

Patient number

Date of report
month day year

BPH FORM E04.1
October, 1993
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FORM NUMBER = (FORM)
FORM VERSION = (VERS)

NIH - BPH CLINICAL TRIAL: PILOT STUDY

ADVERSE EVENT REPORT

Complete this form if the patient has had any adverse experiences, drug reactions, side effects, abnormal laboratory values, hospitalizations, other complications or pre-existing conditions that worsened. (If this is a Standard Follow-up Visit, Question G.1 on Form F01 should be answered "yes".)

This form should be FAXED to the Biostatistical Coordinating Center IMMEDIATELY AT (301) 816-0385.

A. Report Identification

1. Clinic number (CLINIC)

2. Patient Identification number

a. If before randomization, Screening number (SCREEN)

b. If after randomization, Patient number (PATID)

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

3. Patient's initials (INITS)

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

4. Patient's date of birth (DOB)

<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
month	day	year

5. Date of report (ZRIRD)

<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
month	day	year

6. Date of onset of adverse experience (ZRIODT)

<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
month	day	year

B. General Classification

1. Adverse experience (short description) (ZGCAE)

2. Did the adverse experience result in:
(Check all that apply)

☐

Death (ZGCDEA)

☐

Required or prolonged hospitalization (ZGCHOSP)

☐

Permanent or severe disability (ZGCDISA)

If Death checked, CONTINUE.

If Death not checked, SKIP to Question 3.

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a. Date of death (ZGCDDT)

month day year

b. Probable cause of death (ZGCDCAU)

3. Was the adverse experience: (Check all that apply)

☐ Congenital anomaly (ZGCCONA)

☐ Cancer (ZGCCAN)

☐ Life-threatening (ZGCLIFE)

☐ Due to an overdose (ZGCOVD)

IF ANY ITEM IN QUESTION B.2 OR B.3 IS CHECKED, CONTACT THE BIOSTATISTICAL COORDINATING CENTER STAFF IMMEDIATELY AT (301)881-9260.

C. Event Information

1. Onset of adverse experience (ZEIONST)

☐ gradual

☐ sudden

☐ unknown

YES NO

2. Was the patient on coded medication at the time of the adverse experience? (ZEICMED)

☐

☐

If YES, CONTINUE.

If NO, SKIP to Question 3.

a. Was the adverse experience related to coded medication? (ZEICREL)

☐ no

☐ possibly

☐ probably

☐ unknown

YES NO

b. Were the coded medications interrupted or stopped? (ZEICINT)

☐

☐

If YES, CONTINUE.

If NO, SKIP to Question 3.

i. Was the adverse experience reversible when the coded medications were withdrawn? (ZEICREV)

☐

☐

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ii. Were the coded medications re-started? **(ZEICRST)** YES NO

If YES, CONTINUE.
If NO, SKIP to Question 3.

a) How long was the patient off coded medications? days **(ZEIOFFN)** weeks **(ZEIOFFU)** months

If the patient was off coded medications for more than 3 days, Doxazosin must be re-titrated when rechallenging.

b) Did the symptoms recur? **(ZEISREC)** YES NO

3. Was the patient taking any medication other than the coded medications within 14 days of the onset of the adverse experience? **(ZEIMED)**

If YES, list below:

	Medication	Dose	Start Date	Stop Date
a.	(ZEIMEDA)	(ZEIDOSA)	(ZEISRTA)	(ZEISTPA)
b.	(ZEIMEDB)	(ZEIDOSB)	(ZEISRTB)	(ZEISTPB)
c.	(ZEIMEDC)	(ZEIDOSC)	(ZEISRTC)	(ZEISTPC)
d.	(ZEIMEDD)	(ZEIDOSD)	(ZEISRTD)	(ZEISTPD)
e.	(ZEIMEDE)	(ZEIDOSE)	(ZEISRTE)	(ZEISTPE)
f.	(ZEIMEDF)	(ZEIDOSF)	(ZEISRTF)	(ZEISTPF)
g.	(ZEIMEDG)	(ZEIDOSG)	(ZEISRTG)	(ZEISTPG)
h.	(ZEIMEDH)	(ZEIDOSH)	(ZEISRTH)	(ZEISTPH)
i.	(ZEIMEDI)	(ZEIDOSI)	(ZEISRTI)	(ZEISTPI)
j.	(ZEIMEDJ)	(ZEIDOSJ)	(ZEISRTJ)	(ZEISTPJ)

4. Describe the adverse experience in detail:

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5. Overall severity of adverse experience
(Check only one) **(ZEIOSEV)**

- ☐ 1 mild
☐ 2 moderate
☐ 3 severe

6. Duration of adverse experience
(Check only one) **(ZEIDUR)**

- ☐ 1 < 1 day
☐ 2 1 day - 1 week
☐ 3 > 1 week

7. Treatment administered for the adverse
experience (Check only one) **(ZEITRT)**

- ☐ 1 none
☐ 2 self-treatment / OTC drug
☐ 3 outpatient - changes in medication
☐ 4 outpatient procedure
☐ 5 inpatient hospitalization

8. Outcome: (Check only one) **(ZEIOUTC)**

- ☐ 1 recovered, no residual effect
☐ 2 residual effect, no treatment
☐ 3 residual effect, being treated
☐ 4 persistent, no treatment
☐ 5 persistent, being treated
☐ 6 death

D. Conclusion

1. Additional comments:

2. Investigator's signature

Initials of person completing form **(FORMIN)**

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

Date form completed
(FORMDT)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year	

Signature
