

Patient number

Date form completed
month day year

NIH - BPH CLINICAL TRIAL

CLINICAL REVIEW COMMITTEE REPORT

This form is completed by the Clinical Review Committee as documentation of the classification for a patient that had a pre-defined clinical event, discontinued one or both coded medications or discontinued follow-up visits. The Committee's classification is based on a review of the patient's complete data record in the master database at the Biostatistical Coordinating Center (BCC). The original of this form is kept at the BCC. A copy is sent to the corresponding clinical center to be filed in the patient's binder.

A. Patient Identification

Clinic number (CLINIC)

2. Patient Identification number (PATID)
clinic patient

3. Patient's initials (INITS)
first last

4. Patient's date of birth (DOB)
month day year

5. CRC form number (CRCNO)

B. CRC Classification

1. Specify the classification for this patient: (WCLASS)
(check one)

- ¹ Death (Complete Section C)
- ² AUA symptom score event (Complete Section D)
- ³ Creatinine rise event (Complete Section E)
- ⁴ Urinary event (Complete Section F)
- ⁵ Treatment non-compliance (Complete Section G)
- ⁶ Inactive follow-up (Complete Section H)
- ⁷ Crossover to invasive therapy (Complete Section I)

C. Death Specification

1. Date of death (WDDATE)
month day year

2. Probable cause of death (WDCAUS)

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D. AUA Symptom Score Specification

1. AUA Symptom Score:

- a. Baseline (WSSBAS)
- b. Initial Event (WSSIEV)
- c. Confirming Event (WSSCEV)

2. Date of initial event (WSSEVDT)
 month day year

3. Was the patient taking coded medication(s)? (WSSCODE) YES NO
 1 2

IF YES, THEN CONTINUE. IF NO, SKIP TO Question 5

4. Were the coded medication(s) discontinued? (WSSDISC) 1 2

IF YES, THEN CONTINUE. IF NO, SKIP TO Question 5

- a. Coded medication(s) discontinued: 1 Doxazosin (WSSMDD)
- 1 Finasteride (WSSMDF)

b. Date coded medication(s) discontinued (WSSMDDT)
 month day year

5. Is the patient continuing follow-up visits? (WSSCFUV) YES NO
 1 2

IF NO:

a. Date of last visit (WSSLVST)
 month day year

E. Creatinine Rise Specification

1 Creatinine results:

- a. Baseline (WCRBAS) . mg/dl
- b. Initial Event (WCRIEV) . mg/dl
- c. Confirming Event (WCRCEV) . mg/dl

2. Date of initial event (WCREVDT)
 month day year

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3. Was the patient taking coded medication(s)? (WCRCODE) YES NO
 1 2

IF YES, THEN CONTINUE. IF NO, SKIP TO Question 4.

a. Coded medication(s) discontinued: 1 Doxazosin (WCRMDD)
 1 Finasteride (WCRMDF)

b. Date coded medication(s) discontinued (WCRMDDT)
month day year

4. Is the patient continuing follow-up visits? (WCRCFUV) YES NO
 1 2

IF NO:

a. Date of last visit (WCRLVST)
month day year

F. Urinary Event Specification

1 Specify the type of urinary event: (check one) (WUETYP) 1 Acute urinary retention event
 2 Recurrent urinary tract infection
 3 Incontinence event

2. Date of event (WUEEVDT)
month day year

3. Was the patient taking coded medication(s)? (WUECODE) YES NO
 1 2

IF YES, THEN CONTINUE. IF NO, SKIP TO Question 4.

a. Coded medication(s) discontinued: 1 Doxazosin (WUEMDD)
 1 Finasteride (WUEMDF)

b. Date coded medication(s) discontinued (WUEMDDT)
month day year

4. Is the patient continuing follow-up visits? (WUECFUV) YES NO
 1 2

IF NO:

a. Date of last visit (WUELVST)
month day year

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G. Treatment Non-compliance Specification

1 Specify the primary reason for discontinuing coded medications (WTNRSN)

2. Coded medication(s) discontinued: ¹ Doxazosin (WTNMDD)
¹ Finasteride (WTNMDF)

3. Date coded medications discontinued (WTNMDDT)
month day year

4. Was there a crossover to known medical therapy? (WTNXTX) YES NO
¹ ²

If YES, CONTINUE.

a. Specify the medical therapy:
(check all that apply)

¹ Alpha-1 blocker (WTNXA1)

¹ 5-alpha inhibitor (WTNX5A)

¹ Other medication (WTNXO)

specify: _____ (WTNXOX)

H. Inactive Follow-up Specification

Specify the primary reason for discontinuing follow-up visits (WIFRSN)

2. Date of last visit (WIFMDDT)
month day year

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I. Crossover to Invasive Therapy Specification

1. Specify the invasive therapy: (WCTIT)
(check one)

¹ TURP

² TUIP

³ Radical prostatectomy

⁴ Open prostatectomy

⁵ TUNA

⁶ Microwave Therapy

⁷ Laser Therapy

⁸ Stent

⁹ Other

specify: (WCTITX)

2. Date of crossover to invasive therapy (WCTEVDT)

month day year

3. Was the patient taking coded medication(s)? (WCTCODE)

YES NO
 ¹ ²

IF YES, THEN CONTINUE. IF NO, SKIP TO Question 3

a. Coded medication(s) discontinued

¹ Doxazosin (WCTMDD)

¹ Finasteride (WCTMDF)

b. Date coded medication(s) discontinued (WCTMDDT)

month day year

4. Is the patient continuing follow-up visits? (WCTCFUV)

YES NO
 ¹ ²

IF NO:

a. Date of last visit (WCTLVST)

month day year

J. Conclusion of Report

1. Additional comments:

Initials of person completing form
(FORMIN)

first last

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Signature _____