

## **The Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis Trial (HALT-C)**

The Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis Trial (HALT-C) was a randomized clinical trial of long-term use of peginterferon alfa-2a in participants with chronic hepatitis C. The study investigated whether long-term antiviral therapy could prevent progressive liver disease—including cirrhosis, liver failure, hepatocellular carcinoma, and death—in chronic hepatitis C participants. Participants with chronic hepatitis C and advanced fibrosis who failed to respond to prior treatment with peginterferon and ribavirin were enrolled in the study.

Archive files are organized into the following directories:

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

### **Data**

The HALT-C Data directory contains data and analysis files that are grouped in subfolders for Analysis Datasets, Ancillary Studies, Biopsy Adverse Events, Leadin Randomized Phase, Screening Baseline Phase, and a formats file.

### **Data/Analysis Datasets**

The Analysis Datasets folder contains analysis dataset files obtained through sources other than data collection forms, and their corresponding contents files. Most of such data were obtained through laboratory or genetic analyses and provided by the labs.

- “basedata” is the analysis file that summarizes baseline data from several forms.
- “biopsies” is the summary data file for biopsy results that combines data from forms 50, 51, 52 and 53.
- “labsnew” is the analysis file that summarizes laboratory results over time. It combines data from forms 30, 34, 35, and 630.
- “nonlabfu” is the analysis file that summarizes clinical parameters that change over time. It combines data from forms 11, 15 and 146.
- “Outcome\_defs\_2010\_1229.doc” is a description of the outcome variables.
- “pri\_outcome” provides event status and time to event variables for the primary and other outcomes. It contains variables needed for survival analysis of several definitions of outcomes.
- “rand\_assign” is for the treatment group assignment and contains the “Patient type” and “Randomization assignment” data for each subject ID.
- Publication\_datasets subdirectory contains analysis datasets used for four publications:
  - “DiBisceglie\_2005\_rand\_final” is the analysis file for DiBisceglie et al., 2005.
  - “Dienstag\_2011\_chc” is the analysis file for Dienstag et al., 2011.
  - “lok\_2005\_Hepatology” is the analysis file for Lok et al., 2005.
  - “lok\_2011\_hcc\_incidence” is the analysis file for Lok et al., 2011.

## Data/Ancillary Studies

The Ancillary Studies folder contains individual Ancillary Studies (AS) organized by each AS and a formats file for the SAS data files. The study form, QxQ, and data are stored within each AS study subfolder. The MOO for each AS is in the Documents/HAULT-C MOO folder.

Information about the forms and data files for each AS is listed in the table below. Some data were obtained through sources other than data collection forms. Most of such data were obtained through laboratory or genetic analyses and provided by the lab in an Excel file.

Ancillary Study	Forms	SAS Dataset
AS_K1_ImmunologyVirology	170-177, 270-271, 273, 501-502	form170 form171 form172 form173 form174 form176 form177
AS_K2_SteatosisInsulin_and_Adipokine	121	form121 adipokine
AS_K3_SerumFibrosisMarkers	100-103, 503	form100 form103 formwaco_dcp_repeat piinp timp1 wako_chem
AS_K4_CognitiveEffects	150-159	form150 form151 form152 form153 form154 form155 form156 form157 form158 form159
AS_K5_PreStudySerialHistology	none	pssh
AS_K6_QLFT	190-197	form190 form191 form192 form194 form196 form197 qlss QLFT Responder M24 data for repository.xls
AS_K7_RiskFactor	140-144, 146,	form140

