Worldwide Clinical Trials | Oncology

Case Study

Tailored Approach Supports Bladder Cancer Breakthrough

Since 2020, Worldwide Oncology has supported an emerging biotech's oncology program. Focused on developing the first new bladder cancer treatment in over two decades, the sponsor turned to Worldwide for functional services and strategic guidance across a portfolio of studies, including a pivotal Phase III trial. Worldwide demonstrated our customized, flexible model and proven ability to adapt to shifting priorities, evolving clinical demands, and complex organizational dynamics — all amid the challenges of a global pandemic.

At a Glance

Goals

- Stabilize study operations
- Support multi-study work
- Advance bladder therapy

Benefits

- Operational continuity
- Strengthened partnership
- FDA Fast Track achieved

Challenges

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

The partnership began with Worldwide supporting two key bladder cancer studies — a Phase I/II combination therapy trial and a Phase III monotherapy trial — during a period of rapid growth and external disruption. The onset of the COVID-19 pandemic introduced immediate challenges, particularly around patient enrollment. Simultaneously, the sponsor's evolving internal priorities led to shifts in study scope, resourcing models, and vendor relationships.

As the biotech scaled, several internal systems, including EDC, CTMS, and eTMF, were still being implemented or optimized. Worldwide stepped in to bridge gaps, developing interim solutions and offering best-practice guidance to ensure continuity. These dynamics added complexity to site activation, enrollment, and overall operational execution.

Solutions

To combat the challenges faced in this trial, Worldwide implemented several solutions:

Worldwide led the sponsor's oncology program with a customized, full-service approach tailored to evolving needs. The project team delivered global project management across three CROs, ensuring alignment and oversight across a complex, multi-partner landscape. Functional services, including site management, biostatistics, clinical monitoring, data management, safety, and eTMF management, were flexed as needed to meet changing demands.

Worldwide also led site activation for a new study arm, onboarding 15 additional U.S. sites with consistent, trusted staffing. The team provided consultative support on eligibility criteria, TMF indexing, and system implementation — often stepping in to guide and educate internal sponsor teams. When system issues disrupted serious adverse event reporting, Worldwide quickly adapted workflows to maintain data quality. The sponsor was impressed with Worldwide's key functions, citing the team's continuity, responsiveness, and ability to deliver under pressure.

Outcomes

Worldwide achieved several impactful outcomes throughout this trial, including:

Worldwide remained a steady and trusted partner. Our strategic leadership and operational excellence helped the Sponsor achieve Fast Track designation and complete a successful IPO. The sponsor has named Worldwide its preferred safety provider and awarded additional work, including an Expanded Access Program and safety oversight for its Phase III study.

What began as a targeted engagement has evolved into a long-term partnership built on trust, flexibility, and shared success. Worldwide's demonstrated ability to engage with the sponsor across technological, operational, and strategic domains has established us as the partner of choice on the biotech's journey toward regulatory submission and commercialization.

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 60 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.

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