Treatment registry for outcomes in patients with castration-resistant prostate cancer (TRUMPET): a methodology for real-world evidence and research

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Aim: This study seeks to improve the understanding of treatment patterns and associated health-related quality of life (HRQoL), clinical outcomes and healthcare utilization in US patients with castration-resistant prostate cancer (CRPC). **Patients & methods:** Treatment Registry for Outcomes in CRPC Patients (TRUMPET) is a US-based, prospective, observational multicenter registry (NCT02380274) involving patients with CRPC and their caregivers. Patients initiating their first active treatment course will be enrolled from urology and medical oncology practices, with data captured up to 4 years. **Results:** Information on prescribing patterns, HRQoL, clinical outcomes and healthcare utilization will be collected. **Conclusion:** TRUMPET will enable scientific understanding of disease management in terms of HRQoL, clinical outcomes and healthcare utilization in clinical practice for patients with CRPC.

Background

It was estimated that approximately 220,800 new cases of prostate cancer and 27,540 prostate cancer-associated deaths would occur in the USA in 2015 [1]. Androgen deprivation therapy is commonly used for the treatment of patients with prostate cancer whose cancer has spread beyond the prostate and is typically achieved through surgical or medical castration (with gonadotropin-releasing hormone agonists or antagonists).

Progression following traditional androgen deprivation therapy is often observed in patients with advanced disease, resulting in castration-resistant prostate cancer (CRPC), with an estimated incidence in the USA of 36,100 cases in 2009 and 42,970 cases in 2020 [2]. The transition from hormone-sensitive prostate cancer to CRPC, which can occur in the presence of metastases (M1 CRPC) or in the absence of metastases (M0 CRPC), is not yet fully understood; however, research indicates the androgen receptor signaling pathway remains active despite the reduction of androgens to castrate levels [3].

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• Current management of CRPC

Currently, there are no US FDA-approved therapies for patients with nonmetastatic CRPC (M0 CRPC); however, first-generation antiandrogens (flutamide, bicalutamide and nilutamide) and first-generation androgen synthesis inhibitors (ketoconazole) are utilized despite lack of clear evidence from randomized controlled studies [4]. Presently, clinicians can offer FDA-approved therapies for metastatic (M1) CRPC (mCRPC) both to improve survival and to palliate symptoms, with recommendations provided by the American Urological Association and National Comprehensive Cancer Network guidelines. Treatment options for patients with mCRPC include docetaxel-based chemotherapy, immunotherapy (sipuleucel-T) and novel hormonal therapy (such as enzalutamide and abiraterone acetate plus prednisone) [4,5]. If patients are not eligible or fail on these therapies, radiopharmaceutical therapy (radium Ra-223 dichloride) and cabazitaxel are alternative treatment options recommended for mCRPC.

With substantially more treatments available and recommended in approved guidelines, treatment patterns can vary widely due to patient characteristics, patient preferences and physician practices. Little real-world evidence is available regarding the optimal combination or sequence of these treatments to grant maximal survival benefit to patients with CRPC [6].

Recently published randomized clinical trials of new agents for mCRPC have captured elements of the patient experience while on treatment [7]. However, the impact of treatment on health-related quality of life (HRQoL) in patients with CRPC in real-world care settings is not well described. In addition, patients may not be the only ones affected by the disease and the efficacy and safety of the utilized treatments; partners' and/or caregivers' quality of life is also often affected [8]. In previous studies, spouses of patients with advanced prostate cancer had low emotional quality of life [8]. Furthermore, disease symptoms, lack of information, fear of the unknown, fear of what the future will hold and treatment-related concerns can result in spousal distress [9]. Caregivers of patients with mCRPC may also be negatively affected through their caregiving responsibilities, which may manifest physically (i.e., pain, fatigue and sleep disturbance) and psychologically (i.e., depression and anxiety) [10].

