CAMUS Clinical Trial
Eligibility and Randomization Form (CAM01)

Draft

VisDate Completed on ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

Participant ID ☐☐☐S☐☐☐

ParticipantId

Participant Initials

ParticipantIni ☐☐☐

Eligibility is determined based on some or all of the following forms from screening visit 1 (CAM21, CAM23, CAM24, CAM31, CAM32, CAM41, CAM42 CAM45, CAM46, CAM47, and CAM75) and from screening visit 2 (CAM31, CAM42, CAM74, CAM75 and CAM76).

Instructions: Complete this form during both screening visits. Enter eligibility data in the CAMUS Web Data Entry System to receive a random treatment group assignment (in section C) for eligible participants.

A. Eligibility Inclusion Criteria

(All inclusion criteria must be checked "Yes" in order for a participant to be eligible.)

1. Is the participant a male at least 45 years of age? — CM01_Age ☐(1)Yes ☐(2)No

2a. Was the participant's peak urinary flow rate at least 4 ml/sec at both screening visits? — CM01_UrinFlw ☐(1)Yes ☐(2)No

2b. Was the participant's voided volume at least 125 ml at both screening visits? — CM01_VoidVol ☐(1)Yes ☐(2)No

3. Was the participant's AUA symptom score greater than or equal to 8 and less than or equal to 24 at both screening visits? — CM01_AUAScr ☐(1)Yes ☐(2)No

4. Did the participant voluntarily sign an informed consent agreement prior to the performance of any study procedures? — CM01_VolCnsnt ☐(1)Yes ☐(2)No

B. Eligibility Exclusion Criteria

(All exclusion criteria must be checked "No" in order for a participant to be eligible.)

1. Has the participant had any prior invasive interventions for BPH? — CM01_PrInvBPH ☐(1)Yes ☐(2)No

2. Has the participant taken phytotherapy for BPH within 3 months prior to screening visit 1? — CM01_Phytothrpy ☐(1)Yes ☐(2)No

3. Has the participant taken a 5-alpha reductase inhibitor within 3 months prior to screening visit 1? — CM01_Alphreduct ☐(1)Yes ☐(2)No

4. Has the participant taken an alpha blocker within one month prior to screening visit 1? — CM01_AlphBlck1M ☐(1)Yes ☐(2)No

5. Has the participant had an allergic reaction to *Serenoa repens*? — CM01_AlphblkAlrgy ☐(1)Yes ☐(2)No

Reset

CAMUS Clinical Trial
Eligibility and Randomization Form (CAM01)

VisDate Completed on ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

Participant ID ☐☐☐S☐☐☐ ParticipantId

Participant Initials ParticipantIni ☐☐☐

6. Has the participant taken phenylephrine, pseudoephedrine, tricyclic antidepressants, an anticholinergic, or cholinergic medication within 4 weeks of the screening visit 1 (Exception: topical anticholinergic eye drops used for glaucoma)? CM01_PrvMd4Wk ☐(1)Yes ☐(2)No

7. Has the participant taken estrogen, androgen, any drug producing androgen suppression, or anabolic steroids within 6 months prior to screening visit 1? CM01_PrvMd6Mo ☐(1)Yes ☐(2)No

8. Does the participant have known clinically significant renal impairment (i.e., creatinine > 2.0 mg/dL)? CM01_RenalImp ☐(1)Yes ☐(2)No

9. Does the participant have an ALT(SGPT), AST(SGOT) or GGT value greater than 3 times the upper limit of normal, confirmed on a second measurement? CM01_ALT ☐(1)Yes ☐(2)No

10. Does the participant have a prothrombin time greater than 3 seconds above the upper limit of normal or more than 3 seconds above the control value? CM01_PTT ☐(1)Yes ☐(2)No

11. Does the participant have an electrocardiogram reading that suggests active ischemia? CM01_Ischemia ☐(1)Yes ☐(2)No

12. Is the participant's PSA level greater than 10 ng/ml at screening? CM01_PSALev ☐(1)Yes ☐(2)No

13. Does the participant require daily use of a pad or device for incontinence, or have an ICSmaleIS score >14 at baseline? CM01_DailyPad ☐(1)Yes ☐(2)No

14. Has the participant had an unstable medical condition within the past 3 months? CM01_UnMedCond3M ☐(1)Yes ☐(2)No

15. Does the participant have a history of or current evidence of carcinoma of the prostate or bladder, pelvic radiation or surgery, urethral stricture or prior surgery for bladder neck obstruction? CM01_Carcinoma ☐(1)Yes ☐(2)No

16. Does the participant have active urinary tract disease or has the participant undergone cystoscopy or biopsy of the prostate within 1 month prior to screening visit 1 or does he have an imminent need for urologic surgery? CM01_UrTract1M ☐(1)Yes ☐(2)No

VisDate Completed on mm / dd / yyyy

Participant ID: S ParticipantId

Participant Initials: ParticipantIni

17. Does the participant have known primary neurologic conditions such as multiple sclerosis or Parkinson's disease or other neurological diseases known to affect bladder function? CM01_NeurCond (1)Yes (2)No

18. Has the participant had documented bacterial prostatitis within the past year? CM01_BacProstPYr (1)Yes (2)No

19. Has the participant had two documented independent urinary tract infections of any type in the past year? CM01_UrTractPYr (1)Yes (2)No

20. Does the participant have a known severe bleeding disorder or need for ongoing therapeutic anticoagulation with coumadin or heparin? CM01_SevBleed (1)Yes (2)No

21. Does the participant have cancer which is not considered cured (except basal cell or squamous cell carcinoma of the skin)? A potential participant is considered cured if there has been no evidence of cancer within 5 years of study entry. A history of bladder cancer or prostate cancer is exclusionary whether the participant is considered cured or not? CM01_Cancer (1)Yes (2)No

22. Is the participant unable to follow protocol directions due to organic brain or psychiatric disease? CM01_FolDirctn (1)Yes (2)No

23. Does the participant have a history of alcoholism or any other substance abuse, which, in the opinion of the investigator, would affect compliance with the protocol? CM01_Alcohol (1)Yes (2)No

24. Does the participant have any serious medical condition likely to impede successful completion of the long-term study? CM01_SMedCond (1)Yes (2)No

C. Randomization *(provided by DCC)*

1. Date randomized: CM01_RandDate CM01_RandMo / CM01_RandDy / CM01_RandYr (mm / dd / yyyy)

2. Medication ID: M CM01_RandNum

Draft

CAMUS Clinical Trial
Screening Log Form (CAM102)
SV1

*** ParticipantId** ☐☐☐S☐☐☐ ParticipantId

Date ☐☐/☐☐/☐☐☐☐ Date

Age ☐☐ CM102_Age

**** This ID# should be used throughout the study any time a participant is screened and eligible for enrollment.***

Ethnicity (Hispanic or Latino)

☐ (1) Yes
☐ (2) No
☐ (3) Unknown/Not Reported

CM102_aRace

Race (Check all that apply)

☐ American Indian or Alaska Native CM102_bRace1
☐ Asian CM102_bRace2
☐ Native Hawaiian or Other Pacific Islander CM102_bRace3
☐ Black or African-American CM102_bRace4
☐ White CM102_bRace5
☐ Unknown or Not Reported CM102_bRace6

Screening Outcome

☐ (1) Eligible, enrolled
☐ (2) Eligible, but did not enroll
☐ (3) Ineligible

CM102_ScrnOutcome

If not eligible, specify _____ Ineligible_Spec

Instructions: Please fax to the CAMUS Data Coordinating Center within 24 hours.

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Screening Log Form (CAM102)
SV2 / Baseline

*** ParticipantId** | **Date** | **Age**

S _ _ _ _ _ _ _ | _ _ / _ _ / _ _ _ _ | _ _

ParticipantId | ParticipantId | CM102_Age

**** This ID# should be used throughout the study any time a participant is screened and eligible for enrollment.***

Ethnicity (Hispanic or Latino)

- ☐ (1) Yes
- ☐ (2) No
- ☐ (3) Unknown/Not Reported

CM102_aRace

Race (Check all that apply)

- ☐ American Indian or Alaska Native CM102_bRace1
- ☐ Asian CM102_bRace2
- ☐ Native Hawaiian or Other Pacific Islander CM102_bRace3
- ☐ Black or African-American CM102_bRace4
- ☐ White CM102_bRace5
- ☐ Unknown or Not Reported CM102_bRace6

Screening Outcome

- ☐ (1) Eligible, enrolled
- ☐ (2) Eligible, but did not enroll
- ☐ (3) Ineligible

CM102_ScrnOutcome

If not eligible, specify _____ Ineligible_Spec

Randomized

- ☐ (1) Yes
- ☐ (2) No

CM102_Randomized

PID # Assigned

S _ _ _ _ _ _

ParticipantId

If, available, please provide the Med Kit # assigned

M _ _ _ _ _ _

CM102_RandNum

Instructions: Please fax to the CAMUS Data Coordinating Center within 24 hours.

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

Visit Date VisDate ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

Participant Initials ☐☐☐ ParticipantIni

Instruction: The study coordinator or investigator administers this form with the participant in a face-to-face interview. Eligibility criteria are noted throughout the form next to the pertinent items (indicated by the item number in a box). Screening stops when the participant first fails an eligibility criterion.

1. Date consent form signed: ☐☐/☐☐/☐☐☐☐ (mm CM21_CnsntMo / dd CM21_CnsntDy / yyyy CM21_CnsntYr) CM21_CnsntDate
   Excluded if no signed consent form.

2. Were you enrolled in another treatment trial for any disease in the past 30 days? CM21_OthTrial ☐(1)Yes ☐(2)No
   Excluded if enrolled in another treatment trial for any disease in the 30 days before screening visit 1.

3. Is this an initial screening or a rescreening (check one)?
   ☐(1) Initial Screen CM21_ScrnType
   ☐(2) Rescreen ⇨ If rescreen, Date of the first screening: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy) CM21_ScrnDate CM21_ScrnMo CM21_ScrnDy CM21_ScrnYr
   Number attempted screenings (including the current one) ☐☐ CM21_Attempt

A. Demographics and Social Characteristics

4. What is your year of birth? ☐☐☐☐ (yyyy) CM21_DOBYr
   Excluded if < 45 years old.

5. Race / Ethnicity
   (a) Do you consider yourself Hispanic or Latino?
   ☐(1)Yes ☐(2) No ☐(3)Unknown (Individuals not reporting ethnicity) CM21_aRace

   (b) Race: **Check all that apply.** To probe race, for each category (except Unknown or Not Reported) ask "Are you...?" and check the box if the participant responds "yes". Check the Unknown or Not Reported category if the participant responds "no" to all other categories or does not want answer the race question.
   ☐ American Indian or Alaska Native CM21_bRace1
   ☐ Asian CM21_bRace2
   ☐ Native Hawaiian or Other Pacific Islander CM21_bRace3
   ☐ Black or African-American CM21_bRace4
   ☐ White CM21_bRace5
   ☐ Unknown or Not Reported CM21_bRace6

6. Are you married or in a long-term committed relationship?
   ☐(1)Yes ☐(2)No ☐(9)Don't want to respond CM21_Married

Reset

CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐
mm VisMo dd VisDy yyyy VisYr

Participant ID ☐☐☐S☐☐☐
ParticipantId

Participant Initials ☐☐☐
ParticipantIni

7. What is the highest educational level that you achieved (check one)?

☐ (1)Less than high school graduate
☐ (2)High school graduate
☐ (3)Some college or technical school beyond high school
☐ (4)College or technical school graduate
☐ (5)Post-college coursework or degree
☐ (9)Don't want to respond

CM21_HEdu

B. Concomitant Medications

CM21_CnCmtntMed

8. Do you take any medication on a regular basis? ☐ (1)Yes ☐ (2)No

If "Yes", fill out form CAM23(Concomitant Medication form) and CAM24(Urology Medication Tracking form).

Excluded if :
1. *On an alpha-blocker within one month prior to the first screening visit OR*
2. *Phytotherapy or 5-alpha reductase inhibitor for BPH within 3 months prior to the first screening visit OR*
3. *Taken phenylephrine, pseudoephedrine, tricyclic antidepressants, an anticholinergic or cholinergic medication within 4 weeks of the first screening visit (Except topical anticholinergic eye drops used for glaucoma more than 1 month prior to the screening visit 1) OR*
4. *Taken estrogen, androgen, or any drug producing androgen suppression, or anabolic steroids within 6 months prior to the first screening visit*

C. Medical History

In general, ask , "Has a physician ever told you that you have ..."In some instances you may need to ask, "Do you have..."or "Have you had ..." (e.g., vasectomy).

