



Cellular and Gene Therapy

Clinical research using Cellular and Gene Therapy/Editing for malignant and non-malignant disorders has expanded with advances in technology. The complex nature of these type of trials requires a Contract Research Organization (CRO) partner who is well versed in the unique nuances of successfully and efficiently managing all steps of research using cell and gene therapies.

Furthermore, a CRO that has experience in collaborating with other researchers and shares a common, future vision across all phases of clinical development is critical.

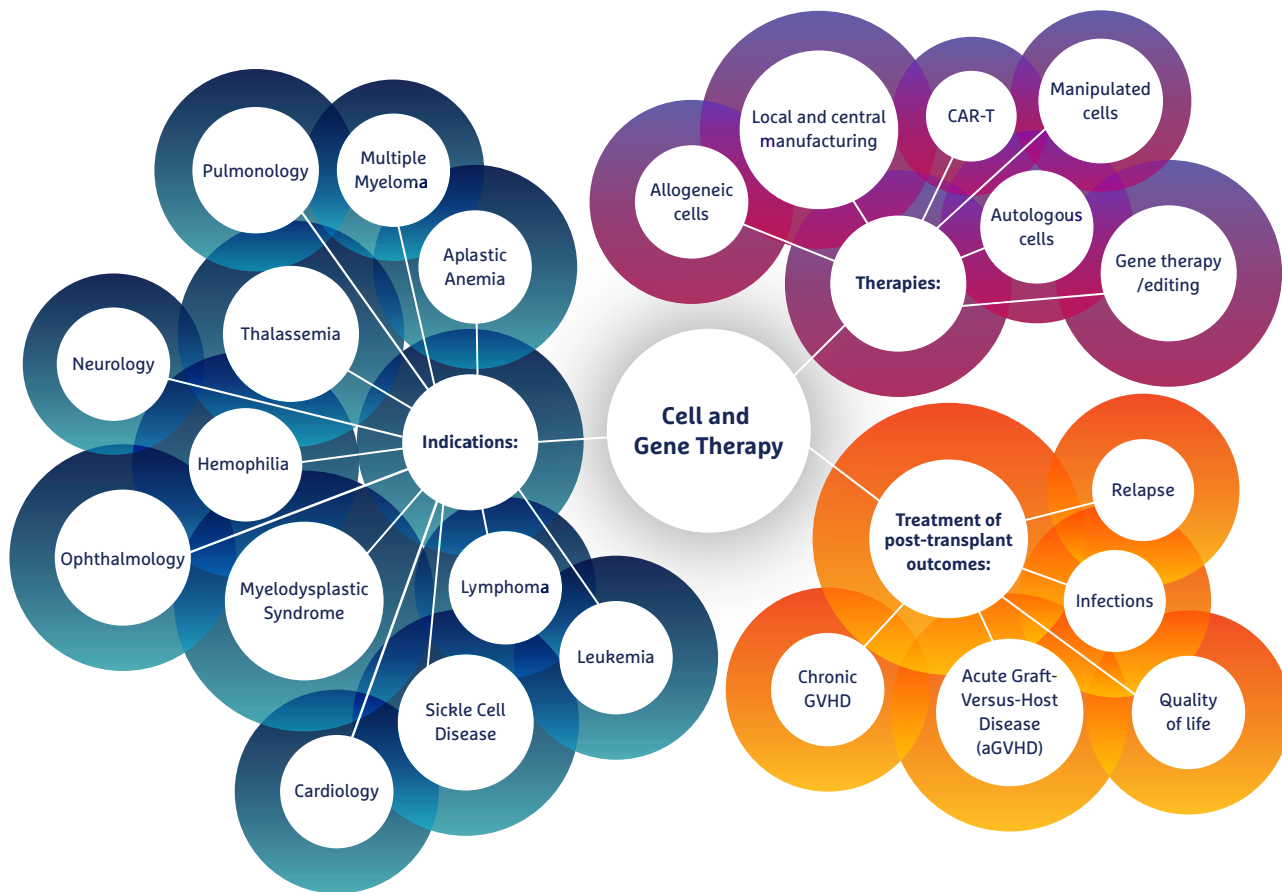
As a full service CRO engaged in global cell and gene therapy studies, Emmes' wide expertise in various cell types and therapies along with complications from cellular therapies provides a strong foundation for a partner to leverage.



Long History:

For the past 35 years we have maintained strong relationships with leading investigators and institutions, enabling our team of clinical research professionals to become adept at designing and conducting complex clinical trials in cell and gene therapies.

- In 1994, established early leadership in cord blood research. We also took part in the first multicenter study to evaluate whether human leukocyte antigen mismatched, unrelated umbilical cord blood stem cell and progenitor cell units offered a clinically acceptable alternative to matched unrelated-donor allogeneic bone marrow for transplantation in patients with malignant and non-malignant disorders.
- Completed the groundbreaking Age-Related Eye Disease Study (AREDS) and subsequent AREDS 2 trial that helped deliver macular degeneration delaying vitamin supplements.
- In 1995, studied the effect of graft-versus-host disease prophylaxis as part of a Phase 2 and 3 trials in recipients of unrelated donor bone marrow.
- Designed and managed several first-in-human studies of various cell types for infusion into patients with cardiac heart failure, beginning in 2005.



Leadership and Collaborations:

- 20+ year relationships with the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute of the National Institutes of Health (NIH).
- Leadership role in the NIH-funded Blood and Marrow Transplant Clinical Trials Network (BMT CTN) - a collaboration between Emmes, The National Marrow Donor Program/Be the Match, and The Center for International Blood and Marrow Transplant Research (CIBMTR).
- Leader of the NHLBI-funded Cure Sickle Cell Initiative (CureSCi) Coordinating Center.
- Leader of the NHLBI-funded Production Assistance for Cellular Therapies (PACT) coordinating center.
- Conducted numerous cell and gene therapy clinical studies for biopharma and public sector leading to market approval.

Key Data:

Built on a long history of helping advance the science of hematology and cell and gene therapies, we believe that true medical advancement depends on learning from past experience, collaborating with other researchers and sharing a common, future vision.

- 100+ published papers.
- 125+ Studies Phase I-III primarily focused on Hematology indications.
- Conducted several global Phase III clinical trials focusing on cellular therapy or the complications of cellular therapy.

For additional information on our Cell and Gene Therapy Center, please visit www.emmes.com/cell-and-gene-therapy