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

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

# 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)** 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)

5. Date of report **(ZRIRDT)** | | | (month | day | year)

6. Date of onset of adverse experience **(ZRIODT)** | | | (month | day | year)

B. General Classification

1. Adverse experience (short description) **(ZGCAE)**

_____

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

- [1] Death **(ZGCDEA)**
- [1] Required or prolonged hospitalization **(ZGCHOSP)**
- [1] Permanent or severe disability **(ZGCDISA)**

If Death checked, CONTINUE.
If Death not checked, SKIP to Question 3.

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

a. Date of death **(ZGCDDT)** | month | day | year |

b. Probable cause of death **(ZGCDCAU)**

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

- [1] Congenital anomaly **(ZGCCONA)**
- [1] Cancer **(ZGCCAN)**
- [1] Life-threatening **(ZGCLIFE)**
- [1] 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)**

- [1] gradual
- [2] sudden
- [3] unknown

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

YES [1] NO [2]

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

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

- [1] no
- [2] possibly
- [3] probably
- [4] unknown

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

YES [1] NO [2]

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

i. Was the adverse experience reversible when the coded medications were withdrawn?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

[1] [2]

ii. Were the coded medications re-started? **(ZEICRST)** YES [1] NO [2]

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

a) How long was the patient off coded medications? **(ZEIOFFN)** [ ][ ]

**(ZEIOFFU)**
[1] days
[2] weeks
[3] months

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

b) Did the symptoms recur? **(ZEISREC)** YES [1] NO [2]

3. Was the patient taking any medication other than the coded medications within 14 days of the onset of the adverse experience? **(ZEIMED)** [1] [2]

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:

_____

_____

_____

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

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)** | | | | | first last

Date form completed **(FORMDT)** | | | | month day year

Signature _____