



Cell & Gene Therapy Development at Worldwide Clinical Trials

When you're developing a cell therapy or gene therapy, you need a CRO who not only has experience with your modality but is also flexible, adaptable, and capable of keeping up with this evolving area of research. Worldwide Clinical Trials' global Cell & Gene Therapy Hub is committed to providing you with a customized approach to tackle your study's scientific, regulatory, medical, and operational needs. Our therapeutically aligned clinical operations team provides full-service solutions across a wide range of therapeutic areas and treatment modalities.

We're excited to be working with sponsors like you to develop these life-changing therapeutics for patients. Every study we support leverages our individual and corporate experience in cell and gene therapy programs in the following therapeutic areas and modalities:

Cell Therapy:

- Autologous Chimeric Antigen Receptor T-Cells (CAR T)
- Allogeneic Chimeric Antigen Receptor T-Cells (CAR T)
- T-Cell Receptor Engineered (TCR) Cells
- Autologous Hematopoietic Stem Cells (HSCs)
- Autologous Mesenchymal Bone Marrow Stromal Cells
- Natural Killer (NK) Cells

Gene Therapy:

- Adeno-associated Virus (AAV)-vectored *in vivo* Gene Therapy
- Adenovirus-vectored *in vivo* Gene Therapy
- Plasmid DNA

RNA Therapy:

- Antisense Oligonucleotides (ASO)
- RNAi
- Non-coding RNAs

Gene Editing:

- *Ex vivo* Gene Editing
- *In vivo* Gene Editing



Therapeutic Areas of Expertise



Rare Disease



Congenital



Oncology



Hematology



Neurology



Metabolic



Ophthalmology



Respiratory



Cardiovascular

Worldwide's Experience

Our team approaches every trial as "solutioneers," offering customized services that address the unique needs of your team and study. While we leverage our history of working with the given modality when applicable, we don't utilize a one-size-fits-all approach. Cell and gene therapy programs require experienced strategy and operational leaders who personalize their approach for every study, stay current on the latest therapeutic developments, and are committed to advancing your program.

Our therapeutic strategy leaders and operational teams not only have the necessary experience to work on these therapeutic programs, but they are also deeply passionate about progressing these exciting treatments for patients who desperately need them.

Our strategic and scientific leaders have:



10+ average years of cell and gene therapy experience



165+ cell and gene therapy trials



An average of 50+ cell and gene therapy publications and presentations

Our Global Clinical Delivery Team has supported:



160+ cell and gene therapy trials across all therapeutic areas and phases

Meet Our Cell and Gene Therapy Team →

An Integrated Approach to Cell & Gene Therapies

Our Cell & Gene Therapy Hub's medical and scientific teams are integrated with our therapeutically aligned operational infrastructure to provide cross-functional development on a global scale. The cell therapy and gene therapy team builds on prior experience while remaining up to date in this evolving regulatory landscape, and this depth of understanding is supported by turnover below 7%. Our senior leaders support your study team and are directly available to you, giving you unparalleled access to the expertise you need for your study. From our subject matter experts and clinical methodology team to our key site and investigator relationships, you can utilize our resources throughout your entire study.

Logistics Orchestration

The need for a customized logistics coordination strategy is driven in part by the complexity of the cell and gene therapy investigational medicinal product and the study assessments. Each study-specific plan will protect endpoints, stabilize patient scheduling, and ensure smooth and efficient oversight of specialized vendors. Our expert professionals are trained in logistics, handling, storage, and shipping conditions for these advanced therapeutics. If helpful, Worldwide can manage all aspects of setup, tracking, management and oversight, and closeout of some of the most complex and time-sensitive vendor solutions. In collaboration with your team and tailored to the needs of your study, Worldwide can:

- Create and enact a logistics manual for your study, including risk assessment/mitigations and inventory tracking
- Serve as a point of contact for sites, vendors, and study team
- Proactively ensure Chain of Custody and Chain of Condition are flawlessly maintained

The Patient & Care Circle

Your patients are important to us, and we work strategically to ensure the trials we deliver are achievable and sustainable for real patients and their care circle. We understand that developing potentially durable treatments relies on building organic and reciprocal relationships with key stakeholders. Our expertise enables us to routinely partner with patient advocacy organizations and offer bespoke global advocacy engagement plans to each study.

Our team's dedication to delivering cell and gene therapy trials, combined with our collaborative approach, aims to provide a development experience that works for you. We are accessible, adaptable, and dedicated to your program, and we're ready to talk about your trial.

Learn more about our Cell & Gene Therapy Hub →

Contact us to talk about your study →

Global & Regional Regulatory Expertise

Whether you're looking for a pre-clinical regulatory consultant or support for your entire program, we have the global regulatory experts in-house to meet your needs.



Access to global regulatory strategy and local regulatory operational expertise



Receive a personalized strategy and direct assistance with your regulatory engagements



Optimized approval pathways and protocol designs to accelerate your development program



Worldwide
Clinical Trials

Worldwide Clinical Trials (Worldwide) is a leading full-service global contract research organization (CRO) that works in partnership with biotechnology and pharmaceutical companies to create customized solutions that advance new medications – from discovery to reality.

For more information on how we can partner with you to support your clinical trial, please [contact us](#).