

ViraHepC Data Collection Protocol

	Screen		Baseline	Treatment Day							Treatment Week												Follow-Up Week					
	1	2	(Day 0)	1	2	3	7	14	21	28	6	8	12	16	20	24	28	32	36	40	44	48	4	12	24	36	48	
SD: Screening Demographic	PT																											
SE: Screening Evaluation	CC																											
SC: Screening Criteria		CC																										
RA: Risk Factor Assessment		CC																										
SQ: Screening Questionnaire		PT																										
QL: Quality of Life		PT																							PT			
CD: CES-D		PT							PT				PT			PT							PT		PT			
SS: Social Support & Self-efficacy		PT														PT												
SA: Symptom Assessment		PT					PT	PT		PT		PT	PT	PT	PT	PT	PT	PT	PT	PT	PT	PT	PT	PT	PT	PT		PT
XM/F:Sexual Functioning		PT								PT			PT			PT							PT		PT			
TE: Treatment Evaluation							CC	CC		CC		CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC						
LE: Laboratory Evaluation	CC		CC				CC	CC		CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC
MA/B: Adherence MATI Checklist			CC							CC			CC		CC		CC		CC									
TW: MEMS Trackcap Worksheet			CC							CC		CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC						
AD: Adherence Questionnaire										PT			PT			PT			PT			PT						
MM: MEMs Questionnaire										PT		PT	PT	PT	PT	PT	PT	PT	PT	PT	PT	PT						
FE: Follow-Up Evaluation																								CC	CC	CC	CC	CC
DC: Dose Change				As needed																								
UE: Unscheduled Evaluation				As needed																								
AE: Adverse Event				As needed																								
DF: Tmt & Study Discontinuation				As needed																								
Viral Genetics & Kinetics (ml) PPT	10		10	10	10		10	10		10		10	10			10			10			10	10	10	10		10	
Pharmacokinetics (ml) redtop			7	7	7		7	7		7		7	7			7						7		7				
Patient Genetics (ml) EDTA & ACD			15																									
Immunology (ml) CPT		56										32				32						32			56		136	
IFN Signaling (ml) CPT			16	16	16		16	16		16															16			
Serum for repository (ml) SST	8		8	8	8		8	8		8		8	8			8			8			8	8	8	8		8	

Nonresponders move into Follow-Up Phase 