Worldwide Clinical Trials | Oncology

Case Study

Delivering Complex Registrational GI Trial for Emerging Biotech Amid Major Protocol Shifts

An emerging oncology biotech developing next-generation bispecific antibody therapies partnered with Worldwide to advance its clinical initiatives. Worldwide was chosen as the CRO for its deep GI oncology expertise, strategic guidance, full-service support, and a reputation for agile, responsive project management, well-suited to the complexities of the sponsor's first U.S. study.

Challenges

Initially awarded as a small Phase Ib/II study with 10 sites and 40 patients, the trial changed significantly mid-startup. Recommendations to revise the design and enrollment criteria shifted it to a registrational Phase II/III study, expanding the scope to over 30 sites and 150 patients. This optimized outcomes but required several protocol amendments during start-up, increasing risk. The expanded scope also drove up costs and financial pressure.

Solutions

Fully committed to supporting the sponsor's goals, Worldwide remained flexible amid ongoing study shifts, continuing to activate sites, sustain momentum, and minimize delays.

To address potential enrollment challenges, Worldwide proactively recommended updating the eligibility criteria and adding a crossover arm to allow patients on the control arm to access the investigational therapy.

These adjustments enhanced patient appeal and strengthened site engagement.

Worldwide also implemented a flexible commercial structure that aligned payments with enrollment milestones—demonstrating a deep commitment to the sponsor's needs to manage cashflow, and to linking cost with trial success.

Outcomes

Worldwide's strategic input and operational agility enabled the sponsor to complete enrollment ahead of revised expectations. A recent interim analysis revealed a positive treatment effect, positioning the sponsor to pursue Breakthrough Therapy Designation (BTD) with the FDA and a potential registrational submission. The study remains on track to be completed within or ahead of the originally scoped timeline despite its dramatic expansion in scope and complexity.

The sponsor has grown to trust Worldwide as a true partner, with the engagement evolving from a transactional relationship into a collaborative alliance.

Worldwide Clinical Trials

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.