ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Adverse Events and Serious Adverse Events (Phase I)

List all adverse events that have newly occurred, changed, or resolved at **EACH** visit from Visit 3 through Visit 15.

1. Were there any new adverse events, resolutions or follow-ups to adverse events from the previous visit, reported by the participant at this visit? ❑$_1$ Yes ❑$_0$ No

If YES, list the number of (S)AEs to be recorded at this visit? __ __

Adverse Event Number	Event Code	Date of Onset Enter date OR check box if AE is continuing from a previous visit	Grade	Duration	Frequency	Relationship to Study Drug	Action taken regarding study drug?	Treatment for event?	Outcome?	Date of Resolution Enter date OR check box if AE is continuing	Was the Event Serious?
AE #	**From CTC List**	mm/dd/yyyy	record one	record one	record one	record one	record one	record one	record most appropriate	mm/dd/yyyy	
__ __ __	__ __ __ __ __ __	__ __/__ __/__ __ __ __ ❑								__ __/__ __/__ __ __ __ ❑	
Specify Event (CTC Criteria):			Description of Event/Comments:								
__ __ __	__ __ __ __ __ __	__ __/__ __/__ __ __ __ ❑								__ __/__ __/__ __ __ __ ❑	
Specify Event (CTC Criteria):			Description of Event/Comments:								
__ __ __	__ __ __ __ __ __	__ __/__ __/__ __ __ __ ❑								__ __/__ __/__ __ __ __ ❑	
Specify Event (CTC Criteria):			Description of Event/Comments:								
__ __ __	__ __ __ __ __ __	__ __/__ __/__ __ __ __ ❑								__ __/__ __/__ __ __ __ ❑	
Specify Event (CTC Criteria):			Description of Event/Comments:								
__ __ __	__ __ __ __ __ __	__ __/__ __/__ __ __ __ ❑								__ __/__ __/__ __ __ __ ❑	
Specify Event (CTC Criteria):			Description of Event/Comments:								

Principal Investigator's Signature: ______________________________ Date: __ __ / __ __ / __ __ __ __ PI ID: __ __ __ __

ICCTG - RCT # 2

Adverse Events and Serious Adverse Events

List all adverse events that have newly occurred, changed, or resolved.

Grade	Duration	Frequency	Relationship to Study Drug	Action Taken Regarding Study Drug
0. None 1. Mild 2. Moderate 3. Severe 4. Life threatening or disabling 5. Fatal 88. Unknown	1. Minutes 2. Hours 3. Days 88. Unknown	1. Once 2. 2 to 3 episodes 3. 4 or more episodes 4. Daily	1. Not related 2. Possibly related 3. Definitely related 88. Unknown/undetermined	0. No action taken 1. Drug interrupted 2. Drug discontinued 99. N/A

Treatment for Event?	Outcome	Was the Event Serious
0. No 1. Yes	1. Resolved/no follow-up needed 2. On-going/treatment continued *3. ER visit/prolonged hospitalization *4. Resulted in persistent or significant disability/incapacity *5. Congenital anomaly *6. Life threatening *7. Fatal * Indicates Serious Adverse Events and **must** be reported to the IRB and DCC. PI signature needed on AEs and SAEs	0. No 1. Yes

Baseline Symptom 1 (Phase I only)

Participant completes at Visit 1.

1. Think about the pain/discomfort associated with your bladder.
   On average, how would you rate this **pain/discomfort** during the past 4 weeks?
   (Please **circle** the number that best describes this **pain/discomfort**.)

None			Mild			Moderate			Severe
0	1	2	3	4	5	6	7	8	9

2. Urgency is defined as the urge or pressure to urinate.
   On average, how would you rate the **urgency** that you have felt during the past 4 weeks?
   (Please **circle** the number that best describes this **urgency**.)

None			Mild			Moderate			Severe
0	1	2	3	4	5	6	7	8	9

3. **On average**, during the past 4 weeks, how many times did you urinate in a 24-hour period?
   (Please **check** the option that best describes your answer.)

   ❑$_1$ 6 times or less ❑$_2$ 7-10 times ❑$_3$ 11 – 14 times ❑$_4$ 15 times or more

4. How long have these urinary symptoms described in Questions #1, 2, and 3 been present?
   (Please **check** the option that best describes your answer.)

   ❑$_1$ less than 24 weeks ❑$_2$ 24 to 52 weeks ❑$_3$ more than 52 weeks

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Baseline Symptom 2 (Phase I only)

Participant completes at Visit 2.

1. Think about the pain/discomfort associated with your bladder.
   On average, how would you rate this **pain/discomfort** during the past 4 weeks?
   (Please **circle** the number that best describes this **pain/discomfort**.)

None			Mild			Moderate			Severe
0	1	2	3	4	5	6	7	8	9

2. Urgency is defined as the urge or pressure to urinate.
   On average, how would you rate the **urgency** that you have felt during the past 4 weeks?
   (Please **circle** the number that best describes this **urgency**.)

None			Mild			Moderate			Severe
0	1	2	3	4	5	6	7	8	9

3. **On average**, during the past 4 weeks, how many times did you urinate in a 24-hour period?
   (Please **check** the option that best describes your answer.)

❑$_1$ 6 times or less ❑$_2$ 7-10 times ❑$_3$ 11 – 14 times ❑$_4$ 15 times or more

ICCTG RCT2	Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
	Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Concomitant Medications (Phase I)

Record all over-the-counter and prescription medications taken at Visits 2, 3, 4, 5, 6, 7, 8, 11 and 15.

Did the participant start or stop any medications at this visit? ❑1 Yes ❑0 No

If YES, list the number of CMEDs to be recorded at this visit? __ __

Line # 3-digits	**Drug Code#** From Medication Reference Tool	**Drug Name**	**Total Daily Dose** Total Daily Dose or PRN	**Unit**	**Route**	**Start Date** Check box if continued from an earlier Visit mm/dd/yyyy	**Stop Date** Check box if continued or enter Stop Date mm/dd/yyyy	**Exclusionary/ Restricted Med?** 1 = Yes 0 = No	**For IC?** 1 = Yes 0 = No	**For Pain?** 1 = Yes 0 = No
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑			
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑			
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑			
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑			
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑			
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑			
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑			
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑			
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑			
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑			

Additional comments, if needed:

Line #	**Comments**
__ __ __	
__ __ __	
__ __ __	

Concomitant Medications

Use the codes below in completing the CMED form.