• Rationale for the TRUMPET study

Several US-based registries of prospective patients with prostate cancer are currently available, with outcome data from patients with prostate cancer receiving localized treatment regimens (Table 1). Although sometimes limited to a selected geographical region or by data collected, such registries have played a key role in the assessment of the safety and efficacy of prostate cancer treatments [11]. Understanding how treatment decisions in everyday clinical practice affect outcomes and total cost of care is essential in the decision-making process for physicians, patients and patients' families. Therefore, collection of these data could provide meaningful information and aid the treatment-related decision-making process.

The Treatment Registry for Outcomes in CRPC Patients (TRUMPET) study (Clinicaltrials.gov NCT02380274) was designed to improve understanding of current treatment patterns and evaluate the impact of treatment and disease progression on HRQoL in patients with CRPC. To capture the management and progression of CRPC, patients with M0 or M1 CRPC will be included in the registry from the urology and oncology treatment settings. By initiating a large prospective observational study, we hope to increase the scientific understanding of treatment patterns and quality-of-life and clinical outcomes, healthcare resource use and costs associated with the therapeutic management of CRPC. In addition to these important outcomes, our goal is to describe the psychosocial and economic burden associated with the disease in a substudy of caregivers.

In this registry, inclusion of patients with CRPC enrolled from both community and academic institutions across the USA provides a contemporary cohort of patients in a rapidly evolving disease state. The secondary, exploratory and substudy objectives we describe here also represent a unique scientific opportunity to understand the overall social and economic burden on caregivers of patients with CRPC. We also hope that increased awareness of the methodology of the TRUMPET registry will encourage greater use of real-world evidence, including perspectives from both patients and caregivers.

Study objectives

The two primary objectives of the study are to describe patterns of care, disease assessment

Table 1. Content of currently active prostate cancer registries based in the USA.	
Registry	**Data collected**
CaPSURE: UCSF Cancer of the Prostate Strategic Urologic Research Endeavor [12]	Initial and subsequent treatments Pathologic and oncologic outcomes QoL General health Resource utilization
AQUA: AUA Quality Registry [13]	Diagnosis, treatment and management Testing utilization Patient communications Treatment decisions
PROCEED: PROVENGE® Registry for Observation, Collection, and Evaluation of Experience Data [14]	Risk of CVE following sipuleucel-T Survival
A Registry for Patients Treated on the Clinical Trial TAX 3503 [15]	Progression-free survival Clinical outcomes Overall survival
LCCC 1231: Observational Longitudinal Study of Pain in Men With Metastatic Castrate-Resistant Prostate Cancer [16]	Pain palliation responders Pain score Prevalence and trajectory of pain progression and palliation Analgesic medicine use Frequency of pain reporting Web avidity of patients
AUA: American Urological Association; CVE: Cerebrovascular event; QoL: Quality of life; UCSF: University of California, San Francisco.	

methods, treatment decisions, treatment settings, physician referral patterns and the characteristics of patients with CRPC associated with these, and to describe HRQoL outcomes associated with CRPC and its management. The secondary objectives of the study are to describe factors influencing treatment decisions, including reason(s) for treatment choices and trigger(s) for changes in treatment, and to describe clinical outcomes based on baseline patient characteristics.

An exploratory objective of the study includes describing the quality-of-life outcomes for caregivers of patients with CRPC. In addition, describing the health utilities using quality-adjusted life years (QALYs) to evaluate the quantity and quality of life associated with disease progression will be described.

Work productivity and service satisfaction for cancer-care questionnaires will be administered to a subset of patients throughout the study. The objective for this substudy is to describe work productivity and patient-treatment satisfaction using validated instruments.

Study design

TRUMPET is a prospective, observational, multicenter registry that was initiated in March 2015 to assess treatment patterns for patients with CRPC in the USA. A patient registry is defined as "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or, exposure and that serves one or more predetermined scientific, clinical, or policy purposes" [17]. A target of approximately 2000 patients will be enrolled from 200 urology and oncology sites over a 24-month study period.

Eligible men with CRPC and a subset of their caregivers will provide informed consent and be enrolled by urologists and medical oncologists. Patients will be followed for up to 4 years or until death or study discontinuation. Enrolled patients will be managed as per the standard of care, and CRPC treatment will be determined separately from the decision to participate in the registry. Clinical assessments will be performed as per routine care, and no clinic visits or procedures are required outside of routine care. Patients or their caregivers will be discontinued from the study in the case of death, loss to follow-up or withdrawal of consent.

