Worldwide Clinical Trials

Case Study

Executing a Complex Global Breast Cancer Trial in a Rapidly Evolving Treatment Landscape

A mid-sized biotech company was developing an innovative therapy for metastatic breast cancer, one of the most competitive areas of oncology drug development. The main therapy already had marketing authorization in a segment of breast cancer patients, allowing the sponsor to bypass a basket trial and go straight into combination therapy for the patient population.

The sponsor needed to initiate a large global study across approximately 140 sites and 16 countries. At the same time, they were undergoing significant organizational change and tasked with aggressive development timelines to meet corporate goals. Throughout development, breast cancer treatment standards of care continued to evolve, creating additional complexity. Knowing they needed to balance speed, flexibility, quality, and global execution, the sponsor turned to Worldwide Clinical Trials.

At a Glance

Study Design

- Global Phase Ib/II breast cancer study
- Activated ~140 sites across 16 countries in NA, EU, LATAM, MENA, and APAC

Benefits

- First Site Initiated in 6 weeks and First Patient In achieved in 8 weeks
- Successfully implemented multiple protocol amendments
- Met or exceeded enrollment goals across all cohorts
- Maintained inspection-ready data throughout study conduct

Study Challenges

Crowded Development Landscape

The sponsor was facing a highly competitive environment, with numerous investigational therapies for breast cancer in development. They needed to remain relevant as treatment paradigms evolved.

Complex Study Design

The global Phase Ib/II umbrella trial required multiple treatment cohorts and combination therapy arms. Throughout protocol amendments, new cohorts continued to be added as standards of care changed.

Enrollment Challenges

The therapy was already approved in a segment of breast cancer patients, which meant physicians could have prescribed it off label with the planned combination therapies, making site enrollment a potential challenge. Additionally, the litany of breast cancer trials available to sites opened the possibility that physicians would not prioritize enrollment for this study.

Startup Constraints

The sponsor required execution under a full Master Services Agreement and Work Order rather than more flexible startup mechanisms, and contractual requirements had potential to delay activation timelines.

Global Regulatory Complexity

The global study included challenging geographies and required coordination across multiple regulatory environments while maintaining aggressive timelines. The study was also the sponsor's first experience using the Clinical Trials Information System (CTIS) for European submission.

Worldwide's Solutions

Worldwide implemented a highly coordinated operational strategy designed to accelerate startup while maintaining study quality.

Rapid Startup Strategy

The Worldwide team established multiple workstreams to advance startup activities simultaneously. Study setup, contractual negotiations, regulatory activities, and site readiness were coordinated in parallel while close communication between sponsor and operational teams was maintained throughout the study.

Strategic Site Network Utilization

Worldwide leveraged established relationships with high-performing oncology sites and utilized Global Alliance Collaboration sites where appropriate. This allowed the team to identify experienced sites that were capable of enrolling quickly and supporting the study's complex protocol requirements.

Regulatory Leadership

The team guided the sponsor through its first CTIS submission process and helped ensure timely approvals in the United Kingdom and multiple countries in Latin America, the Middle East and North Africa, and Asia-Pacific regions. Worldwide efficiently addressed validation and assessment questions and enabled activation across multiple countries without regulatory delays.

Adaptability Throughout Study Conduct

As new treatment options entered the market, Worldwide supported ongoing protocol amendments, adding and managing new study cohorts and providing strategic guidance on the addition of new combination regimens as well as real-time market analysis of the competitive landscape. The team maintained operational continuity despite evolving study requirements and supported planning for future combinations.

Study Outcomes

Working with the sponsor, Worldwide achieved rapid startup and sustained performance.

Accelerated Study Launch

The team met critical startup milestones despite contractual and operational complexities, including First Site Initiated within six weeks over a holiday period and First Patient In achieved the day after IP arrived at the site.

Enrollment Success

Enrollment goals were met or exceeded across study cohorts, with multiple enrollment cohorts achieving rapid completion.

Data & Operational Quality

Inspection-ready data was maintained throughout study conduct. Worldwide supported multiple sponsor data cuts and data-readout milestones and enabled effective presentation and dissemination of study findings.

Long-Term Study Momentum

Despite protocol amendments and evolving standards of care, the team sustained performance and delivered continued operational support as the study expanded and adapted over time.

Navigating Complexity Without Sacrificing Speed

This study highlights Worldwide's ability to navigate complex global oncology trials within a rapidly changing therapeutic environment. Bringing together a stable, experienced study team, Worldwide was able to preserve institutional knowledge and support informed decision making amid significant organizational change. The team's operational agility, global regulatory expertise, strong site relationships, and proactive study management enabled the sponsor to move quickly, adapt to evolving standards of care, and maintain momentum throughout study execution.