Unit	Route
1. mg 2. ml/cc 3. tablets 4. SC 5. tsp 6. drops 7. cream 8. spray 9. tbsp 98. other	1. oral 2. IV 3. IM 4. SC 5. topical 6. rectal 7. nasal 8. transdermal 9. inhalant 10. sublingual 98. other

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Demographics (Phase I only)

Participant completes at Visit 1.

1. What is your date of birth? Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

Please check only ONE box for each question.

2. What is your gender?
   - ❒0 Female
   - ❒1 Male

3. How do you describe yourself?
   - ❒1 Asian or Pacific Islander
   - ❒2 Black/African-American (not Latino/Hispanic)
   - ❒3 Latino/Hispanic/Mexican-American
   - ❒4 Native American
   - ❒5 White/Caucasian (not Latino/Hispanic)
   - ❒6 Multiracial
   - ❒98 Other

4. What is the highest educational level you have attained?
   - ❒1 Less than high school
   - ❒2 High school or GED
   - ❒3 Some college
   - ❒4 Graduated from college
   - ❒5 Graduate or professional school after college

5. What is your current employment status?
   - ❒1 Employed
   - ❒2 Unemployed
   - ❒3 Retired
   - ❒4 Full-time homemaker
   - ❒5 Disabled

6. What is your annual family income?
   - ❒1 $10,000 or less
   - ❒2 $10,001 to $25,000
   - ❒3 $25,001 to $50,000
   - ❒4 $50,001 to $100,000
   - ❒5 More that $100,000

7. Have any family members ever been diagnosed with chronic pelvic pain?
   - ❒0 No
   - ❒1 Yes
   - ❒88 Unknown

8. Have any family members ever been diagnosed with interstitial cystitis (IC)?
   - ❒0 No
   - ❒1 Yes
   - ❒88 Unknown

9. Are you living with a spouse or partner?
   - ❒0 No
   - ❒1 Yes

10. Are you sexually active?
    - ❒0 No
    - ❒1 Yes

    If **NO,** is it because of:
    - ❒1 IC symptoms
    - ❒2 Lack of partner
    - ❒98 Other: _____

11. Do you have pain associated with sexual intercourse?
    - ❒0 No
    - ❒1 Yes
    - ❒99 Not applicable

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Instillation/Dosing Information (Phase I)

Research Coordinator completes at Visits 3, 4, 5, 6, 7 and 8.

1. Has the participant continued to use a medically approved birth control method? ❒1 Yes ❒0 No

2. **(Question # 2 for females only, check N/A for males & post-menopausal women)**
What was the date of onset of the most recent menstrual period? Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

OR ❒ N/A

3. **(Question # 3 for males only, check N/A for females)**
Did the male participant use a barrier for intercourse for 48 hours after treatment? ❒1 Yes ❒0 No ❒99 N/A

(At Visits 3 & 6 only, check N/A for all other treatment visits)

4. Was the pre-treatment catheterized specimen processed for the Biomarker study? ❒1 Yes ❒0 No ❒99 N/A

5. Was the participant's pre-treatment urine Nitrite positive? ❒1 Yes ❒0 No

   a. If **YES**, was microscopic analysis positive for bacteria? ❒1 Yes ❒0 No

If microscopic analysis is positive, a urine culture should be ordered. If the urine culture is positive for bacteria, AE and LAB forms should be completed and INSTILLATION SHOULD BE RESCHEDULED.

6. Instillation date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

7. Time solution prepared for instillation: __ __ : __ __ (Military Time)

If solution was prepared more than 2 hours prior to the instillation, return solution to the Pharmacy and obtain a replacement solution.

8. Time temperature taken: __ __ : __ __ (Military Time)

9. Pre-Instillation temperature: __ __ __ . __ ❒1 0F ❒2 0C

10. Time solution instilled: __ __ : __ __ (Military Time)

11. Volume of solution instilled: __ __ . __ cc

12. Volume of solution discarded: __ __ . __cc

13. Time catheter removed: __ __ : __ __ (Military Time)

14. Time solution voided: __ __ : __ __ (Military Time)

15. Were there problems with the instillation? ❒1 Yes ❒0 No

    If **YES**, specify: _____

16. What was the participant's preferred position during retention? (**Check one**)
    ❒1 Sitting
    ❒2 Supine
    ❒3 Standing

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Eligibility Confirmation (Phase I only)

Research Coordinator and Principal Investigator complete at Visits 1 and 2.

1. When did the participant sign the informed consent? Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
2. When was the participant seen for Visit 1? Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
3. When was the participant seen for Visit 2? Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

INCLUSION CRITERIA: *Responses to questions #5 through #10 must be "**Yes**".*

4.	Is the participant male or female?	❑$_0$ Female	❑$_1$ Male
5.	Is the participant at least 18 years of age or older?	❑$_1$ Yes	❑$_0$ No
6.	Has the participant been diagnosed with IC, confirmed with the results from a cystoscopy/hydrodistention?	❑$_1$ Yes	❑$_0$ No
7.	Has the participant received a minimum of 12 weeks of **standard IC** treatment or a combination of therapies in response to the bladder symptoms (e.g. tricyclic antidepressants, hydroxyzine, other antihistamines, DMSO, pentosan polysulfate, heparin, NSAIDS, anticholinergics?	❑$_1$ Yes	❑$_0$ No
8.	Has the participant (male or female) agreed to use a medically approved method of birth control, other than abstinence?	❑$_1$ Yes	❑$_0$ No
9.	Have the participant's urinary symptoms of frequency and pain/discomfort been present for at least the past 24 weeks at the time of screening?	❑$_1$ Yes	❑$_0$ No
10.	Has the participant reported at least one voided volume of greater than or equal to 75 cc in a 24-hour period, in the baseline voiding diary?	❑$_1$ Yes	❑$_0$ No

