

Draft

CAMUS Clinical Trial Eligibility and Randomization Form (CAM01)

Completed on

VisDate /

mm dd yyyy

Participant ID

Participant ID

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_Phytothrp
 (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

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- 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_PrivMd4Wk
 (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_PrivMd6Mo
 (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

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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: / /

mm dd yyyy

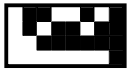
CM01_RandDate

CM01_RandMo CM01_RandDy CM01_RandYr

2. Medication ID:

CM01_RandNum

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CAMUS Clinical Trial Screening Log Form (CAM102) SV1

*** ParticipantId**

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

CM102_aRace

(2) No

(3) Unknown/Not Reported

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

CM102_ScrnOutcome

(2) Eligible, but did not enroll

(3) Ineligible

If not eligible, specify _____

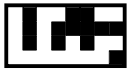
Ineligible_Spec

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

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

*** ParticipantId**

ParticipantId

Date

 / /

ParticipantId

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

CM102_aRace

(3) Unknown/Not Reported

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

CM102_ScrnOutcome

(2) Eligible, but did not enroll

(3) Ineligible

Ineligible_Spec

If not eligible, specify _____

Randomized

(1) Yes

(2) No

CM102_Randomized

PID # Assigned

ParticipantId

If, available, please provide the Med Kit # assigned

CM102_RandNum

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



Draft

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

Visit Date

VisDate / /

mm dd yyyy

VisMo VisDy VisYr

Participant ID

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: / / **CM21_CnsntDate**

Excluded if no signed consent form. mm dd yyyy

CM21_CnsntMo CM21_CnsntDy CM21_CnsntYr

2. Were you enrolled in another treatment trial for any disease in the past 30 days? (1)Yes (2)No **CM21_OthTrial**

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** **CM21_ScrnDate**

(2) Rescreen ⇨ If rescreen, Date of the first screening: / /

mm dd yyyy

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? *Excluded if < 45 years old.* **CM21_DOBYr**

yyyy

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** Black or African-American **CM21_bRace4**

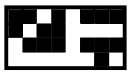
Asian **CM21_bRace2** White **CM21_bRace5**

CM21_bRace3 Native Hawaiian or Other Pacific Islander 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**

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CAMUS Clinical Trial

Demographic Data and Medical History Form (CAM21)

VisDate

Visit Date

mm

VisMo

dd

VisDy

yyyy

VisYr

Participant ID

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 CM21_HEdu
 - (4) College or technical school graduate
 - (5) Post-college coursework or degree
 - (9) Don't want to respond

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

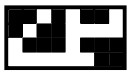
In general, ask, "Has a physician ever told you that you have ..." In some instances you may need to ask, "Do you have..." or "Have you had ..." (e.g., vasectomy).

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? CM21_CngenitalDz
 (1) Yes (2) No
10. Lung disease. Probe with: Have you ever had chronic obstructive pulmonary disorder (COPD), emphysema, asthma, chronic bronchitis, pneumonia, or water on the lungs? CM21_LungDz
 (1) Yes (2) No
11. Kidney disease. Probe with: Do you have kidney or bladder, stones, or kidney problems? CM21_KidneyDz
 (1) Yes (2) No
12. Immune disease. Probe with: Do you have rheumatoid arthritis or lupus? CM21_ImmuneDz
 (1) Yes (2) No

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CAMUS Clinical Trial

Demographic Data and Medical History Form (CAM21)

Visit Date

VisDate

mm	dd	yyyy
VisMo	VisDy	VisYr

Participant ID

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ParticipantId

Participant Initials

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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**

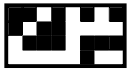
(1)Yes (2)No

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).



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

VisDate

Visit Date

mm	dd	yyyy
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VisMo **VisDy** **VisYr**

Participant ID

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ParticipantId

Participant Initials

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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?

mm	dd	yyyy
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CM21_BiopsyMo **CM21_BiopsyDy** **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
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

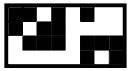
Excluded if

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.

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

Visit Date

VisDate

mm	dd	yyyy
VisMo	VisDy	VisYr

Participant ID

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ParticipantId

Participant Initials

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ParticipantIni

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

CM21_InfectDz

D. Family History (blood relations only)

31. Has anyone in your family been told by a physician that he has BPH? CM21_HisBPHD6

(1)Yes ⇨ Check all that apply:

<input type="checkbox"/> (1) Father CM21_HisBPHD1	<input type="checkbox"/> (1) Two or more brothers
<input type="checkbox"/> (2)No CM21_HisBPHD2	<input type="checkbox"/> (1) Maternal grandfather CM21_HisBPHD7
<input type="checkbox"/> (1) One maternal uncle CM21_HisBPHD3	<input type="checkbox"/> (1) Paternal grandfather
<input type="checkbox"/> (1) Two or more maternal uncles CM21_HisBPHD4	<input type="checkbox"/> (1) One paternal uncle CM21_HisBPHD8
<input type="checkbox"/> (1) One brother CM21_HisBPHD5	<input type="checkbox"/> (1) Two or more paternal uncles CM21_HisBPHD9
	<input type="checkbox"/> (1) Other male relative CM21_HisBPHD10

32. Has anyone in your family been told by a physician that he has prostate cancer? CM21_HisProCncrD6

(1)Yes ⇨ Check all that apply:

<input type="checkbox"/> (1) Father CM21_HisProCncrD1	<input type="checkbox"/> (1) Two or more brothers
<input type="checkbox"/> (2)No CM21_HisProCncrD2	<input type="checkbox"/> (1) Maternal grandfather CM21_HisProCncrD7
<input type="checkbox"/> (1) One maternal uncle CM21_HisProCncrD3	<input type="checkbox"/> (1) Paternal grandfather
<input type="checkbox"/> (1) Two or more maternal uncles CM21_HisProCncrD4	<input type="checkbox"/> (1) One paternal uncle CM21_HisProCncrD8
<input type="checkbox"/> (1) One brother CM21_HisProCncrD5	<input type="checkbox"/> (1) Two or more paternal uncles CM21_HisProCncrD9
	<input type="checkbox"/> (1) Other male relative CM21_HisProCncrD10

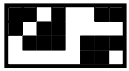
E. BPH Symptoms

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)