CM21_CngenitalDz

9. Congenital disease. *Probe with*: Were you born with a birth defect or an unusual condition such as malformation of the limbs, head, skin, or internal organs? ☐ (1)Yes ☐ (2)No

CM21_LungDz

10. Lung disease. *Probe with*: Have you ever had chronic obstructive pulmonary disorder (COPD), emphysema, asthma, chronic bronchitis, pneumonia, or water on the lungs? ☐ (1)Yes ☐ (2)No

CM21_KidneyDz

11. Kidney disease. *Probe with*: Do you have kidney or bladder, stones, or kidney problems? ☐ (1)Yes ☐ (2)No

CM21_ImmuneDz

12. Immune disease. *Probe with*: Do you have rheumatoid arthritis or lupus? ☐ (1)Yes ☐ (2)No

CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐
mm VisMo dd VisDy yyyy VisYr

Participant ID ☐☐☐S☐☐☐ ParticipantId

Participant Initials ☐☐☐ ParticipantIni

13. Diabetes. *Probe with*: Do you have diabetes, whether you take medication for it or not? CM21_Diabetic ☐(1)Yes ☐(2)No

If yes: a. How long have you had diabetes mellitus? CM21_DiabeticLength ☐☐.☐ years

b. Type of diabetes mellitus: CM21_DiabeticType
☐(1) Non-insulin dependent
☐(2) Insulin dependent
☐(9) Don't want to respond

c. Have you taken any oral agents for diabetes mellitus? CM21_DiabeticOral ☐(1)Yes ☐(2)No

14. Endocrine disorder. *Probe with*: Do you have a pituitary, thyroid, or adrenal gland disorder, or low testosterone? CM21_Endocrin ☐(1)Yes ☐(2)No

15. Liver disease. *Probe with*: Do you have hepatitis or cirrhosis? CM21_LiverDz ☐(1)Yes ☐(2)No

16. Gastrointestinal disease. *Probe with*: Do you have ulcers, serious heartburn, gastrointestinal bleeding, gallstones or other problems with your gallbladder, hemorrhoids, polyps, Crohn's disease or ulcerative colitis, diverticulitis, or pancreatitis? CM21_GastroDz ☐(1)Yes ☐(2)No

17. Skin disease. *Probe with*: Do you have psoriasis, chronic rash, or eczema? CM21_SkinDz ☐(1)Yes ☐(2)No

18. Disease of the nervous system. *Probe with*: Do you have seizures, multiple sclerosis, Parkinson's, stroke, or muscle disease? CM21_NervSysDz ☐(1)Yes ☐(2)No

Excluded if ***known primary neurologic conditions such as multiple sclerosis or Parkinson's disease, or other neurological diseases known to affect bladder function.***

19. Cancer. *Probe with:* Do you have or have you had any cancer or carcinoma? CM21_Carcinoma ☐(1)Yes ☐(2)No

Excluded if ***history or current evidence of carcinoma of the prostate or bladder, or cancer that is not considered cured, except basal cell or squamous cell carcinoma of the skin (cured defined as no evidence of cancer within the past 5 years).***

CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

Participant Initials ☐☐☐ ParticipantIni

20. Anemia. *Probe with:* Do you have anemia? CM21_Anemia ☐(1)Yes ☐(2)No

21. Blood disease other than anemia. *Probe with* : Do you have sickle cell, leukemia, or a bleeding disorder? CM21_BloodDz ☐(1)Yes ☐(2)No

22. History of urinary tract infections. *Probe with* : Do you have any of the following urinary conditions: burning, frequency, urgency, hematuria, or bladder spasm? CM21_UrnTract ☐(1)Yes ☐(2)No

Excluded if
1. Active urinary tract infection or has undergone cystoscopy or biopsy of the prostate within one month prior to screening visit 1 OR
2. Two documented UTIs of any type in the past year.

23. History of urinary retention. *Probe with* : Have you ever had an inability to urinate at all? CM21_UrnRetensn ☐(1)Yes ☐(2)No

24. Prior history of gross or microscopic hematuria. *Probe with* : Have you ever had visible or microscopic blood in your urine? CM21_Hematuria ☐(1)Yes ☐(2)No

25. Prior biopsy of prostate. *Probe with:* Have you previously had a biopsy of your prostate? CM21_Biopsy ☐(1)Yes ☐(2)No

If yes, what was the date of your prostate biopsy?

☐☐/☐☐/☐☐☐☐ CM21_BiopsyDate (mm CM21_BiopsyMo / dd CM21_BiopsyDy / yyyy CM21_BiopsyYr)

Excluded if biopsy of the prostate within the past 4 weeks.

26. Vasectomy. *Probe with:* Have you had a vasectomy? CM21_Vasctmy ☐(1)Yes ☐(2)No

If yes, what was the year? ☐☐☐☐ (yyyy) CM21_VasctmyYr

27. History or current evidence of urethral stricture. *Probe with*: Do you currently or have you had a history of urethral stricture? CM21_HisUrethral ☐(1)Yes ☐(2)No

Excluded if participant has history or current evidence of urethral stricture.

28. Impotence. *Probe with:* Do you have any difficulty with erectile function? CM21_Impotnce ☐(1)Yes ☐(2)No

29. Other genitourinary disease. *Probe with:* Do you have incontinence? CM21_Othgenurn ☐(1)Yes ☐(2)No

If yes, specify ⇨ _____ CM21_OthGenurnD

Excluded if
1. History or current evidence of pelvic radiation or surgery OR
2. Bacterial prostatitis within the past year OR
3. Daily use of a pad or device for incontinence required or a baseline ICSmaleIS score > 14 at baseline.

CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

Participant Initials ☐☐☐ ParticipantIni

30. Infectious disease. *Probe with:* Do you have any infectious diseases such as HIV, herpes, or tuberculosis? CM21_InfectDz ☐(1)Yes ☐(2)No

D. Family History (blood relations only)

31. Has anyone in your family been told by a physician that he has BPH? CM21_HisBPH

☐(1)Yes ⇨ Check all that apply:
☐(2)No

- CM21_HisBPHD1 ☐(1) Father
- CM21_HisBPHD2 ☐(1) Maternal grandfather
- CM21_HisBPHD3 ☐(1) One maternal uncle
- CM21_HisBPHD4 ☐(1) Two or more maternal uncles
- CM21_HisBPHD5 ☐(1) One brother
- CM21_HisBPHD6 ☐(1) Two or more brothers
- CM21_HisBPHD7 ☐(1) Paternal grandfather
- CM21_HisBPHD8 ☐(1) One paternal uncle
- CM21_HisBPHD9 ☐(1) Two or more paternal uncles
- CM21_HisBPHD10 ☐(1) Other male relative

32. Has anyone in your family been told by a physician that he has prostate cancer? CM21_HisProCncr

☐(1)Yes ⇨ Check all that apply:
☐(2)No

- CM21_HisProCncrD1 ☐(1) Father
- CM21_HisProCncrD2 ☐(1) Maternal grandfather
- CM21_HisProCncrD3 ☐(1) One maternal uncle
- CM21_HisProCncrD4 ☐(1) Two or more maternal uncles
- CM21_HisProCncrD5 ☐(1) One brother
- CM21_HisProCncrD6 ☐(1) Two or more brothers
- CM21_HisProCncrD7 ☐(1) Paternal grandfather
- CM21_HisProCncrD8 ☐(1) One paternal uncle
- CM21_HisProCncrD9 ☐(1) Two or more paternal uncles
- CM21_HisProCncrD10 ☐(1) Other male relative

E. BPH Symptoms

33. How long have you had symptoms of BPH? CM21_LengthofBPH ☐☐.☐ years

34. Would you say that over the past year your symptoms have ... CM21_PastYrSym ☐(1) Improved ☐(2) Stabilized ☐(3) Worsened

Draft

CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

Participant Initials ☐☐☐ ParticipantIni

CM21_BPHSym5Yr

35. Have you seen a physician or primary care provider within the past 5 years about BPH symptoms? ☐ (1)Yes ☐ (2)No

If yes, what was...: ⇨ check all that apply in (a) - (d): **Recommended?** **Done?**

(a) Watchful waiting — CM21_BPHSym5YrWR ☐ 1 — ☐ 1 CM21_BPHSym5YrWD

(b) TURP or other surgical procedure — CM21_BPHSym5YrTR ☐ 1 — ☐ 1 CM21_BPHSym5YrTD

Excluded if any prior surgical intervention for BPH.

(c) Prescription Medication — CM21_BPHSym5YrPR ☐ 1 — ☐ 1 CM21_BPHSym5YrPD

If medication taken ⇨ CM21_AlphablkMo CM21_AlphablkDy CM21_AlphablkYr

c1. alpha-blocker last taken: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy) CM21_AlphablkDate

Excluded if on alpha-blocker within one month prior to the first screening visit.

CM21_FinastrdMo CM21_FinastrdDy CM21_FinastrdYr

c2. 5-alpha reductase inhibitor last taken (e.g.finasteride): ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy) CM21_FinastrdDate

Excluded if on 5-alpha reductase inhibitor within 3 months prior to the first screening visit.

Recommended? **Done?**

(d) Phytotherapy — CM21_BPHPhyto5YrPR ☐ 1 — ☐ 1

If phytotherapy taken ⇨ CM21_BPHPhyto5YrPD

d1. phytotherapy last taken: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy) CM21_PhytothrpyMo CM21_PhytothrpyDy CM21_PhytothrpyYr CM21_PhytothrpyDate

Excluded if on phytotherapy within 3 months prior to the first screening visit.

Draft

CAMUS Clinical Trial
History Update Form (CAM22)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

VisitNo Visit Number ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

Participant Initials ☐☐☐ ParticipantIni

1. Have there been changes in or new concomitant medications since the last visit?
   CM22_NewConMed
   ☐ (2) No ☐ (1) Yes ⇨ **If yes, update concomitant medication form (CAM23).**

2. Have there been changes in or new urology medications since the last visit?
   CM22_NewUrolMed
   ☐ (2) No ☐ (1) Yes ⇨ **If yes, update urology medication tracking form (CAM24).**

3. Has the participant experienced any new adverse events since the last visit?
   CM22_NewAdvEvnt
   ☐ (2) No ☐ (1) Yes ⇨ **If yes, update adverse events form (CAM81).**

4. Have previously reported adverse events resolved or worsened since the last visit ?
   ☐ (3) N/A ☐ (2) No ☐ (1) Yes ⇨ **If yes, update adverse events form (CAM81).**
   CM22_ReslvAdvEvnt

5. Does participant currently have a suprapubic catheter, use CIC/ISC, or had a catheter removed since the last visit?
   ☐ (2) No ☐ (1) Yes CM22_SupraCath

6. Has the participant reached a protocol defined BPH outcome?
   CM22_BPHProg
   ☐ (2) No ☐ (1) Yes ⇨ **If yes, update BPH outcome events form (CAM61).**

Reset

Draft

CAMUS Clinical Trial
Concomitant Medication Form (CAM23)

VisDate Visit Date ____/____/____ (mm/dd/yyyy) VisMo VisDy VisYr

Participant ID ___ ___ ___ S ___ ___ ___ ParticipantId

VisitNo Visit Number ___

01=SV1.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

Participant Initials ___ ParticipantIni

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM24). Number page(s) in bottom right corner of the form.

If this is screening visit 1, has the participant taken any medications for the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any medications ?

CM23_StrtStpMed

☐ (1) Yes ⇨ **If "Yes", continue to complete below.**

☐ (2) No ⇨ **If "No", stop here.**

CM23_EntryNum

Entry Number: ___

CM23_Med

Medication *(Give generic name):* _____

CM23_TotDose

Total Dosage: _____

Dosage Units *(See Codes below)* ☐ ⇨ If "other", Specify: _____ CM23_UnitSpec

CM23_Freq CM23_FreqSpec

Frequency *(See Codes below)* ☐ ⇨ If "other", Specify: _____

CM23_DoseUnits

Mode of Administration *(See Codes below)* ☐ ⇨ If "other", Specify: _____ CM23_ModeSpec CM23_ModeAdm

CM23_Ongoing

Ongoing: ☐

Date Started *(mm/dd/yyyy)* ____/____/____ CM23_StartMo CM23_StartDy CM23_StartYr

Or ⇨

Date Stopped *(mm/dd/yyyy)* CM23_StopMo ____/____/____ CM23_StopDy CM23_StopYr

CM23_PriReas

Primary Reason for Use or Change: _____

CM23_EntryNum

Entry Number: ___

CM23_Med

Medication *(Give generic name):* _____

CM23_TotDose

Total Dosage: _____

Dosage Units *(See Codes below)* ☐ ⇨ If "other", Specify: _____ CM23_UnitSpec

CM23_Freq CM23_FreqSpec

Frequency *(See Codes below)* ☐ ⇨ If "other", Specify: _____

CM23_DoseUnits

Mode of Administration *(See Codes below)* ☐ ⇨ If "other", Specify: _____ CM23_ModeSpec CM23_ModeAdm

CM23_Ongoing

Ongoing: ☐

Date Started *(mm/dd/yyyy)* ____/____/____ CM23_StartMo CM23_StartDy CM23_StartYr

Or ⇨

Date Stopped *(mm/dd/yyyy)* ____/____/____ CM23_StopDy CM23_StopYr

CM23_PriReas

Primary Reason for Use or Change: _____

Dosage Units Codes: (1) mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: (1) Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: (1) Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Urology Medication Tracking Form (CAM24)

Visit Date
VisDate ☐☐/☐☐/☐☐☐☐
mm VisMo dd VisDy yyyy VisYr

Participant ID
☐☐☐S☐☐☐
ParticipantId

Visit Number
VisitNo ☐☐

01=SV1.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

Participant Initials
☐☐☐ ParticipantIni

Do not duplicate medications listed on the Concomitant Medication Form (CAM23). Number page(s) in bottom right corner of the form.

If this is screening visit 1, has the participant taken any urology medications for the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any urology medications?

