<i>Ι</i> <i>C</i>	ICCTG
C	PROTOCOL #1

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## Inclusion Criteria (Administrative)

Patient ID:						
Patient Initials:						
Clinical Center:						
Contact Week: 0						
Date: / /						
month day year						
RC ID:						

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Res	earch Coordinator Completed at the Baseline 1 and 2 visits)		
1.	Is the patient 18 years of age or older?	☐ <sub>1</sub> Yes	$\square_0$ No
2.	Has the patient signed and dated the informed consent?	☐ <sub>1</sub> Yes	$\square_0$ No
3.	Has the patient (male and female) agreed to use an effective method of birth control?	P ☐ Yes	$\square_0$ No
4.	Does the patient's response on the Likert Scale indicate a pain/discomfort score of 4 or higher on the ordinal pain scale? (See Question #1 of Baseline Symptoms 1 & 2)	☐ <sub>1</sub> Yes	□ <sub>0</sub> No
5.	Does the patient's response on frequency indicate urination least 11 times within 24 hours?  (See Question #3 of Baseline Symptoms 1 &		□ <sub>0</sub> No
6.	Have these urinary symptoms been present for at least the previous 24 weeks?  (See Question #4 of Baseline Symptoms	1) $\square_1$ Yes	□ <sub>0</sub> No
	If a "NO" response is checked for any que the patient is NOT eligible. If eligible, continue with the screening pr		

Use this table to record the scores from the Baseline Symptoms form given at both the Baseline 1 and the Baseline 2 visits. (This will help you answer Question #3 on the Eligibility Confirmation and Randomization form.)

Record Scores from Baseline Syr	nptom form:	Baseline 1 Visit (See BSYM1)	Baseline 2 Visit (See BSYM2)
Question #1	Pain/Discomfort		
Question #3	Frequency		