	Block_Food_Questionnaire	form141 form142 form143 form144 form146 nutrients food_gm raw ffq
AS_K8_IronHFE	181-184	form181 form182 form183 h01
AS_K9_BayerTMA	none	bayer_b_dna bayer_tma
AS_K10_DCP	none	Dcp Dcp_insulin
AS_K11_AFP-L3	none	waco_dcp waco formwaco_dcp_repeat wako_chem
AS_K12_HostGene	none	Genetics nci_genetic II28b_results.sas7bdat
AS_K13_PortalHTN-Terminated	N/A – study terminated	N/A
AS_K14_HCVSVR	none	bayer_b_dna bayer_tma
AS_K15_VCUPortalHypertension	111	form111
AS_K16_HCV Breakthrough	none	HALT-C AS#16 Breakthrough data for PUBLIC USE.xls
AS_K17_HCVSequenceVariation	none	FileManifest CodonSelection(dNdS)Bias DinucleotideFrequencyAnalysis FinalSampleList HALTC_VarsbyGenome NumberofVariationsBetweenPairs SampleswGenbankIDs TP1_AAskewedPositions Tp1vandTP2_ProteinDistances TP2_AAskewedPositions
AS_K18_BreakthroughQuasispecies	none	breakthrough_qs
AS_K19_NCI-HLA-KIR-data	none	formhla
AS_K20_Suitability-OCT-liver-samples	none	HALTCRNAresults for PUBLIC USE.xls
AS_K21_Rothman-Telomere	none	formtelo

AS_K22_SVR	701, 710, 711, 715, 722, 730, 763, 765	form710 form711 form715 form722 form730 form763 form765
AS_K23_Celera	none	celera_results crada_marker_infor crada_snp_infor
AS_K24_EGF	none	egf_elisa_results
AS_K25_EDRN	none	edrn_phase1_noid edrn_phase2_noid hcc_casectl_noid_new HCC_Sample_Aliquots.doc EDRN_matching.doc EDRN_sample_results.docx EDRN_analysis.sas EDRN_results.sas7bdat Edrn_results_contents.pdf
AS_K25_EDRN_Drexel/Block Results	none	formedrn_drexel
AS_K25_EDRN_Georgetown/Goldman	none	formedrn_gt
AS_K25_EDRN_SLU/Di Bisceglie results	none	formedrn_slu
AS_K26_IFN_Depression	none	data will be submitted to dbGAP
AS_K27_Plasma-Protein_Biomarker	none	no data
AS_K28_Keratin-Genetic-Variants	none	keratin_results
AS_K29_Vitamin D	none	vitamin_d2 vitamin_d
AS_K30_Stats_Biomarker	none	no data
AS_K31_HBV-Outcome	none	formhbv_liver formhbv_serum
AS_K32-Liver-Gene-Expression	none	no data
AS_K33-Systemic-Metabolome	none	Systemic Metabolome Ancillary Study.xls
AS_K34_Telomere-Telomerase	none	Telomerase
AS_K35_HCC_Screening	none	No data
AS_K36_HCV_Mutations	none	No data

### Data/Biopsy Adverse Events

The Biopsy Adverse Events folder contains the below data file in .sas7bdat and .csv format.

- biopsy\_aes

### Data/Leadin Randomized Phase

The Leadin Randomized Phase folder contains documentation files and data files.

- Proc\_Contents
  - Proc Contents files for each data file
- Data files for the Leadin Randomized Phase and Post-Randomized Extended Follow-up and their corresponding forms are listed in the table below

<b>Form No.</b>	<b>Form Name</b>	<b>SAS Dataset Name</b>
9	Genetic Consent Status Change Form	none
10	Study Visit	form010
11	Physical Exam	form011
12	Medications Interview	form007_everherb form007_012_meds_new haltc_meds_code_atc2 haltc_meds_code_atc2.xlsx Medication Description 20110325.docx HALTC Medications.sas
14	Specimen Collection	form014
15	CTP Score	form015
16	Clinical Conditions at End of Study	form016
19	Early Termination of Peginterferon alfa-2a Treatment	form019
21	Randomization Checklist	form021
22	Ultrasound, MRI, CT	form022
23	Endoscopy	form023
24	Missed Visit	form024
25	Early Termination from Trial	form025
26	Peginterferon alfa-2a Accountability Log	form026
27	Ribavirin Accountability Log	form027
28	Peginterferon alfa-2a Dose Adjustments	form028
29	Ribavirin Dose Adjustments	form029
30	Local Lab	form030 34 35
31	Central Lab - HCV RNA	form031 32 37
32	Quantitative HCV RNA	form031 32 37
33	Central Lab - HCV Genotype	form033
34	HALT-C Trial	form030 34 35
35	Screening Visit 2 Local Lab	form030 34 35
36	Repeat AFP	form036
37	Repeat HCV RNA	form031 32 37
38	Express Pre-treatment Blood Work	form038
39	HIV Test Result	none
40	Quality of Life - English	form040
40	Quality of Life - Spanish	form040
41	Skinner	form041
42	Alcohol Use Questionnaire - English	form042
42	Alcohol Use Questionnaire - Spanish	form042
43	Symptoms Form - English	form043