Visit Date

VisDate

mm	dd	yyyy
VisMo	VisDy	VisYr

Participant ID

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ParticipantId

Participant Initials

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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_AlphablckMo CM21_AlphablckDy CM21_AlphablckYr

c1. alpha-blocker last taken:

mm	dd	yyyy
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CM21_AlphablckDate

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
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CM21_PhytothrpMo CM21_PhytothrpDy CM21_PhytothrpYr

CM21_PhytothrpDate

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

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CAMUS Clinical Trial History Update Form (CAM22)

VisDate	Visit Date [][] / [][] [][][][] mm dd yyyy VisMo VisDy VisYr	Participant ID [][][][][][][][][] ParticipantId
VisitNo	Visit Number [][]	Participant Initials [][][][] ParticipantIni

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

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).**

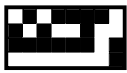
2. Have there been changes in or new urology medications since the last visit?
CM22_NewUrolMed
 (2) No (1) Yes ⇒ **If yes, update urology medication tracking form (CAM24).**

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).**



Draft

CAMUS Clinical Trial Concomitant Medication Form (CAM23)

Visit Date

VisDate / /

mm dd yyyy

VisMo VisDy VisYr

Participant ID

ParticipantId

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
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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.

Entry Number:

CM23_EntryNum

CM23_Med

Medication (Give generic name):

CM23_TotDose _____ CM23_UnitSpec _____

Total Dosage: _____ Dosage Units ⇒ If "other", Specify: _____

(See Codes below)

Frequency ⇒ If "other", Specify: _____ CM23_FreqSpec _____

(See Codes below)

Mode of Administration ⇒ If "other", Specify: _____ CM23_DoseUnits _____ CM23_ModeSpec _____

(See Codes below)

Date Started (mm/dd/yyyy) / /

CM23_StartMo CM23_StartDy

CM23_StartYr

Ongoing:

Or ⇒ CM23_StopMo / /

CM23_ModeAdm

CM23_StopYr

CM23_PriReas

CM23_StopDy

Primary Reason for Use or Change: _____

Entry Number:

CM23_EntryNum

CM23_Med

Medication (Give generic name):

CM23_TotDose _____ CM23_UnitSpec _____

Total Dosage: _____ Dosage Units ⇒ If "other", Specify: _____

(See Codes below)

Frequency ⇒ If "other", Specify: _____ CM23_FreqSpec _____

(See Codes below)

Mode of Administration ⇒ If "other", Specify: _____ CM23_DoseUnits _____ CM23_ModeSpec _____

(See Codes below)

Date Started (mm/dd/yyyy) / /

CM23_StartMo CM23_StartDy

CM23_StartYr

Ongoing:

Or ⇒ CM23_StopMo / /

CM23_ModeAdm

CM23_StopYr

CM23_PriReas

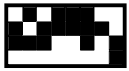
CM23_StopDy

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)



Draft

CAMUS Clinical Trial Urology Medication Tracking Form (CAM24)

Visit Date

VisDate / /

mm dd yyyy

VisMo VisDy VisYr

Participant ID

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.

Entry Number: CM24_Med

Medication (Give generic name): _____

Total Dosage: _____ Dosage Units ⇒ If "other",
(See Codes below) Specify: _____

Frequency ⇒ If "other",
(See Codes below) Specify: _____

Mode of Administration ⇒ If "other",
(See Codes below) Specify: _____

Date Started (mm/dd/yyyy) / / CM24_StartYr

Ongoing: Or ⇒ / / CM24_StopYr

Entry Number: CM24_Med

Medication (Give generic name): _____

Total Dosage: _____ Dosage Units ⇒ If "other",
(See Codes below) Specify: _____

Frequency ⇒ If "other",
(See Codes below) Specify: _____

Mode of Administration ⇒ If "other",
(See Codes below) Specify: _____

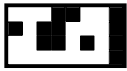
Date Started (mm/dd/yyyy) / / CM24_StartYr

Ongoing: Or ⇒ / / 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)



Draft

CAMUS Clinical Trial Vital Signs Form (CAM31)

VisDate Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
mm		dd	yyyy		
VisMo		VisDy	VisYr		

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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ParticipantId

VisitNo Visit Number

<input type="text"/>	<input type="text"/>	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
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Participant Initials

<input type="text"/>	<input type="text"/>	<input type="text"/>
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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** / **CM31_BPDia** mm Hg
Systolic Diastolic

(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** / **CM31_BPDia1** mm Hg
Systolic Diastolic

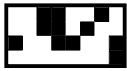
(b) Heart rate reading 1 bpm

CM31_HrtRate1

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

(d) Heart rate reading 2 bpm

CM31_HrtRate2



Draft

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

Visit Date

VisDate /

mm dd yyyy

VisMo VisDy VisYr

Visit Number

VisitNo

01=SV1.0
72=Week 72

Participant ID

ParticipantId

Participant Initials

ParticipantIni

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

Normal Abnormal ⇒ If abnormal, specify

CM32_HENT CM32_HENTAb

1. Head, ears, nose, throat 1 2 ⇒ _____ CM32_EyesAb

2. Eyes 1 2 ⇒ _____ CM32_EyesAb

3. Neck (include bruits) 1 2 ⇒ _____ CM32_NeckAb

4. Heart 1 2 ⇒ _____ CM32_HeartAb

5. Lungs and respiration 1 2 ⇒ _____ CM32_LungRespAb

6. Abdomen (include bruits) 1 2 ⇒ _____ CM32_AbdomenAb

7. Liver 1 2 ⇒ _____ CM32_LiverAb

8. Musculoskeletal 1 2 ⇒ _____ CM32_MsculskltlAb

9. Skin 1 2 ⇒ _____ CM32_SkinAb

10. Neurological 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

CM32_Urogenital CM32_UrogenitalAb

11. Urogenital 1 2 ⇒ _____

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:

CM32_ProstSize

(a) Prostate size: gm

CM32_Noduls

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

CM32_Asymtry

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

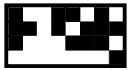
CM32_Cncr

(d) Suspicious for cancer: (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

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Draft

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

VisDate Visit Date

mm	dd	yyyy
<input type="text"/>	<input type="text"/>	<input type="text"/>

VisMo **VisDy** **VisYr**

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------

ParticipantId

VisitNo Visit Number

<input type="text"/>	<input type="text"/>
----------------------	----------------------

01=SV1.0	24=Week 24 48=Week 48 72=Week 72
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Participant Initials

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

ParticipantIni

Serum PSA:

Was a serum PSA sample collected at this visit?