Distribution of study sites will be broadly representative of physicians treating CRPC in the USA (e.g., geographically, by specialty and by community versus academic institutions), and study sites will be monitored to enroll patients reflective of the US population of patients with prostate cancer (e.g., age, ethnic and racial

background, geography and socioeconomic status).

• Inclusion & exclusion criteria

Key criteria for patient inclusion in the registry are males (≥18 years) with a confirmed diagnosis of CRPC (defined by a minimum of two rising prostate-specific antigen [PSA] levels measured at least 7 days apart and serum testosterone level ≤1.73 nmol/l [50 ng/dl] or new evidence of metastatic disease) and an estimated life expectancy of ≥6 months and who are initiating their first course of active treatment for M0 or M1 CRPC (antiandrogens, androgen synthesis inhibitors, chemotherapy, immunotherapy or radiopharmaceutical therapy). Patients must be enrolled within 45 days of initiating the first course of active treatment and be able to complete HRQoL questionnaires with or without assistance.

Patients are excluded if they are currently enrolled in any interventional clinical trial with a nonapproved investigational agent for the primary disease of CRPC, although patients who enroll in an interventional clinical trial after TRUMPET enrollment may remain in the registry. Patients receiving concomitant treatment for other cancers (excluding basal cell carcinoma and hormone-sensitive prostate cancer) within 6 months prior to enrollment are also excluded.

Caregivers for patients may be included in the registry if they meet the definition of unpaid relatives or friends who help patients with their activities of daily living. Caregivers must also be willing and able to complete caregiver-reported outcome questionnaires over the course of patients' participation in the TRUMPET registry.

• Data collection

Baseline demographic and clinical profile data will be collected from enrolled patients, with specific clinical profile data collected during follow-up (Box 1 & Figure 1). Factors underlying decisions for initial CRPC treatment will be ascertained from medical records and directly from patients. Examples of these factors are patient demographics (e.g., age), disease characteristics (e.g., PSA doubling time, biochemical failure only versus presence of metastatic disease, symptoms, performance status and comorbidities) and prior treatment. Information will also be collected on factors (clinical and/or economic) influencing treatment decisions, including reason(s) for treatment choices.

Enrolled patients will also complete a series of validated and reliable patient-centered questionnaires at baseline (Table 2), at 3-month intervals for the first year and at 3- or 6-month intervals thereafter (Figure 1). In the case of M0 patients, a new quality-of-life survey will be collected at the time of progression to M1 disease, at 3-month intervals for the first year and every 6 months thereafter.

• HRQoL instruments

Table 2 lists the patient-centered surveys used to evaluate the burden of comorbidities at baseline and to assess the effects of CRPC and its management on patient and caregiver perceptions of key aspects of quality of life.

These instruments assess different aspects of the patient experience, including overall and prostate cancer-specific quality of life, pain and impact on daily function, work productivity, patient perspective on quality of care and patient anxiety related to prostate cancer. In addition, the experience of caregivers, including mental and emotional distress and burden and work productivity, are to be evaluated.

• Outcomes

This prospective observational cohort study will focus primarily on patient characteristics associated with patterns of care and HRQoL of patients with CRPC. Secondarily, decision factors, clinical outcomes (including progression-free survival for M0 patients and overall survival for all patients) and healthcare resource utilization and costs associated with the observed treatment patterns will be described. Exploratory outcomes will include quality of life of caregivers of patients with CRPC and QALYs associated with disease progression.

• Substudy: work productivity & care satisfaction

A substudy of work productivity and care satisfaction will be conducted from a broadly representative subset of approximately 50 sites. Work productivity and care satisfaction questionnaires for about 500 patients will be obtained.

Statistical considerations
• Sample size

An enrollment goal of approximately 2000 patients was determined to allow for calculation of reasonable statistical estimates of patient and outcome characteristics and for exploratory subgroup analyses. Based on the involvement of

study sites broadly representative of the USA, this sample size will be adequate to describe any observed variations in treatment patterns based on site and patient characteristics. The sample size is also considered sufficient to describe HRQoL and changes in HRQoL over time in this patient population. Due to the observational nature of the study, the proportion of patients in particular treatment subgroups is difficult to predict.

