APPENDIX E: PHYSICIAN QUESTIONNAIRES

IRONMAN: International Registry for Men with Advanced Prostate Cancer –

Discontinuation of Treatment Physician Questionnaire

Site Number:	**Physician Name:**
Date:	**Medidata Subject ID:**
☐ **Follow Up - Year 1** ☐ **Follow Up - Change in Treatment** ☐ #1 ☐ #2 ☐ #3 ☐ #_____ ☐ **Follow Up - Discontinuation of Treatment**	

Discontinuation of systemic treatment: This survey has been designed to capture the reasons for discontinuing treatment by providers of advanced prostate cancer patients in the IRONMAN Registry. We recognize there may be multiple reasons for stopping a treatment in a patient at a given time, so please answer these questions with the best approximate choice(s).

1. Please select the systemic treatment that you have most recently discontinued in this patient (choose only one).
   - ❒ Enzalutamide
   - ❒ Abiraterone acetate
   - ❒ Docetaxel chemotherapy
   - ❒ Radium-223 dichloride
   - ❒ Sipuleucel-T
   - ❒ Cabazitaxel chemotherapy
   - ❒ Bicalutamide, or other anti-androgen
   - ❒ Clinical Trial
   - ❒ Other _____

Please select **PRIMARY REASON** for discontinuing the most immediate treatment with this patient.

☐ Toxicity (Go to **C1**) ☐ Disease Progression (Go to **C2**) ☐ Other (Go to **C3**)

C1. Please indicate the **PRIMARY** toxicity and **UP TO TWO (2) SECONDARY** toxicities that patient experienced that led to your decision to remove the patient from therapy.

Primary Toxicity (Select One)	**Secondary Toxicity (Select One)**	**Secondary Toxicity (Optional)**
Constitutional ☐ Fatigue/ Asthenia ☐ Arthralgia	**Constitutional** ☐ Fatigue/ Asthenia ☐ Arthralgia	**Constitutional** ☐ Fatigue/ Asthenia ☐ Arthralgia
Gastrointestinal ☐ Soreness in mouth/throat	**Gastrointestinal** ☐ Soreness in mouth/throat	**Gastrointestinal** ☐ Soreness in mouth/throat

☐ Diarrhea ☐ Nausea/vomiting ☐ Abdominal pain ☐ Loss of appetite	☐ Diarrhea ☐ Nausea/vomiting ☐ Abdominal pain ☐ Loss of appetite	☐ Diarrhea ☐ Nausea/vomiting ☐ Abdominal pain ☐ Loss of appetite
Cardiovascular and Pulmonary ☐ Hypertension ☐ Cardiac dysfunction ☐ Pneumonitis	**Cardiovascular and Pulmonary** ☐ Hypertension ☐ Cardiac dysfunction ☐ Pneumonitis	**Cardiovascular and Pulmonary** ☐ Hypertension ☐ Cardiac dysfunction ☐ Pneumonitis
Dermatologic/Skin ☐ Soreness in hands/feet ☐ Rash	**Dermatologic/Skin** ☐ Soreness in hands/feet ☐ Rash	**Dermatologic/Skin** ☐ Soreness in hands/feet ☐ Rash
Hematologic and Laboratory ☐ Hemorrhage ☐ Anemia ☐ Neutropenia ☐ Thrombocytopenia ☐ Increased AST, ALT or Bilirubin ☐ Increased Creatinine	**Hematologic and Laboratory** ☐ Hemorrhage ☐ Anemia ☐ Neutropenia ☐ Thrombocytopenia ☐ Increased AST, ALT or Bilirubin ☐ Increased Creatinine	**Hematologic and Laboratory** ☐ Hemorrhage ☐ Anemia ☐ Neutropenia ☐ Thrombocytopenia ☐ Increased AST, ALT or Bilirubin ☐ Increased Creatinine
Other (*SPECIFY*): ☐ _____	**Other (*SPECIFY*):** ☐ _____	**Other (*SPECIFY*):** ☐ _____

C2. Please select the indicator(s) of **DISEASE PROGRESSION** that led to discontinuation of treatment for the patient. **Select ALL that apply.**

PSA	☐ PSA rise from baseline with no decline on therapy ☐ PSA rise following an initial decline from baseline ☐ PSA stable or decline in PSA in the setting of clinical or radiographic progression
Radiographic Progression	☐ New bone lesion(s) on first scan on treatment ☐ New bone lesion(s) following subsequent stable or improved scans on treatment ☐ Increase of existing bone lesion(s) ☐ New soft tissue lesion(s) in entirely new body organ ☐ Lymph nodes ☐ Lung ☐ Liver ☐ Other ☐ Increase of existing soft tissue lesion(s) ☐ Lymph nodes ☐ Lung ☐ Liver ☐ Other
Clinical Progression	☐ Decreased performance status

	☐ Symptomatic Skeletal event ☐ Bone pain requiring radiation therapy ☐ Pathologic fracture ☐ Need for palliative bone surgery ☐ Spinal cord compression ☐ Increase in bone pain ☐ Anorexia/weight loss ☐ Fatigue related to cancer ☐ Other SPECIFY _____

C3. Please select an applicable other reason that led to discontinuation of systemic treatment for the patient.