(1) Yes ⇨ If "Yes", record date of collection.

mm	dd	yyyy
<input type="text"/>	<input type="text"/>	<input type="text"/>

CM41_PSADate

(2) No ⇨ If "No", STOP.

CM41_PSAMo **CM41_PSADy** **CM41_PSAyr**

CM41_PSADone

*Was a serum PSA sample shipped to central lab? (1) Yes

(2) No

CM41_PSAShipped

*If "Yes", record the date of shipment:

mm	dd	yyyy
<input type="text"/>	<input type="text"/>	<input type="text"/>

CM41_PSAShipDate

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*



Draft

CAMUS Clinical Trial Uroflow Measurement Form (CAM42)

Visit Date

VisDate /

mm dd yyyy

VisMo **VisDy** **VisYr**

Participant ID

ParticipantId

Visit Number

VisitNo

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

1. Voiding time: sec

CM42_VoidTime

2. Flow time: sec

CM42_FlowTime

3. Time to maximum flow: sec

CM42_TimeMaxFlow

4. Peak flow rate: . ml/sec

CM42_PeakFlowRt

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

5. Mean flow rate: . ml/sec

CM42_MeanFlowRt

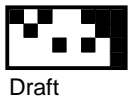
6. Voided volume: ml

CM42_VoidVol

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

7. Post-void residual: ml

CM42_PostVoidRes



CAMUS Clinical Trial

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

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

Participant ID

ParticipantId

VisitNo Visit Number 01=SV1.0 12=Week 12 36=Week 36 60=Week 60
 24=Week 24 48=Week 48 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 Upper limit of normal or control value (Seconds)
CM45_Ptt **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): Value Units ULN
- (h) AST (SGOT): Value Units ULN
- (i) GGT: Value Units 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).



Draft

CAMUS Clinical Trial Urinalysis Form (CAM46)

Visit Date

VisDate /

mm dd yyyy
VisMo VisDy VisYr

Participant ID

ParticipantId

Visit Number

VisitNo

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

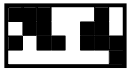
CM46_PH

(a1) pH: .

	0	trace	1+	2+	3+	4+	
(a2) Glucose	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	CM46_UGlucose
(a3) Blood	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	CM46_UBlood
(a4) Ketones	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	CM46_UKetone
(a5) Protein	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	CM46_UProtein
(a6) Leukocyte esterase	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 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	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	CM46_UWBC
(b2) RBC	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	CM46_URBC
(b3) Epithelial cells	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	CM46_UEpiCell
(b4) Mucous	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	CM46_UMucous
(b5) Bacteria	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	CM46_UBacteria
(b6) Casts hyaline	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	CM46_UCstHyaln
(b7) Casts other	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	CM46_UCstOthr



Draft

CAMUS Clinical Trial Serum for Banking Form (CAM47)

VisDate Visit Date

mm	dd	yyyy
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VisMo **VisDy** **VisYr**

VisitNo Visit Number

01=SV1.0
72=Week 72

Participant ID

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ParticipantId

Participant Initials

--	--

ParticipantIni

Was a serum sample collected at this visit?

CM47_SerumDone

(1)Yes ⇨ If "Yes",

CM47_SerumDate

Date of collection:

mm	dd	yyyy
----	----	------

CM47_SerumMo **CM47_SerumDy** **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	dd	yyyy
----	----	------

CM47_SerumShipMo **CM47_SerumShipDy** **CM47_SerumShipYr**

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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
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Participant ID:
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:

# of capsules taken by participant	<input type="text"/>	CM51_TabTkn1A	
# of capsules participant should have taken	<input type="text"/>	CM51_TabTkn2A	CM51_ComplianceA

$$\frac{\text{# of capsules taken by participant}}{\text{# of capsules participant should have taken}} \times 100 = \text{[]} \cdot \text{[]} \% \text{ Compliance}$$

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 **AM or PM**
CM51_DrugTime **CM51_DrugAMPM**
 (1) AM
 (2) PM

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Draft

CAMUS Clinical Trial BPH Outcome Events Form (CAM61)

Visit Date

mm dd yyyy

VisMo VisDy VisYr

Participant ID

ParticipantId

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

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

a. Acute urinary retention

Date of last event

mm dd yyyy

CM61_EventMoA CM61_EventDyA CM61_EventYrA

b. Recurrent symptomatic urinary tract infection or urosepsis

CM61_RecurSymptUTI

CM61_EventMoB CM61_EventDyB CM61_EventYrB

c. New incontinence or progression of minor incontinence

CM61_NewIncontnce

CM61_EventMoC CM61_EventDyC CM61_EventYrC

Investigator Signature Required on page 2.

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Draft

CAMUS Clinical Trial BPH Outcome Events Form (CAM61)

Visit Date

VisDate / /

mm dd yyyy

VisMo **VisDy** **VisYr**

Participant ID

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

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):

- | | |
|---|--|
| <input type="checkbox"/> (1) TURP CM61_TURP | <input type="checkbox"/> (1) Other invasive therapy CM61_OthInvThrpy
Specify other invasive therapy: CM61_InvThrpySpec1 |
| <input type="checkbox"/> (1) TUIP CM61_TUIP
CM61_RadProst
CM61_InvThrpySpec2 | _____ |
| <input type="checkbox"/> (1) Radical prostatectomy
CM61_OpenProst | _____ |
| <input type="checkbox"/> (1) Open prostatectomy
CM61_TUNA | <input type="checkbox"/> (1) Other phytotherapy CM61_OthPhytoThrpy
Specify other phytotherapy therapy: CM61_PhytoThrpySpec1 |
| <input type="checkbox"/> (1) TUNA
CM61_MicrowavThrpy
CM61_PhytoThrpySpec2 | _____ |
| <input type="checkbox"/> (1) Microwave therapy
CM61_LaserThrpy | <input type="checkbox"/> (1) Other medical therapy CM61_OthMedThrpy
Specify other medical therapy: CM61_MedThrpySpec1 |
| <input type="checkbox"/> (1) Laser therapy
CM61_Stent | _____ |
| <input type="checkbox"/> (1) Stent
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 **CM61_SideEffct**
- (3) Intolerable side effects ⇨ Specify: _____
- (4) Other ⇨ Specify: _____

Investigator Signature: _____ Date: _____ **CM61_Other**



Draft

Ensayo Clínico CAMUS

Formulario de Escala de Disfunción del Sueño Jenkins (CAM71S)

VisDate Fecha de la visita

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
mm			dd		aaaa		
VisMo			VisDy		VisYr		

Identificación del participante

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------

ParticipantId

VisitNo Número de la visita

<input type="text"/>	<input type="text"/>
----------------------	----------------------

0 3 =Inicio	24=Semana 24
	48=Semana 48
	72=Semana 72

Iniciales del participante

<input type="text"/>	<input type="text"/>	<input type="text"/>
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ParticipantIni

El participante rellena este formulario.