• **Patient populations & stratification**

All patients who sign informed consent and meet enrollment inclusion criteria will be included in the analysis population. Analyses may be stratified by patient age group, M0 or M1 CRPC at the time of CRPC diagnosis, performance status and other characteristics as appropriate. Pooling of smaller subgroups may be conducted based on an appropriate clinical and scientific rationale for such pooling.

• **Demographics & baseline characteristics**

The baseline demographic and clinical profile of the study population and subpopulations of interest will be described by grouping patients by their initial active CRPC therapy. Continuous variables (e.g., age) will be reported as means and standard deviations. Categorical variables (e.g., sex) will be summarized as number and percentage of the total study population. p-values will be calculated for comparisons between initial anticancer therapy groups for selected baseline variables, using the χ^2 test or Fisher's exact test for categorical variables, as appropriate, and the Kruskal–Wallis test or analysis of variance for continuous variables, depending on the distribution of data. Statistical tests will be two sided, with an α-level of 0.05 for statistical significance. CRPC treatment choice at baseline will be categorized for the purposes of baseline comparisons by the primary component (e.g., enzalutamide, abiraterone, bicalutamide, other first-generation androgen synthesis inhibitors, first-generation antiandrogens, chemotherapy or immunotherapy). Global-modified Total Illness Burden Index scores will be used to characterize the baseline comorbidity burden.

• **Analysis of patient characteristics associated with patterns of care (co-primary objective)**

The study will capture information on patterns of care by assessing the type and timing of disease assessment methods, treatment decisions,

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Box 1. Demographic and clinical data elements to be collected at baseline and follow-up.

Baseline
- Demographics (age, race/ethnicity, marital status)
- Insurance status
- Medical history
- Height
- Weight
- ECOG PS
- Prostate cancer history
- Concomitant medications
- Primary treatments (radical prostatectomy, radiation therapy, hormone therapy, cryotherapy, surveillance)
- Palliative procedures (EBRT, bone surgery)
- Current line of therapy for CRPC
- Laboratory testing/results
- Factors underlying physician decision for initial treatment

Follow-up
- Current line of therapy for CRPC
- Weight
- ECOG PS
- Survival status
- Laboratory testing/results
- Factors underlying physician decision for change in treatment
- New-onset comorbidities
- PCWG-2 criteria for prostate-specific antigen progression (0.2 ng/ml increase from nadir)

CRPC: Castration-resistant prostate cancer; EBRT: External beam radiation therapy; ECOG PS: Eastern Cooperative Oncology Group performance status; PCWG-2: Prostate Cancer Working Group-2.

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treatment settings and patterns of physician referral. The distribution and timing of disease assessment methods from CRPC diagnosis (PSA assessment, other laboratory testing and imaging) will be reported overall and by initial CRPC therapy group. Treatment patterns according to the distribution of prescribing decisions made by clinicians in different treatment settings (i.e., urology vs oncology and academic center vs community practices) and physician referral patterns will be summarized.

The number and proportion of patients treated with initial and subsequent CRPC treatments and changes in treatment patterns over time will be reported. The proportion of patients switching or modifying therapy at each follow-up time point will also be assessed.

• **Analysis of HRQoL (co-primary objective)**

Patient-reported HRQoL instruments will be analyzed to assess the effects of CRPC and its management on patient perceptions of key aspects of HRQoL. Mean scores (and standard deviations) for each HRQoL instrument

