



The Prostate Cancer Registry: First Results from an International, Prospective, Observational Study of Men with Metastatic Castration-Resistant Prostate Cancer (mCRPC)

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BACKGROUND

- Recent years have seen an evolution in the management of mCRPC, with the availability of several newer systemic treatments.¹
- Changes in the management of mCRPC are based on evidence from clinical trials; however, there are gaps in our knowledge on how newer treatments are being integrated into routine clinical practice.
- There is a lack of large-scale registry data focusing on mCRPC and its clinical management. Observational patient registries can play a critical role by providing insights to complement clinical trials.^{2,3}
- The Prostate Cancer Registry, the first international, prospective, observational study of patients with mCRPC, was initiated to examine the management of patients with mCRPC in a real-world setting.

OBJECTIVES

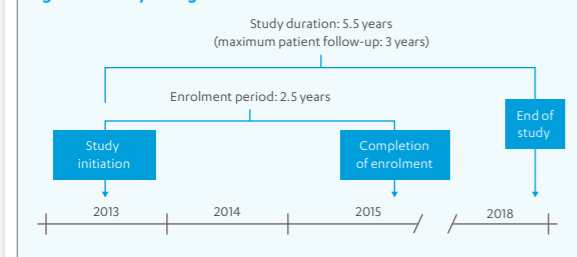
- Document the characteristics and management of patients with mCRPC in routine clinical practice, independent of treatment used.
- Assess sequencing of treatments (initiation, termination and duration), relative effectiveness of treatments, medical resource utilisation, quality of life and survival.

METHODS

Study Design

- Prospective, non-interventional, multicentre registry of 3000 men with mCRPC (ClinicalTrials.gov identifier: NCT02236637; Figure 1).

Figure 1. Study Design and Timelines



- 192 centres are participating in Austria, Belgium, France, Germany, Israel, Italy, Luxembourg, Poland, Portugal, Russia, Slovenia, Spain, Sweden, Switzerland, Turkey and the UK (Figure 2).

- A range of clinical settings are represented, including oncology and urology specialist clinics, small and large practices, in both public and private healthcare systems.

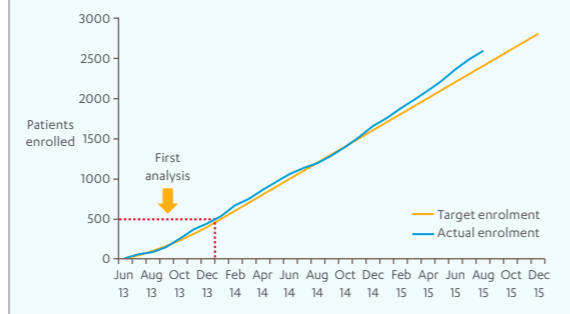
Eligibility Criteria

- Male aged ≥ 18 years.
- Confirmed diagnosis of adenocarcinoma of the prostate with documented metastatic disease, who may enrol at any time after diagnosis.
- Documented castration resistance, defined by disease progression (despite testosterone levels < 50 ng/dL and/or androgen deprivation therapy [ADT] and/or orchiectomy), defined as:
 - Continuous rise in prostate-specific antigen; and/or
 - Worsening of existing disease/symptoms; and/or
 - Appearance of new metastases.
- Not currently receiving active treatment for mCRPC (except ADT and/or bone-sparing therapies) or initiating new treatment for mCRPC within the 30 days preceding or following enrolment.
- Signed informed consent/participation agreement, as applicable.

Data Collection

- Baseline data collected at study entry include:
 - Demographics.
 - Disease history, including dates of diagnosis, metastasis and castration resistance, tumour-node-metastasis (TNM) stage and Gleason score at diagnosis.

