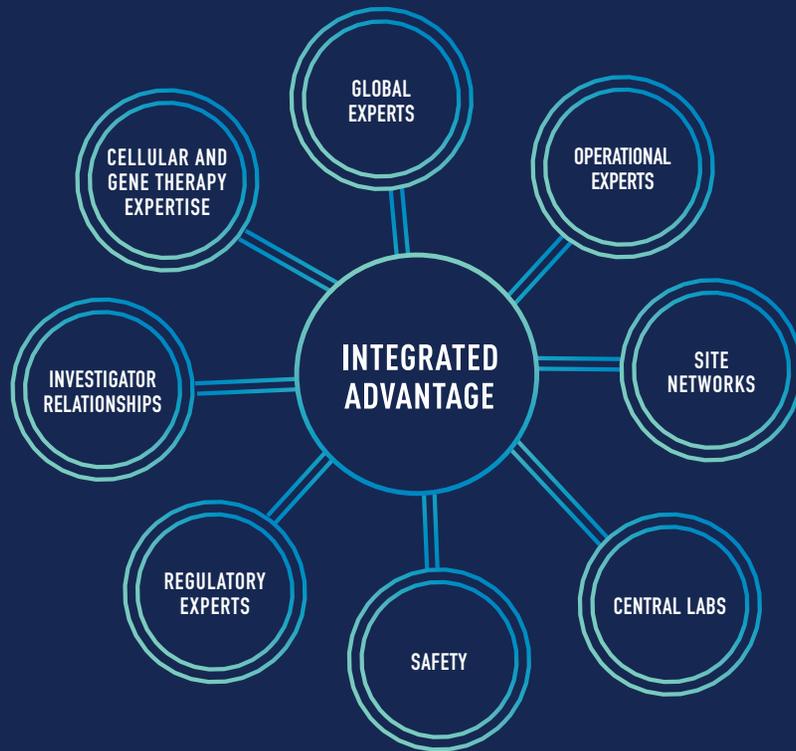


# CELLULAR & GENE THERAPY

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

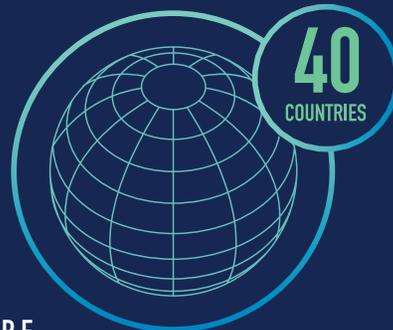


## GLOBAL REACH

OPERATIONAL AROUND THE WORLD — WHEREVER RESEARCH IS HAPPENING

### CENTRAL LAB LOCATIONS

USA • BELGIUM • CHINA • SINGAPORE



GLOBAL CELLULAR AND GENE THERAPY EXPERIENCE ACROSS NUMEROUS THERAPEUTIC AREAS AND GLOBAL REGIONS.

## AREAS OF EXPERTISE

### GENE AND CELL 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

# CELLULAR & GENE THERAPY

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