Data elements	Baseline	Patient follow-up visit data collection (years 1–6) Approximately every 3 months	Patient PRO completion (years 1–6) Approximately every 3 months	Caregiver follow-up (years 1–6) Approximately every 6 months	Study close (or early discontinuation) Final study visit
Informed consent (patient and caregiver)	⊗				
Verify inclusion/exclusion	⊗				
Relevant medical history and new onset comorbidities	⊗	⊗			⊗
Prostate cancer diagnosis and treatment history	⊗				
Patient demographics	⊗				
Patient height/weight (weight updated only during follow-up)	⊗	⊗			⊗
ECOG PS†	⊗	⊗			⊗
Select laboratory results†	⊗	⊗			⊗
Imaging studies†	⊗	⊗			⊗
CRPC treatments and supportive care	⊗	⊗			⊗
Adverse events‡	⊗	⊗	⊗		⊗
Patient-reported outcomes§	⊗		⊗		⊗
Caregiver characteristics	⊗			⊗	⊗
Caregiver-reported outcomes§				⊗	⊗
Healthcare resource utilization§		⊗	⊗		⊗
Vital status	⊗	⊗	⊗		⊗

Figure 1. Study design.

†Results recorded if ordered by the physician as part of routine clinical management.

‡Adverse events related to treatment with Astellas products and pregnancies in female partners of enrolled patients exposed to Astellas products only.

§PRO will be collected at baseline and every 3 months throughout the duration of the study. For the first year after enrollment in the study and for 1 year following progression to M1, patients will complete all PRO instruments at 3-month intervals. At years 2–6 and beginning 1 year following progression to M1, patients will complete the Brief Pain Inventory (Short Form), the Short Form 12 and the Memorial Anxiety Scale for Prostate Cancer (PSA subscale) approximately every 3 months and the Functional Assessment of Cancer Therapy-Prostate, the Work Productivity and Activity Impairment Questionnaire (substudy only) and the Service Satisfaction Scale for Cancer Care (substudy only) approximately every 6 months. Patient-reported healthcare resource utilization will be collected during site visits. Caregiver-reported outcomes will be collected at baseline and every 6 months. These PRO assessments may be collected ±15 days of the planned assessment.

CRPC: Castration-resistant prostate cancer; ECOG PS: Eastern Cooperative Oncology Group performance status; M1: Metastatic; PRO: Patient-reported outcome; PSA: Prostate-specific antigen.

(SF-12v2 Health Survey, Functional Assessment of Cancer Therapy-Prostate and Brief Pain Inventory [Short Form]) will be reported at baseline and at approximately 3- or 6-month follow-up intervals until disease progression results in either referral from urologist to oncologist or initiation of chemotherapy.

• Decision factors (secondary objective)

Factors influencing treatment decisions, including reason(s) for treatment choices and reported trigger(s) for treatment changes, will be summarized. Reasons for treatment discontinuation, add-on or switching will be described categorically.

• Clinical outcomes (secondary objective)

For patients who have no evidence of metastatic disease at baseline, the time to disease progression, based on PSA levels and physician-reported clinical or radiologic progression, will be summarized using Kaplan–Meier methods. For all patients, overall survival duration will be summarized using Kaplan–Meier methods.

The number of patients with each specific clinical outcome and median time to progression or death will be calculated overall and separately according to initial anticancer treatment group. Furthermore, Cox proportional hazard models will be used to assess the association of each clinical outcome with patients' baseline characteristics.

• Healthcare resource utilization & costs (exploratory analysis)

Patient-reported resource utilization data will be collected at the time of patient visit **(Box 2)**.

Questions about utilization of health services since the last clinic visit, including outpatient care (emergency department visits, outpatient procedures, radiology and diagnostic tests, physical and occupational therapy, physician consultations and primary care visits) and the use of medications and nontraditional therapies, will be documented and summarized. Hospitalization data will be summarized (i.e., by number of hospitalizations per patient, length of each stay and reason[s] for hospitalizations). Use of paid professional home healthcare assistance and the number of admissions to skilled nursing, long-term care or long-term acute care facilities (with length of stay and reason for admission, if known) will be captured from the patient or by proxy caregiver.

Standard costs for each unit of healthcare expenses will be estimated from a large nationally representative pharmacy and medical claims database, comprising enrollment information for administrative-services-only lives, Medicaid lives and Medicare-supplemental-insured lives from 1993 to the present day, and includes transactional claims data from hospitalization, medical, pharmacy and laboratory tables.

