Worldwide Clinical Trials

Personalized Cell & Gene Therapy Clinical Development at Worldwide Clinical Trials

When revolutionizing meaningful care for patients, you need a partner as innovative and dedicated to your program as you are. Worldwide Clinical Trials' Cell and Gene Therapy Hub collaborates with drug development partners like you working to advance novel and complex cell and gene therapy programs through clinical development. From the critical non-clinical and Chemistry, Manufacture, and Control Information to real-world evidence generation of Long-Term Follow-Up studies and everything in between, we are here to drive your program's success.

Our teams were constructed with flexibility and adaptability in mind, bringing together the scientific, medical, operational, and regulatory expertise into one integrated and versatile unit. Our experts adopt a collaborative approach that leverages the lessons learned day in and day out of developing these programs and customize their approach to the unique needs of your study. We know no two studies are alike—and we work with each of our sponsors to deliver the custom and personalized experience their program needs.

The strategic and scientific leads in our Hub have:

- **10+** average years of cell and gene therapy experience
- **165+** cell and gene therapy trials supported
- **40+** cell and gene therapy publications and presentations

Meet Your Cell & Gene Therapy Hub

Our cell and gene therapy team has delivered studies across North America and Europe in all therapeutic areas and modalities. Leveraging our diverse experience, we develop a custom, integrated approach for each and every sponsor we support.

Amy Raymond, PhD, PMP

Senior Director, Therapeutic Strategy Lead, Cellular and Genetic Medicines

- 25+ years of drug discovery and development experience; has provided strategic support to more than 50 cell and gene therapy studies across Phase I-IV and all therapeutic areas
- Leads strategic guidance for cell and gene therapy development programs at all stages, especially for programs serving rare disease or oncology patients and families

Aman Khera

Vice President, Global Head of Regulatory Strategy

- 25+ years of clinical research experience; 20+ years in cell and gene therapy development
- Provides global strategic direction for regulatory affairs with the primary aim of serving humanity as a whole; remains close to the pulse of the ever-changing regulatory and clinical research landscape

Virgilio Garcia Lerma

Senior Director, Regulatory Pre-Award Strategy

- 20+ years of clinical research experience; 15+ years in cell and gene therapy development
- Heads the strategic regulatory pre-award team and provides strategic advice on regulatory clinical development for Phase I-IV trials

Meet Your Cell & Gene Therapy Hub (Continued)

Derek Ansel, MS, CCRA

Executive Director, Therapeutic Strategy Lead, Rare Disease

- 12+ years in rare and pediatric clinical research; 6+ years in cell and gene therapy development across all phases
- Leads rare disease and pediatric corporate strategy and drives patient-focused advocacy initiatives; board-eligible genetic counselor

Michael F. Murphy, MD, PhD

Chief Medical and Scientific Officer

- 30+ years of clinical research experience; 7+ years in cell and gene therapy development
- Co-founder of Worldwide; provides early engagement technical and scientific support relevant to clinical trial methodology and regulatory engagement for collaborative drug development

Juliane K. Mills, MS, MPH

Senior Director, Therapeutic Strategy Lead, Rare Disease

- 23+ years of clinical research experience; 3+ years in cell and gene therapy development
- Provides operational strategies that are efficient and effective for delivering rare disease trials while being accessible to patients, caregivers, and families

Dana F. Durst

Executive Director, Site Activation & Regulatory Therapeutic Lead, Oncology

- 16+ years of clinical research experience; 6+ years in cell and gene therapy development
- Heads the Global Site Activation Management Team within Worldwide's Oncology Business Unit, overseeing all aspects of startup activities globally across Phase I-III programs

Jake Boyd

Director, Project Management, Oncology

- 10+ years of Phase I-III clinical research experience, with a primary focus on FIH dose-escalation/expansion studies
- 5+ years focused on the development and oversight of cell and gene therapies in both solid tumor and hematology

Olu Daramola

Associate Director, Project Management, Rare Disease

- 11+ years of clinical research experience; 5+ years in cell and gene therapy development
- Oversees project management of all global study development phases

Kunle Oshin, MD

Associate Director, Project Management, Cardiometabolic & Inflammatory Diseases

- Trained physician anaesthesiologist with 22+ years of experience in global Phase I-IV clinical research; 11+ years in project management in multiple therapeutic areas
- 12+ years of experience in rare disease cell and gene therapy development