Worldwide Clinical Trials | Oncology

# Advancing Ovarian Cancer Therapies: Clinical Research Trends, Challenges, & Proven Strategies

Ovarian cancer remains one of the most lethal gynecologic malignancies, with late-stage diagnosis and treatment resistance driving high global mortality. With over 325,000 new cases and 207,000 deaths reported globally in 2022,[1] the need for specialized expertise in trial design and execution has never been greater. Worldwide brings the depth of therapeutic insight and operational excellence required to meet this challenge. Our team has supported numerous ovarian cancer trials across all phases, including global confirmatory and rescue studies.

## A Shifting Landscape in Ovarian Cancer Research

Ovarian cancer is the 18th most common cancer in women globally and one of the deadliest among cancers of the female reproductive system.[1] Its late-stage diagnosis, often due to vague symptoms and the absence of effective early screening, contributes to poor prognosis and limited treatment options.

Rare subtypes like Low-Grade Serous Ovarian Cancer pose additional challenges, including chemo-resistance and diagnostic ambiguity.

However, the research landscape is rapidly evolving. Advances in molecular diagnostics, biomarker-driven stratification and genetic testing (e.g., BRCA mutations) are enabling earlier detection and more personalized treatment approaches. Novel therapies including tyrosine kinase inhibitors, antibody-drug conjugates, checkpoint inhibitors and CAR-T cell therapies are expanding options for patients. Meanwhile, innovative trial designs such as master protocols and adaptive studies are streamlining development and improving flexibility. In this dynamic environment, biotech sponsors require partners with deep therapeutic expertise and operational agility.

## Navigating Operational & Scientific Challenges

Ovarian cancer trials present unique operational and scientific challenges. Site activation can be delayed due to coordination with cooperative groups such as Gynecologic Oncology Group (GOG) in the U.S. and European Network of Gynaecological Oncological Trial Groups (ENGOT) in Europe.[2,3] Enrollment is particularly difficult in rare subtypes, where patient availability is limited and recruitment rates can fall below 0.1 patients per site per year.

Scientific and regulatory complexities include interpreting Response Evaluation Criteria in Solid Tumors (RECIST) criteria in the presence of peritoneal studding and/or ascites and applying cancer antigen 125 (CA125) response thresholds accurately. Trials seeking accelerated approval must be supported by confirmatory studies already underway, requiring precise planning and execution. Worldwide has demonstrated the ability to navigate these challenges, including adapting to evolving FDA guidance during global confirmatory trials.

**100+** sites activated

**17** countries

## The Role of Cooperative Groups in Trial Success

Cooperative groups such as GOG and ENGOT are instrumental in facilitating site selection, contracting and trial awareness. Their deep networks of gynecologic oncology investigators can accelerate site activation when engaged early and strategically. However, they also introduce operational complexities, including slower initiation timelines and lower site budgets.

Worldwide has developed best practices for navigating these dynamics, including:

Coordinated three-way calls between sponsors, Worldwide, and cooperative groups.

Tailored training for clinical teams on ovarian-specific criteria such as CA125 and RECIST.

Integration of central radiology to ensure consistent interpretation across sites.

## Operational Excellence in Practice

Worldwide's ability to deliver under pressure is best illustrated through two recent case studies. These examples demonstrate how Worldwide's operational agility and therapeutic expertise have helped biotech sponsors overcome major challenges in rare and late-stage ovarian cancer trials.

> This trial has been exceptionally complex, but our team has executed with urgency, precision, and deep therapeutic insight. We've tackled indication-specific challenges, partnered with cooperative groups, and implemented a country-level regulatory strategy aligned with the sponsor's milestones—accelerating site activation and keeping the trial ahead of enrollment targets as it continues."

**Marco Grenningloh**
Associate Director, Project Management, Oncology

## Global confirmatory trial supports accelerated approval

Worldwide activated over 100 sites across 17 countries and collaborated with GOG and ENGOT to support enrollment. Despite anticipated recruitment rates of fewer than 0.1 patients per site per year, Worldwide met all startup and enrollment milestones—contributing to the FDA approval of the therapy, the first ever for the rare indication.

## Rescue of Global Phase III Ovarian Cancer Trial

Worldwide mobilized a full-service team within two weeks, transitioned the study to a new EDC system mid-trial, and completed over 82,000 eCRFs and 80,000 queries. Patient enrollment and database lock were completed on time, and regulatory-ready data was delivered within seven weeks of last patient visit.

## Lessons Learned & Best Practices

Worldwide's experience across diverse ovarian cancer trials has yielded key insights into what drives success in this complex therapeutic area:

- Speed and adaptability are paramount, especially when pursuing accelerated approval pathways, meeting critical milestones or rescuing underperforming trials.
- Data-driven country and site selection, along with a synchronized regulatory strategy, help sponsors meet aggressive timelines.
- Strategic site planning, through early engagement with cooperative groups and seasoned investigators, can dramatically improve activation and enrollment timelines.
- Customized training for clinical teams ensures consistent protocol execution and high-quality data collection. Deep therapeutic expertise allows for nuanced interpretation of ovarian-specific endpoints, including CA125 and RECIST criteria.

- Clinical Scientists offer critical guidance to CRAs and DMs for managing the intricacies of ovarian cancer while ensuring the clinical soundness of data.
- Deep therapeutic expertise allows for nuanced interpretation of ovarian-specific endpoints, including CA125 and RECIST criteria.
- Comprehensive vendor management and effective coordination at both local and global levels are vital to maintaining quality and compliance.

> When we were brought in, the trial was behind schedule and facing serious data integrity risks. Our team mobilized quickly, transitioned technology systems mid-study, and delivered clean, regulatory-ready data on time. It was a true demonstration of Worldwide's ability to lead under pressure and restore confidence."
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> **Sabrina Miles**
> Associate Director, Project Management, Oncology

## Future Directions in Ovarian Cancer Research

Looking ahead, several trends are shaping the future of gynecologic oncology trials:

- Emerging biomarkers and molecular profiling areenabling more precise patient stratification.
- Artificial intelligence and machine learning are being explored for early detection and predictive modeling.
- Regulatory agencies are increasingly open to innovative trial designs, including basket trials and real-world evidence.
- Patient-centric approaches, such as decentralized trials, digital monitoring and logistical support are improving access and retention.

Worldwide is actively investing in these areas of innovation, ensuring that sponsors have access to cutting-edge strategies and technologies to advance their ovarian cancer programs.

## Conclusion

Ovarian cancer trials are among the most complex in oncology, demanding specialized expertise, global coordination and unwavering commitment to quality. Worldwide has repeatedly demonstrated success in this space, from launching confirmatory trials for rare subtypes to rescuing underperforming Phase III studies. With numerous ovarian and gynecologic oncology trials to date and experience with over 300 sites across 17 countries, Worldwide offers biotech sponsors a proven infrastructure and a seasoned team capable of executing even the most challenging ovarian cancer studies.

## References

1. https://www.wcrf.org/preventing-cancer/cancer-statistics/ovarian-cancer-statistics/
2. https://www.gog.org/
3. https://www.esgo.org/network/engot-network/

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.

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