43	Symptoms Form - Spanish	form043
44	Beck Inventory (Not Included)	Form044 bdi
45	Life Events Status Interview	form045
50	Screening Biopsy Evaluation	form050
51	Central Pathology Biopsy Review	form051
52	Clinical Center Biopsy	form052
53	Morphometry	form053
56	HCC Pathology	form056
60	Adverse Event Report	Ae AE_Readme.txt
61	Serious Adverse Event Report	Ae AE_Readme.txt
63	Clinical Outcome	form063
64	Death Report	form064
65	Clinical Outcome Review	form065
66	HCC Diagnosis	form066
67	Liver Transplant Information	form067
68	Pregnancy Report	none
69	Additional HCC Outcome Form	form069
70	Screening 1 Aliquot Form	none
71	Screening 2 Aliquot Form	none
72	Lead In Phase Aliquot Form	none
73	Randomized Phase Aliquot Form	none
74	Week 20 Responder Aliquot Form	none
75	Repeat AFP Aliquot Form	none
76	Repeat HCV RNA Aliquot Form	none
77	R00 Visit Aliquot Form	none
98	Randomization Visit Date	form098
99	Randomization Checklist II (Express & Breakthrough/Relapse)	form099
110	Central Endoscopy Review	form110
505	Histology Shipping Log	form505
604	Extended Follow-up Trial Consent	none
605	Extension 2007 Trial Consent	none
610	Extended Follow-up and Extension 2007 Study Visit	form610
611	Extended Follow-up and Extension 2007 Physical Exam	form611
615	Extended Follow-up and Extension 2007 CTP Score	form615
622	Extended Follow-up and Extension 2007 Ultrasound, MRI, CT	form622
630	Extended Follow-up and Extension 2007 Local Lab	form630
631	Extension 2007 HCV RNA Results	form631
673	Extended Follow-up Aliquot Form	none
674	Extension 2007 Aliquot Form	none
924	Alternative Study Visit	form924
926	Lost Drug Accountability	none
964	Central Death Review	form964
969	HCC Working Group Review Form	form969

## Data/Screening Baseline Phase

The Screening Baseline Phase folder contains documentation files and data files.

- Documentation files
  - Proc contents files for each data file
  - form001\_new\_ReadMe.txt
- Data files for the Screening Baseline Phase and their corresponding forms are listed in the table below

Form No.	Form Name	SAS Dataset Name
1	Trial ID Assignment	form001 form001_new
2	Trial Consent	none
3	Screening Medical History Interview	form003
4	Screening Checklist	form004
5	Trial Ineligibility	none
6	Baseline History	form006
7	Baseline Medications Interview	form007_everherb form007_012_meds_new haltc_meds_code_atc2 haltc_meds_code_atc2.xlsx Medication Description 20110325.docx HALTC Medications.sas
8	Baseline Visit Date	none
94	Express Screening Checklist	form094

## Documents

The HALT-C Documents directory contains two subdirectories:

- The “HALT-C MOO” directory contains 73 files, which comprise the Manual of Operations for the main study and the ancillary studies.
- The “HALT-C Protocol” directory contains the protocol and the memo detailing revisions to the protocol.

## DSIC

The HALT-C Dataset Integrity Check directory contains:

- HALT-C\_Biopsy\_AES\_DSIC.pdf
- HALTC\_DSIC\_Bisceglie\_2008.pdf
- HALTC\_DSIC\_Dienstag\_2011.pdf

## Forms

The HALT-C Forms directory contains two subdirectories:

- The “HALT-C Main Trial Forms” directory contains data collection forms, lab forms, log forms, order forms, and review forms, grouped in “Leadin Phase” and “Randomization and Others Phases”.
- The “HALT-C Main Trial QxQs” directory contains QxQ specifications for the Forms.