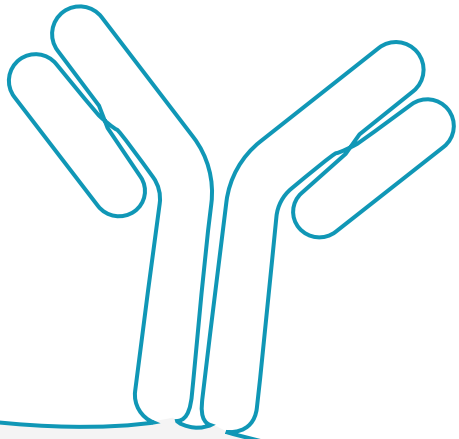
Worldwide Clinical Trials

Antibody-Drug Conjugates & Bispecific Antibodies at Worldwide Clinical Trials

Emerging as some of the latest technologies in cancer treatment, both antibody-drug conjugates (ADCs) and bispecific antibodies (BsAbs) offer a novel approach to cancer treatment, minimizing systemic toxicity and improving patient outcomes. As a global contract research organization (CRO), Worldwide Clinical Trials (Worldwide) offers tailored solutions to facilitate the development and approval of ADCs and BsAbs. With a dedicated commitment to oncology therapeutic innovation, we blend scientific rigor with personalized attention to make strides in cancer treatments.



Global ADC & BsAb Experience

Worldwide is experienced in navigating complex ADC and bispecific trials across their full lifecycle, helping sponsors in their early exploratory studies to assess the safety and efficacy of their new compounds.

60+ ADC studies supported by our project managers and strategic/operational leads

An average of 2.25 years
of ADC experience across ADC project managers

Indications

Hematology-Oncology

- B-cell non-Hodgkin lymphoma
- Acute myelocytic leukemia

Solid Tumor

- Ovarian
- Lung
- Head and neck
- Melanoma

BsAb Construction

To date, the most frequent type of BsAbs we have encountered used CD3 as one of their two antibody-binding domains. CD3 is expressed by a high percentage of circulating peripheral T-cells and forms a complex with the T-cell receptor (TCR), which is involved in the recognition of antigens and the subsequent activation of immunocompetent T lymphocytes. This complex allows the other binding domain to capture an antigen on a tumor cell and brings the T cell into close association with the tumor, initiating cytotoxic effects.

The type of tumor being targeted dictates the second binding domain of the bispecific. Some examples include CD123 and CD33 for hematological malignancies and EpCAM and HER3 for solid tumors.

Newer classes of BsAbs inhibit two tumor proteins on the same cell, which impacts different pathways involved in tumor growth and progression. An example of this is HER2:HER3 for breast cancer.

ADC Construction

The target antigens of the ADC drugs that Worldwide has worked with have used specific proteins overexpressed in cancer cells, such as HER2 in solid tumors. These have been linked to cytotoxic payloads, such as topoisomerase inhibitors and anti-tubulin mitotic inhibitors. The antibody binds to the target antigen and is internalized into the tumor, allowing the cytotoxic to also be brought into the cell.

Regulatory Support

Worldwide provides global regulatory insights to support the complex approval landscapes across the FDA, EMA, ICH, and more. Our teams are located around the world, providing the local and global regulatory knowledge and relationships needed for ADC and BsAb program development.

Operational Excellence

Our Global Site Alliance Collaboration

We offer strategic site selection to ensure optimal patient recruitment, data integrity, and protocol optimization. Early engagement with experienced sites is critical. Our Global Site Alliance relationships and extensive network of ADC- and BsAb-experienced sites help ensure high-quality PI feedback, early engagement, and study enrollment.

Relationships with KOLs

We're also connected to the leading key opinion leaders (KOLs) in ADC and BsAb research for protocol support and early engagement.

Study Design Experience

- Dose-escalation expansion studies
- Cohort management plans
- Data quality and management
- Biological sample management
- Safety education with sites for the recognition of cytokine release syndrome

Meet Our Oncology Experts

Strategic Lead Experts

Jim Eamma
Executive Director, Therapeutic Strategy Lead, Oncology
Meet Jim

Matt Cooper
Executive Director, Therapeutic Strategy Lead, Oncology
Meet Matt

Virgilio Garcia Lerma
Executive Director, Global Regulatory Strategist
Meet Virgilio

Marty Lee
Medical Oncologist
Meet Marty

Project Management Experts

Ahmed Abufarag
Senior Project Manager
Meet Ahmed

Emelyn Davies
Director, Project Management
Meet Emelyn

Shannon Goodman
Senior Project Manager
Meet Shannon

Teri Maraan, MA, CCRP
Senior Director, Project Management
Meet Teri

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Get Support for Your ADC Clinical Trial with Worldwide

As your ADC enters into clinical trials, make sure to partner with a CRO who has the oncology expertise you need to support your drug development program. For more information on our ADC capabilities and to discuss potential collaborations, contact us.

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