

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

	Prescreening	Baseline 1	Randomization Baseline 2	Run-in Phone Contact	Clinic Visit	Phone Contact	Clinic Visit	Phone Contact	Clinic Visit	Phone Contact	Clinic Visit	Post Treatment FU <sup>5</sup>
		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 <sup>1</sup> (VOID)		X <sup>1</sup>	X <sup>1</sup>		X		X		X		X	X <sup>5</sup>
Demographics (DEMO)			X									
Eligibility Confirmation/Randomization (ELIG)			X									
Run-in Med Dispensing Log (RUNINMED)			X									
Study Med Tracking Log (MEDTRAC)			X		X		X		X		X	X <sup>5</sup>
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 <sup>5</sup>
Telephone Contact (PHONE)				X		X		X		X		
Adverse Event/Serious Adverse Event <sup>4</sup> (AE/SAE)												
Unmasking <sup>4</sup> (UNMASK)												
Clinical Center Stop Point <sup>4</sup> (STOP)											X	
Patient Transfer <sup>4</sup> (TRANS)												
Patient Close-out <sup>4</sup> (PTCLOSE)												
Study Close-out <sup>4</sup> (STCLOSE)												
<b>SYMPTOM QUESTIONNAIRES:</b>												
Baseline Symptoms (BSYM1&2)		X	X									
Follow-up Symptoms (FUSYM)					X		X		X		X	X <sup>5</sup>
IC Symptom & Problem Index (SYMPROB)			X		X		X		X		X	X <sup>5</sup>
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 <sup>5</sup>
<b>LABS &amp; PROCEDURES:</b>												
Urine Screening: UA & Culture (URINE)		X										
Urine: Residual Volume (men only) (URINE)		X										
Serum Pregnancy Test <sup>2, 3</sup>		X <sup>2</sup>			X <sup>3</sup>		X <sub>3</sub>		X <sub>3</sub>		X <sub>3</sub>	
Blood: LFTs, coagulation, platelets (LAB) <sup>4</sup>		X									X	
Physical Examination (EXAM)		X									X	
Urine Sample Tracking (for Banking) (UTRAC)			X								X	

<sup>1</sup> Sent home with patient on Baseline 1 visit, to be returned on Baseline 2 visit.

<sup>2</sup> Pregnancy Test – female patients, when applicable

<sup>3</sup> Pregnancy Test - if indicated (see Voiding Diary, question #3)

<sup>4</sup> When indicated

<sup>5</sup> Follow-up every 12 weeks (weeks 36, 48, etc.) until the study closes