

# Post Marketing Surveillance on Long Term Use of JARDIANCE® Tablets in Patients with Chronic Kidney Disease in Japan

**First published:** 29/07/2024

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Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000279

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### Study ID

1000000279

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### DARWIN EU® study

No

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### Study countries

 Japan

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### Study status

Planned

## Contact details

### Study institution contact

Akiko Ito [akiko.ito@boehringer-ingelheim.com](mailto:akiko.ito@boehringer-ingelheim.com)

Study contact

[akiko.ito@boehringer-ingelheim.com](mailto:akiko.ito@boehringer-ingelheim.com)

### Primary lead investigator

Akiko Ito

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/08/2024

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### Study start date

Planned: 01/09/2024

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### Date of final study report

Planned: 30/04/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

# Study protocol

[observational and non-interventional study protocol 1245-0340\\_V1.0\\_redacted.pdf](#) (406.85 KB)

## Regulatory

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

Yes

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

Non-EU RMP only

## 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:**

Cohort study

Non-interventional, single arm study based on newly collected data Patients will be observed for up to 52 weeks after the start of the treatment with JARDIANCE® Tablets or until discontinuation of administration.

**Main study objective:**

Study objective is to investigate the safety and effectiveness of long-term daily use of JARDIANCE® Tablets in patients with CKD under real-world use.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

JARDIANCE

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

EMPAGLIFLOZIN

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**Anatomical Therapeutic Chemical (ATC) code**

(A10BK03) empagliflozin

empagliflozin

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**Medical condition to be studied**

Chronic kidney disease

## Population studied

**Special population of interest**

Renal impaired

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**Estimated number of subjects**

1000

## 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.

## 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