MEDPACE

CELLULAR AND GENE THERAPY CLINICAL DEVELOPEMENT

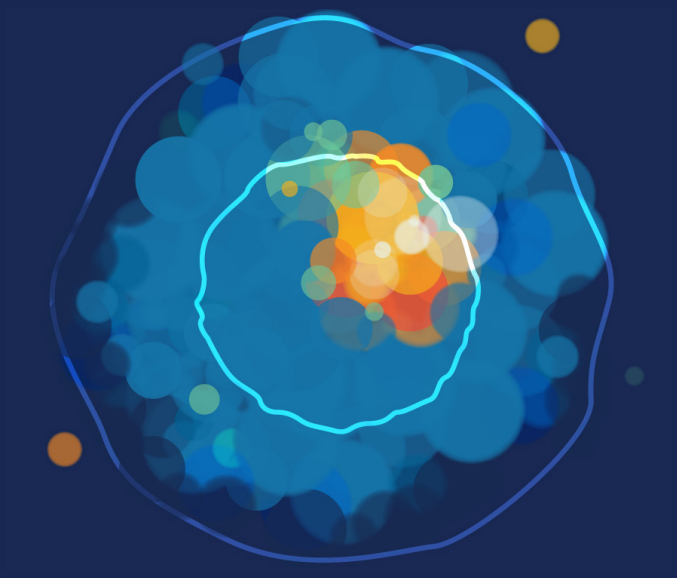
Cellular and gene therapies are rapidly utilizing new technology to deliver novel therapeutics to treat an increasing number of diseases and conditions. From cell therapies to tissue engineering, these novel therapeutic models can involve products, device combinations, and delivery methods that make cellular and gene therapy a complex target of clinical development.

The challenges of developing cellular and gene therapy products requires a committed and experienced partner. In addition to our internal expertise, Medpace works with innovators in biology, medicine and regulatory affairs to guide your product through the clinical development process.

Key Services:

- Trained investigative sites with capabilities to participate in these trials
- Specialized product tracking and delivery capabilities
- Careful study design that considers added operational complexities
- Regulatory knowledge of global guidelines, designations and applications including pediatrics
- Unique safety considerations that address both acute and long-term safety components

This novel area of drug and device development requires complex interactions between study members, regulatory teams, sites, and laboratories.



EXPERTS

- Project teams comprised of medical, regulatory, and clinical professionals with extensive experience designing and conducting trials for cellular and gene therapy products
- World-class, stage setting Regulatory Affairs team with specialized knowledge and experience in cell therapies

EXPERIENCE

- Therapeutic experience across multiple areas including hematology, rare diseases, oncology, cardiovascular, CNS, diabetes, and wound care
- In-depth knowledge of global regulations that apply to advance therapy products

EXECUTION

- Project Management, Regulatory Submissions, Clinical Monitoring, Data Management, Biostatistics, Safety, and Medical Writing services
- Operational and logistical capabilities to safely deliver the cellular and gene therapy to the patient and the data to the sponsor
- Ability to manage drug, device, diagnostics, and combination products
- Wholly-owned Imaging Core Lab and Central Laboratories provide cohesive, streamlined, and standardized trial management

EXPERIENCE

Medpace has considerable cellular and gene therapy experience across a number of therapeutic areas. Some examples include hematology, oncology, rare diseases, wound care, diabetes, CNS, and cardiovascular, including studies in complicated cardiovascular patients using stem cells in Acute Coronary Syndromes (ACS) and Acute Myocardial Infarction (AMI).

Others Include:

- Hematopoietic cell transplantation
- Graft versus host disease
- Gene therapy
- Gene editing
- Cellular therapy, both allogeneic and autologous
- Tissue therapy
- Adaptive immunotherapy
- Tissue engineered products

OPERATIONAL CONSIDERATIONS

From an operational, medical, and regulatory perspective, Medpace is adept at managing the added complexities of cellular and gene therapy trials. From feasibility, research site compatibility, safety, and logistics, Medpace understands the nuances and brings efficiencies and operational excellence to your programs.

REGULATORY

Medpace has a renowned regulatory affairs department led by a team of experts including former government officials. Medpace provides comprehensive regulatory affairs services for sponsors in the US, EU, and other regulated markets. Our regulatory team has strong capabilities relevant to the developers of cellular and gene therapy programs in the EU to which the cellular and gene therapy guidance applies.

INTEGRATED LABS

Medpace offers integrated imaging and central lab capabilities through its wholly-owned business units. This provides cohesive, streamlined, and standardized trial management.

STRENGTH OF SITE RELATIONSHIPS

The long-term relationships developed with investigative sites ensure studies conducted by Medpace receive preferential recruiting. Medpace has been recognized with multiple industry awards in this area.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

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

MAKING THE COMPLEX SEAMLESS®