EXCLUSION CRITERIA: *Responses to questions #11 through #31and #46 must be "**No or N/A**".*

11.	Does the participant have active tuberculosis that requires on-going therapy?	❑$_1$ Yes	❑$_0$ No
12.	Does the participant have a known allergy to or intolerance of BCG or any of its components, as reported by the participant, or derived from medical records?	❑$_1$ Yes	❑$_0$ No
13.	Has the participant been previously treated with intravesical BCG?	❑$_1$ Yes	❑$_0$ No
14.	Is the participant known to be immuno-compromised (hereditary, illness or other drug-related)?	❑$_1$ Yes	❑$_0$ No
15.	Is the participant HIV positive?	❑$_1$ Yes	❑$_0$ No
16.	Is the participant a drug user or has s/he shared a needle?	❑$_1$ Yes	❑$_0$ No
17.	Is the participant a haemophiliac and/or has s/he had a blood transfusion?	❑$_1$ Yes	❑$_0$ No
18.	Does the participant practice unsafe sex?	❑$_1$ Yes	❑$_0$ No

Eligibility Confirmation (Phase I only)

19.	Does the participant have an untreated substance abuse/dependency problem within the past 2 years?	❑$_1$ Yes	❑$_0$ No	
20.	Is the participant unable to void spontaneously?	❑$_1$ Yes	❑$_0$ No	
21.	Does the participant have severe debilitating concurrent medical conditions including severe coronary artery disease, azotemia, moderate to severe hepatic insufficiency, systemic cancer requiring treatment, or similar severe conditions?	❑$_1$ Yes	❑$_0$ No	
22.	Has the participant received treatment with Cytoxan/Cyclophosphamide?	❑$_1$ Yes	❑$_0$ No	
23.	Does the participant have a history of pelvic radiation treatment, bladder calculus, tuberculus cyctitis, neurologic disease affecting bladder function, bladder cancer or cancer in situ, urethral cancer, or any other neoplastic process currently requiring systemic, non-prophylactic treatment?	❑$_1$ Yes	❑$_0$ No	
24.	Has the participant received previous augmentation cystoplasty, cystectomy or cystolysis, neurectomy (hypogastric nerve plexus ablation) or implanted peripheral nerve stimulator, which has affected bladder function?	❑$_1$ Yes	❑$_0$ No	
25.	Does the participant currently have an active urethral calculus, ureteral calculus, or urethral diverticulum?	❑$_1$ Yes	❑$_0$ No	
26.	Is the participant likely to be non-compliant due to an unmanaged medical or psychological problem, including dementia, aphasia, or other deficits of cognition or speech/language function that will interfere with his/her ability to complete the study?	❑$_1$ Yes	❑$_0$ No	
27.	Is the participant planning an imminent change in residence, which could compromise compliance?	❑$_1$ Yes	❑$_0$ No	
46.	Does the participant have a current history of vesicoureteral reflux?	❑$_1$ Yes	❑$_0$ No	

(**Question #s 28 to 30 for males only, check N/A for females**)

28.	Does the male participant have a residual volume of more than 150 cc, measured by ultrasound or catheter?	❑$_1$ Yes	❑$_0$ No	❑$_{99}$ N/A
29.	Is the male participant currently being treated for chronic bacterial prostatitis as documented by a positive urine culture?	❑$_1$ Yes	❑$_0$ No	❑$_{99}$ N/A
30.	Does the participant have a history of prostate cancer?	❑$_1$ Yes	❑$_0$ No	❑$_{99}$ N/A

(**Question # 31 for females only, check N/A for males**)

31.	Is the participant currently pregnant or breastfeeding?	❑$_1$ Yes	❑$_0$ No	❑$_{99}$ N/A

DEFERRAL CRITERIA: - *Responses to questions #32 through #45 must be "**No or N/A**". **Dates** are provided for **administrative** purposes and **not** entered in the database.*

32.	Has the participant initiated any new medications for IC in the past 4 weeks?	❑$_1$ Yes	❑$_0$ No

If **YES**, date new medication initiated: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY

(Must be maintained on the **same** dose for at least **4 weeks**.)

Eligibility Confirmation (Phase I only)

33. Has the participant undergone hydrodistention within 6 weeks prior to study enrollment? ❑1 Yes ❑0 No

If **YES**, date of last procedure: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred at least **12 weeks** from the date of procedure.)

34. Has the participant undergone bladder instrumentation such as urethral dilation, urodynamics, bladder cystoscopy or bladder biopsy under general or regional anesthesia in the past 6 weeks? ❑1 Yes ❑0 No

If **YES**, date of last procedure: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred at least **6 weeks** from the date of procedure.)

35. Has the participant had a positive urine culture (100,000 col. ct) during the past 6 weeks? ❑1 Yes ❑0 No

If **YES**, date of negative urine culture: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be without the condition for at least **6 weeks**.)

36. Does the participant have active genital herpes, or has had active genital herpes during the past 12 weeks? ❑1 Yes ❑0 No

If **YES**, date episode resolved: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred for at least **12 weeks** after resolution.)

37. Has the participant received any intravesical treatment **other than BCG (e.g. DMSO, Heparin, Cystostat)** during the past 12 weeks? ❑1 Yes ❑0 No

If **YES**, date of last treatment received: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred for at least **12 weeks** after the last treatment.)

38. Has the participant been treated with botulinum toxin injections for voiding dysfunction within 24 weeks prior to screening? ❑1 Yes ❑0 No

If **YES**, date of last treatment received: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred for at least **24 weeks** after the last treatment.)

39. Does the participant have a history of incontinence surgery or any other bladder or urethral surgery within the past 24 weeks, which could interfere with bladder function? ❑1 Yes ❑0 No

If **YES**, date of last surgery: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred for at least **24 weeks** after the last surgery.)

