

# Incidence and Prevalence of Interstitial Lung Disease and their progressive fibrosing phenotypes in 6 European Countries (PERSEIDS)

**First published:** 29/05/2020

**Last updated:** 09/12/2020

Study

Finalised

## Administrative details

### EU PAS number

EUPAS34861

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### Study ID

38521

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### DARWIN EU® study

No

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### Study countries

☐ Belgium

☐ Denmark

☐ Finland

- ☐ Greece
  - ☐ Norway
  - ☐ Portugal
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### Study description

Non-interventional, epidemiological, retrospective, site-level (aggregated data) study in 6 European countries (Belgium, Denmark, Finland, Greece, Norway and Portugal). The study will be performed in two phases, both of them based on existing data. The main research questions are: in Phase 1 to know the epidemiology (incidence rate and prevalence) of ILD, SSc and some specific ILD-subtypes by collecting aggregated data from 18 hospital databases, in Phase 2, to describe the prevalence of progressive phenotypes and UIP pattern among other (non-IPF) fibrosing ILD subjects by looking into 100 patient files and reviewing lung function, hospitalizations, oxygen use, deaths and imaging results during a 2-year (retrospective) period.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### TFS HealthScience (TFS)

- ☐ Sweden

**First published:** 01/02/2024

**Last updated:** 03/04/2024

Institution

Non-Pharmaceutical company

ENCePP partner

Multiple centres: 14 centres are involved in the study

## Contact details

### Study institution contact

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Study contact

[stephane.soulard@boehringer-ingelheim.com](mailto:stephane.soulard@boehringer-ingelheim.com)

### Primary lead investigator

Stéphane Soulard

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/01/2019

Actual: 15/01/2019

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### Study start date

Planned: 15/05/2019

Actual: 15/05/2019

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**Data analysis start date**

Actual: 20/04/2020

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**Date of final study report**

Actual: 09/12/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim International GmbH (BI)

## Study protocol

[SSc\\_ILD\\_Epi\\_\(BIN1029\)\\_Protocol\\_Final\\_20190429 \(002\)\\_clean.pdf](#) (1.85 MB)

## 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 topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Phase 1: To estimate, in 6 European countries, the incidence rate and prevalence of SSc, ILD, ILD associated to SSc (SSc-ILD), Fibrosing ILD, IPF and other fibrosing ILD. Phase 2: To estimate, in 6 European countries, the percentage of other (non-IPF) fibrosing ILD patients with a progressive phenotype (PF-ILD), UIP pattern and PF-ILD with UIP pattern

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective epidemiological study

## Study drug and medical condition

## **Medical condition to be studied**

Interstitial lung disease

Idiopathic pulmonary fibrosis

Hypersensitivity pneumonitis

Sarcoidosis

Mixed connective tissue disease

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## **Additional medical condition(s)**

Idiopathic non-specific interstitial pneumonia, Unclassifiable idiopathic interstitial pneumonia, Exposure-related interstitial lung disease, Other fibrosing interstitial lung disease, Systemic sclerosis-associated interstitial lung disease Rheumatoid arthritis-associated interstitial lung disease and Other diffuse connective tissue disease.

# **Population studied**

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

Phase 1: all adults listed in source databases during 2014-2018.

Phase 2: first 100 patients at each database with a code/keyword for any non-IPF F-ILD from 2016.

Inclusion criteria

- Phase 1: All adult subjects listed in the participating hospital databases aged  $\geq 18$  in each calendar year of the index period (i.e. 2014, 2015, 2016, 2017 and 2018) will constitute the source population, which will be used to identify the cases for each studied condition

□ Phase 2: First 100 patients<sup>23</sup> with a health encounter at sites participating in Phase 2 from 1st January 2016 onwards including an ICD/keyword for any "other (non-IPF) fibrosing ILD" (as defined in Phase 1)

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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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## Estimated number of subjects

12990656

# Study design details

## Outcomes

Phase 1: Crude prevalence and crude incidence rate of SSc, ILD, SSc-ILD, fibrosing ILD, IPF and other fibrosing ILD per 100 000 persons in each site/country, overall for the study period (2014-2018) and annuallyPhase 2: Percentage of other (non-IPF) fibrosing ILD patients with PF-ILD, UIP pattern and PF-ILD with UIP pattern, Phase 1: Crude prevalence and incidence rate for each clinical ILD and fibrosing ILD diagnosis overall for the study period (2014-2018) and annually. Phase 2: PPV, overall and by country and site, of the algorithm used for identifying fibrosing ILD (non-IPF) cases in Phase 1.

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## Data analysis plan

Statistical analyses will be of exploratory and descriptive nature. The study is not designed to confirm (or refute) pre-defined hypotheses.Descriptive analyses will be conducted to report the results of this study. Continuous variables will be presented as mean values, medians, ranges, interquartile range (IQR), and standard deviations and categorical variables will be presented as absolute and relative frequencies, together with 95% confidence intervals.

# Documents

## Study results

[PERSEIDS\\_abstract\\_09December2020.pdf](#) (549.47 KB)

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## 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)

Danish registries (access/analysis)

Auria Clinical Informatics (FinOMOP)

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### Data sources (types)

[Other](#)

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### Data sources (types), other

Hospital medical records and national/regional registers

## 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