

# RENAISSANCE - A multi-centre, non-interventional study of RElugolix as aNdrogen-deprivAtion therapy In patientS with advanced hormone-Sensitive prostate cANCER

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Study

Planned

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/1000000077>

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### EU PAS number

EUPAS1000000077

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### Study ID

1000000077

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### DARWIN EU® study

No

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## Study countries

- France
  - Germany
  - Italy
  - Romania
  - Spain
  - United Kingdom
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## Study status

Planned

# Research institutions and networks

## Institutions

[Accord Healthcare Limited](#)

## Contact details

### Study institution contact

Marc Rabbani

[Study contact](#)

[marc\\_rabbani@accord-healthcare.com](mailto:marc_rabbani@accord-healthcare.com)

### Primary lead investigator

Maximilan Burger

[Primary lead investigator](#)

## Study timelines

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

Planned: 01/01/2024

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### **Study start date**

Planned: 01/05/2024

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

Planned: 01/08/2026

## Sources of funding

- Pharmaceutical company and other private sector

## Study protocol

[Relugolix NIS protocol 19022024 VF.pdf](#)(481.84 KB)

## 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

## Methodological aspects

### Study type

### Study type list

**Study topic:**

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:**

Primary data collection

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**Study design:**

The goal of this study is to generate real word evidence from Europe about the population, effectiveness, and persistence of relugolix treatment in patients with advanced hormone-sensitive prostate cancer and their clinical course during treatment.

**Main study objective:**

To describe the effectiveness of relugolix in patients with prostate cancer in a real-life setting.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

ORGOVYX

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

RELUGOLIX

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**Anatomical Therapeutic Chemical (ATC) code**

(L02BX04) relugolix

relugolix

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**Medical condition to be studied**

Prostate cancer

## Population studied

**Age groups**

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

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**Estimated number of subjects**

300

## Study design details

**Setting**

This European, multicentric, prospective cohort study (i.e. non-interventional) will be conducted in patients with advanced hormone-sensitive prostate cancer who are initiating treatment with relugolix with a planned duration of treatment of at least twelve months.

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## **Outcomes**

- Demographics (country, age, ethnicity)
  - Baseline clinical characteristics (ECOG PS, baseline disease stage, location of metastases, baseline PSA level / testosterone, prior prostatectomy / radiotherapy / other local intervention, prior ADT, most recent ADT, concomitant medications for PCa, CV comorbidities/risks)
  - Medical history of prostate cancer (date of diagnosis, cTNM at diagnosis, Gleason, PSA, disease stage)
  - Relugolix data (date of initiation, reason, posology, interruption with the duration and the reason, date of discontinuation and reason)
  - Disease evolution during the follow-up (disease state, TNM, PSA, testosterone, interventions)
  - Concomitant medications for prostate cancer (name of the drug, date of initiation/discontinuation, posology, reason)
  - Safety (all AE, date, causality, severity)
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## **Data analysis plan**

The primary goal of this study is to establish a database of clinical data from patients with prostate cancer treated with relugolix in a real-world practice setting that will characterize treatment patterns for prostate cancer and associated effectiveness and treatment persistence.

As such, no formal hypotheses will be tested in this study.

## **Data management**

### **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