Eligibility Confirmation (Phase I only)

40. Has the participant been on pentosan polysulfate in the past 4 weeks? ❑1 Yes ❑0 No

If **YES**, date of last dose: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred for at least **4 weeks** after the last dose.)

41. Is the participant currently participating in another intervention study, or has received an investigational drug or device 4 weeks prior to screening? ❑1 Yes ❑0 No

If **YES**, date participation ends: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred for at least **4 weeks** after the last date of participation.)

(Question #s 42 to 44 for females only, check N/A for males)

42. Does the female participant have active vaginitis? ❑1 Yes ❑0 No ❑99 N/A

If **YES**, date participant is free of the symptoms:
Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred **until free of condition**.)

43. Has the female participant had any form of transvaginal surgery hysterectomy, prolapse surgery, vaginal or C-section delivery in the past 24 weeks? ❑1 Yes ❑0 No ❑99 N/A

If **YES**, date of last procedure or delivery: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred at least **24 weeks** from the date of procedure or delivery.)

44. Is the female participant currently pregnant or breastfeeding? ❑1 Yes ❑0 No ❑99 N/A

If **YES**, date delivered/stopped breastfeeding:
Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred at least **24 weeks** from delivery date or stopping breastfeeding.)

(Question # 45 for males only, check N/A for females)

45. Has the male participant had a TURP, TUIP, TUIBN, TUMT, TUNA, balloon dilation of the prostate, open prostatectomy, or any other prostate treatment such as cryotherapy or thermal therapy in the past 24 weeks? ❑1 Yes ❑0 No ❑99 N/A

If **YES**, date of last procedure: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred at least **24 weeks** from the date of procedure.)

P.I. Signature: _____ Date: __ __ / __ __ / __ __ __ __
MM DD YYYY

Eligibility Confirmation - General Comments (Phase I only)

Administrative

Use the table below to list comments regarding eligibility questions.

Question #	Comment

Eligibility Confirmation - General Comments (Phase I only)

Administrative

Use the table below to list comments regarding eligibility questions.

Question #	Comment

P.I. Signature: _____ Date: __ __ / __ __ / __ __ __ __
MM DD YYYY

Physical Exam (Phase I)

Physician completes at Visits 2 and 15.

1. Examiner I.D.: __ __ __ __
2. Height: __ __ . __ __ in.
3. Weight: __ __ __ . __ __ lbs.
4. Blood Pressure: __ __ __ systolic (mmHg)
   __ __ __ diastolic (mmHg)
5. Was a physical examination performed according to the Manual of Procedures?
   ❒1 Yes
   ❒0 No
6. Abdominal exam:
   ❒1 Normal
   ❒0 Abnormal

Pelvic Exam is not required at Visit 15.

7. ***Female* Pelvic Exam:**

   External Genitalia:
   ❒1 Normal
   ❒0 Abnormal
   ❒99 Not Applicable

   Bimanual exam:
   ❒1 Normal
   ❒0 Abnormal
   ❒99 Not Applicable

8. ***Male* Pelvic Exam:**

   External Genitalia:
   ❒1 Normal
   ❒0 Abnormal
   ❒99 Not Applicable

   Rectal exam:
   ❒1 Normal
   ❒0 Abnormal
   ❒99 Not Applicable

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Follow-Up Symptoms (Phase I)

Research Coordinator completes at Visits 8, 11, 13 and 15.

1. Think about the pain/discomfort associated with your bladder. **On average,** how would you rate this **pain/discomfort** during the past 4 weeks?

   (Please circle the number below that best describes this **pain/discomfort**.)

None			Mild			Moderate			Severe
0	1	2	3	4	5	6	7	8	9

2. Urgency is defined as the urge or pressure to urinate. **On average,** how would you rate the **urgency** that you have felt during the past 4 weeks?

   (Please circle the number that best describes this **urgency.)**

None			Mild			Moderate			Severe
0	1	2	3	4	5	6	7	8	9

3. **On average**, during the past 4 weeks, how many times did you urinate in a 24-hour period?

   (Please check the option that best describes your answer.)

   ❑$_1$ 6 times or less ❑$_2$ 7-10 times ❑$_3$ 11 – 14 times ❑$_4$ 15 times or more

4. Are you sexually active? ❑$_1$ Yes ❑$_0$ No

   a. If **NO**, is it because of:
   - ❑$_1$ IC symptoms
   - ❑$_2$ Lack of partner
   - ❑$_{98}$ Other

5. Do you have pain associated with sexual intercourse? ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A

6. As compared to when you started the study, how would you rate your interstitial cystitis symptoms now?
   - ❑$_1$ Markedly worse
   - ❑$_2$ Moderately worse
   - ❑$_3$ Slightly worse
   - ❑$_4$ No change
   - ❑$_5$ Slightly improved
   - ❑$_6$ Moderately improved
   - ❑$_7$ Markedly improved

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Clinical Laboratory Results (Phase I)

Research Coordinator completes at Visits 1 **and** 15, and as needed during Phase I Visits.

1. Were any clinical labs ordered at this visit? ❑$_1$ Yes ❑$_0$ No

If **YES**, list the number of specimens/results to be recorded at this visit? __ __

Date of Specimen	WBC ❑ Not ordered				RBC ❑ Not ordered				Platelets ❑ Not ordered				Hematocrit ❑ Not ordered				Hemoglobin ❑ Not ordered			
	*LLN	*ULN	Value	Signif-icant?	*LLN	*ULN	Value	Signif-icant?	*LLN	*ULN	Value	Signif-icant?	*LLN	*ULN	Value	Signif-icant?	*LLN	*ULN	Value	Signif-icant?
				❑$_1$ Yes ❑$_0$ No				❑$_1$ Yes ❑$_0$ No				❑$_1$ Yes ❑$_0$ No				❑$_1$ Yes ❑$_0$ No				❑$_1$ Yes ❑$_0$ No
__ __/__ __/__ __ __ __	**Granulocytes** ❑ Not ordered				**Total Lymphocytes** ❑ Not ordered				**Monocytes** ❑ Not ordered				**Serum Pregnancy** ❑ Not ordered				**Record Urine Culture during treatment & follow-up only** (Visit 1 and 15 is recorded on the **URINE** form.) ❑ Not ordered			
	*LLN	*ULN	Value	Signif-icant?	*LLN	*ULN	Value	Signif-icant?	*LLN	*ULN	Value	Signif-icant?								
				❑$_1$ Yes ❑$_0$ No				❑$_1$ Yes ❑$_0$ No				❑$_1$ Yes ❑$_0$ No				❑$_1$ Positive ❑$_0$ Negative				❑$_1$ Positive ❑$_0$ Negative

*** If ULN or LLN are not applicable to a sample, write in "-1".**

Only one specimen date to be recorded per page; multiple test results can be recorded per visit.

