DCRI HEMODYNAMICS CORE LAB

The DCRI Hemodynamics Core Lab (HCL) leverages an expert group of more than 15 practicing physicians providing independent adjudication of hemodynamic tracings from right and left heart catheterizations for drug and device trials. With high consistency and efficiency, we offer both blinded and unblinded adjudication, establishing the gold-standard in hemodynamic adjudication.

THE DCRI DIFFERENCE

Hemodynamics tracings at DCRI are independently adjudicated by a group of expert practicing cardiologists who are actively treating patients. Our collaborative approach:

- Efficient readings, rapid results
- Cost-effective analysis
- Counter-reading by multiple readers for cross-validation, ensuring consistency and accuracy
- Broad bandwidth to serve multiple large and small-scale studies
- Expert data quality assurance, analysis, and retention.
- Flexible workstreams to support study-specific requirements.
- Meets the FDA's rigorous requirements for validation and compliance

ONGOING STUDIES

Acorai and CardioSense

Large-scale studies utilizing hemodynamics tracing 1,900 patients, and 7,800 adjudications validating heart failure devices:

ACORAI

Acorai Heart Monitor

A non-invasive intracardiac pressure monitoring device

The DCRI HCL is adjudicating 3,800 cath reports for 1,200 participants as Acorai seeks to validate the effectiveness of their device, which received the FDA's Breakthrough Device Designation in August 2023.

CARDIOSENSE

CardioSense

A wireless patient monitoring device integrated with a digital biomarker, clinical AI platform.

Providing 4,000 tracings for 500 patients, the DCRI HCL aims to verify the effectiveness of CardioSense's CardioTag Sensor and Wavesense Platform. CardioSense's novel algorithm received the FDA Breakthrough Device Designation in February 2022.

DCRI CSI+

+ Clinical Events Classification (CEC); + Safety Surveillance (SS); + Imaging Core Lab (ICL); + Arrhythmia Core Lab (ACL); + Hemodynamics Core Lab (HCL)

In addition to HCL services, DCRI is fully equipped to provide a cross-functional approach to the medical services core trial requirements, ensuring a comprehensive and efficient performance of event adjudication, safety surveillance/pharmacovigilance, as well as core labs for centralized imaging interpretation of electrophysiology and/or of imaging across several modalities. DCRI's collaborative approach across our core trial medical adjudication services offers streamlined systems and operations to systematically generate validated, high-quality data.

HCL FACULTY

Marat Fudim, MD, MHS, is an advanced heart failure and cardiology specialist at Duke Health and a leading expert in hemodynamics. His clinical and research focus centers on heart failure, including advanced therapies such as mechanical assist devices and heart transplantation. Dr. Fudim regularly performs cardiac catheterizations and is involved in novel diagnostic and therapeutic strategies in heart failure and cardiovascular disease broadly. As an Associate Professor of Medicine and a member of the Duke Clinical Research Institute, Dr. Fudim contributes significantly to advancing global knowledge of heart failure and improving patient outcomes.

Learn more about Dr. Fudim's Hemodynamics Research

David Kong, MD, is an interventional cardiologist at Duke Health and a Duke Center for Healthcare Informatics faculty member. He's regarded for his expertise in cardiovascular informatics research and integration of evidence from cardiovascular clinical trials. Dr. Kong, who led the machine learning group at the DCRI, is also known for seeking innovative approaches to predicting clinical and cost outcomes in coronary artery disease.

Learn more about the Hemodynamics Core Lab and CSI+

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