Prostate Cancer

IDGN-PC-AO3

I. INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRITERIA

	Yes	No
1. Subject is diagnosed with primary adenocarcinoma of Prostate by histopathology.	☐	☐
2. Subject is of Ashkenazi Jewish origin, as declared by the subject.	☐	☐
3. Subject or subject's legal representative has signed the informed consent form.	☐	☐

EXCLUSION CRITERIA

1. Subject is diagnosed with one of the following:	Yes	No
a. Squamous cell carcinoma of Prostate.	☐	☐
b. Transitional cell carcinoma of Prostate.	☐	☐
c. Carcinoma of the prostatic utricle (a müllerian duct remnant).	☐	☐
d. Mesenchymal carcinosarcomas of Prostate.	☐	☐
e. Metastatic tumors to Prostate (usually carcinoma of the lung, melanoma, or lymphoma).	☐	☐
2. Subject is a known carrier of a blood transmitted infectious disease or suffers from conditions in which phlebotomy is contra-indicated.	☐	☐

Subject is eligible for the study, if all INCLUSION criteria are YES and all EXCLUSION criteria are NO.

INVESTIGATOR'S STATEMENT

I have verified the data entered in the Case Report Form and have determined that it is complete, accurate and compatible with the source documents.

Investigator's name (printed)	Investigator's signature	☐☐ / ☐☐ / ☐☐ Day / Month / Year

Where appropriate mark like this ☒ (not like this √)

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II. DEMOGRAPHICS

1. Year of birth: ☐☐☐☐

2. Country of birth: _____

3. Year of immigration: ☐☐☐☐

4. Height*: ☐☐☐ cm

5. Weight at time of diagnosis*: ☐☐☐ kg

* If measurements cannot be carried out, subject declaration is sufficient.

III. FAMILY HISTORY

1. Maternal			**2. Paternal**		
	Country of birth			Country of birth	
1.1 Mother:	_____		2.1 Father:	_____	
1.2 Grandfather:	_____		2.2 Grandfather:	_____	
1.3 Grandmother:	_____		2.3 Grandmother:	_____	
	Yes	No*		Yes	No*
1.4 Mother is alive	☐	☐	2.4 Father is alive	☐	☐
*If not, specify age at death:	☐☐		*If not, specify age at death:	☐☐	

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III. FAMILY HISTORY – cont.

3. Blood relatives:

3.1 Were there any cancers diagnosed in the family (including grandfathers, uncles or aunts)?

Yes ☐ * No ☐

*If yes, please complete the tables: mark "yes" where appropriate and specify approximate age at onset **only for those relatives diagnosed with cancer:**

	Prostate cancer		Other cancer	
Male family members	Yes	Age at diagnosis	Specify type	Age at diagnosis
Father	☐	☐☐	_____	☐☐
Father's father	☐	☐☐	_____	☐☐
Father's brother	☐	☐☐	_____	☐☐
Mother's father	☐	☐☐	_____	☐☐
Mother's brother	☐	☐☐	_____	☐☐
Brother	☐	☐☐	_____	☐☐
Brother	☐	☐☐	_____	☐☐

	Breast cancer		Other cancer	
Female family members	Yes	Age at diagnosis	Specify type	Age at diagnosis
Mother	☐	☐☐	_____	☐☐
Mother's mother	☐	☐☐	_____	☐☐
Mother's sister	☐	☐☐	_____	☐☐
Father's mother	☐	☐☐	_____	☐☐
Father's sister	☐	☐☐	_____	☐☐
Sister	☐	☐☐	_____	☐☐
Sister	☐	☐☐	_____	☐☐

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IV. CLINICAL CHARACTERISTICS

1. Date of diagnosis (month / year): ☐☐ / ☐☐☐☐

2. Was the tumor diagnosed by screening? yes ☐* no ☐

*If yes, specify (one or more positive tests):

PSA[1] assay ☐ Digital rectal examination ☐ TRUS[2] ☐

3. Stage at diagnosis (TNM classification):

a. Tx ☐ T0 ☐ Tis ☐ T1 ☐ T2 ☐ T3 ☐ T4 ☐

b. Nx ☐ N0 ☐ N1 ☐

c. Mx ☐ M0 ☐ M1 ☐

4. Gleason score at diagnosis: ☐☐

5. PSA[1] level at diagnosis: ☐☐

6. Did the patient undergo prostatectomy? yes ☐ no ☐

7. Did the patient receive radiation therapy?

a. To the primary tumor site yes ☐ no ☐

b. To bone yes ☐ no ☐

8. Did the diease recur? yes* ☐ no ☐ unknown ☐

*If yes, specify date of recurrence (month / year): ☐☐ / ☐☐☐☐

9. Smoking history – no. of years: ☐☐ no. of packs per day: ☐☐.☐

10. Specify other chronic diseases: _____

_____

_____

[1]PSA – Prostate specific antigen.

[2]TRUS – Trans-rectal ultra sound.

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V. MEDICATIONS

1. For a patient treated with hormonal androgenic suppression therapy, please complete the following table:

	Leuprolide (Lucrin)	Goserelin (Zoladex)	Triptorelin (Decapeptyl)	Flutamide (Eulexin)	Bicalutamide (Casodex)	Cyproterone (Androcur, Armocur, Cypron)
No. of treatment months	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
Disease progressed or recurred under treatment	☐	☐	☐	☐	☐	☐

2. If the hormonal therapy was withdrawn due to an adverse reaction, specify the relevant one or mark "not withdrawn":

Not withdrawn due to an adverse reaction	☐	☐	☐	☐	☐	☐
Angina pectoris / ECG change	☐	☐	☐	☐	☐	☐
Peripheral edema	☐	☐	☐	☐	☐	☐
Gastrointestinal[1]	☐	☐	☐	☐	☐	☐
Hot flashes	☐	☐	☐	☐	☐	☐
Gynecomastia / breast tenderness	☐	☐	☐	☐	☐	☐
Impotence	☐	☐	☐	☐	☐	☐
Other: _____	☐	☐	☐	☐	☐	☐

[1]Gastrointestinal – nausea / vomiting / diarrhea / constipation / pain

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