Principal Investigator's Signature: _____ Date: __ __ / __ __ / __ __ __ __ PI ID: __ __ __ __

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Medical History (Phase I only)

Research Coordinator completes at Visit 1.

I'm going to ask you some questions . . .

1. Do you know when your urinary symptoms first began? ❑1 Yes ❑0 No
   If **YES**, at what age did they first begin? ____ age
2. Do you know when your interstitial cystitis (IC) was diagnosed by a doctor? ❑1 Yes ❑0 No
   If **YES**, at what age was your IC diagnosed? ____ age
3. Have you ever received treatment for IC? ❑1 Yes ❑0 No
   a. If **YES**, have you had any of the following treatments?
   - Drug ❑1 Yes ❑0 No
   - Behavioral ❑1 Yes ❑0 No
   - Dietary ❑1 Yes ❑0 No
   - Surgical ❑1 Yes ❑0 No
   - Intravesical ❑1 Yes ❑0 No

I am going to ask you some questions about some medical disorders and conditions.

Have you ever been *diagnosed* as having . . .?

Genito-Urinary Disorders: (Both Women and Men)

4.	Urinary Incontinence	❑1 Yes	❑0 No	❑88 U/K	
5.	Kidney Stones or Urinary Stones	❑1 Yes	❑0 No	❑88 U/K	
6.	Any sexually transmitted disease	❑1 Yes	❑0 No	❑88 U/K	
7.	Childhood bladder problems	❑1 Yes	❑0 No	❑88 U/K	
8.	Urinary tract infection	❑1 Yes	❑0 No	❑88 U/K	

Women Only

9.	Pelvic Inflammatory Disease (PID)	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A
10.	Endometriosis	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A
11.	Vulvodynia	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A

Men Only

12.	Benign Prostatic Hyperplasia (BPH)	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A
13.	Prostatitis	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A

Respiratory Tract Disorders/Allergies: (Both Women and Men)

14.	Asthma	❑1 Yes	❑0 No	❑88 U/K
15.	Drug allergies	❑1 Yes	❑0 No	❑88 U/K
16.	Food allergies	❑1 Yes	❑0 No	❑88 U/K
17.	Skin allergies (contact dermatitis)	❑1 Yes	❑0 No	❑88 U/K
18.	Sinusitis	❑1 Yes	❑0 No	❑88 U/K
19.	Hayfever, allergic rhinitis	❑1 Yes	❑0 No	❑88 U/K
20.	Latex allergies	❑1 Yes	❑0 No	❑88 U/K

Medical History (Phase I only)

Other Disorders: (Both Women and Men)

21.	Diabetes	❑1 Yes	❑0 No	❑88 U/K
22.	Fibromyalgia or Fibromyositis	❑1 Yes	❑0 No	❑88 U/K
23.	Chronic Fatigue Syndrome	❑1 Yes	❑0 No	❑88 U/K
24.	Irritable Bowel Syndrome	❑1 Yes	❑0 No	❑88 U/K
25.	Autoimmune Disorders (for example, Lupus, Rheumatoid Arthritis, Sjogren's,Scleraderma)	❑1 Yes	❑0 No	❑88 U/K
26.	Lumbosacral/Vertebral Disc Disease	❑1 Yes	❑0 No	❑88 U/K
27.	Migraine Headaches	❑1 Yes	❑0 No	❑88 U/K

Now I am going to ask some questions about some surgeries that you may have had.

Have you ever had:

Bladder/Urinary Tract Surgeries, such as: (Both Women and Men)

28.	Cystoscopy/Hydrodistention	❑1 Yes	❑0 No	❑88 U/K
29.	Incontinence surgery	❑1 Yes	❑0 No	❑88 U/K
30.	Other bladder surgery (such as diverticulectomy)	❑1 Yes	❑0 No	❑88 U/K

Gynecologic Surgeries: (Women Only)

31.	Cystocele repair (bladder hernia)	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A
32.	Rectocele repair (rectal hernia)	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A
33.	Enterocele repair (intestinal hernia)	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A
34.	D&C/D&E	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A
35.	Hysterectomy	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A
36.	Tubal Ligation	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A
37.	Removal of one or both ovaries	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A

Other Surgeries: (Both Women and Men)

38.	Laparoscopy	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A
39.	Inguinal hernia repair	❑1 Yes	❑0 No	❑88 U/K	
40.	Other abdominal or pelvic surgery	❑1 Yes	❑0 No	❑88 U/K	
41.	Back Surgery	❑1 Yes	❑0 No	❑88 U/K	

Other Surgeries: (Men Only)

42.	Prostate surgery (for benign disease)	❑1 Yes	❑0 No	❑88 U/K	❑99 N/A

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Telephone Contact During Treatment Phase (Phase I)

Research Coordinator completes on day 1 **and** day 2 after each instillation at Visits 3, 4, 5, 6, 7 and 8.

