# Darolutamide Observational Study in nonmetastatic castration-resistant prostate cancer patients (DAROL)

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## Administrative details

EU PAS number	
EUPAS31734	
Structura ID	
Study ID	
49948	
DARWIN EU® study	
N.I.	
No	
Study countries	
Study countries	
Study countries  Australia	

Canada
China
Colombia
Denmark
Finland
France
Greece
India
Ireland
Italy
Japan
Luxembourg
Mexico
Netherlands
Norway
Russian Federation
Slovakia
Spain
Sweden
Türkiye
United Kingdom
United States

### **Study description**

The purpose of this study is to find out in the real-world setting, if darolutamide is safe and effective for patients diagnosed with prostate cancer that has not spread to other parts of the body. When a patient is enrolled to the study, his/her physician would have already made the decision to treat patient with darolutamide per local standard practice.

### **Study status**

## Research institutions and networks

## Institutions

## Bayer AG

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Institution

## Contact details

### **Study institution contact**

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

Study contact

clinical-trials-contact@bayer.com

## **Primary lead investigator**

Bayer Clinical Trials BAYER AG

Primary lead investigator

# Study timelines

Date when funding contract was signed

Actual: 23/07/2019

### Study start date

Planned: 30/01/2020 Actual: 30/01/2020

### **Date of final study report**

Planned: 01/08/2025

# Sources of funding

Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## 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 type:

Non-interventional study

### Scope of the study:

Safety study (incl. comparative)

### Main study objective:

To describe the safety of darolutamide in patients with nmCRPC, including the incidence of TEAEs in the real-world setting.

# Study Design

### Non-interventional study design

Cohort

# Study drug and medical condition

# **Study drug International non-proprietary name (INN) or common name**DAROLUTAMIDE

### Medical condition to be studied

Prostate cancer

## Population studied

### **Age groups**

• Adults (18 to < 46 years)

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)</li>
- Adults (75 to < 85 years)
- Adults (85 years and over)

### **Estimated number of subjects**

800

# Study design details

#### **Outcomes**

Occurrence of treatment-emergent adverse events (TEAEs) Reasonable causal relationship between darolutamide and an adverse event (AE) Action taken related to darolutamide treatment, Subject's demographics and characteristics, Dosage and dose modification, Initiation and termination dates, Reasons for ending treatment and/or observation/follow-up and discontinuations or changes of treatments, Metastasis-Free Survival, Time to Symptomatic Skeletal Event, Time to Prostate-Specific Antigen progression, Survival rate, Imaging exams, Prior and post darolutamide treatment

#### Data analysis plan

Statistical analyses will be of an exploratory and descriptive nature. The study is not aimed to test predefined hypotheses. All variables will be analyzed descriptively with appropriate statistical methods: categorical variables by frequency tables (absolute and relative frequencies) and continuous variables by sample statistics (i.e. mean, standard deviation, minimum, median, quartiles, and maximum). Continuous variables will be described by absolute value and as change from baseline per analysis time point, if applicable. Patients who took at least one dose of darolutamide will be included in the

safety analysis set (SAF). Patients who took at least one dose of darolutamide, did not violate a major inclusion/exclusion criterion, and had at least one post-baseline assessment after receiving darolutamide will be included in the full analysis set (FAS). Safety data will be analyzed on the SAF, effectiveness data on the FAS.

## 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)**

Other

## Data sources (types), other

Prospective patient-based data collection

# Use of a Common Data Model (CDM)

## **CDM** mapping

No

# Data quality specifications

## **Check stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No