☐ Patient declined continuing treatment

☐ Cost/ Unable to afford treatment

☐ Completed planned treatment

☐ Other (*SPECIFY*): _____

END

IRONMAN: International Registry for Men with Advanced Prostate Cancer –

New Treatment Physician Questionnaire

Site Number:	**Physician Name:**
Date:	**Medidata Subject ID:**

This survey has been designed to capture the reasons for a new treatment choice by providers of advanced prostate cancer patients in the IRONMAN Registry. We recognize there may be multiple reasons for selecting a treatment in a patient at a given time, so please answer these questions with the best approximate choice(s).

1. Which disease state best describes your patient:

   ❒Hormone sensitive

   ❒Castration-resistant

2. Where are the sites of disease? Choose all that apply

   ❒ Prostate gland

   ❒ Bone metastasis

   ❒ Lymph node metastasis

   ❒ Visceral metastasis

   ❒ Soft tissue metastasis

   ❒ Other _____

3. Has your patient undergone any testing for genetic alterations? Choose all that apply.

   ❒ Germline DNA testing

   ❒ Tumor specimen DNA testing

   ❒ Plasma collection for cell-free or circulating tumor DNA

   ❒ Circulating tumor cells for enumeration or profiling

   ❒ None

4. What systemic treatments has your patient previously received for his prostate cancer? Choose all that apply.

   ❒ Androgen deprivation therapy (surgical castration, LH-RH agonist/antagonist)

   ❒ Enzalutamide

   ❒ Abiraterone acetate

   ❒ Docetaxel chemotherapy

❒ Radium-223 dichloride

❒ Sipuleucel-T

❒ Cabazitaxel chemotherapy

❒ Bicalutamide, or other anti-androgen

❒ Clinical Trial

❒ Other _____

5. What treatment is your patient starting? May select more than one if in combination

❒ Enzalutamide

❒ Abiraterone acetate

❒ Docetaxel chemotherapy

❒ Radium-223 dichloride

❒ Sipuleucel-T

❒ Cabazitaxel chemotherapy

❒ Bicalutamide, or other anti-androgen

❒ Clinical Trial

❒ Other _____

6. Please select the <u>most appropriate</u> clinical reason for your therapy choice for this patient:

❒Clinical Guidelines (ASCO, NCCN, other) or based on published Phase III data

❒Published Phase I or II clinical data

❒Preclinical rationale

❒Personal (anecdotal) experience or preference

❒ Known genetic susceptibility (based on patient/tumor profiling)

7. Which patient factors were most important in your treatment choice for this patient (choose all that apply)?

❒ Age
❒ Performance status/frailty
❒ Prior treatments
❒ Co-morbidities (ie diabetes, cardiovascular, neuropathy, etc)
❒ Access to care (travel, family support)
❒ Patient costs
❒ Ability to take pills
❒ Concomitant medications
❒ Known germline genetic alterations

8. Which tumor factors were most important in your treatment choice for this patient? Choose all that apply

    ❒ Variant histology (e.g. small cell, neuroendocrine)
    ❒ Tumor-related symptoms (e.g. pain, weight loss/anorexia, fatigue, etc).
    ❒ Pattern of spread (ie visceral disease, bone only disease, etc)
    ❒ Laboratory abnormalities (ie low hemoglobin, platelets; elevated liver function tests)
    ❒ Known somatic genetic alterations
    ❒ Response/resistance to prior therapy

9. How much did the side effect profile (of this agent vs other options) influence the decision to start treatment? Choose one:
    ❒Primary factor
    ❒Contributing factor
    ❒Not a factor at all

    9a. Your opinion about side effect risk is based primarily on (choose one):
        ❒ Published clinical data
        ❒ Personal clinical experience
        ❒ Experience of others (colleagues or clinical experts)

    9b. In your opinion, which side effect profile is most concerning to this patient? Choose one.
        ❒ Fatigue
        ❒ Cardiovascular risk
        ❒ GI toxicity
        ❒ Hematopoietic toxicity
        ❒ Neurologic toxicity
        ❒ None of the above

10. If another treatment below were available (that currently is not covered/available in this situation), would you choose it over your current choice? Choose all that apply.

    ❒ Enzalutamide
    ❒ Abiraterone acetate
    ❒ Docetaxel chemotherapy
    ❒ Radium-223 dichloride
    ❒ Sipuleucel-T
    ❒ Cabazitaxel chemotherapy
    ❒ Bicalutamide, or other anti-androgen
    ❒ Clinical Trial
    ❒ Would not change treatment choice