Adult Immune Active Data Collection

Short name	Long name	Additional information	
SEIA	Screening Evaluation		
ECIA	Enrollment Criteria		
PRIA	Pathology Review		
BEIA	Baseline Evaluation		
LEIA	Laboratory Evaluation	Variables beginning with “UC” are unconverted lab results. Variables beginning with “UN” are unconverted lab units. For labs with different units at different centers or timepoints, these variables were used to create variables with a common unit.	
VEIA	Visit Evaluation		
SDIA	Study Drug Log		
DDIA	Drug Discontinuation W192		
RTIA	Reinitiation Study Drug Post W192		
FB	Fibroscan		
SAIA	Symptom Assessment		Spanish, Chinese, Korean
CDIA	CES-D		
QLIA	Quality of Life Questionnaire	Health Behavior incorporated into this form. SF-36v2™ Health Survey © 1996, 2000 by QualityMetric Incorporated and Medical Outcomes Trust. All Rights Reserved. SF-36® is a registered trademark of Medical Outcomes Trust. (SF-36v2 Standard, US Version 2.0)	QL: Spanish, Chinese, Korean, Vietnamese Health Behavior: Spanish, Chinese, Korean
FQIA	Fatigue Questionnaire	© 2009 PROMIS Health Organization and PROMIS Cooperative Group	Spanish
CMIA	Concomitant Medication Log		
AEIA	Adverse Events		
MW	MedWatch Form	Serious adverse events	
DCIA	Dose Change Log		
LBIA	Liver Biopsy		
HCIA	HCC Form		
OPIA	Off Protocol		
DSIA	Discontinuation of Treatment or Study		
FR	ALT Flare Resolution		

Short name	Long name	Additional information	
RFIA	Randomization	Accessed via the Data Management System only. When protocol was modified and all participants started on therapy, dataset populated at time of baseline visit.	
BC	Baseline Eval - Coordinator	Use dataset in Adult Cohort Study.	
BP	Baseline Eval – Patient	Health Behavior incorporated into this form. Use dataset in Adult Cohort Study.	Spanish, Chinese, Korean

Dataset	Description
Screen_info_adult_ia	This information is needed to identify the participants eligible for analyses, reasons for ineligibility, study discontinuations, and status at Week 192 (study medication discontinuation). The last screening record is used to determine screening eligibility.

Central Lab Datasets

Name	Description
hbrn_bcp_pc_ia_results	HBV Basal core promoter (BCP) and precore (PC) mutations. The CDC was not available to do the full testing per protocol.
hbrn_drug_resistance_ia_results	HBV drug resistant variant results. The CDC was not available to do the full testing per protocol.
hbrn_cdc_ia_results	HBV genotype and subtype results
hbrn_central_ia_results	Results for the following tests: HBV DNA (quantitative and log10), HBeAg quantitative, HBeAg qualitative, HBsAg quantitative, HBsAg qualitative, HBsAg confirmative, anti-HBs, anti-HDV
hbrn_supp_ia_results	Results for anti-HBe and anti-HBs completed on available samples for cases in which anti-HBe or anti-HBs were not done at the clinical site.
hbrn_pathology_ia_results	Pathology central read results when liver biopsy slides were obtained.

hbrn_event_adj_ia	The following clinical events underwent a central review by the HBRN Adjudication Committee to verify event, etiology when applicable, and date of onset/diagnosis. Refer to Adjudication materials and process_v1.8 for details. - ALT flare - Acute HBV - HBeAg loss - HBsAg LOSS - Cirrhosis - Hepatocellular carcinoma - Liver transplantation - Hepatic decompensation - Death

Notes:

Participant ID variables

ID

- ID assigned at current site. Needed due to participants transferring from one HBRN site to another.

ORIG_ID

- ID at first enrollment in HBRN – if participant moved to a new site during the Cohort Study, a new ID was assigned at that current site. Use ORIG_ID to link participants' data across HBRN datasets.