

# THE WAY FORWARD



ANNUAL  
REPORT  
**2019-2020**



**Duke** Clinical Research Institute

FROM THOUGHT LEADERSHIP  
TO CLINICAL PRACTICE

“The way forward is to use the best methods and learnings of the past while infusing them with innovative methods that enable research to be frictionless, flexible, and even fun.”

**Adrian Hernandez, MD, MHS**

Executive Director, Duke Clinical Research Institute

Vice Dean, Duke University School of Medicine

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## OUR MISSION

To develop, share, and implement knowledge that improves health around the world through innovative clinical research.

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## OUR VISION

To be the leading academic clinical research organization that:

- ▶ Generates world-class evidence to improve health;
  - ▶ Creates novel methods that accelerate clinical research;
  - ▶ Shares and implements knowledge widely;
  - ▶ Develops the next generation; and
  - ▶ Improves health equity through our research.
- 

## OUR VALUES

- ▶ Integrity
- ▶ Excellence
- ▶ Respect
- ▶ Diversity, Equity, and Inclusion
- ▶ Innovation
- ▶ Teamwork

# Welcome from the Executive Director



I am very proud to introduce this year's DCRI annual report and honored to have assumed the role as the Institute's new executive director this year. I have called the DCRI my research home for nearly 20 years. During this time, so much has changed in health care and research—and this year has been no exception. Leading the largest academic clinical research organization in the world through a global pandemic puts progress into perspective.

Like so many of us, this past spring, the DCRI pivoted to address quickly the challenges presented by SARS-CoV-2. From transitioning nearly 1,000 employees to remote working virtually overnight to keeping our trials and studies progressing without interruption, our faculty and operational teams stepped up and jumped in to contribute to the health and safety for all—here at home and around the world.

Our DCRI faculty have been directly involved in helping to establish COVID-19 guidelines for the National Institutes of Health (NIH). In April we launched a platform that creates a community of health care workers to address their needs through a registry and clinical trials, and we are proudly serving as the coordinating center for a multi-million dollar NIH program that will expand COVID-19 testing among underserved and vulnerable populations in the U.S.

Defining how research should be done and leading the way in doing it has been the bedrock of the DCRI, starting with our founding days of ushering in novel, data-driven approaches that advanced cardiovascular care for patients worldwide. Not surprisingly, therefore, ***The Way Forward*** is the theme for this year's annual report.

Inside you will find stories that demonstrate six fundamental qualities that form the foundation of how research will be conducted in the future—even after the coronavirus pandemic has subsided. Today and tomorrow, the DCRI is leading clinical research that is **rapid, embedded, efficient, impactful, disruptive, and inclusive**.

We also have evolved our mission statement to reflect our focus and impact on everyone, everywhere. Our updated mission statement reflects how our people come together to develop, share, and implement knowledge that improves health around the world through innovative clinical research. We are reimagining how we creatively conduct high-quality research that offers trusted answers for our sponsors, partners, and the patients we serve. We are committed to disseminating knowledge widely in order to move health forward. And we remain steadfast in developing the next generation of clinical researchers through our DCRI Fellowship Program.

The way forward is to use the best methods and learnings of the past while infusing them with innovative methods that enable research to be frictionless, flexible, and even fun. The way forward is through an Institute that remains an industry leader and delivers on its mission by finding new ways to do clinical research for high impact. The way forward is how we are doing research at the DCRI.

I am immensely proud of our people—thank you. I am deeply honored to serve alongside colleagues and collaborators to continually advance clinical research methods. And I am looking forward to our work together in leading the way forward for a better, healthier world.

A handwritten signature in black ink, appearing to read 'Adrian'.

**Adrian Hernandez, MD, MHS**  
Executive Director, Duke Clinical Research Institute  
Vice Dean, Duke University School of Medicine





“Rapid start-up of this critical COVID-19 research program required fast action and collaboration of everyone across the DCRI,” said Tyrus Rorick, DCRI’s head of research operations. “The HERO team relied on every functional group, from Grants and Proposals Services to Technology and Data Solutions to Biostatistics. We tested our resilience and resolve in leveraging our talent base and sharing resources—and it worked!”

In a landscape in which new information emerges daily, experts from across the DCRI have been engaged in critical decisions at both the local and federal levels. Naggie, who in addition to being a DCRI faculty member serves as the Duke University School of Medicine's Vice Dean for Clinical Research, was invited by Anthony Fauci, MD, the nation's leading infectious disease expert, to join a panel charged with shaping national COVID-19 guidelines.

DCRI investigators leveraged this expertise to examine pediatric doses of two potential COVID-19 treatments: hydroxychloroquine and remdesivir. Pharmacokinetic modeling for hydroxychloroquine revealed that the recommended adult and pediatric dosage of the drug was way below the level needed for a potential antiviral effect. These findings were cited in the U.S. Food and Drug Administration (FDA)'s decision to revoke the emergency use authorization it had issued for hydroxychloroquine. In addition, the PTN will study potential treatments used in pediatric COVID-19 cases to confirm their modeling data with data taken from patient care.

**Lauren Cohen, MA**

“There is no one-size-fits-all approach in returning to school safely, which is why we’re helping each district analyze local data specific to their community,” Zimmerman said. “When we equip schools with the information they need, they will be able to decide on procedures that keep students and their families safer and healthier.”

Beyond conducting COVID-19 research, DCRI faculty are also practicing physicians, and many of them provide care for patients with COVID-19. Because some cases are associated with cardiovascular complications, DCRI and Duke cardiologists worked together to create a care pathway for patients who have COVID-19 and are experiencing these complications.

**“When we equip schools with the information they need, they will be able to decide on procedures that keep students and their families safer and healthier.”**



**Kanecia Zimmerman, MD, MPH**

The framework, which was published in May in the *American Heart Journal*, outlined guidelines in order to streamline care, evenly distribute resources, and limit risk. The work, which was shared with other health systems to serve as a model, was led by DCRI cardiology fellow Rahul Loungani, MD, under the mentorship of DCRI cardiologist and Duke Heart Center Director Manesh Patel, MD.

## Launching a Nationwide Network

In addition to overseeing the creation of the COVID-19 care pathway, Patel has been involved in another effort that is targeted toward helping people across the country manage their COVID-19 symptoms.

The Pandemic Response Network offers a Community Health Watch program, which operates SMS text reminders and phone calls, as well as an online platform, to support people in monitoring their symptoms and caring for themselves at home.

The network is the brainchild of the Duke Institute for Health Innovation, but since its inception in April, many other Duke entities and external partners have signed on to help the effort, including Patel’s Duke Heart Center Clinical Research Unit. To date, over 7,000

people in 48 states have signed up for symptom monitoring. The DCRI is also providing digital services and other support to the project.



PANDEMIC RESPONSE NETWORK

**Over 7,000 people in 48 states have signed up for symptom monitoring.**

## Replicating Rapid Research

Although the pandemic will one day no longer be a threat, Hernandez doesn’t see any end in sight for rapid-cycle research. Traditionally, clinical trials have been criticized for their lengthy timelines—but the DCRI has proven it can launch quality research in a fraction of the time it would typically take to plan and implement a study.

**“Our ability to rapidly plan and launch studies correlates directly with our ability to quickly find the answers that patients need for improved quality of life and better outcomes.”**



**Adrian Hernandez, MD, MHS**

“I’m proud of our teams, who really took our mission to improve health to heart and worked day and night to ensure successful launches for our COVID-19 research,” Hernandez said. “But regardless of whether there’s a pandemic, we need to replicate this rapid response for other urgent health problems. Our ability to rapidly plan and launch studies correlates directly with our ability to quickly find the answers that patients need for improved quality of life and better outcomes.” ■



# EMBEDDED

## Leveraging real-world data to align research with patient care

This year, the DCRI completed the first randomized controlled trial that fully leveraged a new real-world data system from the U.S. Food and Drug Administration (FDA).

