

An observational cohort study to investigate the risk factors for interstitial lung disease (ILD) among breast cancer patients treated with abemaciclib or endocrine monotherapy using the Medical Data Vision (MDV) database in Japan (I3Y-JE-B008)

**First published:** 17/04/2023

**Last updated:** 23/04/2024

Study

Planned

## Administrative details

**EU PAS number**

EUPAS104511

---

**Study ID**

104512

---

**DARWIN EU® study**

No

---

## Study countries

 Japan

---

## Study description

The primary objective of this study is to investigate risk factors of ILD among patients with HR+/HER2- breast cancer receiving abemaciclib-containing regimens or endocrine monotherapy (both historical and concurrent cohorts) under the real world setting in Japan, and the secondary objective is to describe the baseline characteristics, incidence and prevalence of ILD in each of the study cohorts. The exploratory objective is to compare the incidence rate of ILD in patients initiating abemaciclib relative to reference cohorts of endocrine monotherapy.

---

## Study status

Planned

## Research institutions and networks

### Institutions

[Eli Lilly and Company](#)

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

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

**Institution**

## Contact details

### **Study institution contact**

Seiko Mizuno [jpmail\\_encepp@lilly.com](mailto:jpmail_encepp@lilly.com)

**Study contact**

[jpmail\\_encepp@lilly.com](mailto:jpmail_encepp@lilly.com)

### **Primary lead investigator**

Seiko Mizuno

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 19/07/2019

---

### **Study start date**

Planned: 30/11/2018

---

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

Planned: 01/12/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly Japan K.K.

## 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 type:**

Non-interventional study

---

#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

The primary objective of this study is to investigate risk factors of ILD among patients with HR+/HER2- breast cancer receiving abemaciclib-containing regimens or endocrine monotherapy (both historical and concurrent cohorts) under the real world setting in Japan

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(L01EF03) abemaciclib

abemaciclib

---

## **Medical condition to be studied**

Interstitial lung disease

## Population studied

### **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)
- 

### **Estimated number of subjects**

3312

## Study design details

### **Data analysis plan**

The prevalence, incidence, and incidence rate of ILD for all treatment cohorts will be calculated. Kaplan-Meier method will be used to display the time until patients develop the first ILD (event-free period). The historical endocrine monotherapy cohort will be used for the primary comparator and the concurrent endocrine monotherapy cohort will be used. In the univariable Cox regression analysis, variables will be selected as candidates for the multivariable analysis based on statistical significance as well as clinical

importance/relevance. Multivariable Cox proportional hazard analysis will be used to identify potential risk factors associated with time to ILD onset by each of the three treatment cohorts from variables identified from the univariable analysis, with or without potential interaction terms. Additional multivariable Cox regression analysis that will be conducted to include treatment cohorts as independent variable along with other candidate variables.

## 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 source(s), other

MDV Japan

---

### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

## 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