CM24_StrtStpMed
☐ (1) Yes ⇨ **If "Yes", continue to complete below.**
☐ (2) No ⇨ **If "No", stop here.**

CM24_EntryNum
Entry Number: ☐☐ CM24_Med

Medication *(Give generic name):* _____
CM24_TotDose CM24_UnitSpec

Total Dosage: _____

Dosage Units ☐ ⇨ If "other", Specify: _____
(See Codes below) CM24_DoseUnits

CM24_Freq CM24_FreqSpec
Frequency ☐ ⇨ If "other", Specify: _____
(See Codes below)

CM24_ModeSpec
Mode of Administration ☐ ⇨ If "other", Specify: _____
(See Codes below) CM24_ModeAdm

Date Started *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ CM24_StartMo CM24_StartDy CM24_StartYr

Ongoing: ☐ CM24_Ongoing

Or ⇨ **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ CM24_StopMo CM24_StopDy CM24_StopYr

CM24_EntryNum
Entry Number: ☐☐ CM24_Med

Medication *(Give generic name):* _____
CM24_TotDose CM24_UnitSpec

Total Dosage: _____

Dosage Units ☐ ⇨ If "other", Specify: _____
(See Codes below) CM24_DoseUnits

CM24_Freq CM24_FreqSpec
Frequency ☐ ⇨ If "other", Specify: _____
(See Codes below)

CM24_ModeSpec
Mode of Administration ☐ ⇨ If "other", Specify: _____
(See Codes below) CM24_ModeAdm

Date Started *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ CM24_StartMo CM24_StartDy

Ongoing: ☐ CM24_Ongoing

Or ⇨ **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ CM24_StopMo CM24_StopDy CM24_StopYr

Dosage Units Codes: (1) mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: (1) Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: (1) Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Vital Signs Form (CAM31)

VisDate — Visit Date: mm (VisMo) / dd (VisDy) / yyyy (VisYr)

Participant ID: S — ParticipantId

VisitNo — Visit Number

01=SV1.0 02=SV2.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

Participant Initials — ParticipantIni

CM31_VitalSign

Were vital signs done at this visit? ◯ (1)Yes ◯ (2)No ⇨ **If "No", stop here.**
If "Yes", record below.

CM31_Height

1. Height: ☐☐ inches

CM31_Weight

2. Weight: ☐☐☐ pounds

3. Supine measurements (taken after lying down for 5 minutes):

(a) Blood pressure CM31_BPSys (Systolic) / CM31_BPDia (Diastolic) mm Hg

(b) Heart rate ☐☐☐ bpm

CM31_HrtRate

4. Standing measurements (reading 1 taken immediately, reading 2 taken two minutes later):

(a) Blood pressure reading 1 CM31_BPSys1 (Systolic) / CM31_BPDia1 (Diastolic) mm Hg

(b) Heart rate reading 1 ☐☐☐ bpm

CM31_HrtRate1

(c) Blood pressure reading 2 CM31_BPSys2 (Systolic) / CM31_BPDia2 (Diastolic) mm Hg

(d) Heart rate reading 2 ☐☐☐ bpm

CM31_HrtRate2

Reset

Draft

CAMUS Clinical Trial
Physical and Digital Rectal Exam Form (CAM32)

VisDate — Visit Date: mm (VisMo) / dd (VisDy) / yyyy (VisYr)

Participant ID: S (ParticipantId)

VisitNo — Visit Number: 01=SV1.0, 72=Week 72

Participant Initials (ParticipantIni)

Was a physical examination done at this visit? (1)Yes (2)No ⇨ **If "No", stop here. If "Yes", record below.** (CM32_PhysExam)

	Normal	Abnormal	If abnormal, specify
1. Head, ears, nose, throat (CM32_HENT)	1	2 ⇨	CM32_HENTAb
2. Eyes (CM32_Eyes)	1	2 ⇨	CM32_EyesAb
3. Neck (include bruits) (CM32_Neck)	1	2 ⇨	CM32_NeckAb
4. Heart (CM32_Heart)	1	2 ⇨	CM32_HeartAb
5. Lungs and respiration (CM32_LungResp)	1	2 ⇨	CM32_LungRespAb
6. Abdomen (include bruits) (CM32_Abdomen)	1	2 ⇨	CM32_AbdomenAb
7. Liver (CM32_Liver)	1	2 ⇨	CM32_LiverAb
8. Musculoskeletal (CM32_Msculskltl)	1	2 ⇨	CM32_MsculskltlAb
9. Skin (CM32_Skin)	1	2 ⇨	CM32_SkinAb
10. Neurological (CM32_Neurolgcl)	1	2 ⇨	CM32_NeurolgclAb

Excluded at screening visit 1 if known primary neurologic conditions such as multiple sclerosis or Parkinson's disease, or any other neurological diseases known to affect bladder function.

	Normal	Abnormal	If abnormal, specify
11. Urogenital (CM32_Urogenital)	1	2 ⇨	CM32_UrogenitalAb

Excluded at screening visit 1 if daily use of a pad or device for incontinence required, or a baseline ICSmaleIS score > 14.

12. Digital Rectal Examination (DRE) performed by a physician:

(a) Prostate size: (CM32_Prostsize) gm

(b) Nodules or indurations: (CM32_Noduls) (1)Yes (2)No

(c) Asymmetry: (CM32_Asymtry) (1)Yes (2)No

(d) Suspicious for cancer: (CM32_Cncr) (1)Yes (2)No

Excluded at screening visit 1 if history or current evidence of carcinoma of the prostate or bladder.

(e) Tenderness: (1)Yes (2)No (CM32_Tender)

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
PSA Sample Collection and EKG Form (CAM41)

VisDate Visit Date: mm / dd / yyyy — VisMo / VisDy / VisYr

Participant ID: S — ParticipantId

VisitNo Visit Number: 01=SV1.0; 24=Week 24, 48=Week 48, 72=Week 72

Participant Initials — ParticipantIni

Serum PSA:

Was a serum PSA sample collected at this visit?

CM41_PSADone
- (1)Yes ⇨ If "Yes", record date of collection.
- (2)No ⇨ If "No", STOP.

CM41_PSADate: mm / dd / yyyy — CM41_PSAMo / CM41_PSADy / CM41_PSAYr

CM41_PSAShipped

*Was a serum PSA sample shipped to central lab?
- (1)Yes
- (2)No

CM41_PSAShipDate

*If "Yes", record the date of shipment: mm / dd / yyyy — CM41_PSAShipMo / CM41_PSAShipDy / CM41_PSAShipYr

PSA results from Central Lab: ____.__ ng/ml — CM41_PSAResult

For screening visit 1, *excluded if serum prostate specific antigen level > 10 ng/ml.*

****Does not apply to site# 277***

Reset

Draft

CAMUS Clinical Trial
Uroflow Measurement Form (CAM42)

Visit Date

VisDate ☐☐/☐☐/☐☐☐☐

mm VisMo | dd VisDy | yyyy VisYr

Participant ID

☐☐☐S☐☐☐

ParticipantId

Visit Number

VisitNo ☐☐

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

Participant Initials

☐☐☐ ParticipantIni

CM42_UroFlow

Were uroflow measurements done at this visit? ◯ (1)Yes ◯ (2)No ⇨ **If "No", stop here.**
If "Yes", record below.

CM42_VoidTime

1. Voiding time: ☐☐☐ sec

CM42_FlowTime

2. Flow time: ☐☐☐ sec

CM42_TimeMaxFlow

3. Time to maximum flow: ☐☐☐ sec

CM42_PeakFlowRt

4. Peak flow rate: ☐☐.☐ ml/sec

For screening visits 1 and 2: *Excluded if peak flow rate is less than 4 ml/sec.*

CM42_MeanFlowRt

5. Mean flow rate: ☐☐.☐ ml/sec

CM42_VoidVol

6. Voided volume: ☐☐☐☐ ml

For screening visits: *Excluded if voided volume < 125 ml.*

CM42_PostVoidRes

7. Post-void residual: ☐☐☐ ml

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
CBC, Serum Chemistries, Prothrombin Time and EKG Form (CAM45)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

Visit Number VisitNo ☐☐

01=SV1.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

Participant Initials ☐☐☐ ParticipantIni

---

1. **Complete blood count:** CM45_BloodCntDone

Was a complete blood count done at this visit? ◯ (1)Yes ◯ (2)No

If "No", skip to question 2. If "Yes", record below.

(a) Leukocyte count (WBC):	◯ Normal	◯ Abnormal	◯ Not Done	CM45_WBC
(b) Erythrocyte count (RBC):	◯ Normal	◯ Abnormal	◯ Not Done	CM45_RBC
(c) Hemoglobin:	◯ Normal	◯ Abnormal	◯ Not Done	CM45_Hgb
(d) Hematocrit:	◯ Normal	◯ Abnormal	◯ Not Done	CM45_Hct
(e) Platelet count:	◯ Normal	◯ Abnormal	◯ Not Done	CM45_PltCnt

If any values are abnormal, complete adverse events form (CAM81).

2. **Prothrombin time:** ☐☐ Seconds (CM45_Ptt) ☐☐ Upper limit of normal or control value (Seconds) (CM45_PttULN)

3. **Serum chemistries:** CM45_SerumChemDone

Was a serum chemistry panel done at this visit? ◯ (1)Yes ◯ (2)No

If "No", stop. If "Yes", record below.

(a) Sodium:	◯ Normal	◯ Abnormal	◯ Not Done	CM45_Sodium				
(b) Potassium:	◯ Normal	◯ Abnormal	◯ Not Done	CM45_Potasm				
(c) Chloride:	◯ Normal	◯ Abnormal	◯ Not Done	CM45_Chloride				
(d) Bicarbonate:	◯ Normal	◯ Abnormal	◯ Not Done	CM45_Bicarb				
(e) Glucose:	◯ Normal	◯ Abnormal	◯ Not Done	CM45_Glucose				
(f) Creatinine	◯ Normal	◯ Abnormal	◯ Not Done	CM45_Creat				
(g) ALT (SGPT):	CM45_SgptVal Value		CM45_SgptUnits Units		CM45_SgptULN ULN			
(h) AST (SGOT):	CM45_SgotValue Value		CM45_SgotUnits Units		CM45_SgotULN ULN			
(i) GGT:	CM45_GgtVal Value		CM45_GgtUnits Units		CM45_GgtULN ULN			

4. **Complete this section every Baseline, 24, 48 and 72 week visit only.**

Electrocardiogram: ◯ Normal ◯ Abnormal ◯ Not Done CM45_Ecg

If any values are abnormal, complete adverse events form (CAM81).

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Urinalysis Form (CAM46)

VisDate — Visit Date: ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID: ☐☐☐S☐☐☐ ParticipantId

VisitNo — Visit Number: ☐☐ (01=SV1.0, 72=Week 72)

Participant Initials: ☐☐☐ ParticipantIni

CM46_UrinDone

Was an urinalysis done at this visit? ☐ (1)Yes ⇨ **If "Yes", record the results below.**

☐ (2)No ⇨ **If "No", stop.**

(a) Dipstick

CM46_PH

(a1) pH: ☐.☐

	0	*trace*	*1+*	*2+*	*3+*	*4+*	
(a2) Glucose	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	CM46_UGlucose
(a3) Blood	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	CM46_UBlood
(a4) Ketones	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	CM46_UKetone
(a5) Protein	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	CM46_UProtein
(a6) Leukocyte esterase	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	CM46_ULeuko

(b) If dipstick is positive (> 0) for blood or leukocyte esterase, send specimen for microscopic urinalysis and code results below.

	none, negative, WNL	*1-5, trace, present, slight, rare*	*6-15, moderate*	*16-30, many, frequent*	*>30, innumerable, TNTC*	
(b1) WBC	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	CM46_UWBC
(b2) RBC	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	CM46_URBC
(b3) Epithelial cells	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	CM46_UEpiCell
(b4) Mucous	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	CM46_UMucous
(b5) Bacteria	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	CM46_UBacteria
(b6) Casts hyaline	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	CM46_UCstHyaln
(b7) Casts other	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	CM46_UCstOthr

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Serum for Banking Form (CAM47)

VisDate Visit Date ☐☐ / ☐☐ / ☐☐☐☐
mm VisMo dd VisDy yyyy VisYr

Participant ID ☐☐☐S☐☐☐
ParticipantId

VisitNo Visit Number ☐☐
01=SV1.0
72=Week 72

Participant Initials ☐☐☐ ParticipantIni

Was a serum sample collected at this visit?
CM47_SerumDone

☐ (1)Yes ⇨ If "Yes",

CM47_SerumDate
Date of collection: ☐☐ / ☐☐ / ☐☐☐☐
mm CM47_SerumMo dd CM47_SerumDy yyyy CM47_SerumYr

☐ (2)No ⇨ If specimens were not obtained for CAMUS, please indicate reason (Check only one).
CM47_SerumNotDone

☐ (1)Patient refused to give informed consent for CAMUS serum studies (banking).

☐ (2)Patient was not asked to consider CAMUS serum studies (banking).