1. Was the participant available for this contact? ❒1 Yes ❒0 No
2. Date of contact for DAY 1 post-instillation: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
3. Has the participant recorded his/her temperature? ❒1 Yes ❒0 No
   a. If **YES**, Temperature (from the previous night): __ __ __ . __ ❒1 ^{0}F ❒2 ^{0}C
4. Were post-instillation BCG symptoms/adverse experiences reviewed with the participant? ❒1 Yes ❒0 No
5. Did the participant start or stop any concomitant medications? ❒1 Yes ❒0 No

---

1. Was the participant available for this contact? ❒1 Yes ❒0 No
2. Date of contact for DAY 2 post-instillation: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
3. Has the participant recorded his/her temperature? ❒1 Yes ❒0 No
   a. If **YES**, Temperature (from the previous night): __ __ __ . __ ❒1 ^{0}F ❒2 ^{0}C
4. Were post-instillation BCG symptoms/adverse experiences reviewed with the participant? ❒1 Yes ❒0 No
5. Did the participant start or stop any concomitant medications? ❒1 Yes ❒0 No

---

1. Was an additional contact necessary? ❒1 Yes ❒0 No
2. Was the participant available for this contact? ❒1 Yes ❒0 No
3. Date of contact for additional day post-instillation: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
4. Has the participant recorded his/her temperature? ❒1 Yes ❒0 No
   a. If **YES**, Temperature (from the previous night): __ __ __ . __ ❒1 ^{0}F ❒2 ^{0}C
5. Were post-instillation BCG symptoms/adverse experiences reviewed with the participant? ❒1 Yes ❒0 No
6. Did the participant start or stop any concomitant medications? ❒1 Yes ❒0 No

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Participant Close-Out (Phase I only)

Participant and Research Coordinator completes at Visit 15 or premature termination from the study.

Participant completes question #s 1, 2 and 3:

1. Do you think the current status of your symptoms is related to the study medications?
   - ❒1 Yes
   - ❒0 No

2. Which medication do you think you received?
   - ❒1 Couldn't tell
   - ❒2 BCG solution
   - ❒3 Saline Solution

3. Referring to your response in question # 2, what made you think that?
   - ❒1 IC was better
   - ❒2 IC was worse
   - ❒3 IC remained unchanged
   - ❒4 Experienced side effects
   - ❒5 Did not experience side effects
   - ❒98 Other: _____

Research Coordinator completes question # 4:

4. Which medication do you think the participant received?
   - ❒1 Couldn't tell
   - ❒2 BCG solution
   - ❒3 Saline Solution

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Randomization (Phase I only)

Research Coordinator and Principal Investigator complete at Visit 2.

*Response to question #1 must be "**Yes**".*

1. Does the participant meet all of the eligibility criteria at **Visits 1 and 2**? ❑$_1$ Yes ❑$_0$ No

2. Indicate the registering physician's I.D. number: __ __ __ __

P.I. Signature: _____ Date: __ __ / __ __ / __ __ __ __
MM DD YYYY

3. Perform computer randomization and record randomization number: __ __ __ __ __

Randomization - General Comments (Phase I only)

Administrative

Use the table below to list comments.

Question #	Comment

P.I. Signature: _____ Date: __ __ / __ __ / __ __ __ __
MM DD YYYY

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Health Status Questionnaire (SF-36™) (Phase I)

Participant completed at Visits 2, 8, 11, 13, and 15.

Instructions for Completing the Questionnaire:

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

EXAMPLE

This is for your review. Do not answer this question. The questionnaire begins with the section ***Your Health in General*** below. For each question you will be asked to fill in a bubble in each line:

1. How strongly do you agree or disagree with each of the following statements?

	Strongly agree	Agree	Uncertain	Disagree	Strongly Disagree
a) I enjoy listening to music.	❍1	❍2	❍3	❍4	❍5
b) I enjoy reading magazines.	❍1	❍2	❍3	❍4	❍5

Your Health in General

1. In general, would you say your health is:

Excellent	Very Good	Good	Fair	Poor
❍1	❍2	❍3	❍4	❍5

2. **Compared to one year ago**, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
❍1	❍2	❍3	❍4	❍5

Please turn the page and continue

Health Status Questionnaire (SF-36™) (Phase I)

3. The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a)	**Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports.	❍1	❍2	❍3
b)	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	❍1	❍2	❍3
c)	Lifting or carrying groceries	❍1	❍2	❍3
d)	Climbing **several** flights of stairs	❍1	❍2	❍3
e)	Climbing **one** flight of stairs	❍1	❍2	❍3
f)	Bending, kneeling, or stooping	❍1	❍2	❍3
g)	Walking **more than a mile**	❍1	❍2	❍3
h)	Walking **several blocks**	❍1	❍2	❍3
i)	Walking **one block**	❍1	❍2	❍3
j)	Bathing or dressing yourself	❍1	❍2	❍3

4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		Yes	No
a)	Cut down the **amount of time** you spent on work or other activities	❍1	❍0
b)	**Accomplished less** than you would like	❍1	❍0
c)	Were limited in the **kind** of work or other activities	❍1	❍0
d)	Had **difficulty** performing the work or other activities (for example, it took extra time)	❍1	❍0

5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

		Yes	No
a)	Cut down the **amount of time** you spent on work or other activities	❍1	❍0
b)	**Accomplished less** than you would like	❍1	❍0
c)	Didn't do work or other activities as **carefully** as usual	❍1	❍0

Please turn the page and continue.

Health Status Questionnaire (SF-36™) (Phase I)

6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
❍1	❍2	❍3	❍4	❍5

7. How much <u>bodily</u> pain have you had during the **past 4 weeks**?

None	Very Mild	Mild	Moderate	Severe	Very severe
❍1	❍2	❍3	❍4	❍5	❍6

8. During the **past 4 weeks**, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
❍1	❍2	❍3	❍4	❍5

9. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks…**

		All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a)	did you feel full of pep?	❍1	❍2	❍3	❍4	❍5	❍6
b)	have you been a very nervous person?	❍1	❍2	❍3	❍4	❍5	❍6
c)	have you felt so down in the dumps nothing could cheer you up?	❍1	❍2	❍3	❍4	❍5	❍6
d)	have you felt calm and peaceful?	❍1	❍2	❍3	❍4	❍5	❍6
e)	did you have a lot of energy?	❍1	❍2	❍3	❍4	❍5	❍6
f)	have you felt downhearted and blue?	❍1	❍2	❍3	❍4	❍5	❍6
g)	did you feel worn out?	❍1	❍2	❍3	❍4	❍5	❍6
h)	have you been a happy person?	❍1	❍2	❍3	❍4	❍5	❍6
i)	did you feel tired?	❍1	❍2	❍3	❍4	❍5	❍6

Please turn the page and continue.