Researchers built the IMPACT-AFib trial entirely on data from the FDA-Catalyst System and Sentinel System network of electronic health records (EHRs), as well as insurance claims data from a diverse group of data partners. The trial randomized 80,000 patients with atrial fibrillation to test whether an intervention would improve use of anticoagulants. Results were presented in late summer 2020 at the European Society of Cardiology Congress. IMPACT-AFib, which was led by DCRI's Sean Pokorney, MD, MBA, lays the groundwork for future clinical trials that are embedded in clinical care by using real-world data collected during the course of care.

**“The trial itself was a success, as it demonstrated that it is possible to conduct a clinical trial entirely using embedded real-world data.”**



**Sean Pokorney, MD, MBA**

“The effort was truly a collaboration, with the Clinical Trials Transformation Initiative, Harvard, DCRI, a patient representative,

the FDA, and the data partners (insurance companies) working together closely in order to successfully complete the trial,” Pokorney said. “The actual intervention the trial was testing was not found to be effective—we found out that educational mailers sent to people with atrial fibrillation did not increase usage rates of stroke-preventing oral anticoagulants. However, the trial itself was a success, as it demonstrated that it is possible to conduct a clinical trial entirely using embedded real-world data.”

### Enabling Use of Real-World Data

Most of DCRI's investigators are also clinicians who care for patients. Finding ways to embed research into care helps them to align their research questions with their experience in the clinic, resulting in questions that are more clinically relevant and results that can be implemented into patient care more quickly. Embedded research also has other advantages; for example, it may alleviate participation burden for both patients and sites. In particular, leveraging data that have already been collected reduces data collection burden for research purposes.

Real-world data can be drawn from many different sources, including claims data that document patients' clinical encounters, EHRs used within hospitals and clinics, and wearable devices and apps that allow people to track or enter their own data. And as real-world data becomes recognized as increasingly important—

for example, the FDA has issued guidance on its use—it becomes even more critical to select the right data sources.

“One of the things that’s unique to the DCRI is that we have our finger on the pulse of the landscape of data opportunities,” said Tracy Wang, MD, MHS, MSc, director of DCRI Health Services Research. “We have the expertise to match-make, to pick and choose the best data sources that are fit-for-purpose to answer a specific research question.”

## Creating Data Repositories

The DCRI is known for its expertise in conducting randomized controlled trials, but many of its investigators also engage in another major form of evidence generation by designing and overseeing clinical registries.

“The benefit of registries is that they are embedded in patient care as closely as possible,” said Beth Fraulo, RN, BSN, director of operations for DCRI Health Services Research. “Once patients sign up to be part of a registry, cross-sectional or longitudinal data are collected from their routine clinical care without requiring extra site visits. Registries also allow us to examine a wider, more representative section of the patient population than clinical trials.”

**“We have the expertise to match-make, to pick and choose the best data sources that are fit-for-purpose to answer a specific research question.”**



**Tracy Wang, MD, MHS, MSc**

One longstanding registry coordinated by the DCRI is the Childhood Arthritis and Rheumatology Research Alliance (CARRA) Registry, created in 2015 to fill a gap in research on pediatric rheumatic diseases. The registry, led by DCRI pediatric rheumatologist Laura Schanberg, MD, since its inception, has enrolled over 10,500 children and adolescents to date—and continues to grow. This year, the registry further embedded into patients’ lives by

enabling telehealth follow-up visits when COVID-19 restrictions limited the viability of in-person clinic visits.

The CARRA Registry serves as a data and biological sample repository, providing opportunities for a variety of research projects, identifying participants eligible for future studies, and continuing to collect data into adulthood. This year, the registry helped identify patients with lupus for enrollment in the DCRI-led iPERSONAL study, DCRI’s first direct-to-family trial, which aims to study dosing and medication adherence for teenagers with lupus.



**Enrolled over 10,500  
children and adolescents to date**

The infrastructure of the registry also enables the DCRI-led LIMIT-JIA trial, which is investigating a potential treatment for juvenile idiopathic arthritis, to be fully embedded within the registry. This benefits the team behind the trial, as they can access data already collected by the registry via regular patient visits. The trial team also benefits from working with existing registry infrastructure, such as clinical sites, investigators, and research coordinators who are already accustomed to conducting research because of their involvement in the registry. Most importantly, follow up of the patients in the trial will continue long term, well after the LIMIT-JIA trial protocol-specified follow-up is complete.

**“The benefit of registries is that they are embedded in patient care as closely as possible.”**



**Beth Fraulo, RN, BSN**

“We initially decided to create the Pediatric Migraine Registry because we thought a real-world registry would be a good way to address challenges we were seeing in pediatric migraine drug development,” Hornik said. “The registry, which collects regulatory-compliant data, provides an ideal platform to support embedded trials in this space.”

Another DCRI registry has seen such rapid success that it expanded into another registry this year. DCRI pulmonologist Scott Palmer, MD, MHS, and his team have begun enrollment for the Interstitial Lung Disease-Pro prospective Outcomes (ILD-PRO) Registry.

**Scott Palmer, MD, MHS**

“Because the IPF-PRO Registry has been a proven success, our partners in this project, Boehringer Ingelheim, were confident that this model would also be effective in studying interstitial lung diseases,” said Palmer, who is the principal investigator for both registries and DCRI therapeutic area lead for Medicine Plus. “We look forward to collecting a new repository of data to help us make new discoveries in an equally challenging lung disease.”

Some registry teams also pull data from the EHR to add more power to their insights. cvMOBIUS, a large-scale cardiovascular registry operationalized by the DCRI, seeks to determine the benefits of PCSK9 inhibitors, a lipid-lowering therapy. The registry team will enroll 8,500 patients, and they will also utilize the Cerner network and PCORnet®, the National Patient-Centered Clinical Research Network, to access EHR data, enabling the study to include an even wider population of patients. This work will help them better understand widespread patterns pertaining to PCSK9 inhibitor prescribing rates, adherence, and outcomes.

RAPID ▶ **EMBEDDED** ▶ EFFICIENT ▶ IMPACTFUL ▶ DISRUPTIVE ▶ INCLUSIVE

we still face gaps in improving secondary prevention in cardiovascular disease.”

## Studying Implementation via Registry-Based Trials

Traditionally, clinical trials have been conducted to determine the effectiveness of a medication, or to find out whether one medication is superior to another. At the DCRI, clinical trials are also utilized to study implementation.

“Often, the field has proven treatments or strategies that we know should be used, but on average, it takes 15 to 20 years for this evidence to be implemented into practice across the board,” Fraulo said. “That’s where implementation trials come in. We look at the best way to implement evidence and consider a number of different stakeholders, from the health system to the clinician to the patient.”

**“By embedding this registry into regular practice, and by pulling EHR data alongside our registry data, we’ll be able to evaluate the real-world impact of new therapies.”**



**Linda Davidson-Ray, MA**

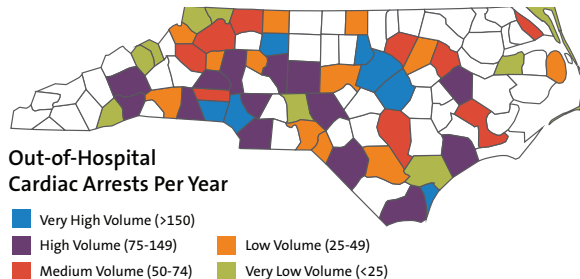
One example of an implementation trial is RACE-CARS, a study funded by the National Institutes of Health (NIH) that will test the implementation of community interventions designed to improve survival for people who experience cardiac arrest.