• Caregiver quality of life (exploratory analysis)

A subset of primary caregivers will provide demographic and other descriptive characteristics, including the relationship to the patient, and will complete the four-domain Caregiver Quality of Life Index-Cancer and the Work Productivity and Activity Impairment Questionnaire, adapted for caregiving instruments, at baseline

Table 2. Patient and caregiver surveys.		
Instruments	**Information captured**	**Ref.**
Patient instruments		
Modified Total Illness Burden Index	Baseline health status for all patients	[18]
SF-12v2 Health Survey	Overall quality of life and map utility	[19]
Functional Assessment of Cancer Therapy-Prostate	Quality of life specific to prostate cancer	[20]
Brief Pain Inventory (Short Form)	Severity of pain and impact on daily functioning	[21]
Work Productivity and Activity Impairment Questionnaire: Specific Health Problem	Work productivity through the course of disease	[22]
Service Satisfaction Scale for Cancer Care	Patient perspective on quality of care	[23]
Memorial Anxiety Scale for Prostate Cancer	Scope of issues contributing to patient anxiety related to prostate cancer; only using the prostate-specific antigen subscale	[24]
Caregiver instruments		
Caregiver Quality of Life Index-Cancer	Mental and emotional distress and burden to the patient caregiver	[25]
Work Productivity and Activity Impairment Questionnaire, adapted for caregiving	Absenteeism and presenteeism in patient caregivers	[22]

and during follow-up approximately every 6 months.

• Preference-based utilities (exploratory analysis)

Results of the SF-12v2 Health Survey will also be converted to the SF-6D, a preference-based utility index, to help understand economic benefit of treatment choices. SF-6D is used in economic evaluation or to determine QALYs. The resulting SF-6D index, scored from 0.0 (worst health state/death) to 1.0 (best health state), can be used in the assessment of QALYs and in studies of the cost–effectiveness of various healthcare interventions. The SF-6D will be scored from SF-12v2 according to the SF-6D algorithms developed by Brazier and colleagues [26]. The descriptive statistics of the SF-6D at baseline and at each follow-up time point and the change from baseline at each follow-up time point will be calculated.

Box 2. Economic data elements.
Resource utilization
● Hospitalizations
● Office visits
● Number of radiology/diagnostic tests
● Outpatient procedures
● Emergency department visits
● Physical/occupational therapy
● Home healthcare
● Long-term care and assisted living status
Patient reported and collected during site visits.

• Substudy: work productivity & care satisfaction

In a subset of patients (see the 'Study design' section), questionnaires regarding work productivity (Work Productivity and Activity Impairment Questionnaire: Specific Health Problem) and care satisfaction (Service Satisfaction Scale for Cancer Care) will be administered. Mean scores (and standard deviations) will be reported at baseline and follow-up time points.

Study limitations

There are a number of potential limitations associated with the observational, nonrandomized study design, given that observational data is best suited for descriptive studies of specific therapies and changes in clinical assessment and treatments and that the integration of clinical variables with patient-reported outcomes (e.g., HRQoL and satisfactions of care) and resource utilization requires longitudinal follow-up and documentation [27]. These limitations include selection bias and unmeasured confounding variables, which may limit the validity of our results. Potential for missing data from loss to follow-up could also bias our results as patient care transitions from urologist to oncologist outside the registry network. Additionally, due to the volume of patient-reported questionnaires in this study, there is also the potential for missing and inconsistent data collection regarding HRQoL, especially

with increasing patient and caregiver fatigue over time as patients' conditions worsen. Last, the TRUMPET registry does not collect or store tissue- or blood-based biomarker data. While such information may improve our understanding of predictive outcomes in CRPC, the scope of data collection was beyond the study's aims and means.

To address the potential limitations discussed, several operational and methodological steps have been included. Additionally, electronic enrollment logs will be maintained at study sites to compare the characteristics of patients enrolling in the registry with those not enrolling. Last, frequent contact with patients may help minimize the proportion lost to follow-up and maintain high rates of follow-up. Results will be reported following reporting standards for observational studies (STrengthening the Reporting of OBservational studies in Epidemiology) [28].