Health Status Questionnaire (SF-36™) (Phase I)

10. During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
❍1	❍2	❍3	❍4	❍5

11. How **true** or **false** is each of the following statements for you?

		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a)	I seem to get sick a little easier than other people	❍1	❍2	❍3	❍4	❍5
b)	I am as healthy as anybody I know	❍1	❍2	❍3	❍4	❍5
c)	I expect my health to get worse	❍1	❍2	❍3	❍4	❍5
d)	My health is excellent	❍1	❍2	❍3	❍4	❍5

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Study Stop Point (Phase I)

Research Coordinator completes at Visit 15, or if the participant withdraws from the study prior to Visit 15.

1. Did the participant complete the study up to visit 15? ❒1 Yes ❒0 No

   a. If **NO**, indicate primary reason:

      i. Use of unacceptable concomitant medications as recorded on the Concomitant Medication (**CMED**) form as: ❒1

      Specify medication: _____ Line # __ __ __

      Visit # __ __

      ii. Positive pregnancy test: ❒2

      Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

      iii. Abnormal Clinical Laboratory Results as defined in the protocol and recorded on the Clinical Laboratory Results (**LAB**) form. ❒3

      Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

      iv. Adverse or serious adverse event as determined by the Principal Investigator and recorded on the Adverse Events (**AE**) form. ❒4

      Specify AE/SAE: _____ AE # __ __ __

      Visit # __ __

      v. Transfer to another Clinical Center during follow-up phase. ❒5

      vi. Participant dissatisfied with treatment. ❒6

      Specify reason: _____

      vii. Participant no longer interested in participating. ❒7

      viii. Other reasons. ❒8

      Specify reason: _____

   b. Date and visit number participant was last seen: Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

      Visit # __ __

Non-Responders:

2. If the participant completed the study, is s/he participating in the open-label trial? ❒1 Yes ❒0 No ❒99 N/A

Responders:

3. If the participant completed the study, is s/he participating in the Phase IIR follow-up study? ❒1 Yes ❒0 No ❒99 N/A

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Study Close-out

Principal Investigator and Research Coordinator complete when participant stops participation in the study.

1. Physician Comments (Optional):

_____

_____

_____

SIGNATURES: Please complete the following section regardless of the reason for termination of study participation.

I verify that all information collected on the ICCTG data collection forms for this participant is correct to the best of my knowledge and was collected in accordance with the procedures outlined in the ICCTG Protocol and Manual of Procedures.

_____ Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Principal Investigator Signature MM DD YYYY

Did the P.I. sign this form? ❑1 Yes ❑0 No

_____ Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Research Coordinator Signature MM DD YYYY

Did the R.C. sign this form? ❑1 Yes ❑0 No

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Standard Visit Inventory (Phase I)

Research Coordinator completes at Visits 9, 10, 11, 12, 13, 14 and 15.

1. Has the participant continued to use a medically approved birth control method? ❑$_1$ Yes ❑$_0$ No

2. **(Question #2 for females only, check N/A for males & post-menopausal women)**
What was the date of onset of the most recent menstrual period? Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

OR ❑ N/A

(At Visit 15 only, check N/A for other visits)

3. Did the participant request narcotics for pain in the past 4 weeks?
❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Interstitial Cystitis Symptom Index and Problem Index (Phase I)

O'Leary, Sant, Fowler, Whitmore, Spolarich-Kroll

Participant completes at Visit 2, 8, 11, 13 and 15.

Interstitial Cystitis Symptom Index:

Q1. During the past month, how often have you felt the strong need to urinate with little or no warning?

0. ___ not at all
1. ___ less than 1 time in 5
2. ___ less than half the time
3. ___ about half the time
4. ___ more than half the time
5. ___ almost always

Q2. During the past month, have you had to urinate less than 2 hours after you finished urinating?

0. ___ not at all
1. ___ less than 1 time in 5
2. ___ less than half the time
3. ___ about half the time
4. ___ more than half the time
5. ___ almost always

Q3. During the past month, how often did you most typically get up at night to urinate?

0. ___ none
1. ___ once
2. ___ 2 times
3. ___ 3 times
4. ___ 4 times
5. ___ 5 or more times

Q4. During the past month, have you experienced pain or burning in your bladder?

0. ___ not at all
2. ___ a few times
3. ___ fairly often
4. ___ usually
5. ___ almost always

Add the numerical values of the checked entries;

Total Score: _____

Interstitial Cystitis Problem Index:

During the past month, how much has each of the following been a problem for you?

Q1. Frequent Urination during the day?

0. ___ no problem
1. ___ very small problem
2. ___ small problem
3. ___ medium problem
4. ___ big problem

Q2. Getting up at night to urinate?

0. ___ no problem
1. ___ very small problem
2. ___ small problem
3. ___ medium problem
4. ___ big problem

Q3. Need to urinate with little warning?

0. ___ no problem
1. ___ very small problem
2. ___ small problem
3. ___ medium problem
4. ___ big problem

Q4. Burning, pain, discomfort, or pressure in your bladder?

0. ___ no problem
1. ___ very small problem
2. ___ small problem
3. ___ medium problem
4. ___ big problem

Add the numerical values of the checked entries;

Total Score: _____

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Treatment Stop Point (Phase I)

Research Coordinator completes at Visit 8, or if the participant withdraws from treatment prior to 10 weeks/6 instillations.

