# A regulatory requirement non-interventional study to monitor the safety and effectiveness of Ofev (Nintedanib, 150mg/100mg, BID) in Korean patients

**First published:** 07/07/2021

**Last updated:** 10/12/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS41912

**Study ID**

47414

**DARWIN EU® study**

No

**Study countries**

☐ Korea, Republic of

**Study description**

To monitor the safety and effectiveness of Ofev in Korean patients in a routine clinical practice setting.

**Study status**

Finalised

# 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**

Hyelin Lee

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**
Planned: 31/12/2020

Actual: 29/12/2020

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**Study start date**
Planned: 31/03/2021

Actual: 16/03/2021

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**Date of final study report**
Planned: 20/07/2023

Actual: 27/07/2023

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim Korea

# Study protocol

1199-0417_CTP_final-rule_Redacted.pdf(1.03 MB)

# Regulatory

**Was the study required by a regulatory body?**

Yes

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Other study registration identification numbers and links

1199-0417

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Main study objective:**

The primary objective is to monitor the safety profile of Ofev in Korean patient in a routine clinical setting.

## Study drug and medical condition

**Name of medicine**

OFEV

**Study drug International non-proprietary name (INN) or common name**

NINTEDANIB

**Anatomical Therapeutic Chemical (ATC) code**

(L01EX09) nintedanib

nintedanib

**Medical condition to be studied**

Idiopathic pulmonary fibrosis

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)

**Special population of interest**

Hepatic impaired

Renal impaired

**Estimated number of subjects**

59

## Study design details

**Data analysis plan**

Descriptive analysis will be performed.

## Documents

**Study report**

1199-0417_redacted Synopsis.pdf(235.37 KB)

# 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

Spontaneous reports of suspected adverse drug reactions

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**Data sources (types), other**

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Yes

**Check completeness**

Yes

**Check stability**

Yes

**Check logical consistency**

Yes

# Data characterisation

**Data characterisation conducted**

Yes