A pragmatic study of the clinical utility of a genomic classifier in guiding prostate cancer treatment decisions: Impact of treatment selection, oncologic outcomes, and treatment-related adverse events (PROMPT-Bx)

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Background

- Prostate cancer (PCa) prognostic models based on clinicopathological features have been widely adopted by clinicians to inform treatment decisions.
- Biomarkers, including genomic classifiers (GCs), have the potential to provide additional information that informs treatment selection and intensification decisions, and additional biomarkers are needed.
- Prolaris provides greater prognostic power for evaluating risk of distant metastases and PCa-specific mortality than traditional risk models.

Biomarker needs:

- Identify patients who would least benefit from definitive therapy
- Identify patients who would benefit most from treatment intensification

- Not all patients who qualify for Prolaris testing receive testing and therefore miss the opportunity to make results-informed critical decisions to manage this pervasive and potentially deadly disease.

This study is the largest pragmatic, prospective assessment of Prolaris as a decision aid for localized prostate cancer (PCa).

Study Premise:

- Prospectively demonstrate the utility of Prolaris as a prostate cancer (PCa) decision aid in a real-world scenario
- Explore balance of oncological outcomes & treatment-associated adverse events in Prolaris-informed treatment decisions
- Describe the impact of Prolaris on management decisions using pre- and post-test assessment of management plans

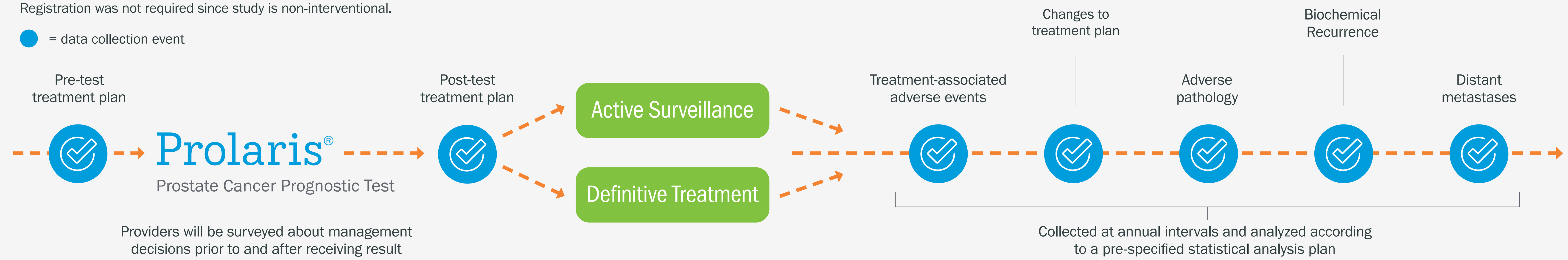
Study Design

- PROMPT-Bx is a multicenter, observational, pragmatic study in patients with newly diagnosed primary PCa.
- Study sites routinely treat newly diagnosed localized PCa and accurately reflect real-world diagnosis and treatment of the disease.
- Patients who are eligible for and elect to pursue GC testing will be informed of the study and offered the chance to participate following provision of informed consent.

PROMPT-Bx is expected to enroll 3350 patients with 5 years of follow up

Figure 1. PROMPT-Bx: Prolaris Risk Outcome Management in Prostate Treatment from Biopsy

Registration was not required since study is non-interventional.



Primary objectives:

Primary objective 1: Evaluate the clinical utility of the Prolaris test to identify candidates for active surveillance vs definitive therapy based on their metastasis risk.

Primary objective 2: Evaluate the clinical utility of the Prolaris test to identify candidates for single-modal vs multi-modal therapy based on their metastasis risk.