1. Did the participant complete 10 weeks or 6 instillations of treatment? ❒1 Yes ❒0 No

   a. If **NO**, indicate primary reason:

      i. Use of unacceptable concomitant medications as recorded on the Concomitant Medication (**CMED**) form as: ❒1

         Specify medication: _____ Line # __ __ __

         Visit # __ __

      ii. Positive pregnancy test: ❒2

         Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

      iii. Abnormal Clinical Laboratory Results as defined in the protocol and recorded on the Clinical Laboratory Results (**LAB**) form. ❒3

         Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

      iv. Adverse or serious adverse event as determined by the Principal Investigator and recorded on the Adverse Events (**AE**) form. ❒4

         Specify AE/SAE: _____ AE # __ __ __

         Visit # __ __

      v. Participant dissatisfied with treatment. ❒5

         Specify reason: _____

      vi. Participant no longer interested in participating. ❒6

      vii. Other reasons. ❒7

         Specify reason: _____

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Unmasking Record

Research Coordinator completes.

Photocopies of this form with signatures must be sent to the DCC.

1. Date of unmasking: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

2. Time of unmasking: __ __ : __ __ (Military time)

3. Was the DCC contacted within 3 days of unmasking? ❒1 Yes ❒0 No

   If **YES**, person contacted: _____

   If **NO**, reason: _____

4. Who unmasked the study medication? ❒1 P.I. ❒2 RC ❒3 Other

5. If unmasked by someone other than the P.I., was the P.I. contacted prior to unmasking? ❒1 Yes ❒0 No

   If **NO**, reason: _____

6. Why was the study medication unmasked?

   Serious Adverse Event as recorded on AE ❒1

   AE # __ __ __

   Hospitalization ❒2

   Other ❒3

P.I. Signature: _____ Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Urine Screening (Phase I)

Research Coordinator completes at Visits 1 and 15.

1. Date urine sample obtained: Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

2. Dipstick Urinalysis: ❒1 Normal ❒0 Abnormal

   If **ABNORMAL**, please check if present:

   a. Nitrite ❒1 Yes ❒0 No

   b. Blood ❒1 Yes ❒0 No

   c. Hemoglobin ❒1 Yes ❒0 No

   d. Leukocytes ❒1 Yes ❒0 No

3. Did this participant have a positive urine culture (colony count of more 10^5 of uropathogens)? ❒1 Yes ❒0 No

(Question #s 4 and 5 for males only, check N/A for females)

4. Date residual urine volume measured: Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

   OR ❒ N/A

(Residual volume at Visit 1 only)

5. Was the residual urine volume greater than 150 cc as measured by ultrasound or catheter? ❒1 Yes ❒0 No ❒99 N/A

Voiding Diary (Phase I)

Participant completes before Visit 2, 11, 13 and 15.

Research Coordinator provides the participant with several photocopies of the second page.

INSTRUCTIONS: Before your next scheduled visit, record the times and amounts of each urination for a consecutive 24-hour period. On this day start at 8:00 (Military time) and continue until 7:59 the next day. Please use the special container that has been provided for you.

Please use black ink.

1. Beginning date of log. Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

2. Ending date of log. Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

(Question # 3 for females only, check N/A for males)

3. What was the date of onset of your most recent menstrual period? Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

OR ❑ Not applicable

4. What time did you go to bed for the night? ___ ___ : ___ ___ (Military time) (hour : minute)

5. What time did you get up for the day? ___ ___ : ___ ___ (Military time) (hour : minute)

6. Which number best describes your pain/discomfort on this day?

(Please circle **ONE** number)

None			Mild			Moderate			Severe
0	1	2	3	4	5	6	7	8	9

7. Which number best describes your urgency on this day?

(Please circle **ONE** number)

None			Mild			Moderate			Severe
0	1	2	3	4	5	6	7	8	9

VOID

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

Voiding Diary (Phase I)

Number of void records: __ __

For Clinical Center Use Only	**Time of Void** (Military Time) **Start at 8:00 in the morning**	**Amount Voided** (cc's)	**Did you wake to void?**
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No
VOID # ___ ___	___ ___ : ___ ___		❑1 Yes ❑0 No

ICCTG RCT2

Participant ID: __ __ __ __ __	Participant Initials: __ __ __	Clinical Center: __ __
Visit Number: __ __	CRF Date: __ __ /__ __ /__ __ __ __	RC ID: __ __ __ __

University of Wisconsin Symptom Survey (Phase I)

Participant completes at Visit 2, 8, 11, 13 and 15.

Please circle the one number answer that comes closest to the way you feel, whether or not you have the following symptoms.

	Symptom	Not at all	(Circle one number on each line)					A Lot
1.	Bladder Discomfort	0	1	2	3	4	5	6
2.	Bladder Pain	0	1	2	3	4	5	6
3.	Other Pelvic Discomfort	0	1	2	3	4	5	6
4.	Headache	0	1	2	3	4	5	6
5.	Backache	0	1	2	3	4	5	6
6.	Dizziness	0	1	2	3	4	5	6
7.	Feelings of Suffocation	0	1	2	3	4	5	6
8.	Chest Pain	0	1	2	3	4	5	6
9.	Ringing in Ears	0	1	2	3	4	5	6
10.	Getting Up at Night to Go to the Bathroom	0	1	2	3	4	5	6
11.	Aches in Joints	0	1	2	3	4	5	6
12.	Swollen Ankles	0	1	2	3	4	5	6
13.	Nasal Congestion	0	1	2	3	4	5	6
14.	Flu	0	1	2	3	4	5	6
15.	Abdominal Cramps	0	1	2	3	4	5	6
16.	Numbness or Tingling in Fingers or Toes	0	1	2	3	4	5	6
17.	Nausea	0	1	2	3	4	5	6
18.	Going to the Bathroom frequently during the day	0	1	2	3	4	5	6
19.	Blind Spots/Blurred Vision	0	1	2	3	4	5	6
20.	Heart Pounding	0	1	2	3	4	5	6
21.	Difficulty Sleeping because of Bladder Symptoms	0	1	2	3	4	5	6
22.	Sore Throat	0	1	2	3	4	5	6
23.	Urgency to Urinate	0	1	2	3	4	5	6
24.	Coughing	0	1	2	3	4	5	6
25.	Burning Sensation in Bladder	0	1	2	3	4	5	6