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

Durante el mes pasado, ¿cuántas veces:

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

Iniciales del Participante : _____

Fecha: _____

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Draft

CAMUS Clinical Trial Jenkins Sleep Dysfunction Scale Form (CAM71)

Visit Date

VisDate /

mm dd yyyy

VisMo VisDy VisYr

Participant ID

ParticipantId

Visit Number

VisitNo

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:

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

Participant Initials : _____ Date: _____

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Page 1 of 1
07/06/2007



Draft

Ensayo Clínico CAMUS Formulario de Función Eréctil (CAM72S)

Fecha de la visita

VisDate /

mm dd aaaa

VisMo VisDy VisYr

Identificación del participante

ParticipantId

Número de la visita

VisitNo

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

- | | |
|--|--|
| <input type="checkbox"/> (0) no hubo actividad sexual | <input type="checkbox"/> (3) a veces (más a menos la mitad de las veces) |
| <input type="checkbox"/> (1) nunca a casi nunca | <input type="checkbox"/> (4) la mayoría de la veces (mucho más de la mitad de las veces) |
| <input type="checkbox"/> (2) unas cuantas veces (mucho menos de la mitad de las veces) | <input type="checkbox"/> (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

- | | |
|--|---|
| <input type="checkbox"/> (0) no hubo actividad sexual | <input type="checkbox"/> (3) a veces (más a menos la mitad de las veces) |
| <input type="checkbox"/> (1) nunca a casi nunca | <input type="checkbox"/> (4) la mayoría de las veces (mucho más de la mitad de las veces) |
| <input type="checkbox"/> (2) unas cuantas veces (mucho menos de la mitad de las veces) | <input type="checkbox"/> (5) siempre o casi siempre |

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

CM72_Quest3

- | | |
|--|--|
| <input type="checkbox"/> (0) no traté de tener relaciones sexuales | <input type="checkbox"/> (3) a veces (más a menos la mitad de las veces) |
| <input type="checkbox"/> (1) nunca a casi nunca | <input type="checkbox"/> (4) la mayoría de la veces (mucho más de la mitad de las veces) |
| <input type="checkbox"/> (2) unas cuantas veces (mucho menos de la mitad de las veces) | <input type="checkbox"/> (5) siempre o casi siempre |

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

CM72_Quest4

- | | |
|--|--|
| <input type="checkbox"/> (0) no traté de tener relaciones sexuales | <input type="checkbox"/> (3) a veces (más a menos la mitad de las veces) |
| <input type="checkbox"/> (1) nunca a casi nunca | <input type="checkbox"/> (4) la mayoría de la veces (mucho más de la mitad de las veces) |
| <input type="checkbox"/> (2) unas cuantas veces (mucho menos de la mitad de las veces) | <input type="checkbox"/> (5) siempre o casi siempre |



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Ensayo Clínico CAMUS Formulario de Función Eréctil (CAM72S)

VisDate
mm dd yyyy
VisMo **VisDy** **VisYr**

Fecha de la visita

Identificación del participante

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

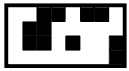
Iniciales del Participante : _____

Fecha: _____

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07/06/2007



Draft

CAMUS Clinical Trial Erectile Function Form (CAM72)

Visit Date

VisDate /

mm dd yyyy
VisMo VisDy VisYr

Participant ID

ParticipantId

Visit Number

VisitNo

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

- | | |
|---|--|
| <input type="checkbox"/> (0) no sexual activity | <input type="checkbox"/> (3) sometimes (about half the time) |
| <input type="checkbox"/> (1) never or almost never | <input type="checkbox"/> (4) most times (much more than half the time) |
| <input type="checkbox"/> (2) a few times (much less than half the time) | <input type="checkbox"/> (5) always or almost always |

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

CM72_Quest2

- | | |
|---|--|
| <input type="checkbox"/> (0) no sexual activity | <input type="checkbox"/> (3) sometimes (about half the time) |
| <input type="checkbox"/> (1) never or almost never | <input type="checkbox"/> (4) most times (much more than half the time) |
| <input type="checkbox"/> (2) a few times (much less than half the time) | <input type="checkbox"/> (5) always or almost always |

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

CM72_Quest3

- | | |
|---|--|
| <input type="checkbox"/> (0) did not attempt sexual intercourse | <input type="checkbox"/> (3) sometimes (about half the time) |
| <input type="checkbox"/> (1) never or almost never | <input type="checkbox"/> (4) most times (much more than half the time) |
| <input type="checkbox"/> (2) a few times (much less than half the time) | <input type="checkbox"/> (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?

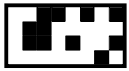
CM72_Quest4

- | | |
|---|--|
| <input type="checkbox"/> (0) did not attempt sexual intercourse | <input type="checkbox"/> (3) sometimes (about half the time) |
| <input type="checkbox"/> (1) never or almost never | <input type="checkbox"/> (4) most times (much more than half the time) |
| <input type="checkbox"/> (2) a few times (much less than half the time) | <input type="checkbox"/> (5) always or almost always |

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07/06/2007



Draft

CAMUS Clinical Trial Erectile Function Form (CAM72)

Visit Date

VisDate / /

mm dd yyyy
VisMo VisDy VisYr

Participant ID

ParticipantId

Visit Number

VisitNo

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 (3) difficult
- (1) extremely difficult (4) slightly difficult
- (2) very 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 (3) sometimes (about half the time)
- (1) never or almost never (4) most times (much more than half the time)
- (2) a few times (much less 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 (3) sometimes (about half the time)
- (1) never or almost never (4) most times (much more than half the time)
- (2) a few times (much less than half the time) (5) always or almost always

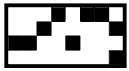
9. If you have to spend the rest of your life with your erectile condition just the way it is now, how would you feel about that?

