# FUJI study: Follow-Up of Jevtana® in real lIfe

**First published:** 15/09/2015

**Last updated:** 24/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS10391

**Study ID**

47140

**DARWIN EU® study**

No

**Study countries**

☐ France

**Study description**

Prostate cancer is the most common cancer in France, it evolves slowly but there is a poor prognosis at the metastatic stage. Several therapeutic strategies are available such as hormonal therapies and chemotherapies. Cabazitaxel is a new taxane that has an European marketing authorization since March 2011

and indicated in the treatment of patients with metastatic castration-resistant prostate cancer previously treated with docetaxel. The availability of this treatment is recent (Dec 2012) and there is only limited data on the use, safety, and effectiveness of cabazitaxel in real-life practice. In this context, French health authorities request a French multicentre observational study. A retrospective cohort will be implemented with 400 patients initiating cabazitaxel from Sept 2013 to Aug 2015, followed 18 months and a prospective cohort with 60 patients initiating cabazitaxel from Mar 2016 to 28 Feb 2017, followed 6 months. The primary objective of the study is to evaluate the overall survival in the whole cohort and by treatment lines. The secondary objectives are to evaluate the safety, quality of life (QoL) and pain in the prospective cohort, to describe analgesic use, the characteristics of the treated study cohort and the conditions of cabazitaxel use in a real-life setting and to evaluate progression-free survival (PFS). The study will be conducted with participation of hospital pharmacists and physicians. A retrospective identification of patients will be performed by pharmacists from hospital pharmacy registers in order to avoid prescriber’s selection. Data collection will be performed by coordinating centre CRAs from the patient's medical records using an e-CRF. The QoL in the prospective cohort will be assessed using the FACT-P QoL questionnaire and pain will be evaluated by the Brief Pain Questionnaire - Short form (BPI-SF), these questionnaires will be completed by patients before each cabazitaxel infusion, up to the last cabazitaxel infusion.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

## Bordeaux PharmacoEpi, University of Bordeaux

France

**First published:** 07/02/2023

**Last updated:** 08/12/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

## Multiple centres: 45 centres are involved in the study

# Contact details


**Study institution contact**

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Study contact

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**Primary lead investigator**

Nicholas Moore

Primary lead investigator


# Study timelines

**Date when funding contract was signed**
Actual: 06/01/2015

**Study start date**
Actual: 30/10/2015

**Data analysis start date**
Actual: 09/06/2017

**Date of interim report, if expected**
Actual: 28/08/2017

**Date of final study report**
Actual: 27/03/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi

## Study protocol

FUJI-ENCePP-PROTOCOL comp HAS approved vs amdt 18 mai 2015_avec logo .pdf (1.81 MB)

FUJI-Protocole Amendement N°2.pdf (1.84 MB)

## Regulatory

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

Yes

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

**Main study objective:**

To evaluate the overall survival of patients treated by cabazitaxel and according to treatment-line

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L01CD04) cabazitaxel

cabazitaxel

## Population studied

**Short description of the study population**

Prostate cancer patients initiating cabazitaxel.

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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

**Special population of interest, other**

Prostate cancer

**Estimated number of subjects**

460

# Study design details

**Outcomes**

Overall survival is defined as the interval between the date of first administration of cabazitaxel (inclusion date) and the date of death, irrespective of cause, Safety based on data collected through medical file (NCI-CTCAE v4.0 toxicity scale and MEDdRA code), QoL and pain based on FACT-P and BPI-SF questionnaire. Description of analgesic use, patient's characteristics and cabazitaxel use. PFS defined as interval between inclusion date and date of progressive disease (radiological evaluation, RECIST criteria, clinical and biological parameters).

**Data analysis plan**

A detailed statistical analysis plan (SAP) will be performed before database lock using SAS® software (latest current version). The SAP will be validated by Scientific Committee. Descriptive statistics including mean, median, standard deviation, minimum, and maximum will be presented for continuous variables. For categorial variables, the number of subjects and percentage within each category will be presented. Describing analyses will concern prescriber recruitment, baseline demographic and clinical characteristics at inclusion date, treatment pattern during follow-up after inclusion date, toxicities by patient, and quality of life, pain and analgesic consumption. Overall and progression-

free survival outcomes will be analysed using Kaplan Meier method and median survival will be reported with 95%CI (adjusted on previous treatment). Multivariate analysis will be using the Cox proportional hazard risk model to assess the factors associated with mortality and progression of disease.

## Documents

**Study results**

FUJI-Summary of study results-ENCePP Final Report-20180605 VF.pdf (1.1 MB)

**Study, other information**

Synopsis FUJI vUK 28-07-2015 clean final version.pdf (514.36 KB)

Synopsis FUJI vUK amendement N°2 version clean 20180110.pdf (599.08 KB)

**Study publications**

Joly F, Oudard S, Fizazi K, Tubach F, Jove J, Lacueille C, Lamarque S, Guiard E...

Rouyer M, Oudard S, Joly F, Fizazi K, Tubach F, Jove J, Lacueille C, Lamarque S...

# 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.

This study has been awarded the ENCePP seal

**Conflicts of interest of investigators**

FUJI-ENCePP- DOI Form NM signé.pdf (1.68 MB)

FUJI-ENCePP-DOI Form AF 20150915.pdf (844.47 KB)

**Composition of steering group and observers**

FUJI-ENCePP-Composition steering committees.pdf (73.65 KB)

**Signed code of conduct**

FUJI-ENCePP-Code of conduct declaration 20150915 .pdf (352.92 KB)

**Signed code of conduct checklist**

FUJI-ENCePP-Code of conduct 20150915.pdf (1.65 MB)

**Signed checklist for study protocols**

FUJI-ENCePP- Checklist Protocol 20150915 VF.pdf (409.77 KB)

# Data sources

**Data sources (types)**

Drug dispensing/prescription data

Other

**Data sources (types), other**

Prospective patient-based data collection, Medical charts, clinic charts, nurses' notes, medical correspondence regarding the human subject, subject progress notes, Pathology reports, Laboratory reports, Study worksheets, Electronic hospital reporting system Questionnaires Quality of life (FACT-P) and Pain (BPI-SF) directly completed by patients

# 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**

No