Fifty counties across North Carolina, encompassing over 80 percent of the state’s population, will be enrolled into RACE-CARS. Because RACE-CARS is designed to be a cluster randomized study, participating counties will then be randomized to either a multifaceted intervention or to usual care.

RACE-CARS is built from the existing Cardiac Arrest Registry to Enhance Survival (CARES), with the entire eligible population of each participating county automatically enrolled with waiver of informed consent from individual patients, making the registry-based trial even more relevant to the study population.

The study intervention, which targets laypeople in the community, emergency medical technicians, and first responders, is focused on improving recognition of cardiac arrest, initiation of CPR, and use of defibrillators, using an integrated approach with audit and feedback. The investigators will then compare outcomes and survival rates between the intervention counties and the counties that continued with usual care.

## RACE-CARS will enroll 50 counties in N.C., encompassing over 80% of the state’s population



“RACE-CARS will create high-quality evidence about how to implement guidelines at the community level to improve survival from cardiac arrest, one of the top causes of death,” said DCRI cardiologist Christopher Granger, MD, co-principal investigator of the study. “Because we’ve designed the study to be embedded within the day-to-day operations of each community and its health systems, it will not only be easier for counties to participate in the study, but it will ensure that study results are highly relevant to similar communities around the U.S.” ■

## Incorporating pragmatic elements to streamline research

“Not only do we need to understand how to use existing antibiotics safely in children, but we need to develop new antibiotics, as many of the existing ones become ineffective with the emergence of antibiotic-resistant infections,” Hornik said. “Many smaller pharmaceutical companies are working on this problem, but they may not have the resources to run clinical trials for each separate drug. That’s where our master protocol comes in to provide the infrastructure and support needed to make research more efficient.”

Pragmatic approaches can be used throughout a study's lifecycle, from recruitment to data collection to dissemination of results. Pragmatic elements in clinical trials have the potential to alleviate burdens for study sites, but more importantly, they also can help address barriers to research participation, ensuring that DCRI's pragmatic research is participant-centered research.

“We are uniquely positioned to help our partners utilize the appropriate pragmatic elements in their studies to enable more efficient research with valid results.”

**Robert Mentz, MD**

## Planning: Designing Studies that are Efficient and Adaptive

The study, ACTIV-1, is part of the National Institutes of Health (NIH)'s Accelerating COVID-19 Therapeutics Interventions and Vaccines (ACTIV) initiative. ACTIV-1 will initially test three immune modulators that may prevent the overactive immune response that occurs in some severe COVID-19 cases. The trial will study how these three drugs impact severity of illness, speed of recovery, mortality, and hospital resource utilization.

“This protocol design is more efficient because it tests all three drugs at once and requires enrollment of fewer patients.”

**Danny Benjamin, MD, PhD, MPH**

“We don’t know if giving any of these immune modulators will work, but we know that several might work,” Benjamin said. “Traditionally, these three drugs would have to be tested in three separate protocols, with 500 patients in each protocol receiving the study drug and 500 receiving a placebo—so 3,000 patients total. This protocol design is more efficient because it tests all three drugs at once and requires enrollment of fewer patients—540 will be assigned to each drug and another 540 will receive placebo, for a total of only 2,160 participants.”

# ACTIV-1

DCRI investigators are also involved in another component of the ACTIV program, ACTIV-4, which consists of adaptive trials conducted in three different care settings: outpatient, hospitalized patients, and recently discharged patients.

DCRI faculty are involved in all three of these trials, which are examining optimal use of oral anticoagulants to prevent COVID-19-associated blood clots. DCRI cardiologist Tracy Wang, MD, MHS, MSc, who is co-leading the post-discharge trial along with Duke hematologist Thomas Ortel, MD, PhD, explained the benefits of ACTIV-4's adaptive design.

“The adaptive design enables us to be as efficient and as patient-centered as possible; if the treatment shows early signals of efficacy, patients can switch from placebo to treatment to give them the best chance at positive outcomes,” Wang said. “COVID-19 has been an incentive to accelerate the adoption of adaptive design, and we will now be able to apply this iterative research model to other clinical areas so that we can recycle research infrastructure and find answers faster.”

When designing studies, DCRI investigators ensure patients are at the forefront so that research will answer questions that can improve their medical care and quality of life.

“By setting broad inclusion criteria and excluding fewer patients, we were able to efficiently enroll a trial population that is representative of patients typically seen in clinical practice.”

## Kevin Anstrom, PhD

“By setting broad inclusion criteria and excluding fewer patients, we were able to efficiently enroll a trial population that is representative of patients typically seen in clinical practice,” Anstrom said. “That means the results from this trial will be easier to implement in clinical care and more likely to work for a wide range of patients.”

DCRI's expertise in implementing pragmatic approaches has also been beneficial in adapting to challenges introduced by the COVID-19 pandemic.

**4 months** into enrollment  
**14%** of participants enrolled  
completely remotely

Wang and DCRI cardiologist John Alexander, MD, MHS, lead PROACT Xa, a cardiology trial testing whether patients with an On-X mechanical aortic valve can safely and effectively take apixaban rather than warfarin. The trial was just beginning enrollment when the pandemic reached the U.S. and curtailed in-person research. Fortunately, the study had already been designed with in-home study drug delivery for all participants. The study team, determined to maintain momentum, was also able to successfully implement remote enrollment—and by four months into enrollment, an unprecedented 14 percent of participants had been enrolled completely remotely in this investigational new drug trial.

## Data Collection and Integration: Leveraging Real-World Environments for Real-World Applications

Because research often requires data from multiple disparate sources, the DCRI has created and incorporated mechanisms for making data collection and integration more efficient.

One study launched this year, EMPACT-MI, is introducing efficiencies by collecting the data needed for the trial through a patient portal. The study, led by DCRI Executive Director Adrian Hernandez, MD, MHS, is exploring whether empagliflozin can prevent heart failure in people who have had a heart attack. In some cases, only the initial site visit will be required, and all other data collection will occur remotely.



Another way the DCRI is incorporating efficiencies in data collection is through the DCRI Master Data Management Repository (MDMR) program, which DCRI's Technology and Data Solutions group has created as a way to integrate and harmonize data into research and analysis datasets.

**“The DCRI has been able to lead in this space and define the ideal implementation to make working in this new data environment as efficient as possible.”**



**Andrew MacKelfresh, MBA**

A pragmatic trial called HiLo, led by DCRI nephrologist Myles Wolf, MD, MMSc, was the first to use the MDMR program. HiLo seeks to determine whether a higher versus a lower blood phosphate level alters clinical outcomes in patients who are receiving dialysis for end-stage renal disease. Study data are drawn from each dialysis center's electronic health record (EHR) system and, through the MDMR, are harmonized at the DCRI in preparation for statistical analysis and reporting.

“With trends in the industry like the use of telemedicine and direct access to data, there are more sources of data and models to support in every research project,” said Andrew MacKelfresh, MBA, a DCRI clinical research informatics project leader. “The DCRI has been able to lead in this space and define the ideal implementation to make working in this new data environment as efficient as possible.”

The DCRI also introduces efficient methods of data collection through its work on collaboratives such as the Lung Transplant Clinical Trials Network (LT-CTN), a group of five adult lung transplant programs (Duke University, Cleveland Clinic, Johns Hopkins University, UCLA, and the University of Toronto).

