

APPENDIX E: PHYSICIAN QUESTIONNAIRE

Prostate Cancer Outcomes: An International Registry to Improve Outcomes in Men with Advanced Prostate Cancer (IRONMAN): *Physician Questionnaire*

Site Number:	Physician Name:
Date:	Medidata Subject ID:
<input type="checkbox"/> Baseline <input type="checkbox"/> Follow Up - Year 1 <input type="checkbox"/> Follow Up - Change in Treatment <input type="checkbox"/> #1 <input type="checkbox"/> #2 <input type="checkbox"/> #3 <input type="checkbox"/> # _____	
<input type="checkbox"/> Follow Up - Discontinuation of Treatment	

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

1. Please list this patient's CURRENT / CHANGE IN TREATMENT(S).
SPECIFY: _____
2. Are you planning on continuing androgen deprivation therapy for this patient?
 - ☐ YES SKIP to Q3
 - ☐ NO
 - 2a. If NO, then please select the reasons you chose to STOP androgen deprivation therapy.
 - ☐ Side effects
 - ☐ Patient preference
 - ☐ Cost
 - ☐ Other SPECIFY: _____
3. Did you select the CURRENT / CHANGE IN TREATMENT(S) mainly because of clinical efficacy?
 - ☐ YES
 - ☐ NO SKIP TO Q4
 - 3a. If yes, would you say your opinion about clinical efficacy is based primarily on
 - ☐ Published clinical data
 - ☐ Personal clinical experience
 - ☐ Guideline recommendations
 - ☐ Other SPECIFY: _____
4. Did you select the CURRENT / CHANGE IN TREATMENT(S) mainly because of side effect risk?
 - ☐ YES
 - ☐ NO SKIP TO Q5
 - 4a. If yes, would you say your opinion about side effect risk is based on
 - ☐ Published clinical data
 - ☐ Personal clinical experience
 - ☐ Experience of others (colleagues or clinical experts)
 - ☐ Other SPECIFY: _____
 - 4b. If yes, which side effect profile is most important for this patient?
 - ☐ Less fatigue
 - ☐ Less cardiovascular risk
 - ☐ Less GI toxicity
 - ☐ Less hematopoietic toxicity
 - ☐ Less neurologic toxicity

☐ Other SPECIFY: _____

5. Did you select the CURRENT / CHANGE IN TREATMENT(S) mainly because of patient characteristics?

☐ YES

☐ NO SKIP TO Q6

- 5a. If yes, which patient characteristics were most important in choosing therapy for this patient?

☐ Age

☐ Performance status/frailty

☐ Co-morbidities SPECIFY: _____

☐ Other SPECIFY: _____

6. Did you select the CURRENT / CHANGE IN TREATMENT(S) mainly because of tumor characteristics?

☐ YES

☐ NO SKIP TO Q7

- 6a. If yes, which tumor characteristics were most important in choosing therapy for this patient?

☐ Variant histology

☐ Tumor-related symptoms (e.g. pain, weight loss, etc).

☐ Visceral disease

☐ Other SPECIFY: _____

7. Did you select the CURRENT / CHANGE IN TREATMENT(S) mainly because of patient preference?

☐ YES SPECIFY: _____

☐ NO SKIP TO Q8

8. Did you select the CURRENT / CHANGE IN TREATMENT(S) mainly because of cost?

☐ YES SPECIFY: _____

☐ NO SKIP TO Q9

9. If you selected the CURRENT / CHANGE IN TREATMENT(S) for a reason not listed in the above questions, please specify:

9a. SKIP TO Q10 if reason for CURRENT / CHANGE IN TREATMENT(S) has been addressed with the above questions.

10. If another treatment were available (approved in another country for this indication) would you choose it over your current choice?

☐ YES

☐ NO SKIP TO END

- 10a. If yes, what agent would be your treatment choice?

☐ Enzalutamide

☐ Abiraterone

☐ Radium 223

☐ Cabazitaxel

☐ Docetaxel

☐ Sipuleucel-T

☐ Platinum based chemotherapy

☐ Other _____

END

Follow Up - Discontinuation of 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 treatment changes in a patient at given time, so please answer these questions with the best approximate choice(s).

