

# Clinical experience with cabazitaxel in patients with metastatic castrate resistant prostate cancer (ECLIPSE) (ELIPSE)

**First published:** 11/07/2017

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS19826

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### Study ID

19827

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### DARWIN EU® study

No

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### Study countries

☐ United Kingdom

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## Study description

A multi-centre, observational, retrospective research study of patients with metastatic castrate resistant prostate cancer (mCRPC) who have received cabazitaxel in England. The primary objective is to describe the anti-cancer treatment pathways for patients who have received cabazitaxel following prior docetaxel treatment

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## Study status

Finalised

# Research institutions and networks

## Institutions

Sanofi

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Institution

Multiple centres: 5 centres are involved in the study

## Contact details

### Study institution contact

Medical Information Sanofi uk-  
medicalinformation@sanofi.com

Study contact

[uk-medicalinformation@sanofi.com](mailto:uk-medicalinformation@sanofi.com)

**Primary lead investigator**

Medical Information Sanofi

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 25/03/2015

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**Study start date**

Actual: 27/03/2015

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**Date of final study report**

Actual: 07/11/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi

## 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:**

Disease /health condition

Human medicinal product

Other

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**Study topic, other:**

Disease/Epidemiology study

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Primary objective: To describe the anti-cancer treatment pathways for patients who have received cabazitaxel following prior docetaxel treatment  
Secondary objectives: To describe the clinical outcomes of patients  
To describe the characteristics of patients  
To describe side effects associated with cabazitaxel use

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational retrospective study

## Study drug and medical condition

**Additional medical condition(s)**

Metastatic castrate resistant prostate cancer

## Population studied

**Short description of the study population**

Male patients diagnosed with metastatic castrate resistant prostate cancer (mCRPC) and had received cabazitaxel following failure of previous docetaxel treatment.

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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**

Metastatic castrate resistant prostate cancer patients

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## **Estimated number of subjects**

150

# Study design details

## **Data analysis plan**

Analyses are descriptive in nature. Nominal variables are described with frequencies and percentages, while ordinal variables are presented as medians and interquartile ranges (IQR). Time-to-event variables (progression-free survival PFS and overall survival OS) were analysed by the Kaplan-Meier method with data presented as survival plots and summarised as median, standard error (SE) and 95% confidence intervals 95% CI, within the follow up period available for each patient (i.e. patients still living at the date of data collection were censored at the date of data collection for analysis of OS and patients still alive and not recorded as progressing at the time of data collection were censored on that date for analysis of PFS).

# Documents

## Study results

[SR Synopsis v1.0 07Nov2016-anonymised scan.pdf](#)(2.75 MB)

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## Data management

### Data sources

#### Data sources (types)

[Disease registry](#)

### 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