The LT-CTN, which is supported by the National Institute of Allergy and Infectious Disease, was formed to address the important problem of chronic lung allograft dysfunction (CLAD), the leading cause of death after lung transplant.

The CTOT-20 study, which was developed by the LT-CTN, employs innovative and pragmatic approaches to data collection by enabling patients to enter their own outcome data directly into an online portal. The study team also interfaces directly with sites' local pulmonary function testing (PFT) laboratories to gather PFT test results obtained during routine clinical care.

The study also uses a novel approach to identify CLAD development through an objective CLAD calculator. Sites perform the final adjudication, ensuring objective and reproducible identification of the condition in real time as it develops. Analysis of these CLAD cases, coupled with translational analysis of biological samples, are providing new insights into the mechanisms that lead to CLAD.



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Another collaborative and efficient study overseen by the DCRI is made possible through a partnership with the U.S. Department of Veterans Affairs (VA). The study team of AIM-Back, a pragmatic trial co-led by DCRI physical therapist and musculoskeletal expert Steven George, PhD, PT, and S. Nicole Hastings, MD, MHS, will be conducting the trial at 16 VA sites.

In an effort to improve lower back pain, the trial will randomize the VA sites to one of two clinical pathways: either guideline adherent care coordinated by a pain navigator or sequenced care combining short-term physical therapy on-site at the local VA with

by the DCRI disseminates results by creating plain-language summaries for many of the studies it conducts.

## Environmental influences on Child Health Outcomes

**Leo Brothers, MPH**

“By asking investigators to pull out the high-level information about their study results, we are helping them to efficiently share with other researchers and parents important research that is being done around the country.”

**Adair Brown**

The plain-language summaries, a relatively novel approach, are one- to two-page reports that share results of a study in a clear and concise way that patients and their families can understand. The summaries also focus on the study's impact and next steps related to its findings.

“By asking investigators to pull out the high-level information about their study results, we are helping them to efficiently share with other researchers and parents important research that is being done around the country,” said Adair Brown, a member of DCRI’s Research and Communications Engagement group who helps to edit and produce the summaries. ■

The Environmental influences on Child Health Outcomes (ECHO) program coordinated



# IMPACTFUL

## Guiding policy, regulatory science, and best practices

In 2019, the U.S. Food and Drug Administration (FDA) issued a new guidance document that featured significant contributions from DCRI pediatricians. The guidance document provides the most up-to-date data and information for conducting research in a traditionally challenging population—newborns.

The DCRI Pediatrics group developed the data that contributed to this FDA guidance over a decade of novel research conducted in conjunction with the Pediatric Trials Network (PTN), a nationwide research network focused on making drugs safer and more effective for children. The PTN is coordinated by the DCRI and funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

“We are pleased that our thought leadership and expertise was reflected in this critical FDA guidance document,” said Micky Cohen-Wolkowicz, MD, PhD, one of the DCRI pediatricians who led this effort.



**PEDIATRIC  
TRIALS NETWORK**

Making drugs safer & more effective  
for use in the youngest patients

“By sharing knowledge that helps to bring clarity to an area where there previously may not have been clear guidance, we can have a significant impact on pediatric drug development, which will help pediatricians everywhere improve care for our most vulnerable patients.”

Since its inception in 2010, the PTN has provided data that have contributed to 15 FDA label changes, meaning that the prescribing information was updated to include pediatric dosing guidelines.

**“Through the PTN’s research, we are providing much-needed data to the FDA and really moving the needle on drug safety and effectiveness for children.”**



**Kanecia Zimmerman, MD, MPH**

“The work of the PTN is so critical because as clinicians, we often don’t know the proper dosages for children, and we have to make inaccurate estimates based on adult dosages,” said DCRI pediatrician Kanecia Zimmerman, MD, MPH, chair of the PTN steering committee. “Through the PTN’s research, we are providing much-needed data to the FDA and really moving the needle on drug safety and effectiveness for children.”

## Informing FDA Decision-Making

In addition to pediatric research, DCRI thought leadership has been considered by the FDA in many other efforts, such as refining the agency's guidance on collection of real-world evidence.

“Over the years, the DCRI has established itself as an objective resource for generating and interpreting evidence,” said DCRI Executive Director Adrian Hernandez, MD, MHS. “DCRI faculty are known for their ability to identify next steps and determine a path forward.”

In 2019, results from a DCRI-led patient preferences survey were presented to an FDA advisory committee tasked with deciding whether esketamine should be approved for use in treatment-resistant depression. The survey, which was designed by DCRI's Preference Evaluation Research (PrefER) group, assessed individuals' willingness to accept certain risks associated with taking the treatment in exchange for certain benefits. When the FDA ultimately approved the treatment, several of the panelists noted that the evidence generated by the survey helped to inform their decision.

**“Over the years, the DCRI has established itself as an objective resource for generating and interpreting evidence.”**



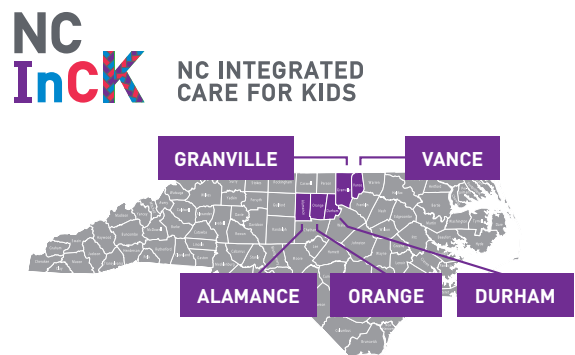
**Adrian Hernandez, MD, MHS**

“Studies such as these can be helpful to reviewers who are charged with making value judgements about benefit-risk tradeoffs on behalf of patients,” said Shelby Reed, PhD, who led the study and serves as DCRI therapeutic area lead for Population Health Sciences Research. “In this instance, the impact of this survey and its results prove the importance of taking patient preferences into account.”

## Breaking Down Siloes Locally

Another collaborative project led by a DCRI pediatrician aims to design and implement a new care delivery and payment model for children's health at the state level. The goal of the project, which is called North Carolina Integrated Care for Kids (NC InCK) model and funded by the Centers for Medicare & Medicaid Services, is to partner with communities to support and bridge services where children live, learn, and play.

The initiative, a joint effort between Duke University, University of North Carolina at Chapel Hill, and the North Carolina Department of Health and Human Services, will serve Medicaid-insured children in five central North Carolina counties from birth up to age 20. The effort will span a wide range of services, including physical and behavioral health, housing and food security, schools, early care and education, child welfare, mobile crisis response services, public health, juvenile justice, and legal services.



“The NC InCK model is a tremendous opportunity for us to transform how we support the well-being of children and their families by breaking down siloes and working together across many different systems,” said DCRI's Charlene Wong, MD, MSHP, executive director of the initiative. “By establishing partnerships, linking data, and better integrating services, we hope to address some of the root causes of poor health and help the state better serve the children it seeks to help.”

Ultimately, findings from the project will be leveraged to create innovative and sustainable pediatric alternative payment models under the state's Medicaid program. The project, which was funded in late 2019, is in the planning phase, with five years of implementation set to begin in 2022.

## Enabling Discoveries by Sharing Data

In addition to conducting its own impactful research, the DCRI bolsters the research of others by making efforts to improve open science. DCRI's Supporting Open Access for Researchers Initiative (SOAR) oversees all DCRI data sharing activities.



