA.CSV
- beia.sas7bdat
- CDIA.CSV
- cdia.sas7bdat
- CMIA.CSV
- cmia.sas7bdat
- DCIA.CSV
- dcia.sas7bdat
- DDIA.CSV
- ddia.sas7bdat
- DSIA.CSV
- dsia.sas7bdat
- ECIA.CSV
- ecia.sas7bdat
- FB.CSV
- fb.sas7bdat
- FBIA.CSV
- fbia.sas7bdat
- FQIA.CSV
- fqia.sas7bdat
- FRIA.CSV
- fria.sas7bdat
- HCIA.CSV
- hcia.sas7bdat
- LBIA.CSV
- lbia.sas7bdat
- LEIA.CSV
- leia.sas7bdat
- MW.CSV
- mw.sas7bdat

- OPIA.CSV
- opia.sas7bdat
- PRIA.CSV
- pria.sas7bdat
- QLIA.CSV
- qlia.sas7bdat
- RFIA.CSV
- rfia.sas7bdat
- RTIA.CSV
- rtia.sas7bdat
- SAIA.CSV
- saia.sas7bdat
- SCREEN_INFO_ADULT_IA.CSV
- screen_info_adult_ia.sas7bdat
- SDIA.CSV
- sdia.sas7bdat
- SEIA.CSV
- seia.sas7bdat
- VEIA.CSV
- veia.sas7bdat

Data/Analytic Datasets
- ALL_IA.CSV
- all_ia.sas7bdat
- IA_LONG.csv
- ia_long.sas7bdat

Data/Analytic Datasets/Contents
- HBRN_ALL_IA_proc contents.pdf
- HBRN_IA_LONG_proc contents.pdf

Data/Ancillary Datasets/HDV
- formats_hdv_ancillary.sas
- HBRNAnc_HDV_proc contents.pdf
- hdv_qmac_results.csv
- hdv_qmac_results.sas7bdat

Data/Ancillary Datasets/IA anti_IFN
- HBRNAnc_IA ANTI-IFN_proc contents.pdf
- ia_anti_ifn.csv
- ia_anti_ifn.sas7bdat

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

Data/Ancillary Datasets/Macrophage
- formats_macrophage.sas
- HBRNAnc_macrophage_proc contents.pdf
- macrophage_scd163.csv
- macrophage_scd163.sas7bdat

Data/Central Results Immune Active Trial
- HBRN_BCP_PC_IA_RESULTS.CSV
- hbrn_bcp_pc_ia_results.sas7bdat
- HBRN_CDC_IA_RESULTS.CSV
- hbrn_cdc_ia_results.sas7bdat
- HBRN_CENTRAL_IA_RESULTS.CSV
- hbrn_central_ia_results.sas7bdat
- hbrn_central_results_formats.sas
- HBRN_DRUG_RESISTANCE_IA_RESULTS.CSV
- hbrn_drug_resistance_ia_results.sas7bdat
- HBRN_EVENT_ADJ_IA.CSV
- hbrn_event_adj_ia.sas7bdat
- HBRN_PATHOLOGY_IA_RESULTS.CSV
- hbrn_pathology_ia_results.sas7bdat
- HBRN_SUPP_IA_RESULTS.CSV
- hbrn_supp_ia_results.sas7bdat

Data/Central Results Immune Active Trial/Contents
- HBRN_BCP_PC_IA_proc contents.pdf
- HBRN_CDC_Adult IA_proc contents.pdf
- HBRN_CDC_IA_proc contents.pdf
- HBRN_central_Adult IA_proc contents.pdf
- HBRN_Drug_Resistance_IA_proc contents.pdf
- HBRN_event_adj_IA_proc contents.pdf
- HBRN_pathology_IA_proc contents.pdf
- HBRN_supp_Adult IA_proc contents.pdf

Data/Contents
- HBRN_AEIA_proc contents.pdf
- HBRN_BEIA_proc contents.pdf
- HBRN_CDIA_proc contents.pdf
- HBRN_CMIA_proc contents.pdf
- HBRN_DCIA_proc contents.pdf
- HBRN_DDIA_proc contents.pdf
- HBRN_DSIA_proc contents.pdf
- HBRN_ECIA_proc contents.pdf
- HBRN_FBIA_proc contents.pdf
- HBRN_FQIA_proc contents.pdf
- HBRN_FRIA_proc contents.pdf
- HBRN_HCIA_proc contents.pdf

