

Case Study

Phase II IPF Enrollment Delivered in a Competitive Global Environment

Surpassed enrollment targets and met the interim analysis on time,
clearing the path for Phase III

Background

A sponsor's Phase II IPF study began enrollment at a moment when several competing studies were actively targeting the same treatment-naive patient population. The sponsor needed to deliver an interim analysis on schedule to support a significant communication milestone, which meant enrollment could not slip even as the competition shifted underneath it.



Accelerated

Enrollment targets in a competitive environment



On-Time

Interim analysis supporting primary and secondary endpoints



Global

Strategic enrollment plan across multiple regions

Competing for a small, aging, treatment-naive patient pool

Challenge



Direct competition for the same patients


Multiple active IPF studies targeted the same treatment-naïve population, with sites pulled in several directions.


Solution




Strategic global enrollment plan


To address this, we built and continuously adapted a regional enrollment strategy that prioritized treatment-naïve populations, with country-level reweighting as needed.


 **Site attention & study execution**
Sites running parallel IPF studies required a clear rationale to prioritize this one above the others.

 **Aging patient population & visit burden**
IPF patients are typically older, and the study visit burden risked screen fail and early discontinuations.


 **Eligible pool smaller than the enrollment target**
Mid-study, it became clear that the globally eligible pool under the original protocol would not support the enrollment target on the sponsor's timeline.


 **Established IPF site relationships & daily site support**
We drew on our existing IPF site network and embedded a Clinical Site Liaison for daily site-level support. Weekly leadership check-ins caught friction points before they affected enrollment, with country-level reweighting applied as needed.

 **Patient-focused trial design support**
Vendor-partnered solutions addressed travel, scheduling, and visit logistics for the target age group, enabling eligible patients to complete enrollment and remain on protocol.


 **Regional protocol expansion**
In response, we proposed and secured regulatory acceptance for an additional protocol that split the population by region, expanding the total patient pool without delaying the interim analysis.

Results

 **Enrollment**
Enrollment targets surpassed, which accelerated the study's overall timeline.

 **Interim Analysis**
Interim analysis delivered on the sponsor's timeline, enabling the planned communication milestone.

 **Endpoints**
All primary and secondary endpoints met.

 **Regulatory**
Regional protocol accepted by the respective regulatory agencies, keeping enrollment compliant and on budget.

Worldwide Respiratory & IPF Experience



390+

Sites activated
in IPF studies



915+

Participants enrolled
in IPF studies



8+

IPF studies
delivered

Expertise across ILD, IPF, asthma, cystic fibrosis, COPD-adjacent endpoints, and bronchiectasis.
Global site networks across North America, Europe, LATAM, and APAC.