

# IDENTIFYING OPPORTUNITIES FOR EARLIER DIAGNOSIS OF IDIOPATHIC PULMONARY FIBROSIS IN ROUTINE CARE IN THE UK: A RETROSPECTIVE CLINICAL COHORT STUDY (OPPORTUNITIES FOR EARLIER IPF DIAGNOSIS)

**First published:** 14/01/2016

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS12086

### Study ID

28880

### DARWIN EU® study

No

### Study countries

United Kingdom

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## Study description

In the UK, all patients who ultimately receive a diagnosis of IPF will have first presented in the primary care setting. Thus by carrying out a historical review of the primary care records for patient in the years preceding their IPF diagnosis, it should be possible to identify common patterns (trends) in healthcare resource utilization (HRU) and identify potential “red flags” to support decision support tools to aid earlier diagnosis. With a view to identifying potential opportunities for earlier referral to specialists and (ultimately) earlier diagnosis of IPF, this study aims to:(i) Evaluate patients’ patterns of HRU in the years preceding their IPF diagnosis.(ii) Characterise the clinical features of patients at the time of their IPF diagnosis.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

**First published:** 06/10/2015

**Last updated:** 19/08/2024

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**ENCePP partner**

## Networks

### Respiratory Effectiveness Group (REG)

- Belgium
- Denmark
- France
- Germany
- Greece
- Hungary
- Italy
- Netherlands
- Spain
- Sweden
- United Kingdom

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

**Last updated:** 04/06/2024

**Network**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

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**Primary lead investigator**

Richeldi Luca

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 29/01/2016

Actual: 29/11/2016

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**Study start date**

Planned: 05/02/2016

Actual: 10/12/2016

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**Date of final study report**

Planned: 28/10/2016

Actual: 21/12/2016

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## Sources of funding

- Other

## More details on funding

Respiratory Effectiveness Group

# Study protocol

[REG\\_IPF Earlier Diagnosis Protocol.pdf \(449.92 KB\)](#)

## Regulatory

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

Unknown

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

Not applicable

## Methodological aspects

### Study type

#### Study type list

##### **Study topic:**

Disease /health condition

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##### **Study type:**

Non-interventional study

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##### **Scope of the study:**

Disease epidemiology

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##### **Data collection methods:**

### **Main study objective:**

With a view to identifying potential opportunities for earlier referral to specialists and (ultimately) earlier diagnosis of IPF, this study aims to:(i) Evaluate patients' patterns of HRU in the years preceding their IPF diagnosis.(ii) Characterise the clinical features of patients at the time of their IPF diagnosis.

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Observational, historical database study

## Study drug and medical condition

### **Medical condition to be studied**

Idiopathic pulmonary fibrosis

## Population studied

### **Short description of the study population**

- Patients who have a diagnostic for Idiopathic pulmonary fibrosis (IPF) between 1990 and 2015
- Have a minimum of 2 years continuous clinical records in the years

immediately preceding their index diagnosis

- Aged 40 years or older at index date

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### **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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### **Special population of interest**

Other

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### **Special population of interest, other**

Idiopathic pulmonary fibrosis (IPF) patients

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### **Estimated number of subjects**

2000

## Study design details

### **Outcomes**

1. Consultations including lower respiratory (LR) consultations
2. Hospitalisations (in-patient attendances): same day or following 7 days
3. Out patient visits with a code for a LR complaint (same day or following 7 days)
4. Accident & Emergency attendances coded for a LR complaint (same day or following 7 days)
5. Chest X-ray

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### **Data analysis plan**

- The analysis will assess changes in HRU over the 25-year period (1990–2015), and in 5-year increments (0–5 years, 6–10 years, 11–15 years, 16–20 years and 21–25 years)
- Summary statistics will be used to characterise patients at time of IPF diagnosis:
  - For variables measured on the interval or ratio scale, summary statistics produced will be:
  - Sample size (n)
  - Percentage non missing
  - Mean
  - Variance/standard deviation
  - Range (minimum- maximum)
  - Median
  - Inter-quantile range (25th and 75th percentile)
  - For categorical variable the summary statistics will include:
  - Sample size (n)
  - Range
  - Count and percentage by category (distribution)
  - Statistically significant results will be defined as  $p < 0.05$  and trends as  $0.05 \leq p < 0.10$ .
  - Suitable tests (e.g. F tests, t tests,  $\chi^2$  tests) and models (e.g. linear models) will be used, as appropriate, to explore the interaction between different clinical characteristics and features (e.g. year, age) of diagnosis.

## 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 source(s)**

Optimum Patient Care Research Database

## **Data sources (types)**

Electronic healthcare records (EHR)

# 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

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# Data characterisation

## **Data characterisation conducted**

Unknown