

ICCTG RCT #2 Visit Schedule - Phase I

		Screening Visits		Treatment Phase (6 txs in 10 wks)						Post-Treatment Follow-Up Phase (24 weeks)						
Event (Phase I)	Form Name	B1	B2	Rx 1	Rx 2	Rx 3	Rx 4	Rx 5	Rx 6	Phone or Clinic (Optional)	Phone	Clinic	Phone	Clinic	Phone	Clinic
Week #		- 4	- 1	1*	*	*	*	*	*	10, 11 or 12	14	18	22	26	30	34
Visit #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Consent	-	X														
Participant Contact Information	PTCONT	X														
Baseline Symptom 1	BSYM1	X														
CBC w/ electronic differential	LAB	X		X*	X*	X*	X*	X*	X*	X*	X*	X*	X*	X*	X*	X
Serum Pregnancy Test	LAB	X		X*	X*	X*	X*	X*	X*	X*	X*	X*	X*	X*	X*	X
Urine Screening/Baseline & End of Phase I	URINE	X														X
Urine Screening/During Treatment	DOSE			X	X	X	X	X	X							
Urine Culture/Baseline & End of Phase I	URINE	X														X
Urine Culture/During Treatment	LAB			X*	X*	X*	X*	X*	X*							
Medical History	MED	X														
Demographics	DEMO	X														
Participant Daily Medication Diaries (given to participant)	PTDIARY	X	X	X	X	X	X	X	X					X		X (if Phase II)
Concomitant Medications (PTDIARY returned by participant)	CMED		X	X	X	X	X	X	X			X				X
Voiding Diary (given to participant)	VOID	X							X			X		X		
Voiding Diary (returned by participant)	VOID		X									X		X		X
Baseline Symptom 2	BSYM2		X													
Eligibility Confirmation	ELIG	X	X													
Randomization	RAND		X													
Physical Exam	EXAM		X													X
Pelvic Exam/DRE	EXAM		X													
IC Symptom and Problem Index	SYM		X						X			X		X		X
Health Status Questionnaire	SF36		X						X			X		X		X
MOS Sexual Functioning Scale	MOS		X						X			X		X		X
University of Wisconsin Symptom Survey	WIS		X						X			X		X		X
Adverse Events and Serious Adverse Events	AE			X	X	X	X	X	X	X	X	X	X	X	X	X
Instillation/Dosing Information	DOSE			X	X	X	X	X	X							
Telephone Contact During Treatment Phase	PHNTP			X	X	X	X	X	X							
Symptoms Assessment Guidelines	SAG			X	X	X	X	X	X							
Follow-Up Symptoms	FUSYM								X			X		X		X
Standard Visit Inventory	STVST									X	X	X	X	X	X	X
Comments Sheet	COMM	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN
Urine Sample Tracking	UTRAC			X			X									X
Participant Collected Urine Sample Tracking (U of IO)	PUTRAC							X								
Urine Sample Tracking Log (U of IO, U of MD, U of PA, U of RO)	ULOG			PRN			PRN									PRN
Treatment Stop Point	TSTOP								X							
Endpoint Worksheet	ENDPT															X
Study Stop Point	SSTOPI															X
Participant Close-Out	PTCL															X
Study Close-Out	STCL															X
Participant Transfer	TRANS															
Unmasking Record	UNMASK															

X* = Ordered on an as-needed basis; data entry required at the specified visits.