Current status

Patient enrollment began in March 2015 at community-based urology sites in the USA. Enrollment will continue until 2017, after which follow-up and observation will continue for up to 4 years. All study research will be overseen and guided by a seven-person scientific advisory committee and medical affairs designates from the sponsor organizations. Evaluation of baseline characteristics of the first 250 patients and caregivers will be conducted 1 year following the first enrolled patient.

As of manuscript submission, 112 sites are actively enrolling, with 262 patients and 139 caregivers consenting to participate. A more comprehensive analysis of baseline information will be published separately and follow appropriate observational reporting (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines [28].

Conclusion

Although randomized controlled studies in mCRPC provide the highest level of clinical evidence on the efficacy and safety of existing treatments, analyses of data from prospective disease-specific registries can also provide clinically relevant information for the treatment and outcomes of patients with mCRPC. The TRUMPET registry is designed to improve the understanding of the treatment patterns of patients with CRPC through the collection of information on patterns of care, including disease assessment, referral patterns and treatment settings, treatments and factors influencing treatment decisions and clinical and HRQoL outcomes associated with CRPC and the management of CRPC. Additionally, the TRUMPET study seeks to describe resource utilization, worker productivity and activity limitations, satisfaction of cancer care and burden on caregivers by assessing their HRQoL. The data being collected in TRUMPET are of clinical relevance to the current population of patients with CRPC. Site initiation visits and ongoing quality control and data checks of clinical and HRQoL information aim to reduce the potential for bias and missing data.

A key strength of the TRUMPET registry is the large sample of treated patients with CRPC enrolled from both community and academic institutions across the USA and the ability to capture changes in treatment patterns and reasons for discontinuation. The secondary and substudy objectives outlined in this paper also represent a unique scientific opportunity to understand the overall social and economic burden on caregivers of patients with CRPC. For these reasons, the TRUMPET study should be viewed as an important addition to the list of current observational studies in the USA.

In conclusion, this large, prospective, observational registry will provide unique and relevant real-world data describing current treatment patterns, disease burden and health resource utilization to further understanding of CRPC and associated disease management strategies.

Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

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EXECUTIVE SUMMARY

Current management of castration-resistant prostate cancer

- Over the last 5 years, treatment options for metastatic castration-resistant prostate cancer (mCRPC) have significantly advanced, leading to more complex clinical decision-making.

Rationale for the TRUMPET study

- The extent of treatment toxicity, tolerability and disease burden on patients' health-related quality of life (HRQoL) is a significant consideration for management of CRPC and is not well understood in real-world treatment settings.

- Understanding the impact of the mCRPC disease burden and outcomes on caregivers is novel to this area and of importance in the overall understanding of care.

Study objectives

- TRUMPET aims to advance the understanding of contemporary treatment patterns and clinical and HRQoL outcomes for patients with CRPC.

- TRUMPET aims to fill a gap in current prostate cancer registries, with the focus on CRPC patients with advanced disease, including patient-/caregiver-reported outcomes.

Study design

- TRUMPET is a prospective, observational, multicenter registry that was initiated in March 2015 to assess treatment patterns for patients with CRPC in the USA.

- Key criteria for patient inclusion in the registry are males (≥18 years) with a confirmed diagnosis of CRPC and an estimated life expectancy of ≥6 months.

- An enrollment goal of approximately 2000 patients will allow for calculation of reasonable statistical estimates of patient and outcome characteristics and for exploratory subgroup analyses.

- Caregivers for patients may be included in the registry.

- Information will be collected on demographics, HRQoL and factors (clinical and/or economic) influencing treatment decisions, including reason(s) for treatment choices.

- Co-primary objectives are the analysis of patient characteristics associated with patterns of care and the effects of CRPC and its management on patient perceptions of key aspects of HRQoL.

Conclusion

- Analyses of data from prospective disease-specific registries can provide clinically relevant information for the treatment and outcomes of patients with mCRPC.

- TRUMPET is a large, prospective, observational registry that will provide unique and relevant real-world data describing current treatment patterns, disease burden and health resource utilization to further understanding of CRPC and associated disease management strategies.

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