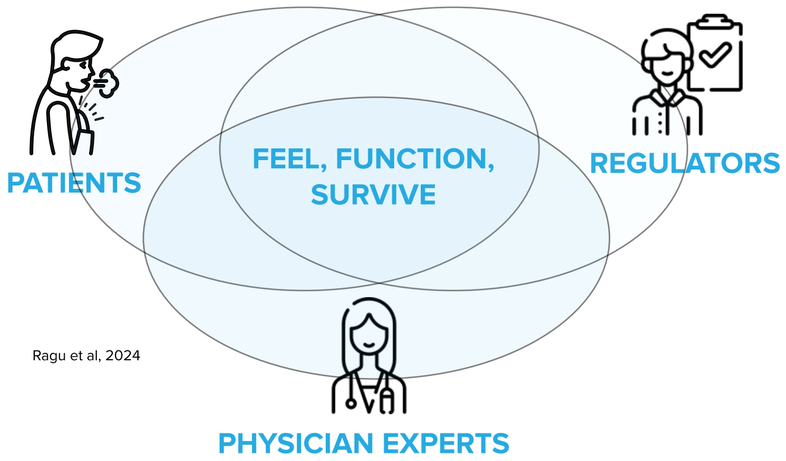
Cough as an Endpoint in Idiopathic Pulmonary Fibrosis (IPF)

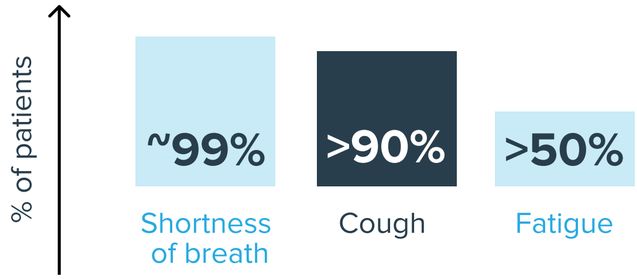
Cough is a highly prevalent and burdensome symptom for patients with IPF. As more emphasis in clinical trials continues to be placed on how patients feel, function and survive, cough has emerged as an important outcome measure, with objective monitoring allowing for more direct, reliable and consistent evidence.

1 Expert consensus suggests IPF trial endpoints should focus on outcomes meaningful to patients



Ragu et al, 2024

2 Cough is one of the top symptoms that matters most to IPF patients



FDA, 2015; Hirons et al, 2023

3 Severe coughing worsens quality of life and may predict disease progression and survival

2.8x higher risk of **death** with severe cough

Wu et al, 2024

1-point decrease in LCQ score

- **6.5%** higher risk of hospitalization
- **7.4%** higher risk of death
- **8.7%** higher risk of transplantation

Lee et al, 2022

4 Cough can be unobtrusively and passively monitored at home, providing a more complete and objective data set

For **patients** this means less travel and broader access to studies

For **investigators** it means enhanced statistical power and precision

Wijsenbeek et al, 2023

Cox, I. A., Borchers Arriagada, N., de Graaff, B., Corte, T. J., Glaspole, I., Lartey, S., Walters, E. H., & Palmer, A. J. (2020). Health-related quality of life of patients with idiopathic pulmonary fibrosis: a systematic review and meta-analysis. European respiratory review : an official journal of the European Respiratory Society, 29(158), 200154. https://doi.org/10.1183/16000617.0154-2020; U.S. Food and Drug Administration (FDA) (2015). Voice of the patient - Idiopathic Fibrosis. https://www.fda.gov/files/about%20fda/published/The-Voice-of-the-Patient--Idiopathic-Pulmonary-Fibrosis.pdf; Hirons, B., Rhatigan, K., Kesavan, H., Turner, R. D., Birring, S. S., & Cho, P. S. P. (2023). Cough in chronic lung disease: a state of the art review. Journal of thoracic disease, 15(10), 5823–5843. https://doi.org/10.21037/jtd-22-1776; Lee et al. (2022). Cough-Specific Quality of Life Predicts Disease Progression Among Patients With Interstitial Lung Disease: Data From the Pulmonary Fibrosis Foundation Patient Registry. Chest, 162(3), 603–613. https://doi.org/10.1016/j.chest.2022.03.025; Raghu et al. (2024). Meaningful Endpoints for Idiopathic Pulmonary Fibrosis (IPF) Clinical Trials: Emphasis on 'Feels, Functions, Survives'. American journal of respiratory and critical care medicine. 209. 10.1164/rccm.202312-2213SO; Wijsenbeek, et al. (2023). Home monitoring in interstitial lung diseases. The Lancet. Respiratory medicine, 11(1), 97–110. https://doi.org/10.1016/S2213-2600(22)00228-4; Wu et al. (2024). Cough Severity Visual Analog Scale Assesses Cough Burden and Predicts Survival in Idiopathic Pulmonary Fibrosis. American journal of respiratory and critical care medicine, 209(9), 1165–1167. https://doi.org/10.1164/rccm.202311-2169LE

www.stradoslabs.com