Post-marketing Surveillance (PMS) on long term use of Ofev Capsules in Systemic Scleroderma associated Interstitial Lung Disease (SSc-ILD) in Japan (PMS for Ofev (SSc-ILD))

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# Administrative details

EU PAS number	
EUPAS32905	
Study ID	
45827	
DARWIN EU® study	
No	
Study countries	
Japan	

#### **Study description**

The primary objective is to confirm the incidence of adverse drug reactions to Ofev Capsules seen in clinical trials with real world data generated in patients with SSc-ILD.

#### **Study status**

Ongoing

## Research institutions and networks

### Institutions

## Boehringer Ingelheim

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Institution

## Contact details

### **Study institution contact**

Toshiro Ohtake zzCDMJP\_PV\_PMS@boehringer-ingelheim.com

Study contact

zzCDMJP\_PV\_PMS@boehringer-ingelheim.com

### **Primary lead investigator**

## Toshiro Ohtake

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Planned: 19/03/2020

Actual: 19/03/2020

#### Study start date

Planned: 01/04/2020

Actual: 27/05/2020

### Data analysis start date

Planned: 30/06/2026

### Date of final study report

Planned: 31/03/2027

# Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Nippon Boehringer Ingelheim Co.,Ltd.

# 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

Disease epidemiology

Drug utilisation

### Main study objective:

Main objective is to confirm the incidence of adverse drug reactions (focus on gastrointestinal symptoms including diarrhea and nausea).

# Study Design

### Non-interventional study design

Other

### Non-interventional study design, other

Longitudinal study

# Study drug and medical condition

#### Name of medicine

**OFEV** 

#### 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**

550

# Study design details

#### **Outcomes**

The incidence of adverse drug reactions (ADRs)

#### Data analysis plan

Analyses are descriptive in nature, including confidence intervals.

# 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 completer	ness		
Unknown			

## **Check stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No