DCRI SOAR provides an independent review committee for datasets from Bristol Myers Squibb, examining factors such as the articulation of the research question and the quality of the statistical analysis plan. Since the group's inception in 2014, it has reviewed nearly 40 different data requests, with the number of requests increasing year-over-year. The group also makes DCRI data available for sharing, such as the Duke Cath dataset, which offers data for both educational purposes and for research. Data requests for this source have come from industry sponsors, fellow academic researchers, and nonprofit organizations.

"By making these datasets available, we're not only encouraging transparency, but we're helping other researchers build on work that has already been done," said Rebecca Wilgus, RN, MSN, a DCRI clinical informatics project leader. "By enabling others to use our datasets and reviewing requests for data, we're helping research be used for more than its original purpose, which allows us to have an even wider impact."

DCRI faculty also contribute influential thought leadership in the data sharing space. This year, Hernandez and DCRI faculty statistician Frank Rockhold, PhD, contributed to a paper making recommendations for the National Institutes of Health (NIH)'s newly updated data sharing policy.

**"By enabling others to use our datasets and reviewing requests for data, we're helping research be used for more than its original purpose, which allows us to have an even wider impact."**



**Rebecca Wilgus, RN, MSN**

"While the NIH has already made significant steps in the realm of data sharing, we have provided recommendations for actions they can take to truly advance open science," Rockhold said. "By investing the effort to create a culture of data sharing now, the NIH and other entities will be setting the stage for a future of efficient and innovative clinical research."

## Developing the Next Generation of Clinical Trials

DCRI's impact does not stop at guiding policy and regulatory science. The Institute is also helping to shape how the next generation of research will be conducted through its role as the coordinating center for the NIH Health Care Systems Research Collaboratory.







## Harnessing cutting-edge methods and technologies to forge a path for research and care

In his role as a clinical psychologist, DCRI's Scott Kollins, PhD, cares for children with attention deficit hyperactivity disorder (ADHD). He knows firsthand the challenges his patients and his families face. So when an opportunity arose to align his research with what he was seeing in the clinic, he jumped at the chance.

Several years ago, Akili Interactive Labs sought to validate its claim that EndeavorRx, a video game it had developed, would improve attention in children between ages 8 and 12 with diagnosed ADHD. The company asked Kollins and a DCRI study team to design and conduct a clinical trial that would examine the video game's efficacy.

Fast forward to this year, and that trial, along with other study data generated through DCRI-led studies, contributed to a precedent-setting decision from the U.S. Food and Drug Administration (FDA)—now, for the first time, a video game can be prescribed as a therapeutic.

The decision came after DCRI's studies not only proved that EndeavorRx compared with standard video games improved attention, but also that it was effective whether or not children were concurrently taking medication for ADHD, and that the effects continued to improve over time.

“All clinicians know that treatment plans are not one size fits all,” Kollins said. “We originally

took on this study because we were intrigued by the possibility of expanding treatment options for kids who are diagnosed with ADHD. Now, the FDA has enabled this expansion by approving prescriptions of EndeavorRx. The fact that our study data helped to support this first-of-its-kind decision really underscores the reliance of regulatory bodies on these kinds of clinical data when assessing novel digital therapeutics.”

“The fact that our study data helped to support this first-of-its-kind decision really underscores the reliance of regulatory bodies on these kinds of clinical data when assessing novel digital therapeutics.”

**Scott Kollins, PhD**

Kollins' work on the Akili studies inspired him to delve deeper into the emerging field of digital therapeutics—and led to the launch of a new research group at the DCRI.

## Novel Apps, Clinical Applications

The group, called DCRI Digital Health Solutions, comprises DCRI investigators who partner with

DCRI's Satasuk Joy Bhosai, MD, MPH, co-directs the group with Kollins. Bhosai is a hospital medicine physician whose clinical experience equips her with the ability to discern whether an innovative idea will be translatable in a real-world clinical setting.

The work of DCRI Digital Health Solutions can help advance digital health applications to disrupt research and can also help technology companies gain a competitive edge. Competition in the industry is fierce, and companies are beginning to pursue rigorously designed and conducted clinical studies to bolster marketing claims and differentiate themselves from competitors.

**DCRI DIGITAL**  
HEALTH SOLUTIONS

**Satasuk Joy Bhosai, MD, MPH**

Digital health technologies can also help people take more of an active role in managing their own health. In some cases, these technologies enable participation in clinical research from the comfort of a patient's own home.

“We’re really flipping the traditional site-based research model on its head,” said Lindsay Singler, MPH, project leader for the study, which is being led by DCRI adult and pediatric rheumatologist Stephen Balevic, MD, MHS. “Through our new direct-to-family research offering from the DCRI, we are using technology and mobile research teams to expand access to studies beyond a clinic or site, making it less burdensome for patients and their families to participate.”

While iPERSONAL's remote delivery was planned from the study's outset, other DCRI studies adapted a hybrid or virtual model mid-study this year. When the COVID-19 pandemic halted most in-person research activities, some study teams responded to the disruption with a plan to conduct disruptive research.



**iPERSONAL**

Individual Patient Exposure and Response in Pediatric Lupus

**“Through our new direct-to-family research offering from the DCRI, we are using technology and mobile research teams to expand access to studies beyond a clinic or site, making it less burdensome for patients and their families to participate.”**



**Lindsay Singler, MPH**

One of these studies is testing whether a digital health device made by Sana Health will help alleviate fibromyalgia-related impairment. When the study team realized that the COVID-19 pandemic would necessitate adaptations, they shifted every component of the study to remove all in-person interactions, figuring out everything from how to build an e-consent platform to how to ship the study device or control device directly to participants' homes.

The study team also relied on technology to automate some study processes; for example, in cases of noncompliance, the app will automatically send reminder text messages rather than a coordinator following up with a phone call. This approach is particularly innovative because it conserves resources, said Anthony Cunningham, manager of DCRI's small trials program.

“This was already a study testing an innovative product, but now we've had to consider ways to innovate the research delivery, as well,” Cunningham said. “For example, now that we won't be seeing patients face-to-face at a clinical site, we've thought of new ways to engage them, such as creating a video and a quick reference guide to help familiarize participants with using their devices.”

## Creating Space for Disruptive Discussions

Not only is the DCRI implementing virtual delivery of its own trials, but the Institute is also leading industry-wide discussions on how to best chart the path forward for these kinds of trials through the DCRI Think Tanks program.

DCRI Think Tanks invite executives with clinical, industry, and regulatory expertise to participate in multi-day discussions about challenges and opportunities for the future of clinical research. Takeaways from DCRI Think Tanks are typically published in academic journals, helping to advance the discussion within the scientific community. In July 2020, the DCRI hosted a virtual think tank focused on direct-to-patient, virtual, and hybrid trials—an especially important discussion in the COVID-19 era.

Past DCRI Think Tanks have also focused on research opportunities presented by novel digital tools and the proliferation of real-world data these tools are able to collect. A January 2020 think tank discussed applications for machine learning in research and potential ethical issues.

“Through DCRI Think Tanks, we've created this pre-competitive space for not just open exchange of ideas, but articulation of the barriers and pain points, as well as discussion of how to solve them,” said DCRI population health scientist Lesley Curtis, PhD, faculty director for the program. “This environment is ideal to discuss how we will move forward as an industry while smoothly integrating truly disruptive technologies and methods.” ■



# INCLUSIVE

## Focusing on equity and addressing health disparities

In the midst of responding to the COVID-19 pandemic, another acute issue rose to the nation's consciousness: systemic racism. In response to police killings of Black individuals, protests were organized across the country in support of the Black Lives Matter movement, which seeks to "eradicate white supremacy and build local power to intervene in violence inflicted on Black communities," according to the organization's website.

