SyNCH Phase II
HCV Group

Data Collection Protocol

			Screen	Treatment - 24 weeks									Follow-Up	
			30 days	0 (BL)	2	4	6*	8	12	16*	20	24	4	12
SE: Screening Evaluation			CC											
SC: Screening Criteria			CC											
RF: Randomization Form				PH										
SD: Screening Demographic			PT											
AD: Adherence Self-Efficacy Scale				PT		PT			PT			PT	PT	
QL: Quality of Life				PT		PT			PT			PT	PT	
QD: Chronic Liver Disease				PT		PT			PT			PT	PT	
CD: CES-D				PT		PT			PT			PT	PT	
PD: Patient Diary Summary				CC	CC	CC		CC	CC		CC	CC		
LE: Laboratory Evaluation			CC	CC	CC	CC		CC	CC		CC	CC	CC	CC
VE: Visit Evaluation					CC	CC		CC	CC		CC	CC	CC	CC
ML: Concomitant Medications			AS NEEDED											
AE: Adverse Event				AS NEEDED										
DC: Dose Change					AS NEEDED									
DS: Discontinuation of Treatment or Study				AS NEEDED										
Pharmacokinetics (ml)	Schedule 1	Blood		9					9			9-12		
		Urine		10					10			10		
	Schedule 2	Blood			9			9			9			
		Urine			10			10			10			
	Non PK pts	Blood		3	3	3		3	3		3	3		
		Urine		10	10	10		10	10		10	10		
Whole blood for genetics component (ml)***				20										
Serum (ml) **				10					5			5	5	
Plasma (ml)				5					3			3	3	

* Phone Interview
** Includes HCV RNA sample for central testing laboratory (treatment weeks 0, 12, 24, and follow-up week 4)
*** The sample for the genetic component should be collected at the baseline visit or at any of the subsequent protocol visits throughout the course of the study.

PT	Patient
CC	Clinical Coordinator
GC	GCRC personnel
PH	Pharmacist