CM72_Quest9

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

Participant Initials : _____ Date: _____

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Ensayo Clínico CAMUS

Formulario de Función Eyaculatoria (CAM73S)

Fecha de la visita

VisDate /

mm dd aaaa

VisMo VisDy 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

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?

- | | | |
|--|--|-------------|
| <input type="checkbox"/> (1) todo el tiempo | <input type="checkbox"/> (4) poca parte del tiempo | |
| <input type="checkbox"/> (2) la mayor parte del tiempo | <input type="checkbox"/> (5) nunca | CM73_Quest1 |
| <input type="checkbox"/> (3) parte del tiempo | <input type="checkbox"/> (6) no he tenido actividad sexual | |

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

- | | | |
|--|---|-------------|
| <input type="checkbox"/> (1) tan fuerte como siempre | <input type="checkbox"/> (4) mucho menos que antes | |
| <input type="checkbox"/> (2) un poco menos que antes | <input type="checkbox"/> (5) significativamente menos que antes | CM73_Quest2 |
| <input type="checkbox"/> (3) algo menos que antes | <input type="checkbox"/> (6) no eyaculé | |

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

- | | | |
|--|---|-------------|
| <input type="checkbox"/> (1) tanto como siempre | <input type="checkbox"/> (4) mucho menos que antes | CM73_Quest3 |
| <input type="checkbox"/> (2) un poco menos que antes | <input type="checkbox"/> (5) significativamente menos que antes | |
| <input type="checkbox"/> (3) algo menos que antes | <input type="checkbox"/> (6) no eyaculé | |

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

- | | | |
|--|---|-------------|
| <input type="checkbox"/> (1) no me ha molestado para nada | <input type="checkbox"/> (4) me ha molestado mucho | CM73_Quest4 |
| <input type="checkbox"/> (2) me ha molestado un poco | <input type="checkbox"/> (5) me ha molestado en extremo | |
| <input type="checkbox"/> (3) me ha molestado moderadamente | | |

Iniciales del Participante : _____ Fecha: _____



Draft

CAMUS Clinical Trial Ejaculatory Function Form (CAM73)

Visit Date

VisDate /

mm dd yyyy
VisMo VisDy VisYr

Participant ID

ParticipantId

Visit Number

VisitNo

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?

- | | |
|---|--|
| <input type="checkbox"/> (1) all of the time | <input type="checkbox"/> (4) a little of the time |
| <input type="checkbox"/> (2) most of the time | <input type="checkbox"/> (5) none of the time CM73_Quest1 |
| <input type="checkbox"/> (3) some of the time | <input type="checkbox"/> (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...

- | | |
|---|---|
| <input type="checkbox"/> (1) as strong as it always was | <input type="checkbox"/> (4) much less than it used to be |
| <input type="checkbox"/> (2) a little less than it used to be | <input type="checkbox"/> (5) very much less than it used to be CM73_Quest2 |
| <input type="checkbox"/> (3) somewhat less than it used to be | <input type="checkbox"/> (6) did not ejaculate |

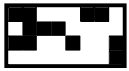
3. In the past month, how would you rate the amount or volume of semen when you ejaculate? Would you say it is...

- | | |
|---|---|
| <input type="checkbox"/> (1) as much as it always was | <input type="checkbox"/> (4) much less than it used to be |
| <input type="checkbox"/> (2) a little less than it used to be | <input type="checkbox"/> (5) very much less than it used to be CM73_Quest3 |
| <input type="checkbox"/> (3) somewhat less than it used to be | <input type="checkbox"/> (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?

- | | |
|--|--|
| <input type="checkbox"/> (1) not at all bothered | <input type="checkbox"/> (4) very bothered |
| <input type="checkbox"/> (2) a little bit bothered | <input type="checkbox"/> (5) extremely bothered CM73_Quest4 |
| <input type="checkbox"/> (3) moderately bothered | |

Participant Initials : _____ Date: _____



Draft

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

Fecha de la visita

VisDate /

mm dd aaaa
VisMo VisDy VisYr

Identificación del participante

ParticipantId

Número de la visita

VisitNo

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

La mayor parte del tiempo = más de las dos terceras partes del tiempo

Durante el mes pasado, ¿con qué frecuencia:

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

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

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

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

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

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

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



VisDate /
mm dd aaaa
VisMo VisDy VisYr

Identificación del participante

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
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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 (3) la mayor parte del tiempo **CM74_Quest4**
 (1) de vez en cuando (4) todo el tiempo
 (2) a veces

5. se le salió la orina mientras dormía?

- (0) nunca (3) la mayor parte del tiempo **CM74_Quest5**
 (1) de vez en cuando (4) todo el tiempo
 (2) a veces

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

- (0) nunca (3) la mayor parte del tiempo **CM74_Quest6**
 (1) de vez en cuando (4) todo el tiempo
 (2) a veces

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

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 (4) moderadamente satisfecho **CM74_Quest7**
 (2) moderadamente insatisfecho (5) muy satisfecho
 (3) más o menos igualmente satisfecho que insatisfecho

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



Draft

CAMUS Clinical Trial Bladder Function Form (CAM74)

Visit Date

VisDate /

mm dd yyyy

VisMo VisDy VisYr

Participant ID

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
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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 past month how often:

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

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

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

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

3. Did urine leak when you coughed or sneezed?

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

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CAMUS Clinical Trial Bladder Function Form (CAM74)

Visit Date

VisDate / /

mm dd yyyy

VisMo VisDy VisYr

Participant ID

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
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Participant Initials

ParticipantIni

In the past month how often:

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

(0) never (3) most of the time **CM74_Quest4**

(1) occasionally (4) all of the time

(2) sometimes

5. Did you leak urine when you were asleep?

(0) never (3) most of the time **CM74_Quest5**

(1) occasionally (4) all of the time

(2) sometimes

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

(0) never (3) most of the time **CM74_Quest6**

(1) occasionally (4) all of the time

(2) sometimes

*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?