- HBRN_LBIA_proc contents.pdf
- HBRN_LEIA_proc contents.pdf
- HBRN_MW_proc contents.pdf
- HBRN_OPIA_proc contents.pdf
- HBRN_PRIA_proc contents.pdf
- HBRN_QLIA_proc contents.pdf
- HBRN_RFIA_proc contents.pdf
- HBRN_RTIA_proc contents.pdf
- HBRN_SAIA_proc contents.pdf
- HBRN_Screen_info_adult_ia_proc contents.pdf
- HBRN_SDIA_proc contents.pdf
- HBRN_SEIA_proc contents.pdf
- HBRN_VEIA_proc contents.pdf

Documents

The HBRN Immune Active Documents directory contains:
- Adjudication materials and process_v1.8.pdf
- Adult Immune Active Read Me.pdf
- Adult Immune Active Trial Bibliography.pdf
- AJG_Randomized_Trial_of_Tenofovir_With_or_Without_Peginterferon_Alpha.pdf
- HBRN Ancillary studies README.pdf
- HBRN Public Website URL.pdf
- HBRN_Immune_Active_Trial_Protocol_v7_20181023 clean.pdf
- README_analysis_datasets.pdf

Documents/Manual of Operations
- AEIA_Adverse_Event_MOP_v1.0.pdf
- BEIA_Baseline_Evaluation_MOP_v1.2.pdf
- CDIA_CES-D_MOP_v1.0.pdf
- CMIA_Concomitant_Medication_Log_MOP_v1.0.pdf
- DCIA_Dose_Change_MOP_v1.0.pdf
- DSIA_Discontinuation_of_Treatment_or_Study_MOP_v1.1.pdf
- ECIA_Enrollment_Criteria_MOP_v1.2.pdf
- FB_Fibroscan_MOP_v1.1.pdf
- FQIA_Fatigue_Questionnaire_MOP_v1.0.pdf
- FR_Flare_Resolution_MOP_v1.2.pdf
- HCIA_HCC_Form_MOP_v1.0.pdf
- IA_Treatment Discontinuation and Reinitiation Process_protocol_MOP.pdf
- LBIA_Liver_Biopsy_MOP_v1.1.pdf
- LEIA_Laboratory_Evaluation_MOP_v1.2.pdf
- MW_MedWatch_MOP_v1.0.pdf
- OPIA_Off-Protocol_Form_MOP_v1.4.pdf
- QLIA_Quality_of_Life_Questionnaire_MOP_v1.0.pdf
- SAIA_Symptom_Assessment_MOP_v1.0.pdf
- SDIA_Study_Drug_Log_MOP_v1.0.pdf

- SEIA_Screening_Evaluation_MOP_v1.0.pdf
- VEIA_Visit_Evaluation_MOP_v1.4.pdf

DSIC

The HBRN Immune Active Dataset Integrity Check (DSIC) directory contains:
- HBRN_Immune_Active_DSIC.pdf

Forms

The HBRN Immune Active Forms directory contains:
- AEIA_Adverse_Event_v1.0_Codebook.pdf
- BEIA_Baseline_Evaluation_v1.2_Codebook.pdf
- CDIA_CES-D_v1.0_Codebook.pdf
- CMIA_Concomitant_Medication Log_v1.0__Codebook.pdf
- DCIA_Dose Change_v1.0_Codebook.pdf
- DDIA_Discontinuation_of_Study_Drug_Week_192_v1.2_Codebook.pdf
- DSIA_Discontinuation_of_Treatment_or_Study_v1.1_Codebook.pdf
- ECIA_Enrollment_Criteria_v1.2_Codebook.pdf
- FB_Fibroscan_v1.1_Codebook.pdf
- FQIA_Fatigue_Questionnire_v1.0_Codebook.pdf
- HCIA_HCC_Form_v1.0_Codebook.pdf
- LBIA_Liver_Biopsy_v1.1_Codebook.pdf
- LEIA_Laboratory_Evaluation_v1.2_Codebook.pdf
- MW_codebook.pdf
- OPIA_Off_Protocol_Form_v1.4_Codebook.pdf
- PRIA_Pathology_Review_Form_v1.0_Codebook.pdf
- QLIA_Quality_of_Life_v1.0_Codebook.pdf
- RTIA_Reinitiation_HBV_Treatment_Post-treatment_Follow-up_v1.3_Codebook.pdf
- SAIA_Symptom_Assessment_v1.0_Codebook.pdf
- SDIA_Study_Drug Log_v1.0_Codebook.pdf
- SEIA_Screening_Evaluation_v1.0_Codebook.pdf
- VEIA_Visit_Evaluation_v1.4_Codebook.pdf