MEDPACE®

CELL & GENE THERAPY CLINICAL RESEARCH

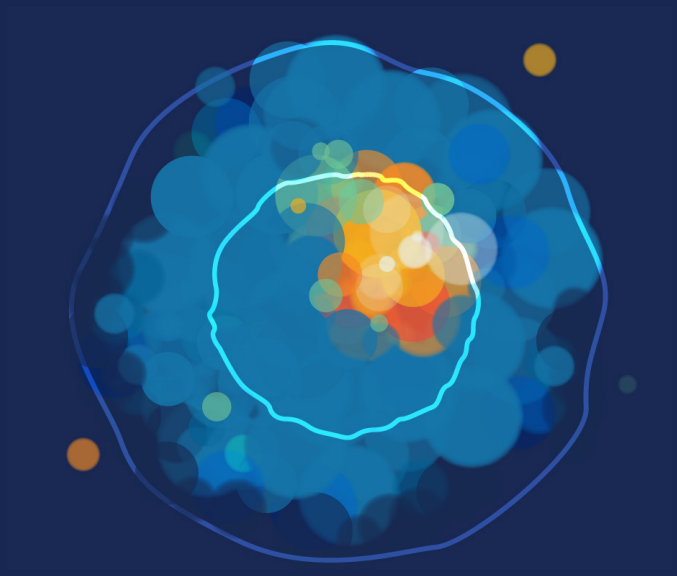
Medpace has global experience conducting Phase I-IV trials for a variety of cell & gene therapies. An international network of sites and strong relationships with Key Opinion Leaders (KOLs) streamlines the development process and is enhanced by our experience and history in recruiting hard-to-enroll patient populations.

DIVERSE THERAPEUTIC EXPERTISE

The Medpace cell & gene therapy team offers cross-functional therapeutic expertise to accelerate the development of cell & gene therapies. Our extensive CGT experience spans:

- CNS / Neuroscience
- Cardiovascular
- Endocrine & Metabolic
- Hematology & Oncology
- Infectious Diseases (ID)
- Ophthalmology
- Pediatrics
- Rare Disease
- Rheumatology

Medpace has conducted more than 160 Phase I-IV cell & gene therapy studies at over 2,900 sites with over 9,900 patients spanning both adult and pediatric populations.



EXPERTS

- Cross-functional medical expertise in diverse indications including rare diseases
- Network of globally trained investigators with the capabilities and experience to store, prepare, and administer these unique products

EXPERIENCE

- Phase I-IV clinical trials spanning adult and pediatric populations
- Extensive experience across various products (cell, gene, and tissue-based)
- Investigational product experience, such as first-in-human (FIH), allogeneic and autologous cellular products, ex vivo and in vivo gene transfer, and gene editing
- Active member and supporter of Rare Disease UK

EXECUTION

- Well-established international relationships with experienced sites, networks, and KOLs
- Global experience in regulatory and contracting procedures for cell & gene therapy
- Regulatory submissions team with a track record for fast study start-up and contracting

REGULATORY & OPERATIONAL EXPERTISE

Cell & gene therapy clinical studies are often delayed due to lack of therapeutic experts. Medpace has a team of therapeutically-aligned operations, regulatory and technical experts with relevant experience in novel therapies, who work collaboratively with our specialized medical team in order to leverage expertise for the benefit of trial programs.

The Medpace Technical Advisor team provides in-depth regulatory support regarding country and regional guidelines, assesses regulatory readiness of the study documentation, develops environmental risk assessments and other technical documents required for Biosafety submissions and assists sites with regulatory activities such as obtaining site level certificates and accreditations.

CENTRAL LAB

Our wholly-owned central laboratories—with locations in the US, Belgium, China, and Singapore—offers a menu of validated biomarkers associated with cell & gene therapy with the ability to rapidly establish and validate novel assays as needed.

Cell and Gene Testing Offerings:

- Vector and Transgene Detection/ Quantitation (qPCR and digital PCR)
- CAR-T Biodistribution Testing
- Sanger Sequencing and Next Generation Sequencing (NGS)
- Drug Product Characterization
- Immune Reconstitution Analysis
- Cytokine Profiling
- Anti-Drug Antibody Assay
- Neutralizing Anti-Transgene Antibodies Assay

Our globally harmonized laboratories utilize standardized platforms, validated workflows, and state-of-the-art instrumentation to deliver consistent high-quality results across global studies.

SCIENTIFICALLY-DRIVEN CLINICAL DEVELOPMENT

Our scientifically-driven approach to clinical development provides Sponsors with the advantage of early and ongoing insight and guidance from therapeutic experts from trial design to execution. Our medical doctors work closely with our regulatory and operations experts to provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. They are embedded throughout every study, providing greater depth and the ability to tackle complex and challenging diseases.

IMAGING CORE LAB

Medpace Core Labs (MCL) provides a breadth of expertise across a broad spectrum of CGT imaging. Notably, we use a web-based image management system with integrated quantitative tools to analyze a wide range of medical imaging modalities such as MRI, CT, PET, x-ray, etc. for confirmation of eligibility, safety, and efficacy evaluations. Our imaging and clinical trial experience ensures that imaging components are seamlessly integrated into the complex structure of CGT trials.

- CGT Specific Medical Imaging Protocols
- Qualitative Visualization
- Serial Quantitative Measurements

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.

MAKING THE COMPLEX SEAMLESS®