At home at the Duke University School of Medicine, leaders held a walk of solidarity to show support for Black colleagues and hosted virtual forums to engage the school community in discussions around current events. Even closer to home, the DCRI is making concerted efforts to better listen to its faculty and staff of color and create an inclusive and equitable place to work. To accomplish these goals, the Institute has established two new initiatives geared toward transformational change in both DCRI's culture and its research mission.

### A Commitment to Critical Self-Reflection

The two executive-sponsored initiatives are overseen by DCRI Executive Director Adrian Hernandez, MD, MHS, and Kevin Thomas, MD, a DCRI cardiologist whose research has long focused on racial health disparities in cardiovascular disease.

The first of the initiatives involves examination of DCRI's people, policy, and practices in order to critically address systemic racism within the Institute and build a path forward to a more inclusive and equitable DCRI. The goal is to leverage DCRI's history and experience to inform solutions for the future and to establish new, antiracist practices and policies.

**"Before we embark on vision-setting for DCRI's future, it is critical to examine our past and conduct a situational analysis of the circumstances that have led to this moment. I'm excited for the opportunity to lead meaningful change within the Institute."**



**Gerald Bloomfield, MD, MPH**

DCRI cardiologist Gerald Bloomfield, MD, MPH, and DCRI clinical psychologist Scott Kollins, PhD, are co-leading the initiative, with LaWillette Wilkins, MBA, associate director for DCRI Grants and Proposals Services, serving as the operations co-lead. The project facilitators are Silvana Lawvere, PhD, associate director for DCRI Clinical Trial Statistics, and Anne-Marie Elliott, administrative manager for DCRI Biostatistics.

“Before we embark on vision-setting for DCRI’s future, it is critical to examine our past and conduct a situational analysis of the circumstances that have led to this moment,” Bloomfield said. “I’m excited for the opportunity to lead meaningful change within the Institute.”

## Addressing Racial Health Disparities

In addition to reviewing people, policy, and practices, the DCRI is also examining its research through its second initiative, which aims to establish a roadmap for the Institute in health equity research.

“I look forward to both making improvements within the DCRI and seeing our teams pursue health equity research with renewed emphasis,” Hernandez said. “Although the DCRI has done some impactful work in this area, it is clear that we can and should make an effort to pursue more equity-focused research. Addressing these critical disparities was one of my goals when I stepped into the executive director role, and I am gratified that a team led by our own people are formulating a plan that we will implement.”

**“Due to the national and global climate around inequality and racism, we at the DCRI have a responsibility to initiate and implement strategies to effect change for future research.”**



### Linda Davidson-Ray, MA

The health equity initiative is co-led by biostatistician Laine Thomas, PhD, and pediatrician Kanecia Zimmerman, MD, MPH, with Linda Davidson-Ray, MA, associate director of clinical trial operations for DCRI Outcomes, serving as operational co-lead. Helen Bristow, MPH, a clinical trials project leader, and Tedryl Bumpass, CCRA, a lead clinical research associate, serve as project facilitators.

“I’m honored to co-lead the effort to expand DCRI’s health equity research platform,” Davidson-Ray said. “Due to the national and global climate

around inequality and racism, we at the DCRI have a responsibility to initiate and implement strategies to effect change for future research. In addition, the team is passionate about designing pathways for the DCRI to meet these goals.”

## Examining Associations Between Race and Outcomes

In addition to co-leading one of the DCRI equity initiatives, Bloomfield is in the midst of leading an observational study funded by the National Institute on Minority Health and Health Disparities and designed to help individuals from underrepresented racial and ethnic minority groups who are living with HIV.

Data show that even if people living with HIV are at high risk for heart disease, they often do not receive the proper referrals to see cardiologists. By conducting hour-long interviews with patients, cardiologists, and doctors who treat HIV, Bloomfield’s study aims to better understand these barriers to referral, how they are exacerbated for minority patients, and impacts on patient outcomes. Ultimately, the goal is to improve quality of care and access to care for these patients.

To assess patterns and outcomes for cardiology referrals for patients with HIV, Bloomfield is leveraging PCORnet®, the National Patient-Centered Clinical Research Network, which involves hundreds of health systems across the U.S. Because the Southeast bears the greatest burden of cardiovascular disease and HIV, the study team is working closely with institutions in the STAR Clinical Research Network—which is part of PCORnet—in North Carolina, South Carolina, and Tennessee. This will help Bloomfield and the study team determine whether cardiology referrals are being made appropriately and whether referrals are associated with clinical outcomes.

“People living with HIV from historically marginalized racial and ethnic groups are telling us that they face multiple obstacles when they are referred to a cardiologist,” Bloomfield said. “Through our interviews, we are starting to uncover system-level problems, and in the next stage, we will link these findings with quantitative outcomes data.”

DCRI gastroenterologist and hepatologist Julius Wilder, MD, PhD, also is focused on exploring health disparities. He is leading a project that seeks to define barriers that people from underrepresented racial and ethnic minority groups face when they undergo evaluation to be added to the liver transplant list. Like Bloomfield's study, Wilder's study will collect both quantitative and qualitative data gleaned from surveys and interviews about people's perceived barriers.

"We know that nationwide, African Americans are significantly less likely to be listed for a liver transplantation even when they qualify," Wilder said. "This study will help us identify any barriers that exist within the Duke Health System and make recommendations to improve health equity in this space."

## Meeting Pressing Needs

In addition to promoting health equity within long-term conditions such as HIV and cardiovascular disease, the DCRI is also examining how acute health crises like the COVID-19 pandemic disproportionately impact underrepresented minorities and other vulnerable populations.

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# RADx<sup>SM</sup>-UP

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In fall 2020, the National Institutes of Health (NIH) selected the DCRI, along with partners UNC Center for Health Equity Research and Community-Campus Partnerships for Health, to become the coordination and data collection center for a program called Rapid Acceleration of Diagnostics for Underserved Populations (RADx<sup>SM</sup>-UP). The program seeks to increase COVID-19 testing and future vaccine uptake in historically marginalized populations. The program will focus not only on racial and ethnic minorities, but also on pregnant women, those experiencing homelessness, older adults, children, and people who are incarcerated.

"We are proud to support this national response with innovative clinical research and community-based outreach to help improve

COVID-19 outcomes for our most vulnerable patients," said Micky Cohen-Wolkowicz, MD, PhD, the DCRI principal investigator for the project.

## Looking to a More Equitable Future

DCRI's commitment to diversity and equity does not end with its own processes and research. DCRI cardiologist Pamela Douglas, MD, is on a mission to use these values to improve the entire field.

Douglas is an expert in both her main scientific focus of cardiovascular imaging and in her work toward diversity, equity, and inclusion within the field of cardiology. She seeks solutions to mitigate inequities, such as more diverse hiring; fair compensation for all cardiologists, regardless of race or gender; and more opportunities for professional advancement for female and other underrepresented cardiologists.

Throughout her career, Douglas has shared her vision with colleagues worldwide through publications, mentorship, and her roles with the American College of Cardiology (ACC), where she has served as president and more recently as the founding chair of the organization's Diversity and Inclusion Task Force. Under her leadership, the ACC implemented a variety of innovations, including annual mandatory reports on diversity and inclusion from each of the organization's committees.

At the ACC 2020 conference, the organization honored Douglas and her work by awarding her with the Distinguished Award for Leadership in Diversity and Inclusion—and then renamed it in her honor.

