



Case Study

From At-Risk to Completion: A Global Phase III Ovarian Cancer Study Turnaround

Worldwide excels at delivering for late-stage clinical oncology biotech companies. When a biotech company approached Worldwide to provide full-service CRO support to rescue their Phase III registrational study, after a large CRO failed to deliver startup activities and lacked the necessary flexibility to meet their needs, the company urgently needed a solution. The biotech company had previously worked with Worldwide on an early phase development program in a different indication. Worldwide addressed these challenges and restored the biotech's Phase III study in ovarian cancer research.

At a Glance



Goals

- ▶ Rescue failing Phase III study
- ▶ Stabilize trial operations
- ▶ Ensure timely study delivery



Benefits

- ▶ Faster team mobilization
- ▶ Improved data integrity
- ▶ On-time regulatory readiness



Challenges

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

- Worldwide had to expedite the timeline due to delayed startup because of a lack of responsivity from previously contracted CRO
- Taking on a large Phase III study involving **~400 patients in 136 sites across 12 countries** (North America, Europe, and the Asia-Pacific region) meant Worldwide had to ensure compliance with multiple regulatory guidelines and complex trial operations
- The client's specialized needs unique to their study that the previous CRO couldn't address, and Worldwide had to create custom-tailored solutions for their needs



Solutions

Worldwide delivered this Phase III study and provided client support including:

- Full-service flexible offerings, such as project management, start-up, clinical monitoring, data management, biostatistics, medical monitoring, and clinical science
- Mobilized and onboarded a study team within two weeks with an established a governance structure
- Completed source data verification and data review of more than 82,000 electronic case report forms
- Issued and closed over 80,000 queries with an average site response time of 14 days
- Coded more than 12,000 terms



Outcomes

Worldwide achieved several impactful outcomes throughout this trial, including:

- Worldwide delivered on a global Phase III ovarian cancer trial with 400 patients with full-service accountability on time and ready for regulatory submission.
- Provided flexibility for the Sponsor
- Successfully completed a mid-study database change from the previous CROs out-of-date EDC technology to a new EDC system
- Completed patient enrollment on time
- Database lock occurred on time and within 6 weeks of the last subject/last visit (LSLV)
- Topline tables, figures, and listings delivered on time and within 7 weeks of LSLV



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.