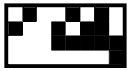
(1) very dissatisfied (4) moderately satisfied **CM74_Quest7**

(2) moderately dissatisfied (5) very satisfied

(3) about equally satisfied and dissatisfied

Participant Initials : _____ Date: _____

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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** **VisTr**

VisitNo Número de la visita
01=SV1.0 12=Semana 12 36=Semana 36 60=Semana 60
02=SV2.0 24=Semana 24 48=Semana 48 72=Semana 72

Identificación del participante
ParticipantId

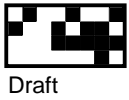
Iniciales del participante
ParticipantIni

El participante rellena este formulario.

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

- | | <i>nunca</i> | <i>menos de
1 en 5
veces</i> | <i>menos de
la mitad
de las
veces</i> | <i>alrededor
de la
mitad de
las veces</i> | <i>más de
la mitad
de las
veces</i> | <i>casi
siempre</i> |
|--|--------------------------------------|--------------------------------------|---|---|---|----------------------------|
| 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? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 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? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| | | | CM75_Quest2 | | | |
| 3. Durante el mes pasado, ¿con qué frecuencia se dio cuenta de que había parado y comenzado varias veces cuando orinaba? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| | | | CM75_Quest3 | | | |
| 4. Durante el mes pasado, ¿con qué frecuencia ha encontrado difícil el posponer orinar? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| | | | CM75_Quest4 | | | |
| 5. Durante el mes pasado, ¿con qué frecuencia ha tenido el flujo de orina débil? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| | | | CM75_Quest5 | | | |
| 6. Durante el mes pasado, ¿con qué frecuencia ha tenido que empujar o hacer un esfuerzo para comenzar a orinar? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 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? | | | | | | |
| | <input type="checkbox"/> (0) ninguna | <input type="checkbox"/> (2) 2 veces | CM75_Quest7 | | | |
| | <input type="checkbox"/> (1) 1 vez | <input type="checkbox"/> (3) 3 veces | <input type="checkbox"/> (4) 4 veces | | | |
| | | | <input type="checkbox"/> (5) 5 veces o más | | | |

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



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 /
mm dd aaaa
VisMo **VisDy** **VisYr**
Número de la visita

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

Identificación del participante
ParticipantId
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
- (4) casi la mitad de las veces **CM75_Quest9**
- (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)

Visit Date

VisDate /

mm VisMo dd VisDy yyyy VisYr

Participant ID

ParticipantId

VisitNo

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

Participant Initials

ParticipantIni

This form is completed by the participant.

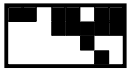
Instructions: For each question, check the one box that best describes your condition.

- | | 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? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| | | | CM75_Quest1 | | | |
| 2. Over the past month, how often have you had to urinate again less than two hours after you finished urinating? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| | | | CM75_Quest2 | | | |
| 3. Over the past month, how often have you found you stopped and started again several times when you urinated? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| | | | CM75_Quest3 | | | |
| 4. Over the past month, how often have you found it difficult to postpone urination? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| | | | CM75_Quest4 | | | |
| 5. Over the past month, how often have you had a weak urinary stream? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| | | | CM75_Quest5 | | | |
| 6. Over the past month, how often have you had to push or strain to begin urination? | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 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 |
| | <input type="checkbox"/> (0) none | <input type="checkbox"/> (2) 2 times | <input type="checkbox"/> (4) 4 times | | | |
| | <input type="checkbox"/> (1) 1 time | <input type="checkbox"/> (3) 3 times | <input type="checkbox"/> (5) 5 or more times | | | |

To be completed by the study coordinator: AUASS =

CM75_AUASS

(Total of items 1-7.)



Draft

CAMUS Clinical Trial

**International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)**

Visit Date

VisDate / /

mm **dd** **yyyy**

VisMo **VisDy** **VisYr**

Participant ID

ParticipantId

Visit Number

VisitNo

01=SV1.0	12=Week 12	36=Week 36	60=Week 60
02=SV2.0	24=Week 24	48=Week 48	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
- (4) About half the time **CM75_Quest9**
- (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	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Identificación del participante	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	mm	dd	aaaa				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	<input type="text"/>	<input type="text"/>	<input type="text"/>	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?

CM76_Quest3 (0) no me molesta

(1) me molesta un poco

(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?

CM76_Quest4 (0) nunca

(1) un poco de tiempo

(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



Draft

CAMUS Clinical Trial BPH Impact Index Form (CAM76)

Participant ID

ParticipantId

Visit Date

VisDate /

mm dd yyyy

VisMo VisDy VisYr

Visit Number

VisitNo

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

CM76_Quest3 (0) not at all bothersome

(1) bothers me a little

(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?

CM76_Quest4 (0) none of the time

(1) a little of the time

(2) some of the time

(3) most of the time

(4) all of the time

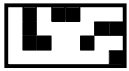
To be completed by the study coordinator: BPH Impact Index Score = CM76_BPHImpScore
(Total of items 1-4.)

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



Draft

Ensayo Clínico CAMUS

Formulario de Evaluación Global Subjetiva (CAM77S)

VisDate Fecha de la visita

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
mm		dd		aaaa	
VisMo		VisDy		VisYr	

Identificación del participante

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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ParticipantId

VisitNo Número de la visita

<input type="text"/>	<input type="text"/>
----------------------	----------------------

24=Semana 24
48=Semana 48
72=Semana 72

Iniciales del participante

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

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?

<input type="checkbox"/> (1) Mucho mejor	<input type="checkbox"/> (4) Casi igual	<input type="checkbox"/> (7) Mucho peor
<input type="checkbox"/> (2) Mejor	<input type="checkbox"/> (5) Un poco peor	
<input type="checkbox"/> (3) Un poco mejor	<input type="checkbox"/> (6) Peor	

CM77_Quest1

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

<input type="checkbox"/> (1) Muy satisfecho	<input type="checkbox"/> (4) Insatisfecho
<input type="checkbox"/> (2) Satisfecho	<input type="checkbox"/> (5) Muy insatisfecho
<input type="checkbox"/> (3) Ni satisfecho ni insatisfecho	

CM77_Quest2

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

<input type="checkbox"/> (1) Mucho mejor	<input type="checkbox"/> (4) Casi igual	<input type="checkbox"/> (7) Mucho peor
<input type="checkbox"/> (2) Mejor	<input type="checkbox"/> (5) Un poco peor	
<input type="checkbox"/> (3) Un poco mejor	<input type="checkbox"/> (6) Peor	

CM77_Quest3

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

<input type="checkbox"/> (1) Muy satisfecho	<input type="checkbox"/> (4) Insatisfecho
<input type="checkbox"/> (2) Satisfecho	<input type="checkbox"/> (5) Muy insatisfecho
<input type="checkbox"/> (3) Ni satisfecho ni insatisfecho	

CM77_Quest4

Iniciales del Participante :

Fecha:

For Official use only



Draft

CAMUS Clinical Trial Subjective Global Assessment Form (CAM77)

Visit Date

VisDate /

mm dd yyyy

VisMo VisDy VisYr

Participant ID

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?

