

SUPPORTING YOUR COMPLEX **IMMUNO-ONCOLOGY TRIALS**

Oncology expertise across cell and gene therapies, biologics and small molecules

At IQVIA Biotech, our extensive immuno-oncology (IO) expertise spans multiple treatment modalities (vaccines, bispecific antibodies, cell and gene therapies (CAGT), etc.) and numerous indications across hematologic malignancies and solid tumors. You want to get the right treatments to the right patients. We want to help you develop and execute the most efficient path through the clinic.

IMMUNO-ONCOLOGY EXPERTISE

IQVIA Biotech's clinical teams have extensive experience running IO clinical trials, including:

- · Multiple next-generation CAR-T trials spanning hematologic malignancies, solid tumors, and autoimmune disease including universal/switchable/ convertible technologies
- Genetically modified T-cell receptors (TCRs) in hematologic malignancies
- NK and CAR-NK cell therapy trials in hematologic malignancies
- Bispecific antibody programs that engage T and NK cells in solid tumor and hematologic malignancies
- Neoantigen and tumor-associated antigen (TAA) cell therapy and cancer vaccine platforms, both allogeneic and autologous in solid tumors
- PD(L)-1 combination trials with novel checkpoint inhibitors, T cell agonists, and kinase inhibitors in a range of indications
- Innate immune effectors including toll-like receptors (TLRs) and STING agonists with biologic delivery mechanisms
- Cytokine-based therapeutic development programs
- Gene therapy and oncolytic virus approaches in solid tumors



More than 140 immuno-oncology projects conducted in the past five years including 39 checkpoint inhibitor and 37 cell therapy clinical trials

We have developed an internal IO training program to address the unique needs and complexities of these cutting-edge therapies. Our IO clinical teams are proficient and knowledgeable with global regulatory requirements for IO agents, unique site capability and training needs, global feasibility, potential drug manufacturing and handling complexities, and the evolving set of immune-related response criteria (iRECIST), immunerelated adverse events (irAEs), and endpoints.

SPECIALTY IN CELL AND GENE THERAPY

Within IO, we are proud to have a particular focus in the cell and gene therapy space. In addition to IO-specific nuances, CAGT trials bring an extra level of complexity such as:

- Cellular IP handling and logistics (particularly for autologous therapies)
- Regulatory and start-up hurdles (IBC approvals in the U.S. or ATMP requirements in the EU)
- A need for enhanced site selection and team training
- Extra vigilance around safety and data capture needs, often required over significant durations

With experience running 37 cell therapy clinical trials, IQVIA Biotech is well versed in these nuances and can help you effectively plan for and navigate trial challenges. We have unique solutions such as a Logistics Manager role, an IO vertical within the division which specifically hires cell and gene therapy experienced staff, a Cell & Gene Therapy (CAGT) Training Academy, proprietary diagnostic and prescription data to help guide site selection, and a robust consulting team via the IQVIA CAGT Center of Excellence which can help with everything from preclinical testing to CMC to planning for commercialization. Adoptive cell therapies in combination with other IO treatment modalities are reshaping the oncology treatment landscape, and we can be your partner in your next breakthrough.

GLOBAL CAPABILITIES

IQVIA Biotech delivers full-service clinical trial solutions to biotech customers around the world, from study design to site selection, enrollment and execution. Our experienced project teams provide a global network of trial sites, local regulatory knowledge, and direct access to site and staff resources around the globe. IQVIA Biotech has dedicated teams serving North America, Europe, Japan and Asia Pacific.

FLEXIBLE SOLUTIONS FOR BIOTECH

With our dedication to biotech and biopharma companies, we provide the hands-on expertise of a specialty provider. Drawing on IQVIA's unparalleled data and advanced analytics, IQVIA Biotech creates intelligent connections to deliver powerful insights and help customers accelerate clinical development of innovative medical treatments.

SPECIALIZED EXPERTISE WITH CUTTING-EDGE IMMUNOTHERAPIES

- Bladder
- Breast
- Cervical
- Colorectal
- Gastric and Gastroesophageal Junction (GEJ)
- Glioblastoma Multiforme (GBM)
- Head and Neck
- Leukemia
- Liver
- Lymphoma
- Lung
- Melanoma
- Mesothelioma
- Multiple Myeloma
- Myelodysplastic Syndrome (MDS)
- Ovarian
- Pancreatic
- Prostate
- Renal
- Soft Tissue Sarcoma
- Solid Tumor
- Companion Diagnostics



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