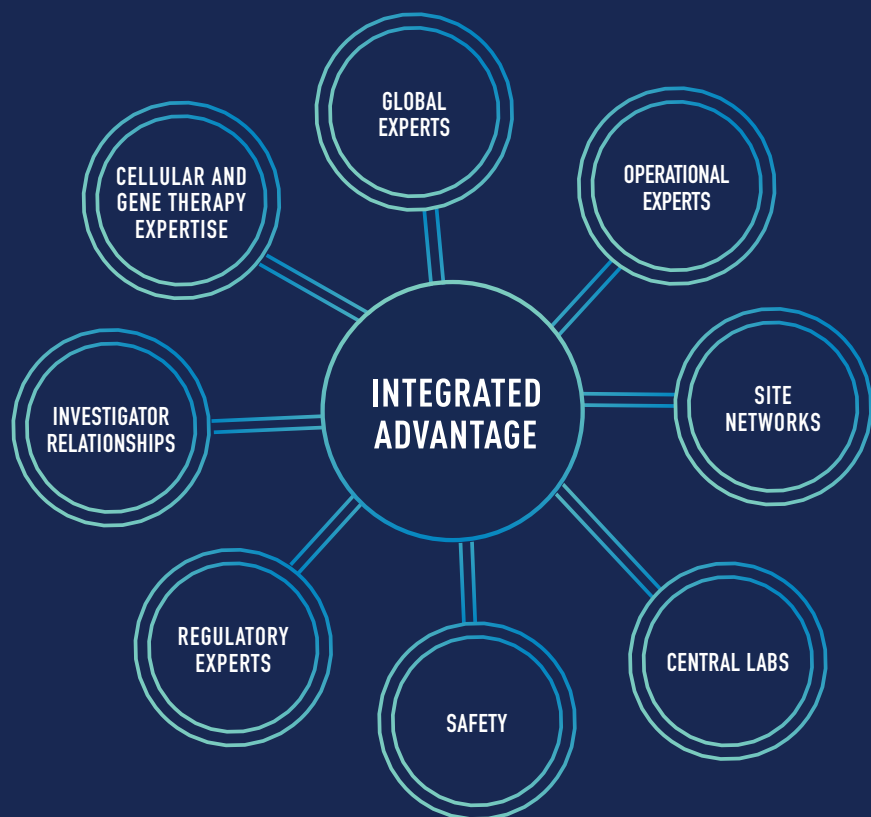


# CELLULAR & GENE THERAPY

A CROSS-FUNCTIONAL, COMPREHENSIVE APPROACH TO ACCELERATE THE DEVELOPMENT OF CELLULAR & GENE THERAPIES

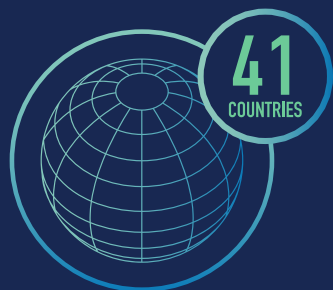


## GLOBAL REACH

*Operational Around  
The World – Wherever  
Research Is Happening*

### CENTRAL LAB LOCATIONS

USA | Belgium | China | Singapore



41  
COUNTRIES

## AREAS OF EXPERTISE

### *Cell and Gene Therapy*

- Hematopoietic Cell Transplantation
- Tissue Therapy
- Gene Editing
- Adoptive Immunotherapy
- Tissue Engineered Products
- Experience in malignant and non-malignant diseases, pediatric and adult
- Cell shipping and tracking including chain of custody and chain of identity

## CENTRAL LABORATORY

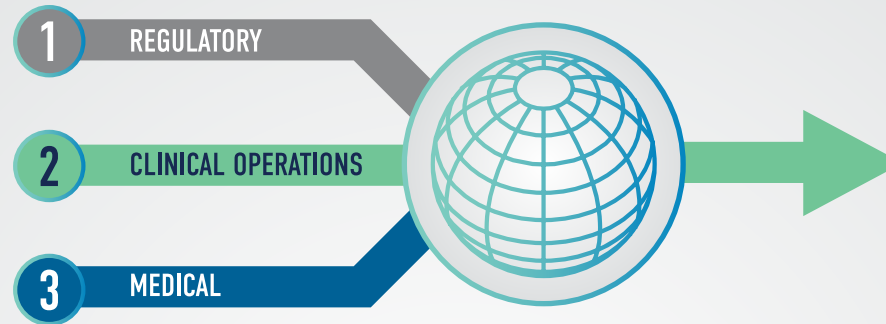
- Specialized product storage and delivery capabilities
- Biomarker development, validation and PD analysis
- Industry-leading quick validation timelines



MEDPACE

# CELLULAR & GENE THERAPY

A CROSS-FUNCTIONAL, COMPREHENSIVE APPROACH TO ACCELERATE THE DEVELOPMENT OF CELLULAR AND GENE THERAPIES



## REGULATORY AND STRATEGIC DEVELOPMENT

- Regulatory strategy and development planning with integrated regulatory and competitive intelligence
- Critical review and gap analysis of programs with nonclinical, CMC, clinical pharmacology, clinical, and device considerations
- Full service regulatory document development and submission support
- Scientific advice meeting support and guidance
- Support for GMO documentation and submissions

## CLINICAL DEVELOPMENT

- Clinical trial managers who manage recruitment, study startup and trial execution, and have experience in project management for many types of studies
- Experience with investigational product supply and management logistics
- Real time cell tracking between investigational, manufacturing and clinical sites

## MEDICAL AND THERAPUTIC DEVELOPMENT

- Scientifically driven medical leaders with deep therapeutic expertise in broad group of medical specialties
- Hands-on experience with cellular, tissue and gene therapies
- Physicians and advanced nurse practitioners integrated into the clinical, operational and regulatory team

MAKING THE COMPLEX  
**SEAMLESS<sup>®</sup>**