

# A Drug Utilization Study of Xofigo Use in Sweden

**First published:** 11/02/2015

**Last updated:** 02/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS8494

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### Study ID

29028

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### DARWIN EU® study

No

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### Study countries

 Sweden

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### Study status

Finalised

## Research institutions and networks

# Institutions

NA

## 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: 10/10/2014

Actual: 10/10/2014

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### Study start date

Planned: 01/05/2015

Actual: 15/04/2015

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### Date of final study report

Planned: 15/12/2017

Actual: 19/12/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

[Xofigo\\_DUS\\_in\\_Sweden\\_Study\\_Protocol\\_Final\\_Oct\\_10\\_2014.pdf](#) (366.73 KB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To evaluate the extent of potential off-label use of Xofigo in Sweden

## Study Design

**Non-interventional study design**

Cohort  
Other

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**Non-interventional study design, other**

Single-arm descriptive observational study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(V10XX03) radium (223Ra) dichloride

radium (223Ra) dichloride

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

Prostate cancer stage II

## Population studied

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

Patients receiving Xofigo with data recorded at nuclear medicine centers in Sweden between 01 July 2014 and 30 June 2016 were included in the study

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### **Age groups**

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Prostate cancer patients

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### **Estimated number of subjects**

200

## Study design details

## Outcomes

1.To evaluate the extent of potential off-label use of Xofigo in Sweden  
2.Proportion of being women of Xofigo use  
3.Proportion of being children of Xofigo use  
4.Proportion of bone metastasis but having a diagnosis of other cancer than mCRPV  
5.Dosage of Xofigo (kBq/kg)  
6.Proportion of participants of dose outside label recommendation

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## Data analysis plan

This is a single arm descriptive observational drug utilization study based on secondary data collection. This study is not aimed to confirm or reject pre-defined hypotheses. Statistical analyses will be descriptive in nature. All variables will be analyzed descriptively with appropriate statistical methods.

## Documents

### Study results

[17399\\_EU-PAS\\_Abstract.pdf](#) (61.73 KB)

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### Study report

[17399\\_CSR\\_EU PAS register.pdf](#) (321.1 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)**

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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**Data source(s), other**

Swedish National Cancer Registry

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**Data sources (types)**

[Disease registry](#)

[Other](#)

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**Data sources (types), other**

Nuclear medicine centers in Sweden

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

Unknown