Duke Clinical Research Institute

DCRI **ARRHYTHMIA CORE LAB**

At the DCRI, the Arrhythmia Core Laboratory (ACL) is dedicated to providing high-quality evaluation, adjudication, and validation of electrocardiographic and electrogram review. Founded by Jonathan Piccini, MD, MHS, and led by director Sean Pokorney, MD, MBA, the ACL has extensive experience in heart rhythm monitoring, 12-lead electrocardiogram and device-based electrogram event adjudication, arrhythmia science, clinical trials design and execution, and outcomes research.

The DCRI ACL has one of the largest group of HRS board-certified clinical cardiac electrophysiology adjudicators across the globe. *We have enrolled more patients in heart rhythm-related trials than any other academic research organization*. Our thought leadership, experience, and collaborative approach across our core trial medical adjudication services at the DCRI set us apart.

Arrhythmia Core Lab
FOUNDED IN 2012

10+
CURRENT AND COMPLETED TRIALS

2,500+
PATIENT DATA REVIEWED

16,000+
ADJUDICATIONS COMPLETED

25+
OPERATIONAL STAFF INCLUDING NURSES AND CLINICAL EXERCISE PHYSIOLOGISTS

10+
ADJUDICATORS

OUR CAPABILITIES AND EXPERTISE

The ACL provides heart rhythm evaluation and adjudication across several modalities and multiple study designs and settings. Our services include:

- Evaluation and adjudication of 12-lead electrocardiograms
- Evaluation and adjudication of ambulatory monitoring tracings and results
- Evaluation and adjudication of device-based diagnostics and electrograms (including but not limited to pacemaker, implantable cardioverter defibrillator, and cardiac resynchronization therapy recordings)
- Design and implementation of core laboratory protocols, study manuals, and procedures
- Quality assurance evaluations and validation for the blinded adjudication process
- Publication and dissemination of study results
- Pre-clinical, phase I, II, and III clinical trials, post-marketing, and observational studies
- Clinical trial design, support, and execution

In addition, our Electronic Adjudication System technology allows reviewers to adjudicate electronically with an Internet connection; track the workflow process, providing a full audit trail (21 CFR part 11-compliant); produce reports from executive summary to detailed information; and provide electronic dossiers.

Select DCRI Electrophysiology Clinical Trials and Core Lab Projects

Trial	Intervention
MOST*	DDDR vs VVIR in Sinus Dysfunction
SCD-HeFT*	Primary prevention ICD
HAT*	Home AED after MI
ROCKET*	Rivaroxaban vs. warfarin
ARISTOTLE*	Apixaban vs. warfarin
CAT HF Arrhythmia Study*	OSA in HF patients with devices
CABANA*	AF ablation vs. medical Rx
GENETIC AF*	Genetic-guided BB dosing in AF
APPRAISE ATP*	Largest randomized ICD trial: ATP vs. no ATP
LUX-Dx PERFORM*	ICM remote programming efficacy
Novel Gene Therapy for Fabry Dz	Arrhythmia Monitoring for safety/ tolerability

**Trial completed*

Innovative. Efficient. Reliable.

DCRI CSI+

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

In addition to ACL 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.

ACL FACULTY

Sean D. Pokorney, MD, MBA, is the director of the Arrhythmia Core Laboratory. He is a clinical cardiac electrophysiologist and assistant professor of medicine at Duke University Medical Center and the Duke Clinical Research Institute. His focus is on the care of patients with heart rhythm disorders, particularly those with atrial fibrillation; complex arrhythmias; and lead and device management, with a focus on lead extraction. Dr. Pokorney serves on the Council of Clinical Cardiology Electrocardiography and Arrhythmias Committee for the American Heart Association. He has published extensive research in heart rhythm medicine, including notable publications in *JAMA, Lancet, Circulation, Journal of the American College of Cardiology, Heart Rhythm, JACC Electrophysiology,* and *Circulation Arrhythmia and Electrophysiology*.

Jonathan P. Piccini, MD, MHS, FHRS, is the founder of the Arrhythmia Core Laboratory. He is a clinical cardiac electrophysiologist and Professor of Medicine at Duke University Medical Center and DCRI. He is the Director of the Cardiac Electrophysiology section at the Duke Heart Center. His focus is on the care of patients with atrial fibrillation and complex arrhythmias, with particular emphasis on catheter ablation and lead extraction. His research interests include the development and evaluation of innovative cardiovascular interventions for the treatment of heart rhythm disorders. He serves on the Board of Trustees of the Heart Rhythm Society, is an Associate Editor at *JACC: Clinical Electrophysiology*, and is an elected member of the American Society for Clinical Investigation. Dr. Piccini has more than 550 publications in the field of heart rhythm medicine and has been the recipient of several teaching and mentorship awards.

DCRI ARRHYTHMIA CORE LAB LEADERSHIP

Sean Pokorney, MD, MBA
Medical Director,
Arrhythmia Core Lab
Assistant Professor of
Medicine, Cardiology

Jon Piccini, MD, MHS, FHRS
Founder,
Arrhythmia Core Lab
Professor of Medicine,
Cardiology

Zak Loring, MD, MHS
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Olivia Wolf, RN
Senior Project Leader,
Clinical Events Classification
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Learn more about the DCRI Arrhythmia Core Lab and CSI+

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