



Case Study

Worldwide FIH Transition Study

A Clinical-Stage Biotech Company with a Critical Startup Milestone

Worldwide transitioned full-service work from a large CRO to help expedite a clinical-stage biotech's first-in-human (FIH) study. Milestones around first site initiated (FSI) were linked to funding, requiring a flexible and rapid response.



Challenges

Our Worldwide team was tasked with several challenging asks during this study, including:

The sponsor contracted with a large CRO for full-service support of its FIH study. Frustrations grew with the large CRO's lack of urgency and its team turnover, rigid processes around contracting, and delays in startup. The study's FSI milestone was critical to both internal goals and a funding round, so the clock was ticking. The sponsor contacted Worldwide to see if we could rapidly and fully rescue the work. This study was a Phase I/II Project Optimus optimized design in solid tumors due to enroll 192 patients (30 in escalation) at 30 sites (six in escalation) across the U.S. and Europe.



Solutions

Worldwide mobilized our management team to create a top team and stepped in to expedite activities such as:

- Project management, start-up, and data management resources assigned immediately
- Contracting done in parallel with letter of intent and executed 14 business days post-award
- Rapid start up activities initiated
 - Regulatory packets submitted to all sites 14 business days after the kick-off meeting
 - First site initiation visit (SIV) at Worldwide early phase network site two months after regulatory packet submitted
- U.S. FDA feedback on the IND application received midstream, necessitating a protocol amendment

At a Glance



Goals

- ▶ Rescue FIH startup
- ▶ Accelerate site activation
- ▶ Stabilize trial execution



Benefits

- ▶ Faster startup timeline
- ▶ Seamless project transition
- ▶ FSI goal exceeded



Outcomes

Worldwide achieved several impactful outcomes throughout this trial, including:

- Engaged with the sponsor, leveraging our values of listening, flexibility, and collaboration to understand current status and key milestones
- Leveraged our value of commitment to assess and communicate whether we could mobilize a team quickly enough
- Stepped through a robust transition process to seamlessly rescue the project
- Beat the Sponsor's FSI goal nine weeks after regulatory pack submission and 12 weeks after the kick-off meeting



About Worldwide Clinical Trials

Worldwide Clinical Trials (Worldwide) is a global CRO serving development-driven biopharmaceutical companies, with more than 4,400 professionals operating across more than 70 countries. The company delivers therapeutically dedicated expertise in neuroscience, oncology, rare disease, and internal medicine, with comprehensive support across every development phase – from early-stage and first-in-human studies through Phase III registration trials.

The company's flexible service model – spanning full-service trial management to functional service partnerships through Worldwide Flex – is powered by a people-first, partnership-driven outsourcing approach that strengthens collaboration, enhances data transparency, and supports more informed decision-making. This provides sponsors with tailored, adaptable solutions that keep pace with the evolving demands of clinical research.

Learn more at www.worldwide.com.