Emmes

Cell and Gene Therapy

Collaborate with our dedicated team of experts, offering strategic leadership and tailored support for your Vaccine and Infectious Disease clinical trials.

Emmes' Cell and Gene Therapy team harness more than 30 years of clinical development expertise, spanning work in both public and private sectors. We provide full-service support across all phases of clinical development. Emmes has deep knowledge and expertise in cell and gene therapy research across many indications and all phases, making our services best placed to advance your research program.

The complex nature of cellular and gene therapy/editing trials requires a Contract Research Organization (CRO) partner well versed in the nuances of cell and gene therapy research. Emmes has deep experience in collaborating with researchers and shares a common, future vision across all phases of clinical development, providing a strong foundation for partnership.

Modernizing clinical research with tech & AI

At Emmes we are modernizing and automating clinical research across the full spectrum of clinical trial activities to operate faster, more efficiently, and with higher quality. We are the industry's first native digital and AI specialty CRO built on a proprietary technology and AI platform.

Services Offerings

- Clinical Trial Management
- Data Management
- Pharmacovigilance
- Quality Assurance
- Biostatistics & Bioinformatics
- Global Regulatory Affairs

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What sets us apart?

Benefits of our services

Access to strong site networks- Emmes collaborates with the majority of US clinical centers who perform HCT. Strong partnership with the Blood and Marrow Transplant Network (BMT CTN) as the acting Data Coordinating Center, has led to Emmes managing 60 trials across 120 sites with 15,000 participants enrolled for trials.

Expertise in biostatistics in small patient populations- Emmes' extensive statistical and scientific knowledge allows for targeted and meaningful data outputs when working in small patient populations.

Global Trace- Our own proprietary technology allows us to manage bio-specimens and ensure they are not lost, damaged or otherwise destroyed – which is critical when dealing with small patient populations where data takes on even higher value and treatments are more expensive.

First of its kind research- Experience supporting groundbreaking and innovative interventions, with examples including conducting several first-in-human cardiac cell therapy studies through the Specialized Centers for Cell-Based Therapy (SCCT) and supporting the first infusion of a genetically modified product for ophthalmology.

Breadth of experience- Over 35 years of cell and gene therapy research experience for biopharma and public-sector clients, across hematology and ophthalmology. Emmes has also been selected as the coordinating center for the NHLBI-funded Cure Sickle Cell Initiative (CureSCi).

Highlights Include

AREDS and ARED2- Coordinating Center for these groundbreaking studies resulting in OTC AREDS vitamins and leading to 90+ co-authored peer-reviewed manuscripts and 119 Conference presentations

Leader of the Cure Sickle Cell Initiative- (CureSCi) Emmes was awarded funding from NHLBI to accelerate promising genetic therapies to cure sickle cell disease. Emmes' partnership with the NHLBI in this effort is bringing together the sickle cell disease community towards a common goal to identify cures.

Innovative trial design- Designed a statistical model that leveraged bilateral data, pre, and post-treatment while utilizing historical data as a control in an Ophthalmic Gene Therapy. This allowed for study continuation following an issue with placebo manufacturing.

The Blood and Marrow Transplant Clinical Trials Network (BMT CTN)- is one of Emmes' longest-running, most collaborative and complex research partnerships where Emmes take on the responsibility of managing study operations across

For additional information on our Cell and Gene Therapy services, please visit **www.emmes.com**

Key Statistics

16,000
Patients enrolled

465+
Scientific manuscripts

125+
Phase I-III studies

100+
Sites in BMT CTN

71
Submissions to regulatory

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