

Interstitial Cystitis Clinical Trials Group - ICCTG Protocol #1 - Visit Schedule (Weeks)

CRFs	Abbrev.	PRE-SCREENING	BASELINE 1	BASELINE 2 / RANDOMIZATION	PHONE CONTACT RUN-IN	CLINIC VISIT	PHONE CONTACT	CLINIC VISIT	PHONE CONTACT	CLINIC VISIT	PHONE CONTACT	CLINIC VISIT	POST- TREATMENT FU
		Weeks											
			-4 to -1	0	1/2/3	3	6	10	14	17	20	24	
Consent Form	-	X											
Patient Contact Information	(PTCONT)		X										
Inclusion Criteria	(INCL)		X										
Exclusion Criteria	(EXCL)		X										
Deferral Criteria	(DEF)		X										
Medical History	(MED)		X										
Voiding Diary ¹	(VOID)		X ¹	X ¹		X		X		X		X	X ⁵
Demographics	(DEMO)			X									
Eligibility Confirmation & Randomization	(ELIG)			X									
Cross Check	(CRSCK)			X									
Run-in Medication Dispensing Log	(RUNINMED)			X									
Study Medication Tracking Log	(MEDTRAC)			X		X		X		X		X	X ⁵
Patient's Daily Medication Diary	(PTDIARY)		X	X		X		X		X		X	
Medication Diary Record	(DIARYREC)					X		X		X		X	
Run-in Dosage Record	(RUNIN)				X								
Standard Visit Inventory	(STVISIT)					X		X		X		X	X ⁵
Telephone Contact	(PHONE)				X		X		X		X		
Adverse Event/Serious Adverse Event ⁴	(AE/SAE)												
Screening Contact Checklist	(SCHK)		X	X									
Clinic Visit Contact Checklist	(VCHK)					X		X		X		X	X ⁵
Phone Contact Checklist	(PCHK)				X		X		X		X		
Data Processing Cover Sheet	(DPCS)		X	X	X	X	X	X	X	X	X	X	X ⁵
Unmasking ⁴	(UNMASK)												
Clinical Center Stop Point ⁴	(STOP)											X	
Patient Transfer ⁴	(TRANS)												
Patient Close-out ⁴	(PTCLOSE)											X	
Study Close-out ⁴	(STCLOSE)												
SYMPTOM QUESTIONNAIRES													
Baseline Symptoms 1	(BSYM 1)		X										
Baseline Symptoms 2	(BSYM 2)			X									
Follow-up Symptoms	(FUSYM)					X		X		X		X	X ⁵
IC Symptom & Problem Index	(SYMPROB)			X		X		X		X		X	X ⁵
Health Status Questionnaire	(SF36)			X								X	
MOS Sexual Functioning Scale	(MOS)			X								X	
Symptom Ranking Cards	(CARDS)			X								X	
U. of Wis. Symptom Survey	(UNIVWIS)			X		X		X		X		X	X ⁵
LAB & PROCEDURES													
Urine Screening: UA & Culture	(URINE)		X										
Urine: Residual Volume (men only)	(URINE)		X										
Serum Pregnancy Test ^{2,3}			X ²			X ³		X ³		X ³		X ³	
Blood: LFTs, Coagulation, Platelets	(LAB) ⁴		X									X	
Physical Examination	(EXAM)		X									X	
Urine Sample Tracking Log	(ULOG)												
Urine Sample Tracking (for Banking)	(UTRAC)			X								X	

¹ Sent home with patient on Baseline 1 visit, to be returned on Baseline 2 visit

² Pregnancy Test - female patients, when applicable

³ Pregnancy Test - if indicated (see Voiding Diary, question #3)

⁴ When indicated

⁵ Follow-up every 12 weeks (weeks 36, 48, etc) until the study closes