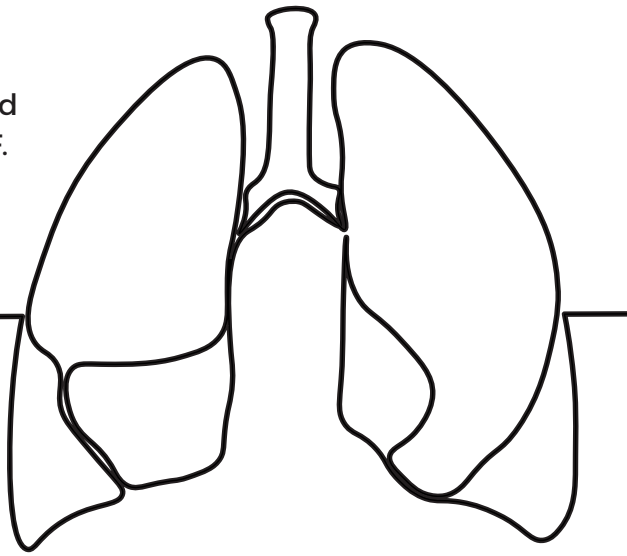
Case Study

Partnering for Precision in an IPF Study: Securing Timely Deliverables and Key Endpoints

A sponsor focused on developing treatments for fibrotic diseases, with a current emphasis on Idiopathic Pulmonary Fibrosis (IPF), needed a CRO partner capable of meeting their aggressive deadlines. The sponsor chose to work with Worldwide Clinical Trials (Worldwide) on a study aimed at exploring the efficacy and safety of their leading investigational product (IP) in treating IPF. The primary objective of the Phase IIa study was to assess the safety, tolerability, and pharmacokinetics of the compound in patients suffering from IPF.



Study at a Glance

Population

176 Screened patients, 125 Randomized

Part A: Feb 2020, 1 Screened, 1 Randomized

Part B: Aug 2020 through April 2021, 48 Screened, 29 Randomized

Part C: June 2021 through December 2021, 87 Screened, 61 Randomized

Part D: Feb 2022 through June 2022, 43 Screened, 29 Randomized

Study Facts

Worldwide managed several sequential study parts for this sponsor, testing increasing doses of the IP and longer treatment durations, up to 48 weeks in Part D. During the COVID pause of Part A, the sponsor completed non-clinical safety studies to support 12 weeks of human dosing, which allowed them to skip the remainder of Part A (4 weeks of dosing). The study met enrollment goals for Part C and significantly exceeded enrollment timelines during Part D.

Locations

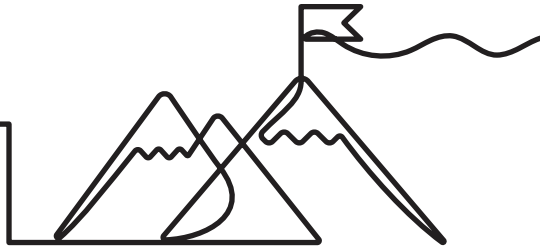
57 sites in 10 countries, including the USA, Canada, Belgium, Germany, Italy, Netherlands, UK, Australia, New Zealand, and South Korea.

Situation

IPF is a chronic condition marked by progressive lung scarring, requiring advanced therapeutic solutions to manage its progression and impact on patient quality of life.

The study involved collaboration between the sponsor and Worldwide's operations team, along with several imaging vendors and study participants.

Study Challenges

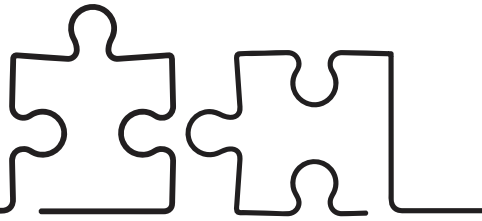


Strict Deadlines

A detailed timeline was agreed between Worldwide and the sponsor for delivery of interim analysis results of study parts A-C. Last Patient Last Visit for part C occurred on April 18, 2022, database lock (DBL) was planned for June 17, 2022, and a firm deadline of July 8, 2022, was established for delivery of interim analysis Tables, Figures, and Listings (TFLs), enabling key corporate milestones, including a public stock offering. Once the July 8, 2022, date for TFL delivery was set, the sponsor made it clear that the date could not be changed, given the planned public announcement.

