FORM NUMBER = (FORM)
FORM VERSION = (VERS)

NIH - BPH TRIAL

ADVERSE EVENT REPORT

This form is to be completed if the participant has had any adverse experiences, drug reactions, side effects, abnormal laboratory values, hospitalizations, other complications or worsening of pre-existing conditions. If an adverse event is serious, the Serious Adverse Event Report (Form E06) must also be completed.

Part I / IDENTIFICATION

A. Patient Identification

1. Clinic number **(CLINIC)** [ ][ ]

2. Patient Identification Number (Complete a **OR** b)

   a. If before randomization, Screening number **(SCREEN)** [S][ ][ ][ ][ ]

   b. If after randomization, Patient number **(PATID)** [ ][ ][ ][ ][ ]
   clinic patient

3. Patient's initials **(INITS)** [ ][ ][ ][ ]
   first last

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

B. Visit Information

1. Date of report **(ZRIRDT)** [ ][ ] [ ][ ] [ ][ ]
   month day year

2. Type of visit **(ZVITYP)**
   - [1] Screening
   - [2] Standard Follow-up
   - [3] Major Follow-up
   - [4] Titration Follow-up
   - [5] Interim Follow-up
   - [6] Unattended

3. If follow-up, week of visit **(ZVIWK)** [ ][ ][ ]

Initials of person completing form **(FORMIN)** [ ][ ][ ][ ]
first last

Form entered in computer? [ ]

Patient Number | | | | | | Date of report | | | | month day year

C. Adverse Event Summary

* For each serious adverse event, complete the Serious Adverse Event Report (Form E06).

Event #	Adverse Event	Onset Date	Date Resolved	Was the event serious? 1 = YES* 2 = NO	On coded medication? 1 = YES 2 = NO If YES, continue >	Relationship to coded medication 1 = no 2 = possibly 3 = probably 4 = unknown	Interrupted or stopped? 1 = YES 2 = NO	If YES, Which medication? 1 = doxazosin 2 = finasteride 3 = both
1.	Short Description (ZGCAE1) COSTART Term (ZCOST1)	month day year (ZODT1)	month day year OR (ZRSDT1) Continuing? 1 (ZCONT1)	(ZSER1) ☐	(ZCMED1) ☐	(ZREL1) ☐	(ZINT1) ☐	(ZSMED1) ☐
2.	Short Description (ZGCAE2) COSTART Term (ZCOST2)	month day year (ZODT2)	month day year OR (ZRSDT2) Continuing? 1 (ZCONT2)	(ZSER2) ☐	(ZCMED2) ☐	(ZREL2) ☐	(ZINT2) ☐	(ZSMED2) ☐
3.	Short Description (ZGCAE3) COSTART Term (ZCOST3)	month day year (ZODT3)	month day year OR (ZRSDT3) Continuing? 1 (ZCONT3)	(ZSER3) ☐	(ZCMED3) ☐	(ZREL3) ☐	(ZINT3) ☐	(ZSMED3) ☐
4.	Short Description (ZGCAE4) COSTART Term (ZCOST4)	month day year (ZODT4)	month day year OR (ZRSDT4) Continuing? 1 (ZCONT4)	(ZSER4) ☐	(ZCMED4) ☐	(ZREL4) ☐	(ZINT4) ☐	(ZSMED4) ☐
5.	Short Description (ZGCAE5) COSTART Term (ZCOST5)	month day year (ZODT5)	month day year OR (ZRSDT5) Continuing? 1 (ZCONT5)	(ZSER5) ☐	(ZCMED5) ☐	(ZREL5) ☐	(ZINT5) ☐	(ZSMED5) ☐
6.	Short Description (ZGCAE6) COSTART Term (ZCOST6)	month day year (ZODT6)	month day year OR (ZRSDT6) Continuing? 1 (ZCONT6)	(ZSER6) ☐	(ZCMED6) ☐	(ZREL6) ☐	(ZINT6) ☐	(ZSMED6) ☐

Patient Number | | | | | | Date of report | | | | month day year

C. Adverse Event Summary

* For each serious adverse event, complete the Serious Adverse Event Report (Form E06).

Event #	Adverse Event	Onset Date	Date Resolved	Was the event serious? 1 = YES* 2 = NO	On coded medication? 1 = YES 2 = NO If YES, continue >	Relationship to coded medication 1 = no 2 = possibly 3 = probably 4 = unknown	Interrupted or stopped? 1 = YES 2 = NO	If YES, Which medication? 1 = doxazosin 2 = finasteride 3 = both
7.	Short Description (ZGCAE7) COSTART Term (ZCOST7)	month day year (ZODT7)	month day year OR (ZRSDT7) Continuing? 1 (ZCONT7)	(ZSER7) ☐	(ZCMED7) ☐	(ZREL7) ☐	(ZINT7) ☐	(ZSMED7) ☐
8.	Short Description (ZGCAE8) COSTART Term (ZCOST8)	month day year (ZODT8)	month day year OR (ZRSDT8) Continuing? 1 (ZCONT8)	(ZSER8) ☐	(ZCMED8) ☐	(ZREL8) ☐	(ZINT8) ☐	(ZSMED8) ☐
9.	Short Description (ZGCAE9) COSTART Term (ZCOST9)	month day year (ZODT9)	month day year OR (ZRSDT9) Continuing? 1 (ZCONT9)	(ZSER9) ☐	(ZCMED9) ☐	(ZREL9) ☐	(ZINT9) ☐	(ZSMED9) ☐
10.	Short Description (ZGCAE10) COSTART Term (ZCOST10)	month day year (ZODT10)	month day year OR (ZRSDT10) Continuing? 1 (ZCONT10)	(ZSER10) ☐	(ZCMED10) ☐	(ZREL10) ☐	(ZINT10) ☐	(ZSMED10) ☐
11.	Short Description (ZGCAE11) COSTART Term (ZCOST11)	month day year (ZODT11)	month day year OR (ZRSDT11) Continuing? 1 (ZCONT11)	(ZSER11) ☐	(ZCMED11) ☐	(ZREL11) ☐	(ZINT11) ☐	(ZSMED11) ☐
12.	Short Description (ZGCAE12) COSTART Term (ZCOST12)	month day year (ZODT12)	month day year OR (ZRSDT12) Continuing? 1 (ZCONT12)	(ZSER12) ☐	(ZCMED12) ☐	(ZREL12) ☐	(ZINT12) ☐	(ZSMED12) ☐