Pediatric Immune Tolerant Trial data collection

Short name	Long name	Additional information	Translated versions
SEPIT	Screening Evaluation		
ECPIT	Enrollment Criteria		
BEPIT	Baseline Evaluation		
LEPIT	Laboratory Evaluation		
VEPIT	Visit Evaluation		
SDPIT	Study Drug Log		
SAPIT	Symptom Assessment		Spanish, Chinese, Korean
CIPIT	CDI Questionnaire	MHS – Copyright © 1982, Maria Kovacs, Ph.D., © 1991, 1992, Multi-Health Systems Inc. All rights reserved. In the U.S.A., P.O Box 950, North Tonawanda, NY 14120-0950, (800) 456-3003. In Canada, 3770 Victoria Park Ave., Toronto, ON M2H 3M6, (800) 268-6011. Internationally, +1-416-492-2627. Fax, +1-416-492-3343 or (888) 540-4484	
CDPIT	CES-D	Center for Epidemiologic Studies-Depression Scale	
CPPIT	Child Health Questionnaire – Parent	CHQ-PF50 © 1991, 1996 Landgraf & Ware. All rights reserved	
CCPIT	Child Health Questionnaire – Patient	CHQ-CF87 © 1991, 1996 Landgraf & Ware. All rights reserved	
HBPIT	Health Behavior		Spanish, Chinese, Korean
TFPIT	Tanner Stage Questionnaire – Female	On paper only. Responses transcribed to BEPIT/VEPIT as appropriate.	
TMPIT	Tanner Stage Questionnaire – Male	On paper only. Responses transcribed to BEPIT/VEPIT as appropriate.	
CMPIT	Concomitant Medication Log		
AEPIT	Adverse Events		
MW	MedWatch Form (SAEs)		
DCPIT	Dose Change Log		
LBPIT	Liver Biopsy		
OPPIT	Off Protocol		
DSPIT	Disc. of Treatment or Study		
RFPIT	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.	
BCP	Baseline Eval – Coordinator		
BPP	Baseline Eval - Patient		Spanish, Chinese, Korean

Dataset	Description
Screen_info_pediatric_it	This information is needed to identify the participants eligible for analyses, reasons for ineligibility, and study discontinuations. The last screening record is used to determine screening eligibility.

Central Lab datasets

Name	Description
hbrn_bcp_pc_itp_results	HBV Basal core promoter (BCP) and precore (PC) mutations on available samples per protocol.
hbrn_drug_resistance_itp_results	HBV drug resistant variant results on available samples per protocol.
hbrn_cdc_itp_results	HBV genotype and subtype results
hbrn_central_itp_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_pathology_itp_results	Pathology central read results when liver biopsy slides were obtained.
hbrn_event_adj_itp	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:

<u>Participant ID variables</u>

ID

- ID assigned at current site. Needed due to participants transferring from one HBRN site to another.
- Protocol was modified from a randomized controlled trial to a single arm pilot study. All participants randomized to the control (no treatment) group were discontinued from trial and were offered the opportunity to be re-screened and re-enrolled in trial under the latest version of protocol. The first site IRB approval date is 10/10/2013.
- All data from the control arm were archived with the patient ID updated to change the numeric portion of the ID to '0XXX' to '9XXX'. For example, the control data for 240033GNO is under ID 249033GNO.

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.