

# **Oncology Clinical Development**

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

IQVIA Biotech offers full-service clinical development solutions to advance your oncology breakthrough. Our strong foundation of therapeutic, scientific and operational expertise enables us to bring unparalleled innovation to oncology clinical development, making your trial more precise, predictable and efficient.

The nuances of oncology trials require a deep understanding of specific malignancies and rapidly evolving science. Our oncology teams are organized into specialty areas to provide support and expertise in solid tumors, hematology and immuno-oncology (IO) studies.

#### **Indication experience**

Experience across all major indications and rare diseases

- Brain tumors
- Breast cancer
- Endocrine and neuroendocrine tumors
- Gastrointestinal
- Genitourinary
- Gynecological
- Head and neck cancers
- Lung and thoracic tumors
- Malignant hematology
- Melanoma and dermatologic cancers
- Palliative and supportive care
- Pediatric tumors
- Sarcomas

# 500 oncology clinical trials for biotech customers in the last 5 years

#### **IMMUNO-ONCOLOGY SPECIALTY**

Our IO clinical teams are proficient in global regulatory requirements, unique site capability and training needs, global feasibility, and drug manufacturing and handling complexities. Recent experience spans multiple treatment modalities and indications, including.

- Next-generation CAR-T and CAR-NK trials spanning hematologic malignancies and solid tumors
- Bispecific antibody programs that engage T and NK cells
- PD(L)-1 combination trials with novel checkpoint inhibitors, T cell agonists, and kinase inhibitors
- Gene therapy and oncolytic virus approaches in solid tumors

## **CELL AND GENE THERAPY**

Our dedicated Cell and Gene Therapy Study Management team provides strategic guidance, scientific expertise and delivery excellence resulting in a seamless experience for biotech customers.

This team can help sponsors navigate the complexity and operational challenges specific to cell and gene therapy clinical trials, including:

- Cellular IP handling, biospecimen collection and other logistics
- Regulatory requirements and start-up
- Enhanced site selection and team training
- Specialized vigilance around safety and data capture needs

#### **EARLY AND LATE PHASE EXPERTISE**

IQVIA Biotech has staff with specific early phase and late phase experience to address the nuances of different phases of development and can grow with you as your pipeline matures.

#### Early phase oncology

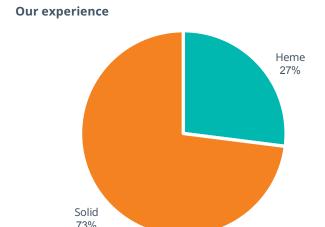
Our extensive experience in early phase oncology clinical development enables us to address the challenges sponsors will face. We are integrating FDA initiatives to shape early clinical trial strategies, such as Project Optimus for dose optimization guidance and Project FrontRunner for guidance on seeking earlier approvals for oncology therapies.

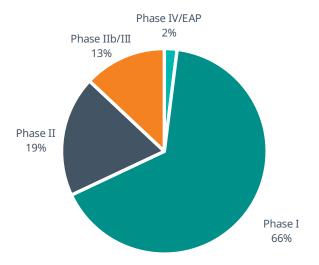
- Global network of specialized Phase I oncology sites
- Technology solutions for enhanced cohort planning
- Active in a range of adaptive, basket and umbrella designs, as well as complex multi-arm platform design trials
- Laboratory services from <u>IQVIA Laboratories</u> for biomarker services, assay validation and development of companion diagnostics

### Late phase oncology

We offer modern solutions for patient-focused trials that accelerate enrollment, reduce site burden, and deliver trials on time and budget.

- Proven decentralized trial solutions
- Global network of trial sites to optimize patient recruitment
- Precision site selection, centralized monitoring, and automated safety case processing
- Global regulatory expertise





#### RADIOPHARMACEUTICAL CLINICAL TRIALS

IQVIA Biotech is supporting studies working in the exciting area of radioligand therapy (RLT), a promising treatment modality for advanced cancers. We offer comprehensive support for radiopharmaceutical clinical trials, including site feasibility, patient recruitment, regulatory compliance and logistics management.

#### A BIOTECH-SPECIALIZED CRO

IQVIA Biotech is a biotech-specialized CRO delivering flexible clinical development solutions for biotech and emerging biopharma companies. Our clinical solutions are built on 25 years of unmatched experience with therapeutically aligned expertise, uniquely designed to deliver full-service solutions on a global scale.

