MEDPACE

ADVANCED THERAPIES CLINICAL DEVELOPMENT

Advanced therapies holds the bold promise of discovering new therapeutic approaches to combat diseases that are still out of reach of traditional drugs and biologicals. From cell therapies to tissue engineering, these novel therapeutic models can involve products, device combinations, and delivery methods that make advanced therapy a complex target of clinical development.

The complexity of developing advanced therapy products requires a committed and experienced partner. In addition to our internal expertise, Medpace is working with innovators, key opinion leaders, and investigators in this area which makes us well-positioned to shepard your product through the development process.

Key Services:

- Trained investigator sites with capabilities to participate in these trials
- Specialized product storage and delivery capabilities
- Careful study design that considers added operational complexities
- Regulatory expertise about the FDA and the EMA for the latest therapy guidelines
- Safety considerations that bring long-term safety components and outcome-based trial registries into the picture while maintaining blinding requirements for placebo-controlled studies

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

MAKING THE COMPLEX

SEAMLESS™

EXPERTS

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

EXPERIENCE

- **Therapeutic experience across multiple areas including cardiovascular, CNS, diabetes, and wound care**
- **In-depth knowledge of global regulations related to advance therapy products**
- **Active member of Alliance for Regenerative Medicine**
- **Multi-site, global trials including outcome-based trial registries**

EXECUTION

- **Project Management, Regulatory Submissions, Clinical Monitoring, Data Management, Biostatistics, Safety, and Medical Writing services**
- **Operational and logistical capabilities associated with conducting trials with advanced therapy investigational products**
- **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 advanced therapy experience across a number of therapeutic areas. Some examples include wound care, diabetes, CNS, and cardiovascular, including studies in complicated cardiovascular patients using stem cells in Acute Coronary Syndroms (ACS) and Acute Myocardial Infarction (AMI). Others include:

- Hematopoietic cell transplantation
- Bone marrow transplantation
- Gene therapy
- Gene editing
- Graft versus host disease
- Cellular therapy
- Tissue therapy
- Adaptive immunotherapy
- Tissue engineered products

OPERATIONAL CONSIDERATIONS

From an operations, medical, and regulatory perspective, Medpace is adept at managing the added complexities of advanced 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 advanced therapy programs in the EU to which the advanced therapy medicinal products (ATMP) 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™