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))

First published: 23/12/2019

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Study Ongoing

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

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Akiko Ito

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 19/03/2020

Study start date

Actual: 27/05/2020

Data analysis start date

Planned: 30/06/2026

Date of final study report
Planned: 30/09/2027

Sources of funding

More details on funding

Nippon Boehringer Ingelheim Co.,Ltd.

Study protocol

non-interventional-study-protocol-1199-0387_ver.5.0_Redacted.pdf (395.78 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 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

Cohort

Other

Non-interventional study design, other

Longitudinal study

Study drug and medical condition

Medicinal product name

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

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No