

Observational Study of Hepatitis B Virus (HBV) in Patients Co-Infected with Human Immunodeficiency Virus (HIV) (HBRN HIV Co-Infection) Data Archive

Since the introduction of highly active antiretroviral therapy (ART) in 1996, there has been a dramatic reduction in morbidity and mortality among those living with HIV. However, chronic liver disease due to co-infection with hepatitis B virus (HBV) or C (HCV) has emerged as the second leading cause of mortality among HIV-infected persons. The natural history of HBV infection is altered in those with HIV. Current guidelines recommend that most co-infected patients be treated for both HIV and HBV infection using combinations of ART that include tenofovir (TDF). Despite widespread adoption in the U.S., the effect of this regimen on long-term outcomes of HBV disease such as histologic severity, progression, risk of emergence of resistant HBV variants, and the long-term risks of TDF therapy remains unanswered.

The Hepatitis B Research Network (HBRN) was the first major effort to elucidate the natural history and treatment outcomes of persons with chronic HBV in the U.S. This HBRN ancillary study provided a unique opportunity to fill major gaps in HBV-HIV knowledge and to compare HBV-HIV infected persons to those with HBV mono-infection participating in the HBRN.

Archive files are organized into the following directories:

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

Data

The HBRN HIV Co-Infection Data directory contains the following datasets:

Data/Analytic Datasets

- FULL_LONG_SET.CSV
- full_long_set.sas7bdat
- MAIN_DATASET.CSV
- main_dataset.sas7bdat
- NONINVASIVE_BL.CSV
- noninvasive_bl.sas7bdat
- OUTCOMES_DATASET.CSV
- outcomes_dataset.sas7bdat
- READ ME Sterling RC Noninvasive Fibrosis Hepatology 2020.pdf
- READ ME Sterling RC Outcomes Hepatology 2021.pdf
- STABLE3.CSV
- stable3.sas7bdat

Data/Event Adjudication

- EVENT_ADJUDICATION.CSV
- event_adjudication.sas7bdat

Data/Raw Datasets

- AH.CSV
- ah.sas7bdat
- AU.CSV
- au.sas7bdat
- BC.CSV
- bc.sas7bdat
- BCP_PC_RESULTS.CSV
- bcp_pc_results.sas7bdat
- BH.CSV
- bh.sas7bdat
- BI.CSV
- bi.sas7bdat
- BONE_RENAL_MARKERS.CSV
- bone_renal_markers.sas7bdat
- BP.CSV
- bp.sas7bdat
- CDC_RESULTS.CSV
- cdc_results.sas7bdat
- CENTRAL_TESTING_RESULTS.CSV
- central_testing_results.sas7bdat
- DRUG_RESISTANCE_RESULTS.CSV
- drug_resistance_results.sas7bdat
- EH.CSV
- eh.sas7bdat
- FB.CSV
- fb.sas7bdat
- FE.CSV
- fe.sas7bdat
- FF.CSV
- ff.sas7bdat
- FH.CSV
- fh.sas7bdat
- FQ.CSV
- fq.sas7bdat
- FR.CSV
- fr.sas7bdat
- HC.CSV
- hc.sas7bdat
- LB.CSV

- lb.sas7bdat
- LIPID_TESTING.CSV
- lipid_testing.sas7bdat
- OI.CSV
- oi.sas7bdat
- PATHOLOGY_RESULTS.CSV
- pathology_results.sas7bdat
- PF.CSV
- pf.sas7bdat
- PQ.CSV
- pq.sas7bdat
- QL.CSV
- ql.sas7bdat
- SA.CSV
- sa.sas7bdat
- SCREEN_INFO.CSV
- screen_info.sas7bdat
- SL.CSV
- sl.sas7bdat
- SV.CSV
- sv.sas7bdat

Data/Raw Datasets/SAS Formats

- formats_hbv_hiv_archive.sas

Data/Raw Datasets/Variable Codebooks

- AH_Antiviral_Therapy_v1.0_Codebook.pdf
- AU_AUDIT_Questionnaire_v1.0_Codebook.pdf
- BC_Baseline_Evaluation_Coordinator_v1.4_Codebook.pdf
- BH_HBVHIV_Baseline_Evaluation_v1.2_Codebook.pdf
- BI_Baseline_Evaluation_Investigator_v1.1_Codebook.pdf
- BP_Baseline_Evaluation_Patient_v1.0_Codebook.pdf
- EH_HBVHIV_Enrollment_Criteria_v1.1_Codebook.pdf
- FB_Fibroscan_1.1_Codebook.pdf
- FE_Follow-up_Events_v1.1_Codebook.pdf
- FF_Follow-up_Evaluation_v1.4_Codebook.pdf
- FH_HBVHIV_Followup_evaluation_v1.2_Codebook.pdf
- FQ_Fatigue_Questionnaire_v1.0_Codebook.pdf
- FR_Flare_Resolution_v1.2_Codebook.pdf
- HC_HCC_form_v1.1_Codebook.pdf
- LB_Liver_Biopsy_v1.4_Codebook.pdf
- OI_Opportunistic_Infections_v1.0_Codebook.pdf
- PF_Pregnancy_Follow-up_v1.2_Codebook.pdf

