

# Incidence of Second primary Malignancies in prostate Cancer patients with bone metastases – an observational retrospective cohort study in Sweden (SMARCOS)

**First published:** 10/11/2016

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS15491

---

### Study ID

26899

---

### DARWIN EU® study

No

---

### Study countries

☐ Sweden

---

## Study description

An observational retrospective cohort study in Sweden to investigate incidence of second primary malignancies in prostate cancer patients with bone metastases

---

## Study status

Finalised

# Research institutions and networks

## Institutions

**EPID Research Oy**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

Bayer Clinical Trials Contact Bayer AG clinical-trials-contact@bayer.com

**Study contact**

[clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)

### Primary lead investigator

# Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 20/11/2015

Actual: 20/11/2015

---

### Study start date

Planned: 15/11/2016

Actual: 15/11/2016

---

### Date of final study report

Planned: 06/10/2017

Actual: 06/10/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer HealthCare Pharmaceutical Inc

## Study protocol

[ER-9508\\_mCRPC\\_Study\\_Protocol \(18105\) 20160120 FINAL.pdf](#)(652.92 KB)

## 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

---

**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:**

To evaluate the incidence of developing any second primary malignancy among prostate cancer patients with bone metastases (mPC) and among a subgroup of mPC patients whom the prostate cancer is castration-resistant (mCRPC).

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medical condition to be studied**

Second primary malignancy

## Population studied

### **Short description of the study population**

Patients with prostate cancer having diagnosis in 1.1.1998 – 31.12.2013 and with bone metastases diagnosis or bone-directed treatments in 1.1.1998 – 31.12.2013 will be initially included into the large study population.

---

### **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 patients

---

## Estimated number of subjects

15000

# Study design details

## Outcomes

incidences of Second primary malignancies that are characterized by the following ICD-10 codes: C00-C76, C81-C96, D00-D09, D37-D48. 1.Incidence of any site-specific second primary malignancies2.Overall survival3.Pathologic fracture4.Spinal cord compression5.Surgery to bone6.Radiation to bone

---

## Data analysis plan

Characteristics of study subjects at cohort entry will be described. The incidence rate (and its 95% Confidence Interval) of any second primary malignancies will be calculated as a ratio of the number of incident cases and total follow-up time. Overall survival will be studied as time from cohort entry to death due to any cause. The survival time will be described with summary statistics. Yearly survival rates and Kaplan-Meier survival curves will be reported. Details on analysis will be described in the Statistical Analysis Plan (SAP).

# Documents

## Study results

## 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 sources (types)

[Disease registry](#)

[Drug registry](#)

[Other](#)

---

### Data sources (types), other

Swedish Population Register, The Cause of Death Register, The National Patient Register (NPR)

## 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