

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)

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 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)

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)

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 year

Part III / TRUS INFORMATION

D. 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:

<input type="checkbox"/>	Normal	(TUIGN)
<input type="checkbox"/>	BPH	(TUIGB)
<input type="checkbox"/>	Calculi	(TUIGC)
<input type="checkbox"/>	Other	(TUIGO)

4. The peripheral zone is:

<input type="checkbox"/>	Normal	(TUPZN)
<input type="checkbox"/>	Hypoechoic	(TUPZH)
<input type="checkbox"/>	Calculi	(TUPZCA)
<input type="checkbox"/>	Cyst	(TUPZCY)
<input type="checkbox"/>	Vascular	(TUPZV)

5. The surgical capsule is:

<input type="checkbox"/>	Normal	(TUSCN)
<input type="checkbox"/>	Calculi	(TUSCC)
<input type="checkbox"/>	Distorted	(TUSCD)

6. The capsule is:

<input type="checkbox"/>	Intact	(TUCINT)
<input type="checkbox"/>	Penetrated	(TUCPEN)
<input type="checkbox"/>	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)	(TCMCONA)	<input type="text"/>	<input type="text"/>	f.	(TCMCONF)	(TCMCONF)	<input type="text"/>	<input type="text"/>
b.	(TCMCONB)	(TCMCONB)	<input type="text"/>	<input type="text"/>	g.	(TCMCONG)	(TCMCONG)	<input type="text"/>	<input type="text"/>
c.	(TCMCONC)	(TCMCONC)	<input type="text"/>	<input type="text"/>	h.	(TCMCONH)	(TCMCONH)	<input type="text"/>	<input type="text"/>
d.	(TCMCOND)	(TCMCOND)	<input type="text"/>	<input type="text"/>	i.	(TCMCONI)	(TCMCONI)	<input type="text"/>	<input type="text"/>
e.	(TCMCONE)	(TCMCONE)	<input type="text"/>	<input type="text"/>	j.	(TCMCONJ)	(TCMCONJ)	<input type="text"/>	<input type="text"/>

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)**