CM47_Specify

☐ (3)Other, specify: _____

CM47_SerumShipped
Was a serum sample shipped to NIDDK repository?
☐ (1)Yes
☐ (2)No

CM47_SerumShipDate
If "Yes", record the date of shipment: ☐☐ / ☐☐ / ☐☐☐☐
mm CM47_SerumShipMo dd CM47_SerumShipDy yyyy CM47_SerumShipYr

---

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Study Drug Administration and Compliance Form (CAM51)

VisDate — Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (Month / Day / Year)

VisMo VisDy VisYr

VisitNo — Visit Number: ☐☐

03=Baseline	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

Participant ID: ☐☐☐S☐☐☐ — ParticipantId

Participant Initials: ☐☐☐ — ParticipantIni

For the initial visit, leave the "Number of capsules returned" blank. For the last visit, leave the "Number of capsules dispensed" blank.

I. Study drug administrations:

CM51_TabRetYN

Were capsules returned at this visit? ◯ (1)Yes ◯ (2)No ⇨ **If "Yes", record the number of capsules returned below.**

CM51_TabDispYN

Were capsules dispensed at this visit? ◯ (1)Yes ◯ (2)No ⇨ **If "Yes", record the number of capsules dispensed below.**

Date capsules returned/dispensed	**Number of capsules returned**	**Number of capsules dispensed**
CM51_RetDispMo / CM51_RetDispDy / CM51_RetDispYr **Month / Day / Year**	CM51_TabRetA	CM51_TabDispA

II. Was study medication temporarily interrupted since last visit?

CM51_InterruptMed

◯ (1) Yes ⇨ If yes, for how many days: CM51_DaysInterrupt ☐☐☐☐

◯ (2) No

III. Participant Compliance Calculation:

CM51_TabTkn1A

# of capsules taken by participant ☐☐☐

# of capsules participant should have taken ☐☐☐ (CM51_TabTkn2A)

x 100 = ☐☐☐.☐☐% **Compliance** (CM51_ComplianceA)

IV. Complete this section for every 12 week visit only:

Record below the time of day in which the participant typically take his medications.

Time — CM51_DrugTime ☐☐

AM or PM — CM51_DrugAMPM

◯ (1) AM

◯ (2) PM

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
BPH Outcome Events Form (CAM61)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

VisitNo Visit Number ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

Participant Initials ☐☐☐ ParticipantIni

To be completed each time a participant meets the protocol definition for BPH progression.

A. BPH Outcomes:

1. Specify the classification of the outcome for the participant below, check only one.

CM61_BPHProgAssmnt

- ☐ (1) Acute urinary retention (Complete Section B)
- ☐ (2) Recurrent symptomatic urinary tract infection or urosepsis (Complete Section B)
- ☐ (3) New incontinence or progression of minor incontinence (Complete Section B)
- ☐ (4) Crossover to invasive or medical therapy for BPH (Complete Section C)

B. Urinary Event Specification:

1. Specify the type of urinary event (check all that apply):

CM61_AcuteUrinReten

Date of last event (mm / dd / yyyy)

a. ☐ Acute urinary retention — CM61_EventMoA / CM61_EventDyA / CM61_EventYrA

CM61_RecurSymptUTI

b. ☐ Recurrent symptomatic urinary tract infection or urosepsis — CM61_EventMoB / CM61_EventDyB / CM61_EventYrB

c. ☐ New incontinence or progression of minor incontinence — CM61_EventMoC / CM61_EventDyC / CM61_EventYrC

CM61_NewIncontnce

Investigator Signature Required on page 2.

Reset

Draft

CAMUS Clinical Trial
BPH Outcome Events Form (CAM61)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

VisitNo Visit Number ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

Participant Initials ☐☐☐ ParticipantIni

C. Crossover to Invasive or Medical Therapy for BPH or Phytotherapy Specification :

1. Specify the invasive or medical therapy for BPH or phytotherapy (check all that apply):

☐ (1) TURP CM61_TURP

☐ (1) TUIP CM61_TUIP

☐ (1) Radical prostatectomy CM61_RadProst

☐ (1) Open prostatectomy CM61_OpenProst

☐ (1) TUNA CM61_TUNA

☐ (1) Microwave therapy CM61_MicrowavThrpy

☐ (1) Laser therapy CM61_LaserThrpy

☐ (1) Stent CM61_Stent

☐ (1) Other invasive therapy CM61_OthInvThrpy
Specify other invasive therapy: CM61_InvThrpySpec1 _____ CM61_InvThrpySpec2 _____

☐ (1) Other phytotherapy CM61_OthPhytoThrpy
Specify other phytotherapy therapy: CM61_PhytoThrpySpec1 _____ CM61_PhytoThrpySpec2 _____

☐ (1) Other medical therapy CM61_OthMedThrpy
Specify other medical therapy: CM61_MedThrpySpec1 _____ CM61_MedThrpySpec2 _____

2. Primary reason given by participant for switching to another therapy for BPH (check one): CM61_SwitchThrpy

☐ (1) Lack of improvement in prostate symptoms

☐ (2) Worsening of prostate symptoms

☐ (3) Intolerable side effects ⇨ Specify: CM61_SideEffct _____

☐ (4) Other ⇨ Specify: _____ CM61_Other

Investigator Signature: _____ **Date:** _____

Draft

Ensayo Clínico CAMUS
Formulario de Escala de Disfunción del Sueño Jenkins (CAM71S)

VisDate Fecha de la visita ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / aaaa VisYr)

Identificación del participante ☐☐☐S☐☐☐ ParticipantId

VisitNo Número de la visita ☐☐ (0 3 =Inicio; 24=Semana 24; 48=Semana 48; 72=Semana 72)

Iniciales del participante ☐☐☐ ParticipantIni

El participante rellena este formulario.

Instrucciones: *Para cada pregunta, marque la caja que mejor describa su condición.*

Durante el mes pasado, ¿cuántas veces:

	para nada	*1-3 días*	*4-7 días*	*8-14 días*	*15-21 días*	*22-31 días*
1. tuvo problemas para dormir? CM71_Quest1	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. se despertó varias veces durante la noche? CM71_Quest2	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. tuvo problemas para permanecer dormido (incluyendo despertarse demasiado temprano)? CM71_Quest3	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. se despertó sintiéndose cansado y agotado después de un tiempo normal de sueño? CM71_Quest4	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Iniciales del Participante : _____ **Fecha:** _____

Reset

Draft

CAMUS Clinical Trial
Jenkins Sleep Dysfunction Scale Form (CAM71)

VisDate Visit Date ☐☐/ ☐☐/ ☐☐☐☐
mm VisMo dd VisDy yyyy VisYr

Participant ID ☐☐☐S☐☐☐
ParticipantId

VisitNo Visit Number ☐☐

03=Baseline	24=Week 24 48=Week 48 72=Week 72

Participant Initials ☐☐☐ ParticipantIni

This form is completed by the participant.

Instructions: *For each question, check the one box that best describes your condition.*

In the past month, how often did you:

	not at all	*1-3 days*	*4-7 days*	*8-14 days*	*15-21 days*	*22-31 days*
1. Have trouble falling asleep? CM71_Quest1	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. Wake up several times per night? CM71_Quest2	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. Have trouble staying asleep (including waking far too early)? CM71_Quest3	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. Wake up after your usual amount of sleep feeling tired and worn out? CM71_Quest4	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Participant Initials : _____ **Date:** _____

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

Ensayo Clínico CAMUS
Formulario de Función Eréctil (CAM72S)

VisDate — Fecha de la visita: mm (VisMo) / dd (VisDy) / aaaa (VisYr)

Identificación del participante: S — ParticipantId

VisitNo — Número de la visita: 0 3 =Inicio; 24=Semana 24; 48=Semana 48; 72=Semana 72

Iniciales del participante: ParticipantIni

El participante rellena este formulario.

Instrucciones: *Para cada pregunta, marque la caja que mejor describa su condición.*

Durante el mes pasado:

1. ¿Con qué frecuencia pudo obtener la erección durante la actividad sexual? CM72_Quest1

- ☐ (0) no hubo actividad sexual
- ☐ (1) nunca a casi nunca
- ☐ (2) unas cuantas veces (mucho menos de la mitad de las veces)
- ☐ (3) a veces (más a menos la mitad de las veces)
- ☐ (4) la mayoría de la veces (mucho más de la mitad de las veces)
- ☐ (5) siempre o casi siempre

2. Cuando tuvo erecciones con estímulo sexual, ¿con qué frecuencia fueron lo suficientemente firmes como para que hubiera penetración? CM72_Quest2

- ☐ (0) no hubo actividad sexual
- ☐ (1) nunca a casi nunca
- ☐ (2) unas cuantas veces (mucho menos de la mitad de las veces)
- ☐ (3) a veces (más a menos la mitad de las veces)
- ☐ (4) la mayoría de las veces (mucho más de la mitad de las veces)
- ☐ (5) siempre o casi siempre

3. Cuando trató de tener relaciones sexuales, ¿con qué frecuencia pudo penetrar (entrar) en su pareja? CM72_Quest3

- ☐ (0) no traté de tener relaciones sexuales
- ☐ (1) nunca a casi nunca
- ☐ (2) unas cuantas veces (mucho menos de la mitad de las veces)
- ☐ (3) a veces (más a menos la mitad de las veces)
- ☐ (4) la mayoría de la veces (mucho más de la mitad de las veces)
- ☐ (5) siempre o casi siempre

4. Durante las relaciones sexuales, ¿<u>con qué frecuencia</u> pudo mantener su erección después de haber penetrado (entrado) en su pareja? CM72_Quest4

- ☐ (0) no traté de tener relaciones sexuales
- ☐ (1) nunca a casi nunca
- ☐ (2) unas cuantas veces (mucho menos de la mitad de las veces)
- ☐ (3) a veces (más a menos la mitad de las veces)
- ☐ (4) la mayoría de la veces (mucho más de la mitad de las veces)
- ☐ (5) siempre o casi siempre

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

Ensayo Clínico CAMUS
Formulario de Función Eréctil (CAM72S)

VisDate — Fecha de la visita: mm (VisMo) / dd (VisDy) / aaaa (VisYr)

Identificación del participante: S — ParticipantId

VisitNo — Número de la visita: 0 3 =Inicio; 24=Semana 24; 48=Semana 48; 72=Semana 72

Iniciales del participante — ParticipantIni

5. Durante las relaciones sexuales, ¿cuán difícil fue mantener su erección para terminar el coito? CM72_Quest5

- ☐ (0) no traté de tener relaciones sexuales
- ☐ (1) sumamente difícil
- ☐ (2) muy difícil
- ☐ (3) difícil
- ☐ (4) un poco difícil
- ☐ (5) no fue difícil

6. ¿Cómo calificaría su confianza en que puede obtener y mantener la erección? CM72_Quest6

- ☐ (1) muy baja
- ☐ (2) baja
- ☐ (3) moderada
- ☐ (4) alta
- ☐ (5) muy alta

7. Cuando tuvo estímulo sexual o relaciones sexuales, ¿con qué frecuencia eyaculó? CM72_Quest7

- ☐ (0) no hubo estímulo ni relaciones sexuales
- ☐ (1) nunca a casi nunca
- ☐ (2) unas cuantas veces (mucho menos de la mitad de las
- ☐ (3) a veces (más a menos la mitad de las veces)
- ☐ (4) la mayoría de las veces (mucho más de la mitad de las veces)
- ☐ (5) siempre o casi siempre

8. Cuando tuvo estímulo o relaciones sexuales, ¿con qué frecuencia tuvo la sensación de orgasmo o clímax? CM72_Quest8

- ☐ (0) no hubo estímulo ni relaciones sexuales
- ☐ (1) nunca a casi nunca
- ☐ (2) unas cuantas veces (mucho menos de la mitad de las veces)
- ☐ (3) a veces (más a menos la mitad de las veces)
- ☐ (4) la mayoría de las veces (mucho más de la mitad de las veces)
- ☐ (5) siempre o casi siempre

9. Si tuviera que pasar el resto de su vida con su condición eréctil así como es ahora, ¿cómo se sentiría al respecto? CM72_Quest9

- ☐ (1) muy insatisfecho
- ☐ (2) moderadamente insatisfecho
- ☐ (3) igualmente satisfecho que insatisfecho
- ☐ (4) moderadamente satisfecho
- ☐ (5) muy satisfecho

Iniciales del Participante : _____ **Fecha:** _____

Draft

CAMUS Clinical Trial
Erectile Function Form (CAM72)

VisDate Visit Date ____/____/____ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ____S____ ParticipantId

VisitNo Visit Number ____ (03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72)

Participant Initials ____ ParticipantIni

This form is completed by the participant.

