A Prospective Observational Registry to describe the disease course and outcomes of Idiopathic Pulmonary Fibrosis patients in a real-world clinical setting (PROOF-R)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/11789

EU PAS number

EUPAS11788

Study ID

11789

DARWIN EU® study

No

Study countries

☐ Belgium

☐ Luxembourg

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Karl Richir

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/04/2013

Study start date

Actual: 22/10/2013

Date of final study report

Planned: 03/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Regulatory

Was the study required by a regulatory body?

Yes

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Main study objective:

To describe the disease course and outcomes in IPF patients.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective observational registry

Study drug and medical condition

Name of medicine

ESBRIET

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)

Special population of interest

Pregnant women

Estimated number of subjects

750

Study design details

Outcomes

Endpoints to describe disease progression, time to:a- first occurrence of decrease ≥ 10% in percent predicted FVCb- first occurrence of a decrease ≥ 15% in percent predicted Hgb corrected DLCOc- death, a-IPF treatment drugs name(s), initial dose, dose changes, drug discontinuation, duration of dose reduction/interruption, lung transplantationb-Change in QoL scorec- ADRs and SADRs, which were defined as occurring after the first dose and within 28 days after the last dose of registry treatment.d-Consultation of HCPs and the relation of these consultations with IPF (treatment).

Data analysis plan

All data will be summarized using descriptive statistics: number of patients, means, medians, standard deviations (SD), minimums, and maximums for continuous variables, and frequencies and percentages for discrete variables.

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