Figure 2. Cumulative Enrolment

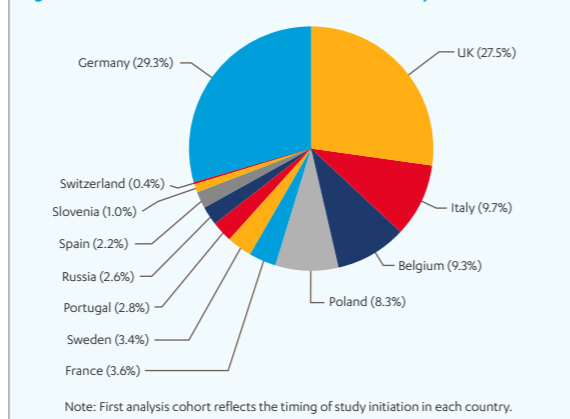


- Prior prostate cancer treatment, including systemic therapy, radiotherapy and surgery.
- Clinical characteristics, including comorbidities, concomitant medications and Eastern Cooperative Oncology Group Performance Status (ECOG PS).
- Quality of life.
- Medical resource utilisation.
- Clinical data collected prospectively at least every 3 months:
 - Systemic and local mCRPC treatment.
 - Rationale for treatment choice and reasons for discontinuation.
 - Duration and sequencing of treatment.
 - Clinical assessments/outcomes, biological parameters and radiological responses.
 - Survival.
 - Medical resource utilisation.
 - Quality of life.
- All clinical data are subject to a validation process to ensure quality control.

FIRST ANALYSIS RESULTS

- Baseline demographics, clinical data and first treatments for the first 505 patients enrolled between June 2013 and January 2014 at sites in 12 European countries are reported (Figure 3).
- Patients were followed up for 9 months (or less, in case of patient withdrawal, loss to follow-up or death); not all data had sufficient maturity to be reported.

Figure 3. Distribution of Patients in the First Analysis



Note: First analysis cohort reflects the timing of study initiation in each country.

Disease History at Study Entry

- Median time from diagnosis of prostate cancer until study entry was 4.7 years (Table 1).
- At initial prostate cancer diagnosis, the majority of patients (59.8%) had a Gleason score of ≥ 8, while 26.5% had node-positive disease and 45.7% had distant metastases.

Table 1. Disease History at Study Entry

Characteristic	First analysis cohort (n = 505)
Median time from diagnosis to enrolment, years (range)	4.7 (0-22)
Gleason score at initial diagnosis, n (%)	(n = 458)
≤ 6	54 (11.8)
7	130 (28.4)
≥ 8	274 (59.8)
T stage at initial diagnosis, n (%)	(n = 488)
Tx	74 (15.2)
T1, T1a-c	51 (10.5)
T2, T2a-c	107 (21.9)
T3, T3a-b	194 (39.8)
T4	62 (12.7)
N stage at initial diagnosis, n (%)	(n = 483)
Nx	188 (38.9)
N0	167 (34.6)
N1	128 (26.5)
M stage at initial diagnosis, n (%)	(n = 484)
Mx	86 (17.8)
M0	177 (36.6)
M1	85 (17.6)
M1a	3 (0.6)
M1b	126 (26.0)
M1c	7 (1.4)
Median time from initial diagnosis to first metastatic diagnosis, years (range)	(n = 369) 2.7 (0-20)
Median time from initial diagnosis to castration resistance, years (range)	(n = 500) 3.0 (0-20)

Treatment History at Study Entry

- Most patients (97.8%) had received systemic anti-cancer therapy, including endocrine therapy (97.4%; Table 2).
- 41.4% of patients had received chemotherapy and 58.6% were chemotherapy-naïve.
- 55.2% of patients had received radiotherapy, including 33.3% of patients who had received radiotherapy to the prostate. In addition, 22.2% of patients had undergone radical prostatectomy.

Table 2. Treatment History at Study Entry

Type of therapy, n (%)	First analysis cohort (n = 505)
Prior systemic anti-cancer therapy	494 (97.8)
Prior endocrine therapy	492 (97.4)
Anti-androgen	426 (84.4)
GnRH agonist	409 (81.0)
Steroids	200 (39.6)
Abiraterone	75 (14.9)
GnRH antagonist	34 (6.7)
Oestrogens and derivatives	21 (4.2)
Enzalutamide	15 (3.0)
Adrenal synthesis inhibitors	8 (1.6)
Other endocrine therapy	11 (2.2)
Chemotherapy	209 (41.4)
Docetaxel	204 (40.4)
Cabazitaxel	27 (5.3)
Other	17 (3.4)
Bone-targeted agents	202 (40.0)
Prior radiotherapy since diagnosis	279 (55.2)
Prostate	168 (33.3)
Spine	57 (11.3)
Limb	18 (3.6)
Costal	16 (3.2)
Brain	1 (0.2)
Other	118 (23.4)
Prior surgery	208 (41.2)
Orchiectomy	33 (6.5)
Radical prostatectomy	112 (22.2)
Other	81 (16.0)

GnRH, gonadotropin-releasing hormone.