Instructions: *For each question, check the one box that best describes your condition.*

In the past month:

1. How often were you able to get an erection during sexual activity? CM72_Quest1

- ☐ (0) no sexual activity
- ☐ (1) never or almost never
- ☐ (2) a few times (much less than half the time)
- ☐ (3) sometimes (about half the time)
- ☐ (4) most times (much more than half the time)
- ☐ (5) always or almost always

2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration? CM72_Quest2

- ☐ (0) no sexual activity
- ☐ (1) never or almost never
- ☐ (2) a few times (much less than half the time)
- ☐ (3) sometimes (about half the time)
- ☐ (4) most times (much more than half the time)
- ☐ (5) always or almost always

3. When you attempted sexual intercourse, how often were you able to penetrate (enter) your partner? CM72_Quest3

- ☐ (0) did not attempt sexual intercourse
- ☐ (1) never or almost never
- ☐ (2) a few times (much less than half the time)
- ☐ (3) sometimes (about half the time)
- ☐ (4) most times (much more than half the time)
- ☐ (5) always or almost always

4. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner? CM72_Quest4

- ☐ (0) did not attempt sexual intercourse
- ☐ (1) never or almost never
- ☐ (2) a few times (much less than half the time)
- ☐ (3) sometimes (about half the time)
- ☐ (4) most times (much more than half the time)
- ☐ (5) always or almost always

Reset

Draft

CAMUS Clinical Trial
Erectile Function Form (CAM72)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

VisitNo Visit Number ☐☐ (03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72)

Participant Initials ☐☐☐ ParticipantIni

5. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse? CM72_Quest5

- ☐ (0) did not attempt intercourse
- ☐ (1) extremely difficult
- ☐ (2) very difficult
- ☐ (3) difficult
- ☐ (4) slightly difficult
- ☐ (5) not difficult

6. How do you rate your confidence that you could get and keep an erection? CM72_Quest6

☐ (1) very low ☐ (2) low ☐ (3) moderate ☐ (4) high ☐ (5) very high

7. When you had sexual stimulation or intercourse, how often did you ejaculate? CM72_Quest7

- ☐ (0) no sexual stimulation or intercourse
- ☐ (1) never or almost never
- ☐ (2) a few times (much less than half the time)
- ☐ (3) sometimes (about half the time)
- ☐ (4) most times (much more than half the time)
- ☐ (5) always or almost always

8. When you had sexual stimulation or intercourse, how often did you have the feeling of orgasm or climax? CM72_Quest8

- ☐ (0) no sexual stimulation or intercourse
- ☐ (1) never or almost never
- ☐ (2) a few times (much less than half the time)
- ☐ (3) sometimes (about half the time)
- ☐ (4) most times (much more than half the time)
- ☐ (5) always or almost always

9. If you have to spend the rest of your life with your erectile condition just the way it is now, how would you feel about that? CM72_Quest9

- ☐ (1) very dissatisfied
- ☐ (2) moderately dissatisfied
- ☐ (3) about equally satisfied and dissatisfied
- ☐ (4) moderately satisfied
- ☐ (5) very satisfied

Participant Initials : _____ **Date:** _____

Draft

Ensayo Clínico CAMUS
Formulario de Función Eyaculatoria (CAM73S)

VisDate Fecha de la visita ____/____/____ (mm VisMo / dd VisDy / aaaa VisYr)

Identificación del participante ___S____ ParticipantId

VisitNo Número de la visita ____

03=Inicio	24=Semana 24 48=Semana 48 72=Semana 72

Iniciales del participante ___ ParticipantIni

El participante rellena este formulario.

Instrucciones: *Estas preguntas se relacionan con la eyaculación. La eyaculación es la liberación de semen durante el orgasmo sexual. A través de sus respuestas a estas preguntas deseamos saber de todas sus eyaculaciones durante la actividad sexual. Éstas podrían incluir las eyaculaciones que usted ha tenido con su esposa o pareja principal, así como las que ha tenido con otras parejas o las que podría haber tenido al masturbarse.*

1. ¿Durante el mes pasado, con qué frecuencia eyaculó durante la actividad sexual?

☐ (1) todo el tiempo
☐ (2) la mayor parte del tiempo
☐ (3) parte del tiempo
☐ (4) poca parte del tiempo
☐ (5) nunca
☐ (6) no he tenido actividad sexual

CM73_Quest1

2. Durante el mes pasado, ¿cómo calificaría usted la fuerza de sus eyaculaciones? ¿Diría usted que fue...

☐ (1) tan fuerte como siempre
☐ (2) un poco menos que antes
☐ (3) algo menos que antes
☐ (4) mucho menos que antes
☐ (5) significativamente menos que antes
☐ (6) no eyaculé

CM73_Quest2

3. Durante el mes pasado, ¿cómo calificaré usted la cantidad o el volumen de semen cuando eyaculó? ¿Diría usted que fue...

☐ (1) tanto como siempre
☐ (2) un poco menos que antes
☐ (3) algo menos que antes
☐ (4) mucho menos que antes
☐ (5) significativamente menos que antes
☐ (6) no eyaculé

CM73_Quest3

4. Durante el mes pasado, si ha tenido dificultades para eyacular o no ha podido hacerlo, ¿le ha molestado esto?

☐ (1) no me ha molestado para nada
☐ (2) me ha molestado un poco
☐ (3) me ha molestado moderadamente
☐ (4) me ha molestado mucho
☐ (5) me ha molestado en extremo

CM73_Quest4

Iniciales del Participante : _____ **Fecha:** _____

Reset

Draft

CAMUS Clinical Trial
Ejaculatory Function Form (CAM73)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

VisitNo Visit Number ☐☐ (03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72)

Participant Initials ☐☐☐ ParticipantIni

This form is completed by the participant.

Instructions: *These questions are about male ejaculation. Ejaculation or cumming is the release of semen or cum during sexual climax. In answering these questions, we want to know about all of your ejaculations when having sexual activity. These could include ejaculations you have had with your wife or main partner, as well as with other partners, or ejaculations you could have had when masturbating by yourself.*

1. In the past month, how often have you been able to ejaculate when having sexual activity?
   - ☐ (1) all of the time
   - ☐ (2) most of the time
   - ☐ (3) some of the time
   - ☐ (4) a little of the time
   - ☐ (5) none of the time CM73_Quest1
   - ☐ (6) no sexual activity

2. In the past month, how would you rate the strength or force of your ejaculation? Would you say it is...
   - ☐ (1) as strong as it always was
   - ☐ (2) a little less than it used to be
   - ☐ (3) somewhat less than it used to be
   - ☐ (4) much less than it used to be
   - ☐ (5) very much less than it used to be CM73_Quest2
   - ☐ (6) did not ejaculate

3. In the past month, how would you rate the amount or volume of semen when you ejaculate? Would you say it is...
   - ☐ (1) as much as it always was
   - ☐ (2) a little less than it used to be
   - ☐ (3) somewhat less than it used to be
   - ☐ (4) much less than it used to be
   - ☐ (5) very much less than it used to be CM73_Quest3
   - ☐ (6) did not ejaculate

4. In the past month, if you have had any ejaculation difficulties or have been unable to ejaculate, have you been bothered by this?
   - ☐ (1) not at all bothered
   - ☐ (2) a little bit bothered
   - ☐ (3) moderately bothered
   - ☐ (4) very bothered
   - ☐ (5) extremely bothered CM73_Quest4

Participant Initials : _____ **Date:** _____

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

Ensayo Clínico CAMUS
Formulario de Función de la Vejiga (CAM74S)

VisDate Fecha de la visita ☐☐/☐☐/☐☐☐☐
mm VisMo dd VisDy aaaa VisYr

Identificación del participante ☐☐☐S☐☐☐
ParticipantId

VisitNo Número de la visita ☐☐

02=SV2.0	12=Semana 12 24=Semana 24	36=Semana 36 48=Semana 48	60=Semana60 72=Semana 72

Iniciales del participante ☐☐☐ ParticipantIni

El participante rellena este formulario.

Instrucciones: *Nos gustaría saber algo de sus síntomas urinarios y agradecemos mucho el que pueda ayudarnos llenando este cuestionario. Por favor, conteste las preguntas pensando en los síntomas que ha tenido durante el mes pasado. Verá que algunas preguntas se refieren a la frecuencia con que se le presenta un síntoma:*

De vez en cuando = menos de una tercera parte del tiempo
A veces = entre una y dos terceras partes del tiemp
La mayor parte del tiempo = más de las dos terceras partes del tiempo

Durante el <u>mes pasado</u>, ¿con qué frecuencia:

1. tuvo que apresurarse a llegar al baño para orinar?

☐ (0) nunca
☐ (1) de vez en cuando
☐ (2) a veces
☐ (3) la mayor parte del tiempo CM74_Quest1
☐ (4) todo el tiempo

2. se le salió la orina antes de que pudiera llegar al baño?

☐ (0) nunca
☐ (1) de vez en cuando
☐ (2) a veces
☐ (3) la mayor parte del tiempo CM74_Quest2
☐ (4) todo el tiempo

3. se le salió la orina cuando tosió o estornudó?

☐ (0) nunca
☐ (1) de vez en cuando
☐ (2) a veces
☐ (3) la mayor parte del tiempo CM74_Quest3
☐ (4) todo el tiempo

Reset

Ensayo Clínico CAMUS
Formulario de Función de la Vejiga (CAM74S)

VisDate — Fecha de la visita: mm (VisMo) / dd (VisDy) / aaaa (VisYr)

Identificación del participante: S — ParticipantId

VisitNo — Número de la visita: 02=SV2.0 | 12=Semana 12, 24=Semana 24 | 36=Semana 36, 48=Semana 48 | 60=Semana60, 72=Semana 72

Iniciales del participante — ParticipantIni

Durante el mes pasado, ¿con qué frecuencia:

4. se le salió la orina sin ninguna razón obvia y sin sentir deseos de ir al baño?

☐ (0) nunca
☐ (1) de vez en cuando
☐ (2) a veces
☐ (3) la mayor parte del tiempo
☐ (4) todo el tiempo

CM74_Quest4

5. se le salió la orina mientras dormía?

☐ (0) nunca
☐ (1) de vez en cuando
☐ (2) a veces
☐ (3) la mayor parte del tiempo
☐ (4) todo el tiempo

CM74_Quest5

6. se le mojaron los pantalones ligeramente unos pocos minutos después de haber terminado de orinar?

☐ (0) nunca
☐ (1) de vez en cuando
☐ (2) a veces
☐ (3) la mayor parte del tiempo
☐ (4) todo el tiempo

CM74_Quest6

To be completed by the study coordinator: *ICSmaleIS Score = (Total of items 1-6.)* ☐☐☐☐ CM74_ICSmaleIS

7. Si tuviera que pasar el resto de su vida con la función urinaria o de la vejiga así como es ahora, ¿cómo se sentiría al respecto?

☐ (1) muy insatisfecho
☐ (2) moderadamente insatisfecho
☐ (3) más o menos igualmente satisfecho que insatisfecho
☐ (4) moderadamente satisfecho
☐ (5) muy satisfecho

CM74_Quest7

Iniciales del Participante : _____ **Fecha:** _____

Draft

CAMUS Clinical Trial
Bladder Function Form (CAM74)

Visit Date VisDate ☐☐/ ☐☐/ ☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

Visit Number VisitNo ☐☐

02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

Participant Initials ☐☐☐ ParticipantIni

This form is completed by the participant.

Instructions: *We would like to find out about your urinary symptoms and we are very grateful that you can help us by filling in this questionnaire. Please answer each question, thinking about the symptoms you have experienced in the last month. You will see that some questions ask how often you have a symptom:*

Occasionally = less than one third of the time
Sometimes = between one and two thirds of the time
Most of the time = more than two thirds of the time

In the <u>past month</u> how often:

1. Did you have to rush to the toilet to urinate?

☐ (0) never
☐ (1) occasionally
☐ (2) sometimes
☐ (3) most of the time CM74_Quest1
☐ (4) all of the time

2. Did urine leak before you could get to the toilet?

☐ (0) never
☐ (1) occasionally
☐ (2) sometimes
☐ (3) most of the time CM74_Quest2
☐ (4) all of the time

3. Did urine leak when you coughed or sneezed?

☐ (0) never
☐ (1) occasionally
☐ (2) sometimes
☐ (3) most of the time CM74_Quest3
☐ (4) all of the time

Reset

Draft

CAMUS Clinical Trial
Bladder Function Form (CAM74)

Visit Date
VisDate ☐☐/ ☐☐/ ☐☐☐☐
mm dd yyyy
VisMo VisDy VisYr

Participant ID
☐☐☐S☐☐☐
ParticipantId

Visit Number
VisitNo ☐☐

02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

Participant Initials
☐☐☐ ParticipantIni

In the <u>past month</u> how often:

4. Did you leak for no obvious reason and without feeling that you wanted to go?

☐ (0) never
☐ (1) occasionally
☐ (2) sometimes
☐ (3) most of the time CM74_Quest4
☐ (4) all of the time

5. Did you leak urine when you were asleep?

☐ (0) never
☐ (1) occasionally
☐ (2) sometimes
☐ (3) most of the time CM74_Quest5
☐ (4) all of the time

6. Did you have a slight wetting of your pants a few minutes after you had finished urinating?

☐ (0) never
☐ (1) occasionally
☐ (2) sometimes
☐ (3) most of the time CM74_Quest6
☐ (4) all of the time

To be completed by the study coordinator: *ICSmaleIS Score =* ☐☐☐☐ CM74_ICSmaleIS
(Total of items 1-6.)

7. If you had to spend the rest of your life with your urinary or bladder function just the way it is now, how would you feel about that?

☐ (1) very dissatisfied
☐ (2) moderately dissatisfied
☐ (3) about equally satisfied and dissatisfied
☐ (4) moderately satisfied CM74_Quest7
☐ (5) very satisfied

Participant Initials : _____ **Date:** _____

Draft

Ensayo Clínico CAMUS
Formulario IPSS de Calificación Internacional de Síntomas de Próstata (CAM75S)
(Calificación de Síntomas AUA y Preguntas acerca de la calidad de vida IPSS)

VisDate Fecha de la visita ☐☐/☐☐/☐☐☐☐ (mm/dd/aaaa) VisMo VisDy VisYr

Identificación del participante ☐☐☐S☐☐☐ ParticipantId

Número de la visita VisitNo ☐☐

01=SV1.0 02=SV2.0	12=Semana 12 24=Semana 24	36=Semana 36 48=Semana 48	60=Semana 60 72=Semana 72

Iniciales del participante ☐☐☐ ParticipantIni

El participante rellena este formulario.

