

# A Multicenter, Single-arm, Open-label, Post-marketing Safety Study to Evaluate the Risk of Seizure Among Subjects with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Treated with Enzalutamide Who Are at Potential Increased Risk of Seizure

**First published:** 31/03/2014

**Last updated:** 31/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5552

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### Study ID

32806























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### DARWIN EU® study

No

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### Study countries

-  Argentina
  -  Australia
  -  Belgium
  -  Brazil
  -  Canada
  -  Chile
  -  Finland
  -  France
  -  Germany
  -  Greece
  -  Hong Kong
  -  Hungary
  -  Israel
  -  Italy
  -  Korea, Republic of
  -  New Zealand
  -  Singapore
  -  Spain
  -  Sweden
  -  Taiwan
  -  United Kingdom
  -  United States
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## **Study status**

Finalised

## Research institutions and networks

### Institutions

Astellas Pharma Global Development, Inc.

Multiple centres: 100 centres are involved in the study

## Contact details

### Study institution contact

Sr. Medical Director [astellas.registration@astellas.com](mailto:astellas.registration@astellas.com)

Study contact

[astellas.registration@astellas.com](mailto:astellas.registration@astellas.com)

### Primary lead investigator

Sr. Medical Director

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/01/2013

Actual: 15/01/2013

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### Study start date

Planned: 20/10/2013

Actual: 23/09/2013

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### **Data analysis start date**

Planned: 11/01/2019

Actual: 12/01/2019

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

Planned: 15/08/2019

Actual: 24/07/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Astellas Pharma Global Development, Inc.

## 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:**

Clinical trial

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**Main study objective:**

To evaluate the incidence of seizures and monitor the safety of enzalutamide treatment in subjects with metastatic castration-resistant prostate cancer known to have risk factor(s) for seizure.

## Study Design

**Clinical trial regulatory scope**

Post-authorisation interventional clinical trial

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**Clinical trial phase**

Therapeutic use (Phase IV)

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**Clinical trial randomisation**

Non-randomised clinical trial

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**Clinical trial types**

Single-arm trial

## Study drug and medical condition

**Medicinal product name**

XTANDI

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**Medical condition to be studied**

Metastases to prostate

## Population studied

**Short description of the study population**

Metastatic Castration-Resistant Prostate Cancer (mCRPC) Treated with Enzalutamide Who Are at Potential Increased Risk of Seizure.

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**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)
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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**

400

## Study design details

## Outcomes

The proportion of evaluable subjects with at least one confirmed seizure as adjudicated by the Independent Adjudication Committee (IAC) during the 4-month treatment duration.

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## Data analysis plan

All data will be summarized with descriptive statistics (number of subjects, mean, standard deviation, minimum, median and maximum) for continuous endpoints, and frequency and percentage for categorical endpoints.

## Documents

### Study results

[9785-cl-0403-eos-clrrs-02-disc01-en-final-02.pdf](#) (129.32 KB)

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## 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

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**Data sources (types), other**

Prospective patient-based data collection

## 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