

# Investigating Trends in Quality of Life in Patients with Idiopathic Pulmonary Fibrosis (IPF) Under Treatment with Nintedanib (QUALIFY IPF)

**First published:** 08/10/2018

**Last updated:** 15/12/2021

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS25664

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### Study ID

44734

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### DARWIN EU® study

No

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### Study countries

 Greece

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### Study description

Multi-center, non-interventional, prospective cohort study aiming to enroll 120 IPF patients receiving treatment with nintedanib in a consecutive manner from 10-12 reference centers across Greece.

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### **Study status**

Ongoing

## Contact details

### **Study institution contact**

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**Study contact**

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### **Primary lead investigator**

Georgios Patentlakis

**Primary lead investigator**

## Study timelines

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

Planned: 15/06/2018

Actual: 15/06/2018

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### **Study start date**

Planned: 05/03/2019

Actual: 05/03/2019

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

Planned: 31/12/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

BOEHRINGER INGELHEIM ELLAS SA

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

QoL evaluation

**Main study objective:**

To evaluate the HRQoL changes of IPF patients treated in current clinical practice in Greece with nintedanib over a 52-weeks period

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

NINTEDANIB

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**Medical condition to be studied**

Idiopathic pulmonary fibrosis

## 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)
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### **Estimated number of subjects**

240

## Study design details

### **Outcomes**

Mean change from baseline in HRQoL in patients under treatment with nintedanib over 52 weeks follow-up period, Change from baseline of dyspnoea burden as measured by mMRC questionnaire Mean change from baseline of cough burden as measured by the cough - VAS Percentage of adhered patients to nintedanib treatment Mean change from baseline of anxiety as measured by the GAD-7 questionnaire. Percentage of patients that use LTOT over the 52 weeks follow up period

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### **Data analysis plan**

The nature of the statistical analyses will be exploratory and descriptive.

## 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

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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

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

## **Data characterisation conducted**

No