

# Global Evaluation of the Interstitial Lung Disease Diagnostic Pathway (Global ILD-MDT study)

**First published:** 13/12/2017

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS22002

### Study ID

22003

### DARWIN EU® study

No

### Study countries

☐ Italy

☐ United Kingdom

### Study description

This two-phase study aims to characterise the global practice of diagnosing interstitial lung disease (ILD) and identify the features of ILD multidisciplinary team (MDT) meetings associated with more accurate diagnosis of ILD. Phase I is a global, standardised, systematic evaluation of the diagnostic process employed by a range of dedicated and non-dedicated ILD centres worldwide. An electronic questionnaire will be distributed through local leads, and national and international consortia. A pragmatic “strategic-opportunistic” approach will be taken, combining easily-scalable electronic data capture with local expertise to invite responses from a wide and representative range of (ultimately self-selecting) clinics and centres. Phase II is a global MDT ILD case review and diagnosis study to assess the diagnostic agreement across ILD MDTs and assess the diagnostic accuracy of ILD MDTs. Appropriate definition of these Phase II design components will be critical to the robustness and relevance of the study. The Phase II definition of an MDT, and the study’s geographical scope and case mix distribution, will aim to reflect real-life (as far as is practically possible) as established in Phase I. Centres identified in phase I will be invited to participate. Participants will be sent digitised reference cases, including pathology data, and diagnostic responses will be collected. Diagnostic accuracy will be determined against the diagnosis given by the reference case provider, against an expert MDT with global representation, and where possible, against the diagnostic inference of available follow up data.

---

## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

Multiple centres: 500 centres are involved in the study

## 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

Naomi Launders [naomi@effectivenessevaluation.org](mailto:naomi@effectivenessevaluation.org)

Study contact

[naomi@effectivenessevaluation.org](mailto:naomi@effectivenessevaluation.org)

**Primary lead investigator**

Luca Richeldi

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/08/2016

Actual: 01/08/2016

---

**Study start date**

Planned: 10/11/2016

Actual: 10/11/2016

---

**Data analysis start date**

Planned: 01/02/2017

Actual: 01/02/2017

---

**Date of interim report, if expected**

Planned: 01/12/2017

Actual: 01/03/2017

---

**Date of final study report**

Planned: 27/11/2017

Actual: 27/11/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Financial: Roche, Boehringer Ingelheim and Three Lakes Partnership, in kind: Veracyte

## Study protocol

[GlobalILDEvaluation\\_Protocol060616.pdf](#) (889.77 KB)

## Regulatory

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

No

---

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

Not applicable

## Other study registration identification numbers and links

REG-RES1505

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

Other

---

**Study topic, other:**

Disease/Epidemiology study

**Study type:**

Non-interventional study

---

**Scope of the study:**

Other

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

Diagnostic practice/accuracy

**Data collection methods:**

Primary data collection

---

**Main study objective:**

To identify features of ILD MDTs associated with more accurate diagnosis of IPF with a view to improving diagnostic accuracy and patient stratification to optimise treatment outcomes worldwide.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

## Medical condition to be studied

Interstitial lung disease

## Population studied

### Short description of the study population

Interstitial lung disease patients.

---

### Age groups

- Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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

Other

---

### Special population of interest, other

Interstitial Lung Disease (ILD) patients

---

### Estimated number of subjects

60

## Study design details

## Data analysis plan

Phase I analysis will be descriptive, comparing reported diagnostic practices by region, country economic status, and participant expertise. Phase II analysis will also be descriptive, with the use of agreement measures such as Cohen's Kappa statistic to explore diagnostic agreement. Diagnostic accuracy compared to the several different reference groups: the diagnosis of the clinician providing the case details, the diagnosis of an expert MDT with global representation, the diagnosis as indicated by available follow-up data.

## 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](#)

---

### Data sources (types), other

Data for both phases will be generated through completion of an electronic questionnaire by participating centres.

## 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

Unknown