The ACC website detailed the impact Douglas has had on the organization and on the field of cardiology as a whole: "Her leadership and vision have resulted in a comprehensive strategy for achieving a profession and a College that is diverse, inclusive, and equitable." ■

# Letter from the Deputy Executive Director



As DCRI's deputy executive director, my role is to guide our research mission. My goals include growing our research portfolio, starting at the intersection of therapeutic area differentiation and novel design and delivery of trials and studies.

The stories in this year's annual report reflect the far-reaching impact of DCRI's innovation in clinical research. They honor our contributions to cardiovascular care, yet, importantly, highlight the breadth of our thought leadership across many other therapeutic areas. Today, our research in the infectious diseases, musculoskeletal, nephrology, pediatrics, and respiratory fields grows at an accelerated pace and shows how our impact is broadening. In the spirit of this year's annual report theme, DCRI's growth continues across key areas of health and beyond the traditional randomized controlled trials as the Institute's way forward.

This year, we segmented and streamlined our areas of therapeutic focus and aligned them with areas of excellence across Duke. We also incorporated more pragmatic approaches in our trials, conducted more virtual and direct-to-family studies, and introduced master protocols to existing research programs. This progress puts the DCRI squarely at the forefront of reimagining how research is done.

We remain deeply committed to working with our academic colleagues and institutions around the world, yet we are also leading the way forward in incorporating the direct involvement of local communities, especially during the COVID-19 pandemic. Our RADx-UP and ABC Science Collaborative programs, both discussed in this report, exemplify these efforts.

I am honored to be leading DCRI's physician-researchers, who are transforming research and health care—for everyone. I look forward to the year ahead.

A handwritten signature in black ink that reads "DANNY". The letters are stylized and connected.

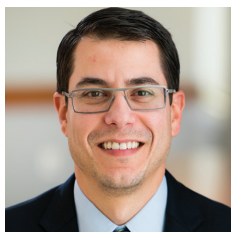
**Danny Benjamin, MD, PhD, MPH**  
Deputy Executive Director, Duke Clinical Research Institute  
Distinguished Professor of Pediatrics, Duke University

# Therapeutic Area Leads



**Kevin J. Anstrom, PhD**

Professor, Department of Biostatistics and Bioinformatics  
DCRI Therapeutic Area Lead, Statistics and Data Science



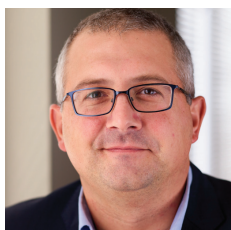
**Michael (Micky) Cohen-Wolkowicz, MD, PhD**

Kiser-Arena Distinguished Professor of Pediatrics  
DCRI Therapeutic Area Lead, Pediatrics Research



**G. Michael Felker, MD**

Professor of Medicine, Division of Cardiology  
Vice Chief of Cardiology for Clinical Research  
DCRI Therapeutic Area Lead, Cardiovascular Research



**Steven Z. George, PT, PhD, FAPTA**

Laszlo Ormandy Distinguished Professor in Orthopaedic Surgery  
DCRI Therapeutic Area Lead, Musculoskeletal and Surgical Sciences



**Scott M. Palmer, MD, MHS**

Professor of Medicine, Immunology, and Population Health  
Vice Chair for Research, Department of Medicine  
DCRI Therapeutic Area Lead, Medicine Plus



**Shelby D. Reed, PhD**

Professor in Population Health Sciences  
DCRI Therapeutic Area Lead, Population Health Sciences Research

# Service Offerings and Site Network

## Our Services

DCRI's full-service clinical research capabilities are supported by our physician-researchers as well as over 750 operational employees. From design to implementation to publication, the DCRI manages every facet of clinical research, ensuring a seamless experience for our sponsors.

As part of an academic clinical research organization, our experienced teams have the independence to challenge the status quo and think beyond traditional methods. Taken together, our faculty, operational staff, and data

and biostatistical experts yield credible study results that ultimately change clinical practice.

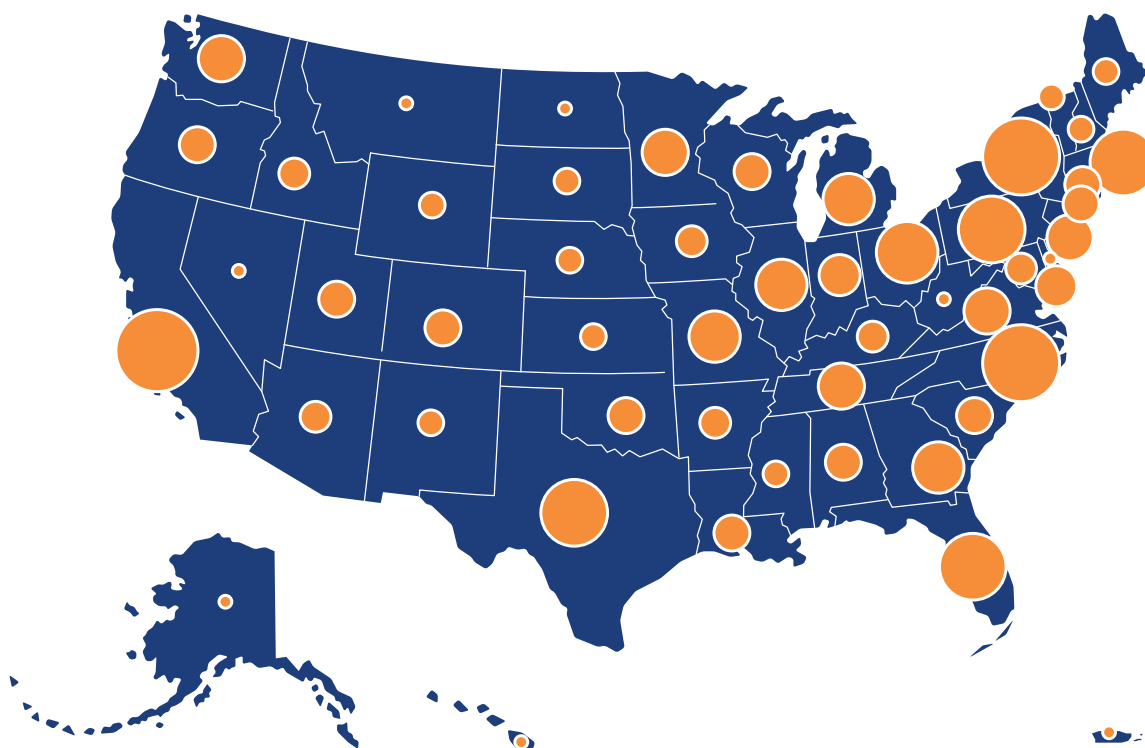
**The DCRI has comprehensive operational capabilities for every phase of research:**

- ▶ Trial Design
- ▶ Clinical Trial Programs, Phase I-IV
- ▶ Analytics and Data Science
- ▶ Trial Support Services
- ▶ Health Services Research and Outcomes

## Our Site Network

The depth and breadth of DCRI's collaborations reach around the globe to over 40 countries. In the U.S. alone, the DCRI site network includes every state, with nearly 1,100 total sites.

