

Post-marketing Surveillance of Ofev Capsules in Chronic (PMS for PF-ILD)

First published: 04/08/2020

Last updated: 22/04/2024

Study

Ongoing

Administrative details

EU PAS number

EUPAS36605

Study ID

40512

DARWIN EU® study

No

Study countries

☐ Japan

Study description

The primary objective is to evaluate the incidence of adverse drug reactions (focus on hepatic function disorders) of Ofev Capsules under the real world setting in patients with PF-ILD.

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

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Study contact

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Primary lead investigator

Makiko Ohnishi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/09/2020

Actual: 28/09/2020

Study start date

Planned: 01/10/2020

Actual: 02/10/2020

Date of final study report

Planned: 31/12/2025

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 (ADRs) by overall, each individual (especially focus on the safety specification on J-RMP: hepatic function disorders)

Study Design

Non-interventional study design

Cohort

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

440

Study design details

Outcomes

The incidence of adverse drug reactions (ADRs)

Data analysis plan

analyses are descriptive in nature, including confidence intervals.

Data management

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