Message from the Executive Director

Let me begin by wishing all of you a wonderful holiday season. I hope you have opportunities to spend time with family and friends and reflect on our accomplishments of the past year. We have had another wonderful year at the DCRI, and I want to sincerely thank you for your collaboration and support of our mission.

We recently celebrated the accomplishments of one of our most distinguished faculty members, Dr. Kerry Lee. This event was held at the Washington Duke Inn in Durham and was widely attended by many researchers who have collaborated with Dr. Lee over his long, successful career. His work has greatly influenced the field of medicine in multiple ways. For decades, he has been a leader and teacher of biostatistics, and he conducted the statistical analyses for some of the most important cardiology clinical trials of the past decades, including GUSTO, SCD-HeFT, and STICH. He is one of the many members of the DCRI that make this place unique.

In this edition of the newsletter, we highlight many of the DCRI accomplishments in 2016 and also showcase exciting new opportunities ahead. You will notice that there are a variety of new innovative collaborations with the National Institutes of Health. With projects like the Trial Innovation Center and the ECHO study, we demonstrate our shared goal: to improve the care of patients and promote health through innovative research.

Happy holidays, and I look forward to working with you in 2017.

Eric D. Peterson, MD, MPH, FAHA, FACC
Executive Director
Duke Clinical Research Institute
Professor of Medicine, Cardiology
Fred Cobb Distinguished Professor of Medicine

The DCRI at AHA 2016

DCRI faculty, staff, and fellows were well-represented at this year’s annual Scientific Sessions of the American Heart Association in New Orleans. Visit dcri.org/dcri-aha to see news stories, videos, presentations, and more from the meeting.
The DCRI honors Kerry Lee

The DCRI recently held a retirement celebration for Kerry Lee, PhD, at the Washington Duke Inn. The event was attended by many of Lee’s friends and colleagues from throughout his long career at Duke. The DCRI’s Kevin Anstrom, PhD, and Michael Pencina, PhD, made formal remarks at the event.

“Kerry has been a tremendous influence on my career at Duke,” Anstrom later said. “There are a number of trials that would have never been completed had it not been for Kerry’s skillful leadership. Whenever difficult issues such as conflict of interest or authorship would arise, Kerry was the ideal mentor and counselor. To this day he is my go-to person when there is a surprise on a clinical trial. He set a very high standard for biostatisticians at Duke and DCRI.”

Lee became faculty leader of DCRI clinical trial biostatistics in 1985. He taught biostatistics for more than 20 years at both Duke and the University of North Carolina at Chapel Hill. Lee served on the editorial board for both the American Heart Association’s Circulation and the American Heart Journal. He also has chaired the American Statistical Association’s Biometrics Section and sat on the National Heart, Lung, and Blood Institute’s Clinical Trials Review Committee.

Lee coauthored dozens of peer-reviewed articles and conducted the statistical analyses of some of the most important cardiology clinical trials conducted by Duke, including the GUSTO studies, MUSTT, and MOST. He will continue to serve the DCRI and the Department of Biostatistics as Professor Emeritus.

Innovation Station

Researchers at the DCRI and Vanderbilt University Medical Center have received a major federal grant to study how multisite clinical trials of new drugs and therapies in children and adults can be conducted more rapidly and efficiently.

The seven-year, $26.5 million grant for a joint Trial Innovation Center (TIC) is supported by the National Center for Advancing Translational Sciences of the National Institutes of Health (NIH). The center will be a key component of the Trial Innovation Network, which is the newest part of the Clinical and Translational Science Award Program.

Danny Benjamin MD, MPH, PhD, faculty associate director of the DCRI, and Gordon Bernard, MD, director of the Vanderbilt Institute for Clinical and Translational Research, are the grant’s principal investigators.

“The DCRI and Vanderbilt partnership is a perfect fit for the TIC,” said Benjamin. “The academic research organization model at the DCRI and Vanderbilt’s informatics and central institutional review board model are poised to immediately contribute to the NIH’s vision of high-functioning networks for clinical research.”

Read more here.
Early Warning

Duke University could receive up to $19 million to lead early-stage clinical trials for new drugs to treat neurological conditions such as Alzheimer’s disease and neuropathy.

The National Institute of Neurological Disorders and Stroke, part of the National Institutes of Health, awarded the 10-year contract to Duke to design, manage, and conduct Phase I clinical trials. The trials will be conducted at the DCRI’s Early Phase unit. The Early Phase unit’s 34-bed study and observation facility is one of a small number of academic early phase research units in the country.

“This award reinforces Duke’s position as a leader in early-phase trials,” said Andrew Krystal, MD, director of the Neurosciences Medicine Research Program at the DCRI, who will serve as the principal investigator for the trials. “It’s an opportunity for faculty across multiple disciplines to contribute, and for Duke to be engaged at the ground level in the development of new treatments for neurological disorders.” Read more here.

