

Case Study

Accelerating a Global, FIH ADC Therapy Trial for Lung Cancer

An innovative biotech was developing a next-generation antibody-drug conjugate (ADC) for the treatment of non-small cell lung cancer (NSCLC) – the most common form of lung cancer and a disease with high unmet medical need. Initially planning a U.S.-only, first-in-human (FIH) dose escalation, the sponsor pivoted in response to increased competition and evolving regulatory expectations, including the U.S. Food and Drug Administration's Project Optimus initiative.

With much at stake, the sponsor needed a CRO with global reach, flexibility to execute a complex FIH trial, deep expertise in ADC safety and operational challenges and a proven track record designing and delivering Project Optimus-compliant trials.

At a Glance

Goals

- ▶ Accelerate global enrollment
- ▶ Optimize dose escalation
- ▶ Enhance competitive edge

Benefits

- ▶ Faster global activation
- ▶ Regulatory-aligned design
- ▶ Early efficacy signals



Challenges

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

1. The biotech engaged Worldwide to design and deliver a large, global FIH study of a novel ADC therapy for NSCLC.
2. Facing compressed timelines, the sponsor needed to evolve the study from a traditional 3+3 all comers solid tumor dose escalation into a global, dose escalation and expansion trial aligned with Project Optimus principles.
3. Adding to the urgency, the competitive landscape was shifting rapidly, with other biopharma companies accelerating development timelines for similar therapies—raising the stakes for securing first-to-market position.



Solutions

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

Worldwide rapidly mobilized our regulatory, medical, and statistical experts to revise the study protocol, replacing the 3+3 design with a backfilling Bayesian optimal interval design (BF-BOIN) model. This enabled global enrollment of more than 250 patients and accelerated timelines by enrolling NSCLC patients from the outset, bypassing traditional escalation across multiple solid tumor indications. To avoid delays and competing protocols, Worldwide expanded early beyond the U.S., activating 55 sites across seven countries in Europe and Asia-Pacific. This enabled the U.S. team to remain focused on dose escalation and cohort management.

A seamless protocol with multiple expansion arms and go/no-go inflection points supported rapid progression to registrational studies and fundraising. Worldwide applied flexible commercial terms to support Sponsor cash flow and align project and corporate goals. A robust governance framework enabled agile problem-solving and direct executive alignment, reinforced by quarterly meetings, shared KPIs and milestone celebrations – solidifying Worldwide and the sponsor as true development partners.



Outcomes

Worldwide achieved several impactful outcomes throughout this trial, including:

With dose escalation successfully completed, the study is enrolling ahead of schedule in the expansion phase, supported by early safety and efficacy signals and data presented at key industry events. Backed by FDA Fast Track designation, the sponsor is evaluating a transition to a registration trial. They are extremely pleased with Worldwide's proactive approach, responsiveness, and ability to deliver a global FIH ADC trial that has put them on track to bring a best-in-class ADC therapy to NSCLC patients.

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 peoplefirst, partnershipdriven outsourcing approach that strengthens collaboration, enhances data transparency, and supports more informed decisionmaking. 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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