Worldwide Clinical Trials | Oncology

Case Study

Rapid FPI Milestone for Brain Cancer Trial

A drug and device biotech hired Worldwide to support its upcoming trial for a new therapy for patients with glioblastoma (GBM), a highly aggressive form of brain cancer. GBM is a devastating cancer indication with a five-year survival rate of only ~5%, underscoring a large unmet medical need for new treatment options. The sponsor had motivated sites ready to go and needed Worldwide to initiate the study rapidly to help bring this therapy to patients in need.

Challenges

Recognizing that sites are largely closed during December holidays and the client's rapid startup goal of first patient in (FPI) requested for the new year's first quarter, work was initiated to lay the foundations for a fast start. Worldwide needed to start sites, begin clinical database build, and secure a central imaging solution. As site initiation drew closer, a patient was ready to be dosed, and Worldwide needed to expedite contracting for regulatory and legal coverage to be in place for this initial patient's treatment in early January.

Solutions

Using a passionate and dedicated team, Worldwide designed a responsive plan that helped to get the first patient dosed as quickly as possible. As there was an absolute deadline beyond which this patient would become ineligible, Worldwide:

- Engaged with the sponsor to leverage sites that had prior experience with this therapy and could initiate quickly via central reviews
- Leveraged flexible processes to waive redundant qualification steps
- Deployed a clinical database rapidly via established oncology standards and forms
- Quickly onboarded an imaging technology solution due to robust existing partnerships
- Expedited site and CRO contracting to ensure patient dosing could occur within the eligibility window

The Worldwide team members involved are highly experienced in oncology research and were empowered and enabled to make decisions.

Outcomes

Worldwide successfully delivered on the sponsor's FPI milestone in less than two months, and most importantly, the initial GBM patient received access to a novel, potentially beneficial treatment. Worldwide continues to support the company's drug and device development program and has added additional patients to the active trial.

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.