Instrucciones: *Para cada pregunta, marque la caja que mejor describa su condición.*

	nunca	*menos de 1 en 5 veces*	*menos de la mitad de las veces*	*alrededor de la mitad de las veces*	*más de la mitad de las veces*	*casi siempre*
1. Durante el mes pasado, ¿con qué frecuencia ha tenido la sensación de que su vejiga no se vaciaba completamente después de terminar de orinar?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest1			
2. Durante el mes pasado, ¿con qué frecuencia ha tenido que volver a orinar durante las dos horas después de haber terminado de orinar?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest2			
3. Durante el mes pasado, ¿con qué frecuencia se dio cuenta de que había parado y comenzado varias veces cuando orinaba?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest3			
4. Durante el mes pasado, ¿con qué frecuencia ha encontrado difícil el posponer orinar?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest4			
5. Durante el mes pasado, ¿con qué frecuencia ha tenido el flujo de orina débil?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest5			
6. Durante el mes pasado, ¿con qué frecuencia ha tenido que empujar o hacer un esfuerzo para comenzar a orinar?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest6			

7. Durante el mes pasado, ¿cuántas veces se ha levantado durante la noche para orinar desde el momento en que se acostó hasta que se levantó en la mañana?

CM75_Quest7

☐ (0) ninguna ☐ (1) 1 vez ☐ (2) 2 veces ☐ (3) 3 veces ☐ (4) 4 veces ☐ (5) 5 veces o más

To be completed by the study coordinator: *AUASS* = ☐☐☐☐ CM75_AUASS
(Total of items 1-7.)

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Ensayo Clínico CAMUS
Formulario IPSS de Calificación Internacional de Síntomas de Próstata (CAM75S)
(Calificación de Síntomas AUA y Preguntas acerca de la calidad de vida IPSS)

VisDate Fecha de la visita mm dd aaaa
VisMo VisDy VisYr

Identificación del participante
S
ParticipantId

VisitNo Número de la visita

01=SV1.0 02=SV2.0	12=Semana 12 24=Semana 24	36=Semana 36 48=Semana 48	60=Semana 60 72=Semana 72

Iniciales del participante
ParticipantIni

8. Si tuviera que pasar el resto de su vida con su condición urinaria como es ahora, ¿cómo se sentiría con respecto a eso?

- ☐ (1) muy feliz
- ☐ (2) feliz
- ☐ (3) satisfecho
- ☐ (4) satisfecho e insatisfecho (los dos sentimientos igualmente) CM75_Quest8
- ☐ (5) insatisfecho
- ☐ (6) triste
- ☐ (7) terrible

9. Durante el mes pasado, cuando sentía deseos de orinar, ¿con qué frecuencia dejó escapar orina antes de poder llegar al baño?

- ☐ (1) nunca
- ☐ (2) menos de 1 en 5 veces
- ☐ (3) menos de la mitad de las veces

CM75_Quest9

- ☐ (4) casi la mitad de las veces
- ☐ (5) más de la mitad de las veces
- ☐ (6) casi siempre

Iniciales del Participante : _____ **Fecha:** _____

Draft

CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

VisitNo Visit Number ☐☐

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

Participant Initials ☐☐☐ ParticipantIni

This form is completed by the participant.

Instructions: *For each question, check the one box that best describes your condition.*

	not at all	*less than 1 time in 5*	*less than half the time*	*about half the time*	*more than half the time*	*almost always*
1. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest1			
2. Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest2			
3. Over the past month, how often have you found you stopped and started again several times when you urinated?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest3			
4. Over the past month, how often have you found it difficult to postpone urination?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest4			
5. Over the past month, how often have you had a weak urinary stream?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest5			
6. Over the past month, how often have you had to push or strain to begin urination?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
			CM75_Quest6			

7. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning? CM75_Quest7

☐ (0) none ☐ (1) 1 time ☐ (2) 2 times ☐ (3) 3 times ☐ (4) 4 times ☐ (5) 5 or more times

To be completed by the study coordinator: *AUASS =* ☐☐☐☐ CM75_AUASS
(Total of items 1-7.)

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

Visit Date
VisDate ☐☐/☐☐/☐☐☐☐
mm VisMo dd VisDy yyyy VisYr

Participant ID
☐☐☐S☐☐☐
ParticipantId

Visit Number
VisitNo ☐☐

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

Participant Initials
☐☐☐ ParticipantIni

8. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?

- ☐ (1) Delighted
- ☐ (2) Pleased
- ☐ (3) Mostly satisfied
- ☐ (4) Mixed-about equally satisfied and dissatisfied CM75_Quest8
- ☐ (5) Mostly dissatisfied
- ☐ (6) Unhappy
- ☐ (7) Terrible

9. Over the past month, how often when you felt the urge to urinate, did you leak urine before you could get to the toilet?

- ☐ (1) Not at all
- ☐ (2) Less than 1 time in 5
- ☐ (3) Less than half the time

CM75_Quest9

- ☐ (4) About half the time
- ☐ (5) More than half the time
- ☐ (6) Almost always

Participant Initials : _____ **Date:** _____

Draft

Ensayo Clínico CAMUS
Formulario de Índice de Impacto BPH (CAM76S)

VisDate Fecha de la visita ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / aaaa VisYr)

Identificación del participante ☐☐☐S☐☐☐ ParticipantId

VisitNo Número de la visita ☐☐ (02=SV2.0 | 12=Semana 12, 24=Semana 24 | 36=Semana 36, 48=Semana 48 | 60=Semana 60, 72=Semana 72)

Iniciales del participante ☐☐☐ ParticipantIni

El participante rellena este formulario.

Instrucciones: *Para cada pregunta, marque la caja que mejor describa su afección urinaria.*

1. Durante el mes pasado, ¿cuánta molestia física le causaban los problemas urinarios?

CM76_Quest1 ☐ (0) ninguna ☐ (1) sólo un poco ☐ (2) alguna ☐ (3) mucha

2. Durante el mes pasado, ¿cuánto se preocupó por su salud a causa de algún problema urinario?

CM76_Quest2 ☐ (0) nada ☐ (1) sólo un poco ☐ (2) algo ☐ (3) mucho

3. En general, ¿cuán molesto le ha sido cualquier problema urinario durante el mes pasado?

☐ (0) no me molesta

☐ (1) me molesta un poco

CM76_Quest3 ☐ (2) me molesta algo

☐ (3) me molesta mucho

4. Durante el mes pasado, ¿por cuánto tiempo le ha impedido cualquier problema urinario hacer las cosas que normalmente hace?

☐ (0) nunca

☐ (1) un poco de tiempo

CM76_Quest4 ☐ (2) parte del tiempo

☐ (3) la mayor parte del tiempo

☐ (4) todo el tiempo

To be completed by the study coordinator: *BPH Impact Index Score =* ☐☐☐☐ CM76_BPHImpScre
(Total of items 1-4.)

5. En comparación con el inicio del estudio, ¿cómo se siente en este momento con respecto a su situación urinaria?

CM76_Quest5 ☐ (1) peor ☐ (2) igual ☐ (3) un poco mejor ☐ (4) mucho mejor

Iniciales del Participante : _____ **Fecha:** _____

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
BPH Impact Index Form (CAM76)

Visit Date
VisDate mm VisMo / dd VisDy / yyyy VisYr

Participant ID
S
ParticipantId

Visit Number
VisitNo

02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

Participant Initials
ParticipantIni

This form is completed by the participant.

Instructions: *For each question, check the one box that best describes your urinary condition.*

1. Over the past month, how much physical discomfort did any urinary problems cause you?

CM76_Quest1 ☐ (0) none ☐ (1) only a little ☐ (2) some ☐ (3) a lot

2. Over the past month, how much did you worry about your health because of any urinary problems?

CM76_Quest2 ☐ (0) none ☐ (1) only a little ☐ (2) some ☐ (3) a lot

3. Overall, how bothersome has any trouble with urination been during the past month?

☐ (0) not at all bothersome
☐ (1) bothers me a little
CM76_Quest3
☐ (2) bothers me some
☐ (3) bothers me a lot

4. Over the past month, how much of the time has any urinary problem kept you from doing the kinds of things you would usually do?

☐ (0) none of the time
☐ (1) a little of the time
CM76_Quest4 ☐ (2) some of the time
☐ (3) most of the time
☐ (4) all of the time

To be completed by the study coordinator: *BPH Impact Index Score =* CM76_BPHImpScre
(Total of items 1-4.)

5. Compared to the beginning of the study, how do you feel about your urination now?

CM76_Quest5 ☐ (1) worse ☐ (2) no change ☐ (3) a little better ☐ (4) a lot better

Participant Initials : _____ **Date:** _____

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

Ensayo Clínico CAMUS
Formulario de Evaluación Global Subjetiva (CAM77S)

VisDate — Fecha de la visita: mm / dd / aaaa (VisMo / VisDy / VisYr)

Identificación del participante: S — ParticipantId

VisitNo — Número de la visita: 24=Semana 24, 48=Semana 48, 72=Semana 72

Iniciales del participante — ParticipantIni

El participante rellena este formulario.

Instrucciones: *Para cada pregunta, marque la caja que mejor describa los síntomas de su afección urinaria.*

1. En comparación con el inicio del estudio, ¿cómo se encuentran ahora sus síntomas urinarios?

☐ (1) Mucho mejor ☐ (4) Casi igual ☐ (7) Mucho peor
☐ (2) Mejor ☐ (5) Un poco peor
☐ (3) Un poco mejor ☐ (6) Peor

CM77_Quest1

2. ¿Cuán satisfecho o insatisfecho se encuentra usted con cualquiera de los síntomas urinarios que tiene?

☐ (1) Muy satisfecho ☐ (4) Insatisfecho
☐ (2) Satisfecho ☐ (5) Muy insatisfecho
☐ (3) Ni satisfecho ni insatisfecho

CM77_Quest2

3. En comparación con el inicio del estudio, ¿cómo se encuentran ahora sus síntomas de incontinencia urinaria?

☐ (1) Mucho mejor ☐ (4) Casi igual ☐ (7) Mucho peor
☐ (2) Mejor ☐ (5) Un poco peor
☐ (3) Un poco mejor ☐ (6) Peor

CM77_Quest3

4. ¿Cuán satisfecho o insatisfecho se encuentra usted con cualquiera de los síntomas de incontinencia urinaria que tiene?

☐ (1) Muy satisfecho ☐ (4) Insatisfecho
☐ (2) Satisfecho ☐ (5) Muy insatisfecho
☐ (3) Ni satisfecho ni insatisfecho

CM77_Quest4

Iniciales del Participante : _____ **Fecha:** _____

Reset

Draft

CAMUS Clinical Trial
Subjective Global Assessment Form (CAM77)

Visit Date
VisDate ☐☐/☐☐/☐☐☐☐
mm VisMo dd VisDy yyyy VisYr

Participant ID
☐☐☐S☐☐☐
ParticipantId

Visit Number
VisitNo ☐☐
24=Week 24
48=Week 48
72=Week 72

Participant Initials
☐☐☐ ParticipantIni

This form is completed by the participant.

Instructions: *For each question, check the one box that best describes your urinary symptoms.*

1. Compared to the beginning of the study, how are your urinary symptoms now?

CM77_Quest1
☐ (1) Much better
☐ (2) Somewhat better
☐ (3) A little better
☐ (4) About the same
☐ (5) A little worse
☐ (6) Somewhat worse
☐ (7) Much worse

2. How satisfied or dissatisfied are you with any urinary symptoms you have now?

CM77_Quest2
☐ (1) Very satisfied
☐ (2) Somewhat satisfied
☐ (3) Neither satisfied nor dissatisfied
☐ (4) Somewhat dissatisfied
☐ (5) Very dissatisfied

3. Compared to the beginning of the study, how are your urinary incontinence symptoms now?

CM77_Quest3
☐ (1) Much better
☐ (2) Somewhat better
☐ (3) A little better
☐ (4) About the same
☐ (5) A little worse
☐ (6) Somewhat worse
☐ (7) Much worse

4. How satisfied or dissatisfied are you with any urinary incontinence symptoms you have now?

CM77_Quest4
☐ (1) Very satisfied
☐ (2) Somewhat satisfied
☐ (3) Neither satisfied nor dissatisfied
☐ (4) Somewhat dissatisfied
☐ (5) Very dissatisfied

Participant Initials : _____ **Date:** _____

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

Ensayo Clínico CAMUS
Índice de Síntomas de Prostatitis Crónica de NIH (NIH-CPSI) (CAM78S)

VisDate Fecha de la visita ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / aaaa VisYr)

Identificación del participante ☐☐☐S☐☐☐ ParticipantId

VisitNo Número de la visita ☐☐☐☐.☐ (03=Inicio; 24=Semana 24; 48=Semana 48; 72=Semana 72)

Iniciales del participante ☐☐☐ ParticipantIni

El participante rellena este formulario.