(1) Much better (4) About the same (7) Much worse

CM77_Quest1 (2) Somewhat better (5) A little worse

(3) A little better (6) Somewhat worse

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

(1) Very satisfied (4) Somewhat dissatisfied

CM77_Quest2 (2) Somewhat satisfied (5) Very dissatisfied

(3) Neither satisfied nor dissatisfied

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

(1) Much better (4) About the same (7) Much worse

CM77_Quest3 (2) Somewhat better (5) A little worse

(3) A little better (6) Somewhat worse

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

(1) Very satisfied (4) Somewhat dissatisfied

CM77_Quest4 (2) Somewhat satisfied (5) Very dissatisfied

(3) Neither satisfied nor dissatisfied

Participant Initials : _____

Date: _____



Draft

Ensayo Clínico CAMUS

Índice de Síntomas de Prostatitis Crónica de NIH (NIH-CPSI) (CAM78S)

VisDate Fecha de la visita

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
mm		dd		aaaa	
VisMo		VisDy		VisYr	

Identificación del participante

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------

ParticipantId

VisitNo Número de la visita

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------	----------------------	----------------------

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

Iniciales del participante

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

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



Draft

Ensayo Clínico CAMUS

Índice de Síntomas de Prostatitis Crónica de NIH (NIH-CPSI) (CAM78S)

Fecha de la visita

VisDate /

mm dd aaaa

VisMo VisDy 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

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

(0) Deleitado (4) Principalmente insatisfecho

(1) Contento (5) Infeliz

(2) Principalmente satisfecho (6) Terrible

(3) Igualmente satisfecho como insatisfecho

CM78_Quest9

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)

Visit Date

VisDate / /

mm dd yyyy

VisMo VisDy VisYr

Participant ID

ParticipantId

Visit Number

VisitNo

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

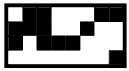
Urination

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

	<i>not at all</i>	<i>less than 1 time in 5</i>	<i>less than half the time</i>	<i>about half the time</i>	<i>more than half the time</i>	<i>almost always</i>
	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

^{CM78_Quest5}

For Official use only



Draft

Ensayo Clínico CAMUS

Formulario de percepciones del participante sobre el tratamiento (CAM79S)

VisDate Fecha de la visita

[]	[]	/	[]	[]	[]	[]	
mm			dd		aaaa		
VisMo			VisDy		VisYr		

Identificación del participante

[]	[]	[]	[]	[]	[]	[]
-----	-----	-----	-----	-----	-----	-----

ParticipantId

VisitNo Número de la visita

[]	[]
-----	-----

24=Semana 24
48=Semana 48
72=Semana 72

Iniciales del participante

[]	[]	[]
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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?

- 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.

CM79_Quest1

Iniciales del Participante :

Fecha:

For Official use only



Draft

CAMUS Clinical Trial Participant Treatment Perception Form (CAM79)

VisDate Visit Date

mm		dd		yyyy			
VisMo		VisDy		VisYr			

Participant ID

--	--	--	--	--	--	--	--

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).
- 3. I think I am getting the Saw palmetto plant extract.
- 4. I am not taking any CAMUS pills right now.

CM79_Quest1

Participant Initials : _____ **Date:** _____

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CAMUS Clinical Trial Adverse Event Form (CAM81)

Visit Date

VisDate / /

mm dd yyyy

VisMo VisDy VisYr

Participant ID

ParticipantId

Visit Number

<input type="text"/> <input type="text"/>	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
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VisitNo

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: / /

mm dd yyyy

CM81_OnsetMo **CM81_OnsetDy** **CM81_OnsetYr**

Continuing **CM81_Continue** OR **CM81_ReslvMo** **CM81_ReslvDy** **CM81_ReslvYr**

mm dd yyyy

CM81_Serious **CM81_Severity**

Serious? (2) No (1) Yes ⇒ Complete SAE Form (CAM82)

Relationship to Study (See Codes): **CM81_ActnTkn2** Outcome (See Codes): **CM81_ActnTkn4** **CM81_ActnTkn6** Anticipated? (2) No (1) Yes

CM81_Relatnshp **CM81_Outcome** **CM81_Anticipated**

CM81_ActnTkn1 **CM81_ActnTkn3** **CM81_ActnTkn5** **CM81_ActnTknDrg**

Action Taken 1 2 3 4 5 6 Action Taken Regarding Study Drug

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

MEDDRA Code:

CM81_MEDDRACode **CM81_AEDescript**

Description: _____

Date of Onset: / /

mm dd yyyy

CM81_Serious **CM81_Severity**

Continuing **CM81_Continue** OR **CM81_ReslvMo** **CM81_ReslvDy** **CM81_ReslvYr**

mm dd yyyy

Serious? (2) No (1) Yes ⇒ Complete SAE Form (CAM82)

Relationship to Study (See Codes): **CM81_ActnTkn2** Outcome (See Codes): **CM81_ActnTkn4** **CM81_ActnTkn6** Anticipated? (2) No (1) Yes

CM81_Relatnshp **CM81_Outcome** **CM81_Anticipated**

CM81_ActnTkn1 **CM81_ActnTkn3** **CM81_ActnTkn5** **CM81_ActnTknDrg**

Action Taken 1 2 3 4 5 6 Action Taken Regarding Study Drug

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

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

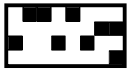
Severity: (1) Mild, (2) Moderate, (3) Severe, (4) Life Threatening, (5) Death

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

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CAMUS Clinical Trial Serious Adverse Event Form (CAM82)

VisDate Report Date

mm	dd	yyyy
<input type="text"/>	<input type="text"/>	<input type="text"/>

VisMo **VisDy** **VisYr**

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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ParticipantId

VisitNo Visit Number

<input type="text"/>	<input type="text"/>
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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

<input type="text"/>	<input type="text"/>	<input type="text"/>
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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**

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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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
<input type="text"/>	<input type="text"/>	<input type="text"/>

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.