A Breath of Fresh Air

Boehringer Ingelheim Pharmaceuticals, Inc. and the DCRI announced today the expansion of the Idiopathic Pulmonary Fibrosis – PROspective Outcomes (IPF-PRO) Registry, a patient registry developed to uncover insights into IPF, a rare and serious lung disease. The expansion will increase the study enrollment from 300 patients at 18 study sites to 1,500 patients at approximately 45 sites, creating the largest registry of newly diagnosed IPF patients.

The IPF-PRO Registry, which was launched in June 2014, was the first multicenter longitudinal disease state registry in the United States focused specifically on IPF. Boehringer Ingelheim and the DCRI have agreed to expand the IPF-PRO Registry based on the quality of the data and insights obtained from the first 300 patients enrolled in the registry and the growing scientific need for diverse, real-world data to understand IPF disease progression, disease history, patient-reported outcomes and disease biomarkers.

“Expanding the IPF-PRO Registry is important to the IPF community because it will substantially advance the understanding of this rare and fatal lung disease,” said Scott Palmer, MD, director of Pulmonary Research at the DCRI. “In collecting data from a larger, more diverse group of patients from multiple centers nationwide – all of whom are newly diagnosed with IPF – this registry will allow us to better assess the impact of the disease over time on clinical and patient centered outcomes.” Read more here.
**Feature**

**Kid Stuff**

The DCRI has been named the coordinating center as part of a $157-million federal initiative involved in studying how environmental factors affect childhood health.

The grant from the National Institutes of Health (NIH) will fund the organizational framework of the Environmental Influences on Child Health Outcomes (ECHO) initiative. The DCRI has been awarded $14.7 million in fiscal year 2016. This award is a seven-year grant with a total value of $119 million.

As the coordinating center for the research initiative, the DCRI will provide support to the study’s steering committee, lead site training for participating research teams, develop common rules and standard procedures, monitor quality controls, and establish and maintain websites and other communications tools.

The ECHO coordinating center at DCRI will also include an Opportunities and Infrastructure Fund to support pilot projects, encourage development of junior investigators, and introduce new tools and technologies in the context of the ECHO program.

“We are certainly honored to be selected as the coordinating center for this important research initiative at the NIH,” said principal investigator Brian Smith, MD, a Duke neonatologist and faculty member of the DCRI. “This builds on a number of our strengths in clinical research, notably in pediatric clinical research, where we have developed specific expertise.” [Read more here.](#)

**Selected Publications**

**Gait speed and operative mortality in older adults following cardiac surgery**

**Assessing agreement with relative area under the coverage probability curve**

**Statin utilization and recommendations among HIV- and HCV-infected veterans: A cohort study**

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SELECTED PUBLICATIONS

Implementing MACRA: Implications for physicians and for physician leadership

Change in angina symptom status after acute myocardial infarction and its association with readmission risk: An analysis of the Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients’ Health Status (TRIUMPH) Registry

Rationale and design of the Affordability and Real-world Antiplatelet Treatment Effectiveness after Myocardial Infarction Study (ARTEMIS): A multicenter, cluster-randomized trial of P2Y12 receptor inhibitor copayment reduction after myocardial infarction

1-year outcomes of FFRCT-guided care in patients with suspected coronary disease: The PLATFORM Study

Defining a mobile health roadmap for cardiovascular health and disease

Comparison of risk scores for the prediction of stroke in African Americans: Findings from the Jackson Heart Study

Clinicians’ adherence to guidelines on evaluation of hypertension in children and adolescents

Radioactive iodine treatment is associated with improved survival for patients with Hurthle cell carcinoma

Regional systems of care demonstration project: American Heart Association Mission: Lifeline STEMI Systems Accelerator

Improving conduct and feasibility of clinical trials to evaluate antibacterial drugs to treat hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia: Recommendations of the Clinical Trials Transformation Initiative Antibacterial Drug Development Project Team

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SELECTED PUBLICATIONS

**Risk factors and in-hospital outcomes following tracheostomy in infants**

**Rationale and design of the First Brazilian Cardiovascular Registry of Atrial Fibrillation: The RECALL study**

**Relationship of right ventricular size and function with respiratory status in Duchenne muscular dystrophy**

**Maladaptive aortic properties after the Norwood procedure: An angiographic analysis of the Pediatric Heart Network Single Ventricle Reconstruction Trial**

**The RENEW Trial: Efficacy and safety of intramyocardial autologous CD34(+) cell administration in patients with refractory angina**

**Cinacalcet, dialysate calcium concentration, and cardiovascular events in the EVOLVE trial**

**Safety and efficacy of rivastigmine in children with Down syndrome: A double blind placebo controlled trial**

**Frailty is associated with worse outcomes in non-ST-segment elevation acute coronary syndromes: Insights from the TaRgeted platelet Inhibition to clarify the Optimal strateGy to medically manage Acute Coronary Syndromes (TRILOGY ACS) trial**

**Risk of premature cardiovascular disease vs the number of premature cardiovascular events**

**Evaluation of compliance for treatment of sudden hearing loss: A CHEER Network study**