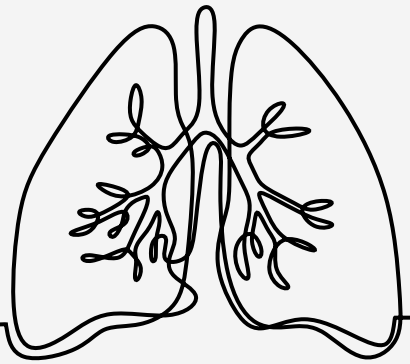
Worldwide Clinical Trials

Avoid Recruitment Challenges on Your Next IPF Study with a Customized Recruitment Plan from Worldwide



Idiopathic pulmonary fibrosis (IPF) studies frequently require long development timelines and are subject to disruptions like drug approvals and environmental factors that can cause delays. Recruiting patients to participate in a clinical trial for a competitive and complex indication like IPF takes a flexible and strategic team who can adapt as the environment changes. From study onset, recruitment plans must be innovative and carefully constructed to successfully navigate patient and site needs while having the built-in ability to pivot as recruitment occurs.

The rare respiratory team at Worldwide Clinical Trial has extensive experience supporting numerous IPF studies, with a strong knowledge base around spirometry that helps us to predict and mitigate the risk of the common pitfalls for sites. Our teams nurture established relationships with key opinion leaders in IPF, have global site networks with sites experienced in IPF clinical trial participation, and maintain relationships with IPF patient advocacy organizations.

See How We Do It: Site and Patient-Focused Solutions to Drive Enrollment

Challenge

Our sponsor's Phase II IPF study began enrollment when several competing studies were actively targeting the same patients.

Solutions

- **Strategic global enrollment plans:** We carefully constructed enrollment plans and then adjusted them during conduct to react to the changing competitive environment and to target treatment naïve patients in countries that supported fast enrollment.
- **Nurtured relationships with sites:** We tapped into our established site relationships to drive prioritization of our sponsor's study.
- **Site support:** We met weekly with the Clinical Site Liaison, who provided daily site support.
- **Patient-focused solutions:** We employed our vendor relationships to provide decentralized site visits in support of the aging target population.
- **Regulatory assistance:** We leveraged the expertise of our local regulatory personnel to manage regulatory challenges and address our sponsor's questions and concerns.

Results

Because of our strategic plans and approach to the site relationships, we surpassed enrollment targets which allowed us to accelerate the study's timelines.

We met the sponsor's aggressive timelines for the interim analysis, allowing them to release results in support of a public stock offering.

The final study results were delivered ahead of schedule, demonstrating that the primary and all secondary endpoints were met.

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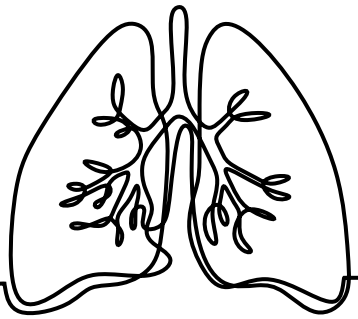

See How We Do It: Addressing Recruitment Needs After Unexpected Regulatory Feedback

Challenge

Our sponsor received conflicting feedback from regulatory agencies that jeopardized the timelines and budget parameters of their Phase III IPF study.

Solutions

- **Strategic solution:** After careful consideration, we added an additional protocol that split the population by region, increasing the total patient pool to ensure that the differences in both protocols matched the region-specific characteristics of the patient population and regulatory preferences.
- **Data-driven recruitment strategy:** The new protocol required an entirely new recruitment strategy and increased the number of patients needed to enroll. Our proprietary projection tool provided locale-specific data that allowed us to optimize our site targeting.
- **Weekly high-level collaboration:** We met weekly with the sponsor to consider options to boost enrollment through various strategies and pivoting within our flexible structure.

Results

The proposed protocols were accepted by their respective agencies, allowing the study to move forward with enrollment in compliance with regulatory requirements while minimizing the impact on timelines and budgets.

Worldwide has a comprehensive understanding of IPF clinical development and the experience to support your upcoming trial with a customized approach. We look at your study, consider our previous experience, and design a unique approach customized to your study and needs. With our personalized and flexible approach, you can be confident that your study receives the hands-on attention it deserves.

Our IPF Experience

8+ Studies

915+ Patients

390+ Sites

Let's talk about how we can support your upcoming trial. Contact us.