

Sponsor	Institut National de la Santé et de la Recherche Médicale (Inserm)
Title	<p>Non interventional study of the management of patients with Idiopathic Pulmonary Fibrosis (IPF) in clinical (real world) practice: a specific research project from the RaDiCo-PID (Rare Disease Cohort – Pneumopathies Interstitielles Diffuses) cohort.</p> <p>Caractéristiques des patients atteints de FIP et évaluation de la mortalité et de la morbidité chez les patients traités par Ofev® (nintedanib).</p> <p>Characteristics of patients diagnosed with IPF and assessment of the mortality and morbidity among patients treated with Ofev® (nintedanib).</p>
Country	France
Private partner	Boehringer Ingelheim
Research Question and Objectives	<p>In the context of the clinical assessment of Ofev® by HAS, Transparency Commission requested “real-world practice data on the characteristics of treated patients, and the impact of this drug in terms of morbidity and mortality, to be provided”.</p> <p>In line with HAS’ requests and the design of the study, the objectives of this post-registration investigation are:</p> <ul style="list-style-type: none"> ✓ Primary objective: To describe the characteristics of patients diagnosed with IPF in France ✓ Secondary objective: To assess the morbidity and mortality in patients treated with nintedanib in real-world practice in France.
Population	IPF diagnosis less than 3 years included in RaDiCo-PID between July 2017 and July 2019.
Regulatory	Cohort RaDiCo-PID protocol, sponsored by Inserm, receiving a favorable opinion of Inserm Ethics Committee on 16 October 2015 and of CCTIRS on 23 March 2016. CNIL approved Cohort RaDiCo-PID protocol on 3 November 2016.