DCRI CARDIOVASCULAR

Innovating to Improve Patient Care

As the world's leading academic clinical research organization, the DCRI has a rich history of conducting cardiovascular clinical trials and outcomes studies while educating the next generation of clinical researchers. The institute is dedicated to streamlining and advancing clinical research through innovative study design, fit-for-purpose approaches, thoughtful analytics, and a commitment to rapid knowledge dissemination—ultimately helping to improve patient outcomes.

Comprehensive services for the development of highly efficient events adjudication programs include:

DCRI's knowledgeable, world-class clinician investigators, biostatisticians, data scientists, and operations teams offer our collaborators their wide range of expertise on:

- Traditional clinical trials (phase I-IV)
- Pragmatic clinical trials
- Real-world data and evidence
- Implementation science
- Cardiovascular devices
- Integration of mobile technologies into research

- Direct-to-participant research
- Management of multiple national registries
- Participant and site engagement
- Clinical event adjudication
- Medical editing and research communications
- Evidence dissemination and academic publications

OUR MODEL

The DCRI combines the benefits of a premier teaching hospital with the full-service capabilities of a CRO.

OUR COMMITMENT TO QUALITY

Faculty Thought Leadership

- Our 100+ practicing physicians apply their clinical experience to design realistic protocols that train and support investigator sites.
- Renowned biostatisticians and data scientists find the question that most effectively probes the research question and delivers high-quality, reproducible data.

Patient- and Site-Focused

- Patient safety, engagement, and outcomes that are meaningful to patients are at the center of our work.
- Collaborative relationships with sites and multiple national registries are essential to our success.

Quality and Integrity of Trial Conduct

- Phase I-IV clinical and outcomes research adhere to guiding principles.
- Operations are data-driven and utilize efficient processes.
- Trials integrate with standard-of-care clinical practice.



SHARING KNOWLEDGE

From 1996-2023,

21,600+ DCRI publications

> have been cited in



DCRI CARDIOVASCULAR

REAL-WORLD EXPERIENCE, WORLD-CLASS INVESTIGATORS

Our faculty and operational experts translate novel therapeutic concepts into well-designed clinical trials across the spectrum of cardiovascular conditions, including:

- Heart failure
- Cardio-metabolic disorders
- Diabetes mellitus and cardiovascular disease
- Acute coronary syndromes
- Antithrombotics/thrombosis
- Chronic coronary artery disease and coronary atherosclerosis
- Dyslipidemia and hyperlipidemia
- Cardiac surgery
- Cardiovascular genetics and genomics
- Cardiac diagnostic testing
- Electrophysiology
- Atrial fibrillation
- Pacemakers and implantable defibrillators

PRAGMATIC APPROACHES TO RESEARCH

From 2015 to 2021, the DCRI led the ADAPTABLE Pragmatic Approaches in Landmark Research study, a pragmatic clinical trial conducted to determine the optimal dose of aspirin for patients with existing cardiovascular disease. The landmark study was the demonstration project for using PCORnet[®], the National Patient-Centered Clinical Research Network, to conduct research. ADAPTABLE utilized certain pragmatic elements in order to make the trial more efficient and less burdensome for both patients and clinicians:

- Broad eligibility criteria
- Large-scale recruitment using electronic health records
- · Electronic informed consent
- Completely electronic participation

DCRI CARDIOVASCULAR LEADERSHIP



G. Michael Felker, MD, MHS Director, Cardiovascular Research, DCRI Professor of Medicine, Cardiology Duke University School of Medicine michael.felker@duke.edu



Carolyn Moore Arias, MPH Director Industry Partnerships and Strategic Programs, DCRI carolyn.arias@duke.edu



Karen Hagerty

Assistant Director Industry Partnerships and Strategic Programs, DCRI karen.hagerty@duke.edu

Learn more about DCRI Cardiovascular

dcri.org/cardiovascular



- Antiarrhythmic agents
- Geriatric cardiology
- Pediatric cardiology
- Peripheral vascular disease
- Risk modeling for coronary disease
- Valvular heart disease

SPOTLIGHT ON AEGIS-II

A Global Phase III Study to Reduce Cardiovascular Risk Among Patients with Recent Myocardial Infarction

 A collaborative effort from the DCRI faculty, project management, site management/monitoring, data management, and DCRI Research Together™ patient advisory group, accomplished with partners around the world and supported by CSL Behring.

OUTCOMES

- Successfully enrolled 18,226 patients in 46 countries worldwide with only two patients lost to follow up
- The DCRI managed 193 U.S. sites that enrolled more than 1,800 high-risk acute MI patients, much of it during COVID-19 pandemic, with no patients lost to follow up
- Met 50% and 85% site activation goals one to two weeks ahead of schedule
- Recruited an average of 1.0 patients per site per month (0.6 projected) ahead of schedule
- Compliance with infusions greater than 96%
- High adherence to standard of care treatment after MI



The Aspirin Study