

## SyNCH HCV Phase II Data Archive

The SyNCH HCV Phase II is a multicenter, randomized, double-masked, placebo-controlled Phase II study to assess the safety and efficacy of a standardized orally administered silymarin preparation (legalon®) for the treatment of patients with chronic hepatitis c who failed conventional antiviral therapy. This report describes the public release of SyNCH HCV Phase II dataset. This SyNCH HCV Phase II Archive contains the study summary, protocol, manual, forms, and datasets.

The files are organized into the following directories:

- SyNCH\_HCV\_PHASEII\_Documentations
- SyNCH\_HCV\_PHASEII\_Forms
- SyNCH\_HCV\_PHASEII\_Data
- SyNCH\_HCV\_PHASEII\_Dataset\_Integrity\_Check

### **1. \SyNCH HCV PHASEII Documentations**

This directory contains 2 subdirectories:

- Protocol
  - HCV Protocol v02-08-08\_original.pdf
  - HCV Protocol v12-16-09\_final.pdf
  - HCV Protocol Modifications Table.pdf
  - \Appendices
- Manuals – see “Manuals” in the following table

### **2. \SyNCH HCV PHASEII Forms**

The Data Collection Forms and their associated data files, codebooks, and manuals are listed in the table below. The data files and codebooks are in the Data directory; the manuals are in the Documentations directory.

<b>Form</b>	<b>Form Name</b>	<b>Data file (SAS, excel)</b>	<b>Codebook</b>	<b>Manuals</b>
AD	Adherence Self Efficacy (AD)_v1.0	AD	AD	AD
AEV	Adverse Event (AE)_v1.0	AEV	AEV	AEV
CD	CES-D (CD)_v1.0	CD	CD	CD
DC	Dose Change (DC)_v1.0	DC	DC	DC
DS	Discontinuation (DS)_v1.1	DS	DS (v1.0 – 1.1)	DS (v1.0 – 1.1)
LEV	Laboratory Evaluation (LEV)_v3.0	LEV	LEV	LEV
ML	Concomitant Medication Log (ML)_v1.0	ML	ML	ML
OP	Off Protocol (OP)_v2.0	OP	OP	None
PD	Patient Diary Summary (PD)_v2.0	PD	PD	PD
QD	Chronic Liver Disease (QD)_v1.0 (copyrighted)	QD	QD	QD
QL	Quality of Life (QL)_v1.0 (copyrighted)	QL	QL	QL
SC	Screening Criteria (SC) (v1.0 – 5.0)	SC	SC (v1.0 – 5.0)	SC (v1.0 – 5.0)
SD	Screening Demographic (SD)_v1.0	SE (SD is a patient self-administered questionnaire, SD data is transcribed in SE)	SE	SD
SE	Screening Evaluation (SE) (v1.0 – 3.0)	SE	SE (v1.0 – 3.0)	SE (v1.0 – 3.0)
VE	Visit Evaluation (VE)_v2.0	VE	VE	VE
n/a	Medwatch	n/a	n/a	n/a
n/a	n/a	RF	Randomization (RF)	n/a
n/a	n/a	hcvrna_results	n/a	n/a
n/a	n/a	PK-Study_SilybinA_conc.xls	n/a	n/a
n/a	n/a	T-CELL-Study.xls	n/a	n/a
n/a	n/a	n/a	Codebook_v5.1	n/a
n/a	n/a	n/a	RTI_SYNCH_hcv_COLUMNS	n/a
n/a	n/a	n/a	n/a	HCV Data Collection Timetable

Form	Form Name	Data file (SAS, excel)	Codebook	Manuals
n/a	n/a	n/a	n/a	Sample Collection Protocol
n/a	n/a	n/a	n/a	Special Codes using for Forms

### **3. \SyNCH HCV PHASEII Data**

The SyNCH HCV Phase II data folder contains 18 data files as listed in the table above, 1 SAS formats file, and their associated codebooks and proc contents files.

### **4. \SyNCH HCV PHASEII Dataset Integrity Check**

The SyNCH HCV Phase II Data Archive also contains a report of an examination of the repository for completeness by statisticians and quality control specialists at the Repository. The published data from the SyNCH HCV Phase II study were compared to values recalculated from the SyNCH HCV Phase II data in the NIDDK repository to check for dataset completeness.