Demographic and Clinical Characteristics at Study Entry

- Most patients were > 70 years (mean: 71.5 years) with ECOG PS 0 (40.9%) or 1 (42.6%).
- The bone was the most common site of metastasis (78.9% of patients) and 28.7% of patients had ≥ 10 bone lesions.

Table 3. Demographic and Clinical Characteristics at Study Entry

Characteristic	First analysis cohort (n = 505)
Mean age, years (range)	71.5 (47-94)
PSA, ng/mL (range)	(n = 491) 57.0 (0.0-10,710.0)
ECOG PS, n (%)	(n = 472)
0	193 (40.9)
1	201 (42.6)
≥ 2	78 (16.5)
Site of lesions, n (%)	(n = 384)
Bone	303 (78.9)
Node	168 (43.8)
Prostate	60 (15.6)
Liver	23 (6.0)
Lung	33 (8.6)
Other	31 (8.1)
Site of nodes, n (%)	(n = 167)
Sub-diaphragmatic	144 (86.2)
Supra-diaphragmatic	54 (32.3)
Number of bone metastases, n (%)	(n = 362)
0	15 (4.1)
1-5	93 (25.7)
5-9	61 (16.9)
≥ 10	104 (28.7)
Not evaluable	89 (24.6)

ECOG PS, Eastern Cooperative Oncology Group Performance Status; PSA, prostate-specific antigen.

Comorbidities and Concomitant Therapies at Study Entry

- 62.8% of patients had comorbidities requiring treatment (Table 4), the most common being cardiovascular disease (including hypertension), diabetes and neurological disorders.
- 79.2% of patients were receiving concomitant medications, with a high proportion receiving anti-hypertensives or other agents to treat cardiovascular disease.
- Analgesics were being utilised by 47.9% of patients.

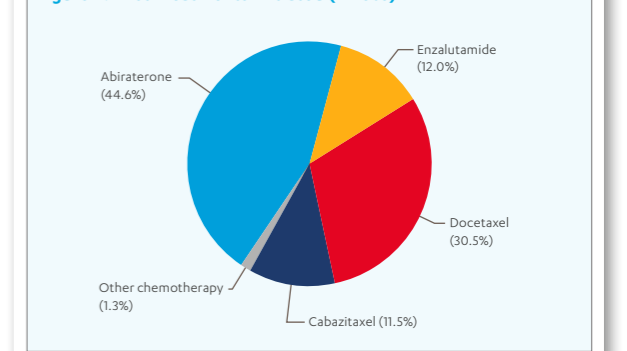
Table 4. Comorbidities and Concomitant Medications at Study Entry

Type of therapy, n (%)	First analysis cohort (n = 505)
Comorbidities requiring treatment	317 (62.8)
Cardiovascular	277 (54.9)
Hypertension	225 (44.6)
Diabetes	67 (13.3)
Type 1 diabetes	11 (2.2)
Type 2 diabetes	56 (11.1)
Neurological	44 (8.7)
Respiratory	29 (5.7)
Renal	37 (7.3)
Hepatic	9 (1.8)
Infection	4 (0.8)
Concomitant therapies	400 (79.2)
Cardiovascular disease therapies	281 (55.6)
Hypertension therapies	227 (45.0)
Analgesics	242 (47.9)
Diabetes therapies	61 (12.1)
Anti-thrombotic agents	49 (9.7)
Nervous system disorder therapies	21 (4.2)
Anti-infective agents	14 (2.8)
Growth factors	7 (1.4)
Blood substitutes	6 (1.2)

First Treatments for mCRPC

- In the first analysis, 75.8% of patients initiated 1 or more new treatments for mCRPC (Figure 4).

Figure 4. First Treatments Initiated (n = 383)



CONCLUSIONS

- The Prostate Cancer Registry is the first international, observational study of current treatment patterns and outcomes, in a real-world cohort of patients with mCRPC.
- This first analysis indicates the enrolment of a broad range of patients, with a high prevalence of comorbidities and concomitant medication use, reflecting the real-world nature of the population.
- As expected in the current treatment landscape, the majority of patients (76%) initiated a new treatment for mCRPC.
- We anticipate that future analyses of the Prostate Cancer Registry will provide unprecedented insights into contemporary management of mCRPC in routine clinical practice.
- These insights can be used as a real-world complement to clinical trial evidence to optimise future care and improve outcomes in mCRPC.

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