

NIH - BPH TRIAL TRUS AND BIOPSY INFORMATION

This form should be completed any time a TRUS is performed (with or without biopsy). TRUS is performed in all patients at Screening Visit 2. For patients participating in the biopsy substudy, TRUS and biopsy are performed at Screening Visit 2, 12-Month Major Follow-up Visit and End-of-Study.

Part I / IDENTIFICATION

A. Patient Identification

1. Clinic number (CLINIC)

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

a. If before randomization, Screening number (SCREEN)

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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 visit (TVSTDT)

month	day	year

2. Type of visit (TVITYP)

1	Screening
2	12-month Follow-up
3	End of Study
4	Other Follow-up

3. If Follow-up Visit, week of visit (TVIWK)

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4. Sonologist's initials (TVISONI)

first		last	

5. Type of ultrasound equipment (TVIUEQ)

1	Bruel and Kjaer
2	Dornier
3	Other

a. If other, please specify: (TVIUEQO)

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Part II / DIAGNOSTIC CENTER MAILING INFORMATION

C. Mailing Information

1. Was at least one biopsy performed? (TMIBXP)

YES	NO
1	2

If YES, CONTINUE. If NO, SKIP to Section D and do NOT complete Section E.

a. Date tissue sent to the Diagnostic Center (TMIDT)

month	day	year

Patient number Date of visit
month day yearPart III / TRUS INFORMATIOND. Ultrasound Measurements

1. Total Gland

a. Transverse view

i. Height cm (TUGTH)ii. Width cm (TUGTW)

b. Longitudinal view

i. Height cm (TUGLH)ii. Length cm (TUGLL)c. Ellipsoid volume cc
(TUGEV)

2. Transition Zone

a. Transverse view

i. Height cm (TUZTH)ii. Width cm (TUZTW)

b. Longitudinal view

i. Height cm (TUZLH)ii. Length cm (TUZLL)c. Ellipsoid volume cc
(TUZEV)

For each question in this section, please check all that apply.

3. The inner gland (transition zone) is:

1	Normal	(TUIGN)
1	BPH	(TUIGB)
1	Calculi	(TUIGC)
1	Other	(TUIGO)

4. The peripheral zone is:

1	Normal	(TUPZN)
1	Hypoechoic	(TUPZH)
1	Calculi	(TUPZCA)
1	Cyst	(TUPZCY)
1	Vascular	(TUPZV)

5. The surgical capsule is:

1	Normal	(TUSCN)
1	Calculi	(TUSCC)
1	Distorted	(TUSCD)

6. The capsule is:

1	Intact	(TUCINT)
1	Penetrated	(TUCPEN)
1	Suspicious	(TUCSUS)

Part IV / CONCOMITANT MEDICATIONS

If at least one biopsy was performed (question C.1 is YES), CONTINUE.

E. Concomitant Medications

1. Is the patient currently taking any medication other than the coded medications? (TCMCON)

YES
1 NO
2

If YES, list below:

a.	(TCMCONA) (TCMCODA)			f.	(TCMCONF) (TCMCONF)		
b.	(TCMCONB) (TCMCODB)			g.	(TCMCONG) (TCMCONG)		
c.	(TCMCONC) (TCMCONC)			h.	(TCMCONH) (TCMCONH)		
d.	(TCMCOND) (TCMCOND)			i.	(TCMCONI) (TCMCONI)		
e.	(TCMCONE) (TCMCONE)			j.	(TCMCONJ) (TCMCONJ)		

2. Has the patient taken viagra (sildenafil citrate) since the last visit? (TCMVIAG)

1 2

Form entered in computer?

first last

Initials of person completing form (FORMIN)