Dolor o molestia

1. Durante la semana pasada, ¿experimentó usted algún dolor o molestia en las siguientes áreas?

   (a) El área entre el recto y los testículos (perineo)? ☐(1) Sí ☐(0) No CM78_Quest1A

   (b) Los testículos? ☐(1) Sí ☐(0) No CM78_Quest1B

   (c) La punta del pene (no relacionado con orinar)? ☐(1) Sí ☐(0) No CM78_Quest1C

   (d) Abajo de la cintura, en las áreas púbicas o de la vejiga? ☐(1) Sí ☐(0) No CM78_Quest1D

2. Durante la semana pasada, ¿experimentó usted:

   (a) dolor o ardor al orinar? ☐(1) Sí ☐(0) No CM78_Quest2A

   (b)dolor o molestia durante o después del coito (eyaculación)? ☐(1) Sí ☐(0) No CM78_Quest2B

3. Durante la semana pasada, ¿con qué frecuencia experimentó usted dolor o molestia en alguna de estas áreas?

CM78_Quest3

☐(0)Nunca ☐(1)Raramente ☐(2)Algunas veces ☐(3)A menudo ☐(4)Usualmente ☐(5)Siempre

4. ¿Cuál número mejor describa su PROMEDIO de dolor o molestia en los días en que lo experimentó durante la semana pasada.

CM78_Quest4

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10

AUSENCIA DE DOLOR — **EL DOLOR MÁS INTENSO QUE PODRÍA IMAGINAR**

Micción

5. Durante la semana pasada, ¿con qué frecuencia ha tenido la sensación de que su vejiga no se vaciaba completamente después de terminar de orinar?

nunca	*menos de 1 en 5 veces*	*menos de la mitad de las veces*	*alrededor de la mitad de las veces*	*más de la mitad de las veces*	*casi siempre*
☐0	☐1	☐2	☐3	☐4	☐5

CM78_Quest5

Reset

Draft

Ensayo Clínico CAMUS
Índice de Síntomas de Prostatitis Crónica de NIH (NIH-CPSI) (CAM78S)

Fecha de la visita — VisDate — mm VisMo / dd VisDy / aaaa VisYr

Identificación del participante — ParticipantId

Número de la visita — VisitNo — 03=Inicio; 24=Semana 24; 48=Semana 48; 72=Semana 72

Iniciales del participante — ParticipantIni

Continuación de micción

	nunca	*menos de 1 en 5 veces*	*menos de la mitad de las veces*	*alrededor de la mitad de las veces*	*más de la mitad de las veces*	*casi siempre*
6. Durante la semana pasada, ¿con qué frecuencia ha tenido que volver a orinar durante las dos horas después de haber terminado de orinar?	0	1	2	3	4	5

CM78_Quest6

Impacto de los síntomas

7. Durante la semana pasada, ¿cuánto le han impedido sus síntomas urinarios que hiciera las cosas que normalmente haría?

CM78_Quest7

(0) Nada (1) Solamente un poco (2) Algo (3) Mucho

8. Durante la semana pasada, ¿cuánto pensó acerca de sus síntomas ?

CM78_Quest8

(0) Nada (1) Solamente un poco (2) Algo (3) Mucho

Calidad de vida

9. Si tuviera que pasar el resto de su vida con sus síntomas así como han sido durante la semana pasada, ¿cómo se sentiría al respecto?

CM78_Quest9

(0) Deleitado
(1) Contento
(2) Principalmente satisfecho
(3) Igualmente satisfecho como insatisfecho
(4) Principalmente insatisfecho
(5) Infeliz
(6) Terrible

To be completed by the study coordinator:

Scoring the NIH-Chronic Prostatitis Symptom Index Domains

Pain: Total of items 1a, 1b, 1c, 1d, 2a, 2b, 3, and 4 = CM78_PainScore

Urinary Symptoms: Total of items 5 and 6 = CM78_UrinSymp

Quality of Life Impact: Total of items 7, 8 and 9 = CM78_QOLImpact

Iniciales del Participante : _____ **Fecha:** _____

Draft

CAMUS Clinical Trial
NIH-Chronic Prostatitis Symptom Index (NIH-CPSI) (CAM78)

VisDate Visit Date: ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID: ☐☐☐S☐☐☐ ParticipantId

VisitNo Visit Number: ☐☐ (03=Baseline; 24=Week 24; 48=Week 48; 72=Week 72)

Participant Initials: ☐☐☐ ParticipantIni

This form is completed by the participant.

Pain or Discomfort

1. In the past week, have you experienced any pain or discomfort in the following areas?

   (a) Area between rectum and testicles (perineum)? CM78_Quest1A ☐ (1) Yes ☐ (0) No

   (b) Testicles? CM78_Quest1B ☐ (1) Yes ☐ (0) No

   (c) Tip of the penis (not related to urination)? CM78_Quest1C ☐ (1) Yes ☐ (0) No

   (d) Below your waist in your pubic or bladder area? CM78_Quest1D ☐ (1) Yes ☐ (0) No

2. In the past week, have you experienced:

   (a) Pain or burning during urination? CM78_Quest2A ☐ (1) Yes ☐ (0) No

   (b) Pain or discomfort during or after sexual climax (ejaculation)? CM78_Quest2B ☐ (1) Yes ☐ (0) No

3. How often have you had pain or discomfort in any of these areas over the last week?
   CM78_Quest3
   ☐ (0) Never ☐ (1) Rarely ☐ (2) Sometimes ☐ (3) Often ☐ (4) Usually ☐ (5) Always

4. Which number best describes your AVERAGE pain or discomfort on the days that you had it, over the last week?
   CM78_Quest4
   ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
   NO PAIN — **PAIN AS BAD AS YOU CAN IMAGINE**

Urination

5. How often have you had a sensation of not emptying your bladder completely after you finished urinating, over the last week?

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

CM78_Quest5

Draft

CAMUS Clinical Trial
NIH-Chronic Prostatitis Symptom Index (NIH-CPSI) (CAM78)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

Visit Number VisitNo ☐☐ (03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72)

Participant Initials ☐☐☐ ParticipantIni

Urination Continued

	not at all	*less than 1 time in 5*	*less than half the time*	*about half the time*	*more than half the time*	*almost always*
6. How often have you had to urinate again less than two hours after you finished urinating, over the last week? CM78_Quest6	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Impact of Symptoms

7. How much have your symptoms kept you from doing the kinds of things you would usually do, over the last week? CM78_Quest7

☐ (0) None ☐ (1) Only a little ☐ (2) Some ☐ (3) A lot

8. How much did you think about your symptoms, over the last week? CM78_Quest8

☐ (0) None ☐ (1) Only a little ☐ (2) Some ☐ (3) A lot

Quality of Life

9. If you were to spend the rest of your life with your symptoms just the way they have been during the last week, how would you feel about that? CM78_Quest9

☐ (0) Delighted
☐ (1) Pleased
☐ (2) Mostly satisfied
☐ (3) Mixed (about equally satisfied and dissatisfied)
☐ (4) Mostly dissatisfied
☐ (5) Unhappy
☐ (6) Terrible

To be completed by the study coordinator:

Scoring the NIH-Chronic Prostatitis Symptom Index Domains

Pain: Total of items 1a, 1b, 1c, 1d, 2a, 2b, 3, and 4 = ☐☐ CM78_PainScore

Urinary Symptoms: Total of items 5 and 6 = ☐☐ CM78_UrinSymp

Quality of Life Impact: Total of items 7, 8 and 9 = ☐☐ CM78_QOLImpact

Participant Initials : _____ **Date:** _____

Draft

Ensayo Clínico CAMUS
Formulario de percepciones del participante sobre el tratamiento (CAM79S)

VisDate Fecha de la visita ☐☐/☐☐/☐☐☐☐
mm (VisMo) dd (VisDy) aaaa (VisYr)

Identificación del participante ☐☐☐S☐☐☐
ParticipantId

VisitNo Número de la visita ☐☐
24=Semana 24
48=Semana 48
72=Semana 72

Iniciales del participante ☐☐☐ ParticipantIni

La pregunta 1 se contestará cada 24, 48 y 72 semanas.

1. ¿Cuál es su mejor suposición acerca de qué tratamiento está recibiendo como parte del estudio CAMUS?

CM79_Quest1

- ☐ 1. No estoy seguro acerca de qué tratamiento estoy recibiendo.
- ☐ 2. Creo que estoy recibiendo las píldoras placebo (tratamiento inactivo).
- ☐ 3. Creo que estoy recibiendo el extracto de la planta Saw palmetto.
- ☐ 4. No estoy tomando ningunas de las píldoras del estudio CAMUS en este momento.

Iniciales del Participante : _____ **Fecha:** _____

For Official use only

Reset

Draft

CAMUS Clinical Trial
Participant Treatment Perception Form (CAM79)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐
mm VisMo dd VisDy yyyy VisYr

Participant ID ☐☐☐S☐☐☐
ParticipantId

VisitNo Visit Number ☐☐
24=Week 24
48=Week 48
72=Week 72

Participant Initials ☐☐☐ ParticipantIni

Question 1 is to be completed at every 24, 48, and 72 weeks.

1. What is your best guess about what treatment you are getting as part of the CAMUS study?

☐ 1. I am not sure which treatment I am getting.

☐ 2. I think I am getting the placebo pills (no active treatment).

CM79_Quest1

☐ 3. I think I am getting the Saw palmetto plant extract.

☐ 4. I am not taking any CAMUS pills right now.

Participant Initials : _____ **Date:** _____

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Adverse Event Form (CAM81)

Visit Date — VisDate — mm / dd / yyyy — VisMo / VisDy / VisYr

Participant ID — S — ParticipantId

Visit Number — VisitNo

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

Participant Initials — ParticipantIni

Has the participant experienced an adverse event since the last visit ? ☐ (1) Yes ⇨ If "Yes", record below.

CM81_LstVisAe ☐ (2) No ⇨ If "No", stop here.

MEDDRA Code: CM81_MEDDRACode CM81_AEDescript

Description:

Date of Onset: CM81_OnsetMo / CM81_OnsetDy / CM81_OnsetYr (mm / dd / yyyy)

Continuing ☐ CM81_Continue

OR

Date Resolved: CM81_ReslvMo / CM81_ReslvDy / CM81_ReslvYr (mm / dd / yyyy)

CM81_Serious

Serious? ☐ (2) No ☐ (1) Yes ⇨ *Complete SAE Form (CAM82)*

CM81_Severity

Severity *(See Codes)*: ☐

CM81_Relatnshp

Relationship to Study *(See Codes)*: ☐

CM81_Outcome

Outcome *(See Codes)*: ☐

CM81_Anticipated

Anticipated? ☐ (2) No ☐ (1) Yes

CM81_ActnTkn2 CM81_ActnTkn4 CM81_ActnTkn6 CM81_ActnTknDrg

Action Taken CM81_ActnTkn1 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6

(See Codes & check all that apply): CM81_ActnTkn3 CM81_ActnTkn5

Action Taken Regarding Study Drug ☐ *(See Codes)*:

MEDDRA Code: CM81_MEDDRACode CM81_AEDescript

Description:

Date of Onset: mm / dd / yyyy

Continuing ☐ CM81_Continue

OR

Date Resolved: mm / dd / yyyy

CM81_Serious

Serious? ☐ (2) No ☐ (1) Yes ⇨ *Complete SAE Form (CAM82)*

CM81_Severity

Severity *(See Codes)*: ☐

CM81_Relatnshp

Relationship to Study *(See Codes)*: ☐

CM81_Outcome

Outcome *(See Codes)*: ☐

CM81_Anticipated

Anticipated? ☐ (2) No ☐ (1) Yes

CM81_ActnTkn2 CM81_ActnTkn4 CM81_ActnTkn6 CM81_ActnTknDrg

Action Taken CM81_ActnTkn1 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6

(See Codes & check all that apply): CM81_ActnTkn3 CM81_ActnTkn5

Action Taken Regarding Study Drug ☐ *(See Codes)*:

Relationship to Study Codes: (1) Unrelated, **(2)** Unlikely, **(3)** Possible, **(4)** Probable, **(5)** Definite

Severity: (1) Mild, **(2)** Moderate, **(3)** Severe, **(4)** Life Threatening, **(5)** Death

Outcome Codes: (1) Complete recovery w/o residual effect, **(2)** Recovered w/ residual effect, **(3)** Recovered w/ persistent effect , **(4)** Not yet recovered, **(5)** Died

Action Taken Codes: (1) Self or OTC treatment, **(2)** Office, clinic, ER, or out-pt visit, **(3)** In-pt visit or hosp admit, **(4)** Rx, **(5)** Procedure performed, **(6)** None

Action Taken Regarding Study Drug Codes: (0) Not applicable, **(1)** None, **(2)** Reduced, **(3)** Interrupted, **(4)** Discontinued

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Serious Adverse Event Form (CAM82)

VisDate Report Date ☐☐/ ☐☐/ ☐☐☐☐
mm dd yyyy
VisMo VisDy VisYr

Participant ID ☐☐☐S☐☐☐
ParticipantId

VisitNo Visit Number ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

Participant Initials ☐☐☐ ParticipantIni

Note: *This form is completed by a clinician investigator for each serious adverse event. Send form to DCC as soon as event is reported. Immediately forward copies of the discharge summary and other pertinent documents related to the event to the DCC. Remove personal identifiers and write patient's study ID number in the upper right-hand corner of each page. Report SAE to your institution's IRB.*

1. MEDDRA Code (from Adverse Event Log) CM82_MEDDRACode ☐☐☐☐☐☐☐☐

2. Description of event CM82_EvntDesc1

CM82_EvntDesc2

CM82_EvntDesc3

3. Grade of adverse event (check one):
CM82_Grade
   - ☐ (2) Moderate
   - ☐ (3) Severe
   - ☐ (4) Life threatening
   - ☐ (5) Death

4. Date of onset ☐☐/ ☐☐/ ☐☐☐☐
mm dd yyyy
CM82_OnsetMo CM82_OnsetDy Cm82_OnsetYr

5. Relationship to study drug (check one)
CM82_RelatStdyDrug
☐ (1) Unrelated ☐ (2) Unlikely ☐ (3) Possible ☐ (4) Probable ☐ (5) Definite

6. Duration (check one)
☐ (1) < 1 day ☐ (2) 1 day to 1 week ☐ (3) > 1 week CM82_Duration

Investigator Signature Required on page 2.

