# 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

## 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.

- 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



## SHARING KNOWLEDGE

From 1996-2023,

20,300+ 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 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<sup>®</sup>, 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

## Learn more about DCRI Cardiovascular

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dcri.org/cardiovascular





The Aspirin Study

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

## **SPOTLIGHT ON AEGIS-II**

- A Phase 3 study evaluating the efficacy of CSL112, an intravenous formulation of human apoA-I derived from plasma, to reduce cardiovascular risks for individuals with recent myocardial infarction.
- Successfully enrolled 18,226 patients in 46 countries worldwide with only two patients lost to follow up
- DCRI managed 193 US sites that enrolled more than 1,800 highrisk acute MI patients, much of it during COVID-19 pandemic, with no patients lost to follow up in the U.S.
- Collaborative effort from the DCRI faculty, project management, site management/monitoring, data management, DCRI Research Together™ patient advisory group, and statistical risk-based monitoring, with sponsors and partners including:
  - Baim Institute for Clinical Research
  - Canadian Vigour Centre (CVC)
  - CSL Behring
  - Green Lane Coordinating Center (GLCC – New Zealand)
  - South Australian Health and Medical Research Institute (SAHMRI - Australia)
  - Fortrea