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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.[2-5]
- 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

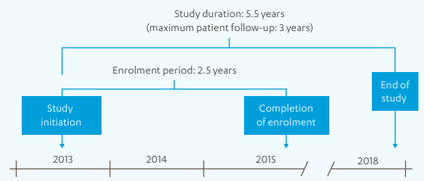
- Document the characteristics and management of patients with mCRPC in routine clinical practice, independent of treatment used.
- Assess sequencing of treatments (initiation, termination and duration), relative effectiveness of treatments, medical resource utilisation, quality of life and survival.

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.

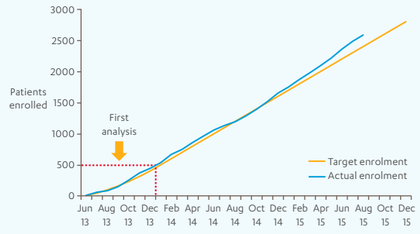
Eligibility Criteria

- 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.
  - 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.

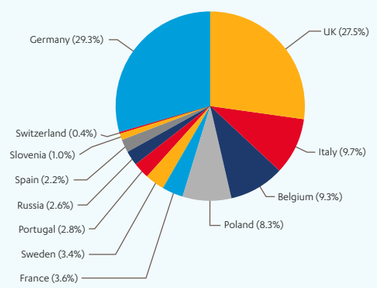
Figure 2. Cumulative Enrolment



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
Median time from diagnosis to enrolment, years (range)	(n = 505) 4.7 (0-22)
Gleason score at initial diagnosis, n (%) ≤ 6 7 ≥ 8	(n = 458) 54 (11.8) 130 (28.4) 274 (59.8)
T stage at initial diagnosis, n (%) Tx T1, T1a-c T2, T2a-c T3, T3a-b T4	(n = 488) 74 (15.2) 51 (10.5) 107 (21.9) 194 (39.8) 62 (12.7)
N stage at initial diagnosis, n (%) Nx N0 N1	(n = 483) 188 (38.9) 167 (34.6) 128 (26.5)
M stage at initial diagnosis, n (%) Mx M0 M1 M1a M1b M1c	(n = 484) 86 (17.8) 177 (36.6) 85 (17.6) 3 (0.6) 126 (26.0) 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 Anti-androgen GnRH agonist Steroids Abiraterone GnRH antagonist Oestrogens and derivatives Enzalutamide Adrenal synthesis inhibitors Other endocrine therapy	492 (97.4) 426 (84.4) 409 (81.0) 200 (39.6) 75 (14.9) 34 (6.7) 21 (4.2) 15 (3.0) 8 (1.6) 11 (2.2)
Chemotherapy Docetaxel Cabazitaxel Other	209 (41.4) 204 (40.4) 27 (5.3) 17 (3.4)
Bone-targeted agents	202 (40.0)
Prior radiotherapy since diagnosis Prostate Spine Limb Costal Brain Other	279 (55.2) 168 (33.3) 57 (11.3) 18 (3.6) 16 (3.2) 1 (0.2) 118 (23.4)
Prior surgery Orchiectomy Radical prostatectomy Other	208 (41.2) 33 (6.5) 112 (22.2) 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
Mean age, years (range)	(n = 505) 71.5 (47-94)
PSA, ng/mL (range)	(n = 491) 57.0 (0.0-10,710.0)
ECOG PS, n (%) 0 1 ≥ 2	(n = 472) 193 (40.9) 201 (42.6) 78 (16.5)
Site of lesions, n (%) Bone Node Prostate Liver Lung Other	(n = 384) 303 (78.9) 168 (43.8) 60 (15.6) 23 (6.0) 33 (8.6) 31 (8.1)
Site of nodes, n (%) Sub-diaphragmatic Supra-diaphragmatic	(n = 167) 144 (86.2) 54 (32.3)
Number of bone metastases, n (%) 0 1-5 5-9 ≥ 10 Not evaluable	(n = 362) 15 (4.1) 93 (25.7) 61 (16.9) 104 (28.7) 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.

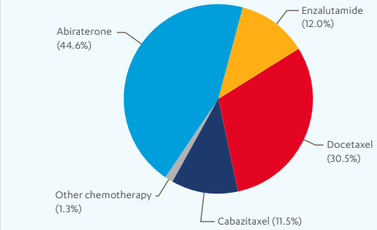
Table 4. Comorbidities and Concomitant Medications at Study Entry

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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