# Second primary cancers in patients with castration resistant prostate cancer (BOCARP)

**First published:** 04/03/2016

**Last updated:** 13/05/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS12665

**Study ID**

26612

**DARWIN EU® study**

No

**Study countries**

Germany

**Study description**

This study aims at estimating the incidence of second primary malignancies as well as the overall survival among metastasized prostate cancer (mPC) and metastasized castrate-resistant prostate cancer (mCRPC) patients not treated with radium-223-dichloride.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

**First published:** 29/03/2010

**Last updated:** 30/03/2026

Institution | Not-for-profit | ENCePP partner

# Contact details

**Study institution contact**

Riedel Oliver riedel@bips.uni-bremen.de

Study contact

riedel@bips.uni-bremen.de

**Primary lead investigator**

Riedel Oliver

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Planned: 10/07/2015

Actual: 10/07/2015

---

**Study start date**
Planned: 15/03/2016

Actual: 15/03/2016

---

**Date of final study report**
Planned: 30/11/2017

Actual: 20/10/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

Study 18044_Protocol_2016-03-03_final.pdf (607.63 KB)

18044_study protocol_v1.2_2017-05-02.pdf (1.15 MB)

## Regulatory

**Was the study required by a regulatory body?**

No

---

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Other

---

**Study topic, other:**

Disease/Epidemiology study

**Study type:**

Non-interventional study

---

**Scope of the study:**

Other

**If ‘other’, further details on the scope of the study**

Background Incidence Study

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

Incidence of second primary malignancies in patients with castration resistent prostate cancer.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Prostate cancer metastatic

## Population studied

**Short description of the study population**

Prostate cancer patients with bone metastases (mPC) and among a subgroup of Mpc patients among whom the prostate cancer was castration-resistant (mCRPC).

Patients with valid information on sex, age and the region of residence, a period of at least 12 months of continuous insurance preceding cohort entry, diagnosis of PC (ICD-10 Code C61) in the study period (January 1, 2004 – December 31, 2011), diagnosis of bone metastases (ICD-10 Code C79.5) in the enrolment

period (January 1, 2005 – December 31, 2011) were included in the mPC cohort. Members of the mCRPC cohort should have one of the following in the enrolment period and before or at the same time with bone metastases
a. Discontinuation of the initial chemical castration, change of the agent or modality of the ADT, or start of treatment for advanced PC after the primary ADT
b. Surgical castration and initiation of ADT treatment
c. Treatment with medication specific to mCRPC or hormone-refractory PC. These are cabazitaxel, enzalutamide, abiraterone, estramustine, docetaxel, mitoxantrone, as well as sipuleucel-T, which are indicated for advanced hormone-refractory PC in Germany

---

**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

---

**Special population of interest**

Other

---

**Special population of interest, other**

Prostate cancer metastatic patients

---

**Estimated number of subjects**

2100

## Study design details

**Outcomes**

Incidences of Second primary malignancies are characterized by the following ICD-10 codes: C00-C76, C81-C96, D00-D09, D37-D48. - Up to 10 years, Overall survival - Up to 10 years

---

**Data analysis plan**

The incidence of second primary malignancies will be calculated. Overall survival will be described. Details on analysis will be described in the Statistical Analysis Plan (SAP).

## Documents

**Study results**

18044_EU-PAS_Abstract_2018-11-12.pdf (69.18 KB)

---

# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

**Data source(s)**

German Pharmacoepidemiological Research Database

**Data sources (types)**

Administrative healthcare records (e.g., claims)

# Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

Unknown