



# Purpose-Built for ADC Development

Antibody-drug conjugates (ADCs) are transforming cancer care by combining precision antibody targeting with potent payloads to improve patient outcomes.

Worldwide Oncology is a specialty CRO dedicated to guiding biopharma companies from first-in-human development through to late-phase success. With 40 years of oncology experience and over **20 active ADC trials** today spanning Phases I - III, Worldwide offers scientific depth, operational agility, and a people-first approach. Our flexible, data-driven infrastructure enables real-time trial monitoring, while strong PI/KOL relationships and advanced technology ensure efficient, high-quality execution.

## Navigating the Complexities of Early Phase ADC Trials

ADC development is especially demanding in First-in-Human (FIH) and early phase clinical trials. Sponsors must balance scientific ambition with operational feasibility, all while navigating a crowded and competitive landscape. Common challenges include:

### **Project Optimus Protocol Design & Speed to Proof-of-Concept**

Sponsors must design protocols that address evolving FDA expectations around dose escalation, optimization, and expansion while maintaining speed and flexibility.

### **Global Feasibility & Site Selection**

With over 1,100 ADCs in development globally, competition for sites and patients is fierce. Sponsors must stand out with novel ADC technology, compelling protocols, and streamlined operations.

### **Safety & Toxicity Management**

ADCs often present unique toxicity profiles – ocular, neurologic, pulmonary, and hematologic – that require vigilant monitoring and adaptive dosing strategies.

### **Biomarker-Driven Recruitment & CDx Development**

Identifying the right patients through validated assays and eligibility criteria is critical, as is balancing timelines and when to deploy a companion diagnostic strategy.

## Positioned for Phase III Success

With a global reach in 70+ countries, Worldwide can help bring your ADC through registration to patients in need by navigating common challenges like:

### Competitive Landscape & Access to KOLs

In a highly competitive landscape, speed matters. Worldwide leverages its global presence and robust KOL connections to accelerate enrollment, helping sponsors advance their path to market.

### Quality Oversight & Accelerated Approvals

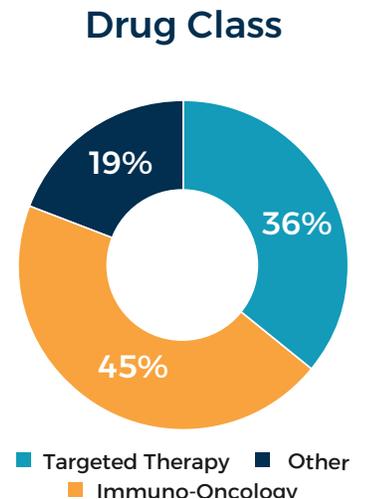
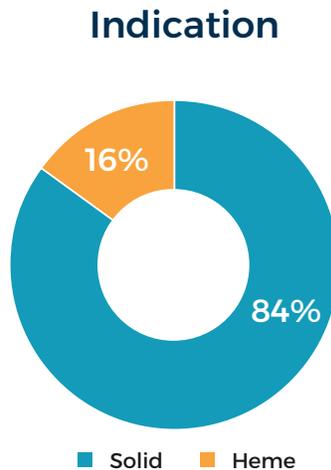
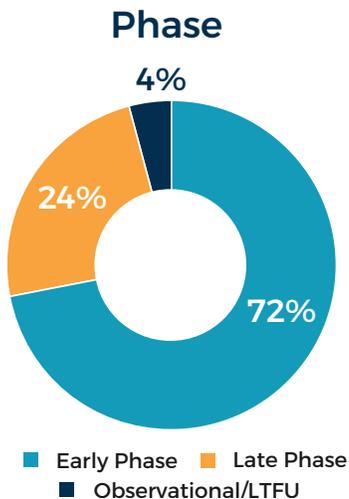
Regulatory and quality strategies including accelerated paths, confirmatory trials, and payer access are critical to plan early. Inspection steadiness is key from the outset.

## Proven ADC Trial Expertise

Worldwide's ADC portfolio spans solid tumors and hematologic malignancies, advancing therapies through:

- **20+ active ADC trials** including FIH studies with rapid FPI goals and Phase 3 registrational studies conducted across more than 100 global sites
- **Global footprint** with 4,400+ staff spanning North America, Europe, Latin America, and Asia-Pacific
- **Operational scale** with ADC study experience across >200 sites and PIs
- **Next generation technologies** with specialized expertise working with novel antigens, linkers and

## Active Next-Gen Oncology Experience



### 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](http://www.worldwide.com)