

# Therapy of metastatic castration-resistant prostate cancer with Talazoparib + Enzalutamide under real world conditions in Germany – an observational medical chart review study (PROTEGE study)

**First published:** 17/12/2025

**Last updated:** 09/01/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000593

### Study ID

1000000593

### DARWIN EU® study

No

### Study countries

Germany

## Study description

This is a non-interventional, observational, retrospective, multicenter study with secondary data collection and human review of medical charts in patients with mCRPC, who received talazoparib + enzalutamide under daily routine conditions in hospitals or practices in Germany.

The primary objective of the study is to describe the effectiveness of talazoparib + enzalutamide in mCRPC patients treated in real-world clinical settings in Germany.

For patients aged 18 and older with a confirmed diagnosis of mCRPC, whose treatment with talazoparib and enzalutamide was already initiated according to routine clinical practice, EHR data will be extracted retrospectively at multiple timepoints for up to 24 months after index date (date of talazoparib + enzalutamide initiation), or until loss to follow up, death, or study termination, whichever occurs the earliest.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

[Pfizer](#)

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

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

[Institution](#)

## Contact details

### **Study institution contact**

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[Study contact](#)

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### **Primary lead investigator**

Giovanni Zanotti

[Primary lead investigator](#)

## Study timelines

### **Date when funding contract was signed**

Planned: 30/10/2024

Actual: 30/10/2024

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### **Study start date**

Planned: 29/12/2025

Actual: 16/12/2025

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

Planned: 31/05/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer Inc.

## Regulatory

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

No

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

Not applicable

## Other study registration identification numbers and links

C3441071

## 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:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

This is a non-interventional, observational, retrospective, multicenter, study with secondary data collection and human review of medical charts in patients with mCRPC, who received a therapy with talazoparib + enzalutamide under daily routine conditions in hospitals or practices in Germany.

**Main study objective:**

Primary Objective, To describe the real-world progression-free survival (rwPFS) of talazoparib + enzalutamide

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

TALZENNA

XTANDI

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

TALAZOPARIB

ENZALUTAMIDE

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**Anatomical Therapeutic Chemical (ATC) code**

(L01XK04) talazoparib

talazoparib

(L02BB04) enzalutamide

enzalutamide

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**Medical condition to be studied**

Prostate cancer metastatic

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**Additional medical condition(s)**

metastatic castration-resistant prostate cancer mCRPC

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## Population studied

**Short description of the study population**

The patient population eligible for this study includes any patient with mCRPC who have already initiated talazoparib and enzalutamide according to the locally approved label, as well as: Participants age  $\geq 18$  years of age and assigned male sex at birth with diagnosis of mCRPC, as defined by histologically or cytologically confirmed adenocarcinoma of the prostate (ICD.revision 10 C61)

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**Age groups**

- **Adult and elderly population ( $\geq 18$  years)**

- Adults (18 to  $< 65$  years)
    - Adults (18 to  $< 46$  years)
    - Adults (46 to  $< 65$  years)
  - Elderly ( $\geq 65$  years)
    - Adults (65 to  $< 75$  years)
    - Adults (75 to  $< 85$  years)
    - Adults (85 years and over)
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### **Estimated number of subjects**

95

## Study design details

### **Setting**

This observational, retrospective, secondary data collection study will take place in Germany, within oncological and urological practices as well as in hospitals with urological/oncological departments that have a focus on systemic treatment for prostate cancer. Up to  $n = 30$  study sites are planned to be included.

Patients aged 18 and older with a confirmed diagnosis of mCRPC whose treatment with talazoparib and enzalutamide was already initiated according to routine clinical practice and for whom informed consent is obtained, will be included in the study. EHR data will be extracted retrospectively at multiple data collection points, at baseline and roughly 3, 6, 12 and 24 months after index date, or until loss to follow up, death, or study termination, whichever occurs the earliest.

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### **Comparators**

Not Applicable

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## **Outcomes**

### Primary Outcome

1. Progression-free survival of talazoparib + enzalutamide as landmark PFS rates

### Secondary outcomes

2. Overall survival rates from start of talazoparib + enzalutamide, expressed at pre-defined timepoints
  3. Describe pre-treatments given prior to the initiation of talazoparib and enzalutamide, as well as the time from pretreatment start and end to talazoparib + enzalutamide initiation
  4. Time from assessment of castration resistance to initiation of talazoparib + enzalutamide
  5. Best responses (PSA and/or radiological) to talazoparib + enzalutamide
  6. Duration of response (PSA and/or radiological) to talazoparib + enzalutamide
  7. Time-to-radiological- and/or -PSA-progression to talazoparib + enzalutamide
  8. Time-to-next-therapy from start of talazoparib + enzalutamide
  9. Frequency and type of dose modifications and discontinuations during therapy with talazoparib + enzalutamide
  10. Reasons for modifications and discontinuations of talazoparib + enzalutamide
  11. Treatment continuation after modifications and discontinuations during therapy with talazoparib + enzalutamide
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## **Data analysis plan**

All analyses in this study are descriptive in nature. The effectiveness analysis set will include all enrolled participants who received at least one dose of talazoparib and enzalutamide.

Descriptive statistics will be presented to characterize patients in terms of demographic and clinical characteristics during the baseline period closest to the index date. Means with standard deviations, medians with interquartile will be provided for continuous variables. Numbers and percentages will be provided for dichotomous variables or categorical variables.

Patient characteristics captured during baseline and at timepoints following initiation of talazoparib + enzalutamide will be summarized using descriptive statistics (frequencies and percentages for categorial variables and mean (STD) and/or median (IQR) for continuous variables). Additionally, treatment patterns during follow up period will be described using the previously described summary statistics.

Time-to-event outcomes on basis of real-world data (rwPFS, rwOS, rwTTNT) will be summarized using the Kaplan-Meier method and estimated survival curves will be displayed graphically when appropriate. Graphs will describe the number of patients at risk over time. The median, quartiles, and probabilities of an event at particular points in time will be estimated by the Kaplan-Meier method. The 95% CIs for medians and quartiles are based on the Brookmeyer-Crowley method (Brookmeyer/Crowley 1982). CIs for the estimated probability of event at a particular time point will be generated using the log(-log) method with back transformation to a CI on the untransformed scale. Summaries of the number and percentages of patients with an event will also be provided on summary tables and figures.

Real-world response rate (rwRR) will be summarized using frequencies and percentages.

Differences in effectiveness outcome measures by pre-treatment status will also be assessed and summarized.

## 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), other**

Electronic Heath Records (EHR)

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## 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**

No