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CAMUS Clinical Trial Serious Adverse Event Form (CAM82)

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

Participant ID:
 Participant ID:

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:
 Participant Ini:

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_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: / /
 mm dd yyyy **CM82_DeathMo CM82_DeathDy CM82_DeathYr**

⇒ Probable cause of death: _____ **CM82_ProbCause**

Investigator Signature: _____

Date: _____

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CAMUS Clinical Trial Death Form (CAM91)

VisDate

Visit Date

VisMo	VisDy	VisYr
mm	dd	yyyy

Participant ID

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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

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ParticipantIni

CM91_DthStatus

1. Status at time of death

1=On Study Medication

2=Off Study Medication

2. Date of death :

CM91_DeathMo CM91_DeathDy CM91_DeathYr

3. Date of last protocol treatment :

CM91_LstProtTrtMo CM91_LstProtTrtDy CM91_LstProtTrtYr

4. Primary cause of death:

CM91_PrimCause1

CM91_PrimCause2

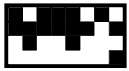
5. Contributing cause of death:

CM91_ContrCause1

CM91_ContrCause2

Investigator Signature: _____ Date: _____

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CAMUS Clinical Trial Missed Visits Form (CAM92)

VisDate Visit Date / /
mm VisMo dd VisDy yyyy VisYr

Participant ID
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. Date of missed visit: / /
mm VisMo dd VisDy yyyy VisYr
CM92_MissVisMo CM92_MissVisDy CM92_MissVisYr

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

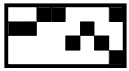
3. Reason for missed visit (check all that apply):

- 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_SpecifyB2** _____
CM92_ReasnB (2) Problems related to disease, Specify: _____
- c. Participant hospitalized **CM92_MissReasnC** **CM92_SpecifyC1**
 (1) Adverse event related to study drug, Specify: **CM92_SpecifyC2** _____
CM92_ReasnC (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: _____

4. Resolution (check all that apply):

- a. Next visit scheduled. Items missed will be made up at the new visit. **CM92_Resolutn4A**
CM92_Resolutn4B Date of next scheduled visit: / /
mm VisMo dd VisDy yyyy VisYr **CM92_SchedVisMo CM92_SchedVisDy CM92_SchedVisYr**
- b. Discontinued study
- c. Adverse event reported (fill out AE form CAM81) **CM92_Resolutn4C**

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CAMUS Clinical Trial Comments Form (CAM93)

VisDate Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
mm		dd	yyyy		
VisMo		VisDy	VisYr		

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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ParticipantId

VisitNo Visit Number

<input type="text"/>	<input type="text"/>	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

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

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_InactiveFup**
 - g. Missed required clinical visits **CM93_MissedVis**
 - h. Other reason \Rightarrow Specify: **CM93_OtherSpec**
- CM93_Other**

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**



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CAMUS Clinical Trial Interim Visit Checklist Form (CAM94)

VisDate Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
mm	dd	yyyy			
VisMo	VisDy	VisYr			

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
ParticipantId							

VisitNo Visit Number

<input type="text"/>	<input type="text"/>	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

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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
CM94_RecurSymptUTI
- b. Recurrent symptomatic urinary tract infection or urosepsis (Complete form CAM61)
- c. Incontinence event (Complete form CAM61) CM94_NewIncontnce
- d. Adverse event (Complete form CAM81) CM94_AdverseEvt
- e. Dispense medication (Complete form CAM51) CM94_DispenseMed
- f. Intercurrent illness event (Complete Question 2 of this form) CM94_IIllnessEvt

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

- b. Is this a serious event ? (1)Yes (2)No CM94_SeriousEvt
CM94_IntercurIll2
- c. Specify action taken for the intercurrent illness: CM94_ActnTkn1

- d. Intercurrent illness event declared ? CM94_ActnTkn2
 - (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:** _____



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CAMUS Clinical Trial Protocol Exemption Form (CAM95)

Completed on
VisDate / /
mm dd yyyy

Participant ID

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_SiteContact **CM95_SiteFaxNo** **CM95_SiteInv**

Site Contact: _____ Specific Site Investigator: _____

Date of request: / /
mm dd yyyy **CM95_RequestMo** **CM95_RequestDy** **CM95_RequestYr** Participant's Birth Year: **CM95_BirthYr**
yyyy

Protocol Exemption Description (check one):

- (1) Inclusion/Exclusion criteria If yes, specify criterion #(s) on CAM01 form: **CM95_ExemptDesc** **CM95_Criterion1**
 (2) Study procedure/timeline requirement **CM95_OthSpec** **CM95_Criterion2**
 (3) Other ⇨ Specify: _____

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: _____

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CAMUS Clinical Trial Participant Relocation Tracking Information Form (CAM96)

Date of Visit

VisDate **VisMo** / **VisDy** / **VisYr**

mm dd yyyy

Participant ID

ParticipantId

Participant Initials

ParticipantIni

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

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: **CM96_RandNum**

3. Participant's year of birth: **CM96_DOBYr**

4. Date of last visit at current clinic: / / **CM96_LstVisMo** **CM96_LstVisDy** **CM96_LstVisYr**

mm dd yyyy

5. Date of first expected visit at new clinic: / / **CM96_FstVisMo** **CM96_FstVisDy** **CM96_FstVisYr**

mm dd 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:

<u>Task</u>	<u>Check if done</u>	<u>Date</u>	<u>Initials</u>
		mm dd yyyy	
Form entered in the web data entry system	<input type="checkbox"/> CM96_Task1 CM96_Task1Mo	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> CM96_Task1Dy CM96_Task1Yr	_____
Web data entry system changed	<input type="checkbox"/> CM96_Task2 CM96_Task2Mo	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> CM96_Task2Dy CM96_Task2Yr	_____
Drug distribution center notified	<input type="checkbox"/> CM96_Task3 CM96_Task3Mo	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> CM96_Task3Dy CM96_Task3Yr	_____
Clinics notified	<input type="checkbox"/> CM96_Task4 CM96_Task4Mo	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> CM96_Task4Dy CM96_Task4Yr	_____

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