Reset

Draft

CAMUS Clinical Trial
Serious Adverse Event Form (CAM82)

VisDate Report Date ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) VisMo VisDy VisYr

Participant ID ☐☐☐S☐☐☐ ParticipantId

VisitNo Visit Number ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

Participant Initials ☐☐☐ ParticipantIni

7. Action taken / corrective therapy (check all that apply or check "None")

☐ (1) None CM82_ActnTkn1

☐ (1) Self treatment or OTC therapy CM82_ActnTkn2

☐ (1) Office, clinic, ER, or out-patient visit CM82_ActnTkn3

☐ (1) Inpatient visit or hospital admission CM82_ActnTkn4

☐ (1) Prescription medication CM82_ActnTkn5

☐ (1) Procedure performed CM82_ActnTkn6

8. Action taken regarding study drug (check one)

☐ (1) None

☐ (2) Reduced

CM82_ActnTknDrg

☐ (3) Interrupted

☐ (4) Discontinued

9. Outcome (all that apply): CM82_ReslvMo CM82_ReslvDy CM82_ReslvYr

CM82_Outcome1 ☐ (1) Resolved ⇨ Date of resolution: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

☐ (1) Recovered with residual effect CM82_Outcome2

☐ (1) Required or prolonged hospitalization CM82_Outcome3

☐ (1) Resulted in permanent or severe disability CM82_Outcome4

☐ (1) Required intervention to prevent permanent damage or disability CM82_Outcome5

CM82_Outcome6 ☐ (1) Died ⇨ Complete form

⇨ Date of death: CM82_DeathMo CM82_DeathDy CM82_DeathYr ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

⇨ Probable cause of death: CM82_ProbCause _____

Investigator Signature: _____ **Date:** _____

Draft

CAMUS Clinical Trial
Death Form (CAM91)

VisDate Visit Date: VisMo (mm) / VisDy (dd) / VisYr (yyyy)

Participant ID: S — ParticipantId

VisitNo Visit Number:

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

Participant Initials: ParticipantIni

CM91_DthStatus

1. Status at time of death .....
   1=On Study Medication
   2=Off Study Medication

2. Date of death : mm / dd / yyyy

CM91_DeathMo CM91_DeathDy CM91_DeathYr

3. Date of last protocol treatment : mm / dd / yyyy

CM91_LstProtTrtMo CM91_LstProtTrtDy CM91_LstProtTrtYr

4. Primary cause of death:

CM91_PrimCause1

CM91_PrimCause2

5. Contributing cause of death:

CM91_ContrCause1

CM91_ContrCause2

Investigator Signature: _____ **Date:** _____

Draft

CAMUS Clinical Trial
Missed Visits Form (CAM92)

Visit Date
VisDate ☐☐/☐☐/☐☐☐☐
mm dd yyyy
VisMo VisDy VisYr

Participant ID
☐☐☐S☐☐☐
ParticipantId

Visit Number
VisitNo ☐☐

04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

Participant Initials
☐☐☐ ParticipantIni

---

1. Date of missed visit: ☐☐/☐☐/☐☐☐☐
   mm dd yyyy
   CM92_MissVisMo CM92_MissVisDy CM92_MissVisYr

2. Type of missed visit: ☐ (1) Scheduled Visit ☐ (2) Interim Visit CM92_MissVisType

3. Reason for missed visit (check all that apply):
   - ☐ a. Participant forgot CM92_MissReasnA
   - ☐ b. Participant felt too sick to come in CM92_MissReasnB CM92_SpecifyB1
     - ⇨☐ (1) Adverse event related to study drug, Specify: _____ CM92_ReasnB CM92_SpecifyB2
     - ☐ (2) Problems related to disease, Specify: _____
   - ☐ c. Participant hospitalized CM92_MissReasnC CM92_SpecifyC1
     - ⇨☐ (1) Adverse event related to study drug, Specify: _____ CM92_ReasnC CM92_SpecifyC2
     - ☐ (2) Problems related to disease, Specify: _____
   - ☐ d. Participant could not get off work CM92_MissReasnD
   - ☐ e. Participant unable to obtain dependent care CM92_MissReasnE
   - ☐ f. Participant had transportation problems CM92_MissReasnF
   - ☐ g. Participant unhappy with frequency of visits CM92_MissReasnG
   - ☐ h. Scheduling conflict CM92_MissReasnH
   - ☐ i. Participant had decided to discontinue study CM92_MissReasnI CM92_SpecifyJ
   - ☐ j. Other ⇨Specify: _____ CM92_MissReasnJ

4. Resolution (check all that apply):
   - ☐ a. Next visit scheduled. Items missed will be made up at the new visit. CM92_Resolutn4A
     Date of next scheduled visit: ☐☐/☐☐/☐☐☐☐ CM92_Resolutn4B CM92_SchedVisMo CM92_SchedVisDy CM92_SchedVisYr
     mm dd yyyy
   - ☐ b. Discontinued study
   - ☐ c. Adverse event reported (fill out AE form CAM81) CM92_Resolutn4C

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Comments Form (CAM93)

VisDate Visit Date ☐☐/☐☐/☐☐☐☐ (mm VisMo / dd VisDy / yyyy VisYr)

Participant ID ☐☐☐S☐☐☐ ParticipantId

VisitNo Visit Number ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

Participant Initials ☐☐☐ ParticipantIni

1. Reason for recording comment(s) (check all that apply):

- ☐ a. Abnormal physical examination CM93_AbnPhysExm
- ☐ b. Abnormal lab results CM93_AbnLabs
- ☐ c. Required lab not done CM93_LabND
- ☐ d. Treatment non-compliance CM93_TrtNonCompl
- ☐ e. Adverse events CM93_AdvEvent
- ☐ f. Inactive follow-up CM93_InactveFup
- ☐ g. Missed required clinical visits CM93_MissedVis
- ☐ h. Other reason ⇨ Specify: _____ CM93_Other CM93_OtherSpec

2. Record all the relevant dates of action and comments, keep legible.

CM93_Comment1

CM93_Comment2

CM93_Comment3

CM93_Comment4

CM93_Comment5

CM93_Comment6

CM93_Comment7

CM93_Comment8

Reset

Draft

CAMUS Clinical Trial
Interim Visit Checklist Form (CAM94)

VisDate Visit Date: mm / dd / yyyy
VisMo VisDy VisYr

Participant ID: S
ParticipantId

VisitNo Visit Number

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

Participant Initials: ParticipantIni

This form should be completed at any visits that are not scheduled follow-up visits. Additionally, this form should be completed if medications are mailed to the participant.

1. Reason for the interim visit (check all that apply):

a. ☐ Acute urinary retention (Complete form CAM61) CM94_AcuteUrinReten
b. ☐ Recurrent symptomatic urinary tract infection or urosepsis (Complete form CAM61) CM94_RecurSymptUTI
c. ☐ Incontinence event (Complete form CAM61) CM94_NewIncontnce
d. ☐ Adverse event (Complete form CAM81) CM94_AdverseEvnt
e. ☐ Dispense medication (Complete form CAM51) CM94_DispenseMed
f. ☐ Intercurrent illness event (Complete Question 2 of this form) CM94_IIllnessEvnt

If "f=Intercurrent illness event" is checked for question 1, continue to complete the following questions, otherwise stop here. Please note, investigator signature is required only if question 2 is completed.

2. Intercurrent illness event:

a. Specify the intercurrent illness: CM94_IntercurIll1

_____

_____ CM94_IntercurIll2

b. Is this a serious event ? ☐ (1)Yes ☐ (2)No CM94_SeriousEvnt

c. Specify action taken for the intercurrent illness: CM94_ActnTkn1

_____

_____ CM94_ActnTkn2

d. Intercurrent illness event declared ?

☐ (1)Yes ⇨If "Yes", date of confirmation by clinical review committee: mm / dd / yyyy
☐ (2)No CM94_EvntDecl CM94_ConfMo CM94_ConfDy CM94_ConfYr

Investigator Signature: _____ **Date:** _____

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Protocol Exemption Form (CAM95)

VisDate Completed on ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

Participant ID ☐☐☐S☐☐☐ ParticipantId

Participant Initials ☐☐☐ ParticipantIni

Complete Section A of this form, and fax the form to the Chairman, Clinical Review Committee (see the Manual of Operations for details); exemption decision will be returned via fax to the number entered below.

Section A. To be Completed by the study site requesting exemption.

Study Site: ☐☐☐ CM95_StudySite

Site Fax Number: CM95_SiteFaxNo (☐☐☐) ☐☐☐ - ☐☐☐☐

Site Contact: CM95_SiteContact _____

Specific Site Investigator: CM95_SiteInv _____

Date of request: CM95_RequestMo CM95_RequestDy CM95_RequestYr ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

Participant's Birth Year: CM95_BirthYr ☐☐☐☐ (yyyy)

Protocol Exemption Description (check one): CM95_ExemptDesc

☐ (1) Inclusion/Exclusion criteria — If yes, specify criterion #(s) on CAM01 form: CM95_Criterion1 ☐☐ CM95_Criterion2 ☐☐

☐ (2) Study procedure/timeline requirement

☐ (3) Other ⇨ Specify: CM95_OthSpec _____

Protocol Exemption Details: Please keep legible and brief.

CM95_ExemptDetail1

CM95_ExemptDetail2 _____

CM95_ExemptDetail3 _____

CM95_ExemptDetail4 _____

Section B. Complete by the Chairman of the Clinical Review Committee or the Chairman's designee.

Decision by the Chairman of the Clinical Review Committee (check one):

☐ (1) Approved ⇨ If approved, exemption number: ☐☐☐ CM95_ExemptNo

☐ (2) Denied CM95_Decision

Comments from the Chairman of the Clinical Review Committee: CM95_Comment1

CM95_Comment2 _____

CM95_Comment3 _____

Signature of the Chairman or his designee : _____ **Date:** _____

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset

Draft

CAMUS Clinical Trial
Participant Relocation Tracking Information Form (CAM96)

VisDate — Date of Visit: VisMo (mm) / VisDy (dd) / VisYr (yyyy)

Participant ID: ____S____ — ParticipantId

VisitNo — Visit Number

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

Participant Initials: ____ ParticipantIni

This form is to be completed any time a participant relocates and will be followed at another clinic. This form should be completed by the clinic from which the participant is moving (Current Clinic). Please fax this form to the DCC for data entry as soon as it is completed.

A. Participant Identification (This section is to be completed by the Current Clinic staff.**)**

1. Current clinic number: ____ CM96_OldClinNo

2. Medication ID: M____ CM96_RandNum

3. Participant's year of birth: ____ (yyyy) CM96_DOBYr

4. Date of last visit at current clinic: CM96_LstVisDate — CM96_LstVisMo (mm) / CM96_LstVisDy (dd) / CM96_LstVisYr (yyyy)

5. Date of first expected visit at new clinic: CM96_FstVisDate — CM96_FstVisMo (mm) / CM96_FstVisDy (dd) / CM96_FstVisYr (yyyy)

6. New clinic number: ____ CM96_NewClinNo

7. Complete the following checklist:

- ☐ 1. Notify the coordinator at the New Clinic — CM96_Check1
- ☐ 2. Copy all CRFs and information in the patient binder — CM96_Check2
- ☐ 3. Copy all source documentation — CM96_Check3
- ☐ 4. Send copies to the New Clinic — CM96_Check4
- ☐ 5. Send any undispensed medication to the New Clinic — CM96_Check5

Initials of person completing form : ____ CM96_CmpFormInit
F M L

B. Administrative Information (This section is to be completed by the DCC staff.**)**

1. Complete the following checklist:

Task	Check if done	Date (mm / dd / yyyy)	Initials
Form entered in the web data entry system	CM96_Task1	CM96_Task1Mo / CM96_Task1Dy / CM96_Task1Yr	_____
Web data entry system changed	CM96_Task2	CM96_Task2Mo / CM96_Task2Dy / CM96_Task2Yr	_____
Drug distribution center notified	CM96_Task3	CM96_Task3Mo / CM96_Task3Dy / CM96_Task3Yr	_____
Clinics notified	CM96_Task4	CM96_Task4Mo / CM96_Task4Dy / CM96_Task4Yr	_____

For Official use only

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Reset