A multicentre, non-interventional, cohort analysis describing the patients' experience focusing on safety events among metastatic hormone-sensitive prostate cancer patients treated with Androgen Receptor Pathway Inhibitors (ARPIs) followed through a Telemonitoring tool funded by the French national healthcare insurance complemented with a chart review (ESPERANTO)

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# Administrative details

#### **EU PAS number**

EUPAS1000000759

#### Study ID

1000000759

# No Study countries France

#### **Study description**

Currently, there is a significant lack of real-world data regarding the use, tolerability, and patient experiences during ARPI treatment.

The data that exists is often collected from databases that rely on using proxies for the patient experience such as claims or physician notes.

While this approach can convey valuable information it may not fully represent the patient experience.

This study offers a unique and innovative approach to understanding the patients experience by leveraging the Cureety remote monitoring platform to collect information directly from the patient perspective without proxies. The dual approach of also leveraging the charts allows for collection of disease specific factors which are best identified from clinicians and also collection of additional data such as treatment duration. This dual data collection strategy—leveraging both the Cureety remote monitoring platform and patient medical records—will yield a richer, more nuanced understanding of the mHSPC patient experience during ARPI treatment.

#### **Study status**

Planned

Research institutions and networks

### Institutions

# Astellas Pharma Europe Ltd.

#### Contact details

#### **Study institution contact**

Clinical Trial Registration Department clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

#### **Primary lead investigator**

**Trevor Stanbury** 

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Actual: 21/05/2025

#### Study start date

Planned: 31/10/2025

#### Data analysis start date

Planned: 28/02/2026

#### Date of final study report

Planned: 31/05/2026

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Astellas Pharma Europe Ltd.

# Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

# Other study registration identification numbers and links

9785-MA-3673

# Methodological aspects

Study type

Study type list

**Study topic:** 

Disease /health condition

#### Human medicinal product

#### Study type:

Non-interventional study

#### Scope of the study:

Drug utilisation

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

#### **Data collection methods:**

Secondary use of data

#### Study design:

Study design: French, multicenter, non-interventional cohort study with secondary data. Review of medical records of participants/participant-reported events from French medical centers from Jul 2019-Sep 2026. Study for collecting information only. Individual's doctor decides treatment, not sponsor.

#### Main study objective:

The main aims of this study are to collect safety information on different ARPIs given to men with mHSPC in France. Other aims are to learn how long the men use ARPIs, if they tolerate treatment and reasons for stopping treatment.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### **Medicinal product name**

XTANDI

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

**ENZALUTAMIDE** 

#### **Anatomical Therapeutic Chemical (ATC) code**

(L02BB04) enzalutamide

enzalutamide

#### Medical condition to be studied

Prostate cancer metastatic

#### Additional medical condition(s)

metastatic hormone-sensitive prostate cancer (mHSPC)

# Population studied

#### Short description of the study population

Prostate cancer affects the prostate gland in men and needs male sex hormones such as testosterone, to grow. Androgen receptor pathway inhibitors (ARPIs) are a type of hormone therapy used to treat men with prostate cancer. They work by reducing the amount of testosterone in the body. The ARPIs are usually given with other prostate cancer treatments.

This study is for men in France who are treated with ARPIs for their prostate cancer. The men have metastatic hormone-sensitive prostate cancer (mHSPC). Metastatic means the cancer has spread to other parts of the body. Hormone sensitive means the cancer needs male sex hormones such as testosterone to

#### Age groups

- Adult and elderly population (≥18 years)
  - Adults (18 to < 65 years)</li>
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

#### **Estimated number of subjects**

950

# Study design details

#### **Outcomes**

Primary

• Rate of treatment discontinuation due to Adverse Events (AEs).

#### **Data analysis plan**

AE rates will be calculated overall and for each ARPI along with the 2-sided 95% CI using the Clopper-Pearson method (exact CI for a binomial proportion as computed by default by the FREQ procedure using the EXACT option). For rates per person-year, Poisson regression or negative binomial (GENMOD) will be considered.

# 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 data source

#### Data source(s), other

Chart Review (Medical Health Records)

Cureety Remote Monitoring Tool

#### Data sources (types)

Electronic healthcare records (EHR)

# 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