Conflicting Data Review Timelines

The sponsor requested two statistical analysis dry runs to occur during the DBL to check the content and layout of each table, which usually takes place prior to the DBL for confirmation of SAP specifications. The Biostats timelines for those deliveries were significantly reduced to allow them to occur during the DBL. The dry run outputs of the listings from Biostats were also used as another tool to thoroughly clean the data, not a process that is usually implemented for database lock. The sponsor's TFL edits, SAP specifications, data review, and queries were activities that continued throughout the DBL process. These sponsor activities did not coincide with EDC or vendor data review timelines, which resulted in extensive additional effort from the Worldwide team.



Worldwide's Solutions

01 Result Delivery

The Worldwide team delivered the results of an interim analysis of the first three of four dose cohorts in this global Phase IIa IPF study against an aggressive timeline. The GPL created a very detailed timeline to track the completion of each activity needed for DBL, including duration and dependencies leading to each deliverable. Despite the challenges, the database was locked within the original timeline of 42 workdays.

02 Vendor Management

Worldwide took on the responsibility of managing an additional six vendors to coordinate the data transfers and create specification details that were not yet defined in the vendor master service agreements. These were six sponsor-managed vendors for the central lab, multiple PK and PD specialty labs, ERT, ECG, and HRCT. These vendors required significant oversight for lab sample tracking and processing, transfer of lab results, as well as the analysis of subject assessment data.

03 Streamlined Communication

The study leadership team met daily to review progress, prioritize activities, and align functional area leads to confirm status, completion, and planning for subsequent tasks to mitigate any risks to the timeline. The frequency of comprehensive sponsor and Worldwide study team meetings was increased to weekly for the duration of the DBL. Key vendor meetings were arranged to coincide with their data reconciliations, analysis, and transfers.

04 Operational Excellence

Worldwide's clinical operations team played a critical role in assuring PI availability during the summer season. Through their efforts, EDC access was confirmed, PI contact information verified, or a delegate was identified to perform a final review of the eCRFs to sign and lock the site's EDC data.

05 Deadline Adherence

Worldwide adhered to a rigorous schedule, aligned interrelated timeline tasks, leveraged resourcing, extended the workday of an international team, maintained effective communication, and overcame challenges of performing additional contract scope to meet the interim analysis deadline. This prompt delivery played a crucial role in supporting a successful $230M fundraising effort through a public stock offering by the sponsor on July 15, 2022.

Study Outcomes

- Over a 12-week period, the compound was well tolerated, with no serious adverse events or discontinuations reported.
- Both primary and secondary endpoints were achieved, confirming the drug's safety and effective pharmacokinetics. The results of these exploratory endpoints exceeded the sponsor's expectations.
- Worldwide successfully delivered on-time results, allowing the sponsor to meet their corporate goals for the press release of results and completion of the stock offering.
- These promising results bolster the potential of the compound as a treatment for IPF. As a result, the sponsor has plans to discuss late-stage clinical development with the FDA.

Why Choose Worldwide for Your IPF Study?

Worldwide is a leading full-service global CRO that often works in partnership with small biotechnology and pharmaceutical companies, which may have tight timelines for reporting study results to support ongoing fundraising activities. We employ tools like Gantt chart software (MS Project) to create and manage detailed micro-timelines for key deliverables, ensuring every milestone is tracked efficiently. Additionally, we establish a cadence of recurring stand-alone meetings to review study progress and mitigate risks proactively. By involving sponsor-managed vendors in our process, we ensure timely delivery of vendor data, helping to prevent delays. Regardless of the size of our partner, Worldwide leverages our customized solutions and deep therapeutic knowledge to help advance their new medications from discovery to reality. To learn more about how we can support your study, contact us.

Worldwide Clinical Trials

By partnering with us, you can expect a commitment to excellence and a tailored approach to achieve outstanding results.

Contact Us

Last Update: 10012024