Emmes

RESEARCH FOR A
HEALTHIER WORLD

Cardiovascular Experience in 40+ Clinical Trials

WHAT MAKES OUR CARDIOVASCULAR GROUP QUALIFIED?

1. **Production Assistance for Cellular Therapies (PACT)**

   PACT provides education, leadership & production assistance to the cell therapy community through contract manufacturing of therapeutic cell products.

2. **Pharmacogenomic Evaluation of Antihypertensive Responses (PEAR)**

   The PEAR study is designed to evaluate 800 randomized subjects with a history of hypertension controlled by medication.

3. **Best Pharmaceuticals for Children Act (BPCA)**

   The BPCA DCC supports multiple clinical trials involving exclusively infants and children designed to improve labeling of drugs for pediatric use.

Cardiovascular Experience

- Acute Coronary Syndrome (ACS)
- Arrhythmia
- Artery Occlusive Disease
- Atrial Fibrillation
- Bypass Surgery
- Dyslipidemia
- Heart Failure
- Hypertension
- Pacemaker
- Stable Angina
- Stent
- And More

Early Heart Attack Program (1981 – 1986)

Between 1981 and 1986, Emmes served as the Coordinating Center for a post-infarct intervention program that was supported by the private resources of a medical device manufacturer. The focus of this activity was a 1,000-participant prospectively randomized clinical trial designed to evaluate a coronary monitoring and intervention system used in post-myocardial infarction participants to reduce mortality. The study's purpose was to determine whether trans-telephonic electrocardiogram (ECG) monitoring and emergency lidocaine injection can have a favorable impact on survival and other clinical outcomes, as well as on quality of life. Emmes developed an approach to analyzing routine transmissions as a diagnostic methodology that considered time-varying covariate problems.

Specialized Centers for Cell-Based Therapy (SCCT) (2005 – 2012)

The SCCT funded three specialized clinical centers and one Data Coordinating Center (DCC) in 2005 with the mission of stimulating clinically relevant, multidisciplinary collaborations leading to basic science and clinical research efforts on important public health problems for individuals with heart, lung, and blood diseases. Emmes served as the DCC and was involved in all aspects of the grant. Eight Phase I protocols were conducted under the SCCT grant with a total accrual of 177 patients. Emmes provided full-service support for the studies, including three Phase I clinical trials administering cell therapy to patients with cardiovascular disease. For each study, Emmes collaborated with the investigators on protocol design and development, Investigational New Drug application (IND) submissions, case report form (CRF) design, database development, data management, site monitoring, statistical support, regulatory support, administrative support, medical monitoring, data analysis, and manuscript preparation. The grant resulted in more than 150 publications, of which Emmes was directly involved with publications from three clinical trials with additional publications submitted to peer-reviewed journals.