# Post Marketing Surveillance in Japan on Drug Use of JARDIANCE® Tablets in Elderly Patients with type 2 Diabetes Mellitus (Japanese PMS, elderly patients)

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# Administrative details

**Study description** 

EU PAS number		
EUPAS8663		
Study ID		
20374		
DARWIN EU® study		
No		
Study countries		
Japan		

Study to investigate the safety and efficacy of daily use of JARDIANCE® Tablets in Japanese elderly patients with type 2 diabetes mellitus.

## **Study status**

Finalised

# Research institutions and networks

# Institutions

# Boehringer Ingelheim

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Institution

Multiple centres: 500 centres are involved in the study

# Contact details

# Study institution contact

Rie Ikeda zzCDMJP\_PV\_PMS@boehringer-ingelheim.com

Study contact

zzCDMJP\_PV\_PMS@boehringer-ingelheim.com

## **Primary lead investigator**

# Rie Ikeda

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Planned: 25/07/2014

Actual: 25/07/2014

### Study start date

Planned: 23/02/2015 Actual: 24/02/2015

### Data analysis start date

Planned: 23/02/2015 Actual: 24/02/2015

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

Planned: 26/08/2017 Actual: 25/07/2017

# 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 98 protocol synopsis.pdf (107.95 KB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

### Study type:

Non-interventional study

# Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness Effectiveness study (incl. comparative)

### **Data collection methods:**

Primary data collection

# Main study objective:

To investigate the safety and efficacy of daily use of JARDIANCE® Tablets in Japanese elderly patients with type 2 diabetes mellitus.

# Study Design

### Non-interventional study design

Cohort

Other

### Non-interventional study design, other

Non-interventional, prospective, observational, single arm

# Study drug and medical condition

## **Medicinal product name**

**JARDIANCE** 

### Medical condition to be studied

Type 2 diabetes mellitus

# Population studied

## Short description of the study population

Male and female elderly patients (age 65 and over) with type 2 diabetes mellitus who have never been treated with JARDIANCE® Tablets before the enrolment and start taking JARDIANCE® Tablets within 3 months after launch in Japan.

### Age groups

- Adults (65 to < 75 years)</li>
- Adults (75 to < 85 years)
- Adults (85 years and over)

### **Special population of interest**

Other

### Special population of interest, other

Diabetes mellitus patients

### **Estimated number of subjects**

720

# Study design details

### **Outcomes**

Incidence of adverse drug reactions, Change from baseline in HbA1c to the lastobservation on treatment. Change from baseline in Fasting plasma glucose to the last- observation on treatment.

### Data analysis plan

Descriptive statistics will be summarized for safety and efficacy. A mixed model repeated measures analysis will be performed for HbA1c over time. Incidence of adverse drug reactions. Change from baseline in HbA1c to the last- observation

on treatment. Change from baseline in Fasting plasma glucose to the lastobservation on treatment.

# 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

# Data sources (types), other

Prospective patient-based data collection

# Use of a Common Data Model (CDM)

# **CDM** mapping

No

# Data quality specifications

# Unknown Check completeness Unknown

# **Check stability**

**Check conformance** 

Unknown

# **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

Unknown