

# Post Marketing Surveillance on Long Term Drug Use of JARDIANCE® Tablets in Patients with chronic heart failure in Japan (PMS of JARDIANCE in CHF)

**First published:** 22/11/2021

**Last updated:** 29/09/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS44340

### Study ID

46998

### DARWIN EU® study

No

### Study countries

☐ Japan

### Study description

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

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### Study status

Ongoing

## Research institutions and networks

### Institutions

**Boehringer Ingelheim**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

### Contact details

#### Study institution contact

Sakurako Watanabe sakurako.watanabe@boehringer-ingelheim.com

**Study contact**

[sakurako.watanabe@boehringer-ingelheim.com](mailto:sakurako.watanabe@boehringer-ingelheim.com)

#### Primary lead investigator

Sakurako Watanabe

## Study timelines

### Date when funding contract was signed

Planned: 17/03/2022

Actual: 13/12/2021

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### Study start date

Planned: 01/04/2022

Actual: 01/04/2022

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### Data analysis start date

Planned: 01/08/2024

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### Date of final study report

Planned: 30/06/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Nippon Boehringer Ingelheim Co., Ltd., Eli Lilly Japan K.K.

## Study protocol

[1245-0286\\_protocol\\_redacted.pdf](#) (1.4 MB)

[1245-0286-non-interventional-study-protocol\\_ver.4.0\\_Redacted.pdf](#) (400.62 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:

Disease /health condition

Human medicinal product

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#### Study type:

Non-interventional study

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#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

#### Main study objective:

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

## Study Design

## Non-interventional study design

Cohort

## Study drug and medical condition

### Name of medicine

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

Cardiac failure

## Population studied

### Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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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## Estimated number of subjects

1200

## Study design details

### Outcomes

Incidence of adverse drug reactions (ADR), Incidence of all-cause death

Incidence of CV death Incidence of hospitalizations for heart failure

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### Data analysis plan

Analyses are descriptive in nature, including confidence intervals.

## Documents

### Study results

[1245-0286\\_Synopsis.pdf](#) (348.44 KB)

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### Study publications

[Link to full article "Safety and effectiveness of empagliflozin in Japanese pat...](#)

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## 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 sources (types)**

Other

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## **Data sources (types), other**

Prospective patient-based data collection

# 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