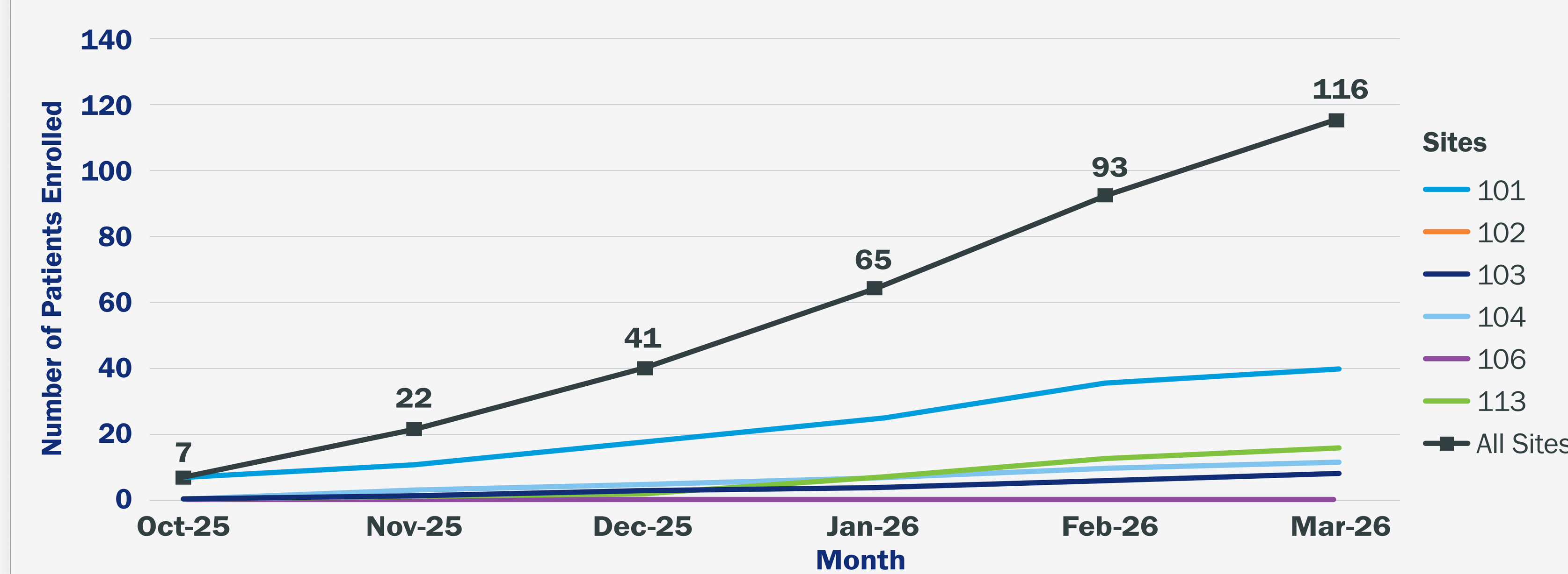
Secondary objectives:

- Evaluate the clinical utility of the Prolaris test to spare patients from treatment-related adverse events based on the test's recommendation to active surveillance vs definitive therapy.
- Evaluate the clinical utility of the Prolaris test to spare patients from treatment-related adverse events based on the test's recommendation to single-modal vs multi-modal therapy.
- Evaluate the impact of Prolaris testing on decisions to pursue active surveillance vs definitive therapy.
- Evaluate the impact of Prolaris testing on decisions to pursue single modal vs multi-modal therapy.
- Evaluate the ability of Prolaris testing to prognosticate the durability of active surveillance in patients who are initially managed with active surveillance.
- Evaluate the ability of the Prolaris test to prognosticate metastasis.
- Evaluate the ability of the Prolaris test to prognosticate biochemical recurrence.

Exploratory objectives:

- Evaluate the ability of the Prolaris test to prognosticate Gleason upgrade at follow-up biopsies in patients on active surveillance.
- Evaluate the ability of the Prolaris test to predict adverse pathology outcomes from radical prostatectomy.

Figure 2. Current Enrollment by Site by Month



Inclusion Criteria	Exclusion Criteria
Patient age 18 years or older or age of majority in state of residence	Patient has evidence of distant metastatic disease (M1)
Patient has confirmed diagnosis of prostate cancer (PCa) (Stage T1-T3a; All NCCN risk categories permitted)	PSA > 100ng/mL
Patient eligible for genomic classifier testing as per NCCN or other relevant guidelines	Patient has received pelvic radiation prior to biopsy
Patient with recent diagnostic biopsy performed (i.e. within ~6 months) and available for use in Prolaris testing	Patient has received androgen deprivation therapy (ADT) prior to biopsy; however, 5 alpha-reductase inhibitor (5-ARI) use is permitted
Patient can be monitored for disease progression according to standard of care per NCCN or other relevant guidelines	Patient has currently active additional cancer diagnosis (except nonmelanoma skin cancer)
Provider and patient are willing to share information on the management of the prostate cancer (PCa) after receiving Prolaris	Patient has estimated life expectancy < 10 years as per NCCN or other relevant guidelines
	Patient is currently participating in an interventional clinical trial

Conclusions

- This study provides one of the first opportunities to better understand the utility of GC testing for patients and providers in a real-world setting.
- The trial is enrolling as planned, and first data analysis will occur 6 months after full enrollment.

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