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 <input type="checkbox"/> Fatigue/ Asthenia <input type="checkbox"/> Arthralgia	Constitutional <input type="checkbox"/> Fatigue/ Asthenia <input type="checkbox"/> Arthralgia	Constitutional <input type="checkbox"/> Fatigue/ Asthenia <input type="checkbox"/> Arthralgia
Gastrointestinal <input type="checkbox"/> Soreness in mouth/throat <input type="checkbox"/> Diarrhea <input type="checkbox"/> Nausea/vomiting <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Loss of appetite	Gastrointestinal <input type="checkbox"/> Soreness in mouth/throat <input type="checkbox"/> Diarrhea <input type="checkbox"/> Nausea/vomiting <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Loss of appetite	Gastrointestinal <input type="checkbox"/> Soreness in mouth/throat <input type="checkbox"/> Diarrhea <input type="checkbox"/> Nausea/vomiting <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Loss of appetite
Cardiovascular and Pulmonary <input type="checkbox"/> Hypertension <input type="checkbox"/> Cardiac dysfunction <input type="checkbox"/> Pneumonitis	Cardiovascular and Pulmonary <input type="checkbox"/> Hypertension <input type="checkbox"/> Cardiac dysfunction <input type="checkbox"/> Pneumonitis	Cardiovascular and Pulmonary <input type="checkbox"/> Hypertension <input type="checkbox"/> Cardiac dysfunction <input type="checkbox"/> Pneumonitis
Dermatologic/Skin <input type="checkbox"/> Soreness in hands/feet <input type="checkbox"/> Rash	Dermatologic/Skin <input type="checkbox"/> Soreness in hands/feet <input type="checkbox"/> Rash	Dermatologic/Skin <input type="checkbox"/> Soreness in hands/feet <input type="checkbox"/> Rash
Hematologic and Laboratory <input type="checkbox"/> Hemorrhage <input type="checkbox"/> Anemia <input type="checkbox"/> Neutropenia <input type="checkbox"/> Thrombocytopenia <input type="checkbox"/> Increased AST, ALT or Bilirubin <input type="checkbox"/> Increased Creatinine	Hematologic and Laboratory <input type="checkbox"/> Hemorrhage <input type="checkbox"/> Anemia <input type="checkbox"/> Neutropenia <input type="checkbox"/> Thrombocytopenia <input type="checkbox"/> Increased AST, ALT or Bilirubin <input type="checkbox"/> Increased Creatinine	Hematologic and Laboratory <input type="checkbox"/> Hemorrhage <input type="checkbox"/> Anemia <input type="checkbox"/> Neutropenia <input type="checkbox"/> Thrombocytopenia <input type="checkbox"/> Increased AST, ALT or Bilirubin <input type="checkbox"/> Increased Creatinine
Other (SPECIFY): <input type="checkbox"/> _____	Other (SPECIFY): <input type="checkbox"/> _____	Other (SPECIFY): <input type="checkbox"/> _____

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

PSA	<input type="checkbox"/> PSA rise from baseline with no decline on therapy <input type="checkbox"/> PSA rise following an initial decline from baseline <input type="checkbox"/> PSA stable or decline in PSA in the setting of clinical or radiographic
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	progression
Radiographic Progression	<input type="checkbox"/> New bone lesion(s) on first scan on treatment <input type="checkbox"/> New bone lesion(s) following subsequent stable or improved scans on treatment <input type="checkbox"/> Increase of existing bone lesion(s) <input type="checkbox"/> New soft tissue lesion(s) in entirely new body organ <ul style="list-style-type: none"> <input type="checkbox"/> Lymph nodes <input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Other <input type="checkbox"/> Increase of existing soft tissue lesion(s) <ul style="list-style-type: none"> <input type="checkbox"/> Lymph nodes <input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Other
Clinical Progression	<input type="checkbox"/> Decreased performance status <input type="checkbox"/> Symptomatic Skeletal event <ul style="list-style-type: none"> <input type="checkbox"/> Bone pain requiring radiation therapy <input type="checkbox"/> Pathologic fracture <input type="checkbox"/> Need for palliative bone surgery <input type="checkbox"/> Cord compression <input type="checkbox"/> Increase in bone pain <input type="checkbox"/> Anorexia/weight loss <input type="checkbox"/> Other SPECIFY _____

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

- ☐ Patient declined ongoing treatment
- ☐ Cost/ Unable to afford treatment
- ☐ Other (*SPECIFY*): _____

END

APPENDIX F: SITE SPECIFIC ADDENDUM