- PQ_Pregnancy_Questionnaire_v1.2_Codebook.pdf
- QL_Quality_of_Life_v1.0_Codebook.pdf
- SA_Symptom_Assessment_v1.0_Codebook.pdf
- SL_Screening_Log_v4.1_Codebook.pdf
- SV_Special_Visit_Evaluation_v1.3_Codebook.pdf

Documents

The HBRN HIV Co-Infection Documents directory contains:

- Adjudication materials and process_v1.8.pdf
- HBRN HBV HIV Coinfected Protocol_v3.0_clean 20170420.pdf
- HBVHIV Ancillary Study Read Me File.pdf
- HIV Ancillary Bibliography.pdf

Documents/MOPs

- AH_HBV_HIV Antiviral Therapy_MOP_v1.0.pdf
- AU_AUDIT_Questionnaire_MOP_v1.0.pdf
- BC_Baseline_Evaluation_Coordinator_MOP_v1.4.pdf
- BH_Baseline_Evaluation_Coordinator_MOP_v1.2.pdf
- BI_Baseline_Evaluation_Investigator_MOP_v1.1.pdf
- BP_Baseline_Evaluation_Patient_MOP_v1.0.pdf
- Data Collection Timeline v1.3_HBV_HIV Ancillary Study.pdf
- EH_Enrollment_Criteria_MOP_v1.0.pdf
- FB_Fibroscan_MOP_v1.1.pdf
- FE_Followup_Events_MOP_v1.1.pdf
- FF_Followup_Evaluation_MOP_v1.4.pdf
- FH_Followup_or_Special_Visit_Evaluation_MOP_v1.2.pdf
- FQ_Fatigue_Questionnaire_MOP_v1.0.pdf
- FR_Flare_Resolution_MOP_v1.2.pdf
- HCC_Form_MOP_v1.1.pdf
- LB_Liver_Biopsy_MOP_v1.4.pdf
- OI_HBV_HIV Opportunistic Infection_MOP_v1.0.pdf
- PF_Pregnancy_Followup_MOP_v1.2.pdf
- PQ_Pregnancy_Questionnaire_MOP_v1.1.pdf
- QL_Quality_of_Life_Questionnaire_MOP_v1.0.pdf
- SA_Symptom_Assessment_MOP_v1.0.pdf
- SL_Screening_Log_MOP_v4.1.pdf
- SV_Special_Visit_MOP_v1.3.pdf

DSIC

The HBRN HIV Co-Infection Data Integrity Check (DSIC) directory contains:

- HBRN_HIV_Co-Inf_DSIC.pdf

Forms

The HBRN HIV Co-Infection Forms directory contains:

- AH_Antiviral_Therapy_v1.0.pdf
- AU_AUDIT_Questionnaire_v1.0.pdf
- BC_Baseline_Evaluation_Coordinator_v1.4.pdf
- BH_HBVHIV_Baseline_Evaluation_v1.2.pdf
- BI_Baseline_Evaluation_Investigator_v1.1.pdf
- BP_Baseline_Evaluation_Patient_v1.0.pdf
- EH_HBVHIV_Enrollment_Criteria_v1.1.pdf
- FB_Fibroscan_v1.1.pdf
- FE_Follow-up_Events_v1.1.pdf
- FF_Follow-up_Evaluation_v1.4.pdf
- FH_HBVHIV_Followup_Evaluation_v1.2.pdf
- FQ_Fatigue_Questionnaire_v1.0.pdf
- FR_Flare_Resolution_v1.2.pdf
- HC_HCC_form_v1.1.pdf
- LB_Liver_Biopsy_v1.4.pdf
- OI_Opportunistic_Infections_v1.0.pdf
- PF_Pregnancy_Follow-up_v1.2.pdf
- PQ_Pregnancy_Questionnaire_v1.2.pdf
- QL_Quality_of_Life_v1.0.pdf
- SA_Symptom_Assessment_v1.0.pdf
- SL_Screening_Log_v4.1.pdf
- SV_Special_Visit_Form_v1.3.pdf