ForPatients
by Roche

Idiopathic Pulmonary Fibrosis (IPF)

A Study to Characterize the Disease Behavior of Idiopathic Pulmonary Fibrosis (IPF) and Interstitial Lung Disease (ILD) During the Peri-Diagnostic Period

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT03261037 2016-005114-22 MA39297

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

An International Study to Characterize the Disease Behaviour of Idiopathic Pulmonary Fibrosis and Interstitial Lung Disease During the Peri-Diagnostic Period

Trial Summary:

This international clinical study will enroll participants with a suspected diagnosis of IPF/ILD. This study will characterize the disease behavior of IPF and ILD in the peri-diagnostic period. This objective will be achieved using a multidimensional approach assessing changes in pulmonary function, measured by daily handheld spirometry and site spirometry as well as assessing physical functional capacity at home (accelerometry) and at site (6-minute walk tests [6MWT]). Daily handheld spirometry or physical functional capacity assessments are not routinely performed in this participant population. By following participants' lung function before and after diagnosis using home spirometry, levels of physical activity, as well as self-assessment data from the participants (patient reported outcomes; PRO), the study would provide potentially more rapid information on disease behavior and eventually progression compared to usual clinic measurements that occur only every 3-6 months. By receiving data from daily handheld spirometry measurements, treating physicians may have an improved chance of detecting earlier and outside of hospital visits a decline in lung function that could potentially lead to improvements in both diagnosis and treatment for participants with IPF/ILD.

Hoffmann-La Roche	**N/A**
Sponsor	Phase

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Trial Identifiers

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Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	**# 50 Years**	**No**

Inclusion Criteria:

- Able to comply with the study protocol, in the Investigator's judgment - for example, the ability to use the provided spirometer and tablet and the ability to fill in the required patient reported outcomes questionnaires
- Suspicion of IPF/ILD: radiological evidence of IPF/ILD in symptomatic participants (unexplained dyspnea on exertion and/or cough)

Exclusion Criteria:

- Participation in any investigational study within 28 days prior to inclusion
- History of clinically significant cardiac disease that could explain the patient's symptomatology in the opinion of the Investigator
- Known history of any connective tissue disease, including, but not limited to, rheumatoid arthritis, scleroderma, systemic lupus erythematosus, or mixed connective tissue disease