*Data Based on Active Studies during Fiscal Year 2020*

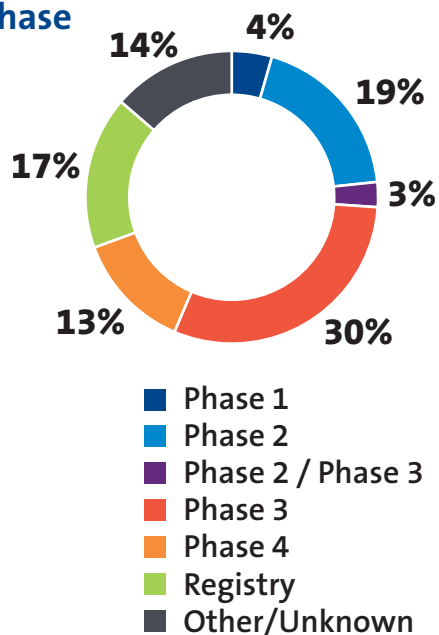


# DCRI At A Glance

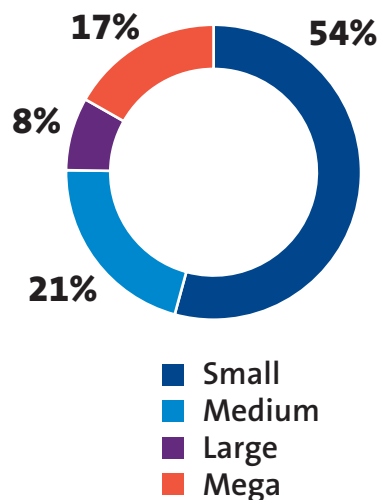
## Our Studies

As part of the Duke University School of Medicine, the DCRI is known for conducting groundbreaking multinational clinical trials, managing major patient registries, and performing landmark outcomes research. Our thought leadership influences the care of patients across the lifespan and extends to every phase of research—from early phase to post-market surveillance.

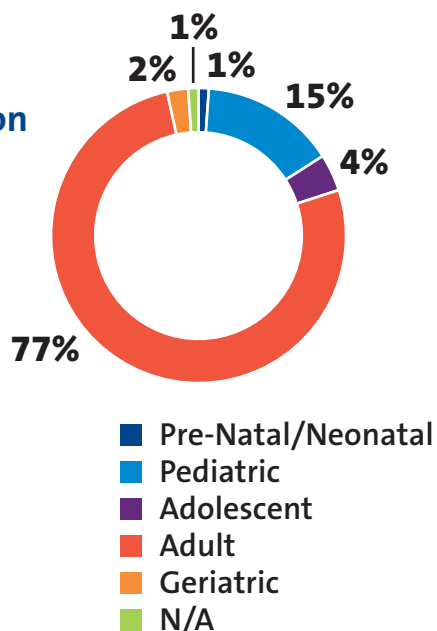
### Study Phase



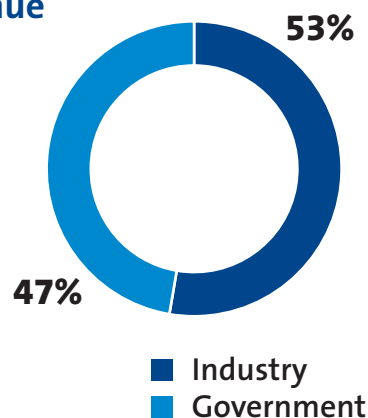
### Study Size



### Study Population



### Study Revenue Source



Data Based on Active Studies during Fiscal Year 2020

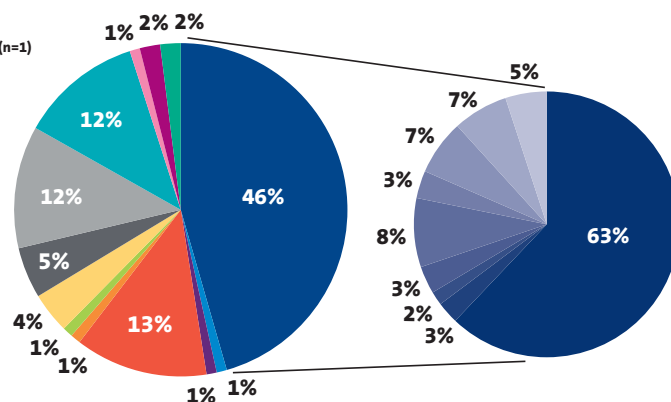
# DCRI At A Glance

## Our Faculty

DCRI's world-renowned faculty provide scientific leadership across multiple therapeutic areas. We are dedicated to advancing clinical research through innovation, designing scientifically rigorous studies, sharing knowledge, and education.

### All Departments Total Faculty: 128

- School of Medicine (n=59)
- Anesthesiology (n=1)
- Biomedical Engineering (n=1)
- Biostatistics & Bioinformatics (n=17)
- Civil & Environmental Engineering (n=1)
- Electrical & Computer Engineering (n=1)
- Neurology (n=5)
- Orthopaedics (n=7)
- Pediatrics (n=15)
- Population Health Sciences (n=15)
- Public Policy (n=1)
- Psychiatry & Behavioral Sciences (n=3)
- Urology (n=2)

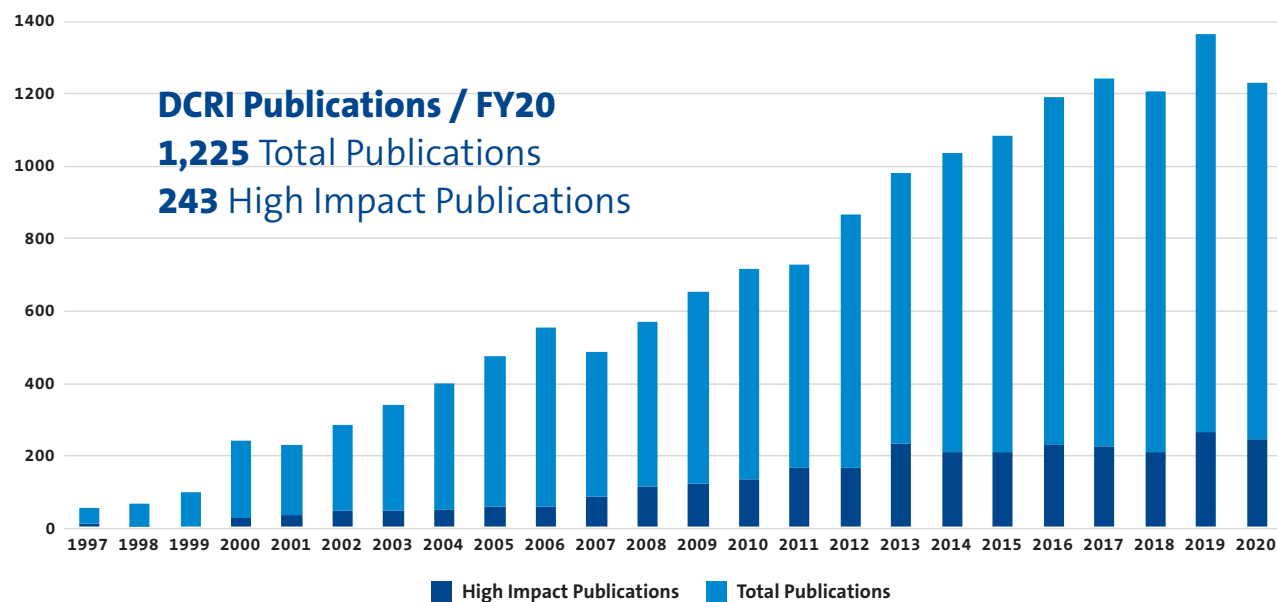


### Department of Medicine: 59

- Cardiology (n=37)
- Clinical Pharmacology (n=1)
- Dermatology (n=1)
- Endocrinology (n=2)
- Gastroenterology (n=5)
- General Internal Medicine (n=2)
- Infectious Diseases (n=4)
- Nephrology (n=4)
- Pulmonary (n=3)

## Our Publications

Since 1996, the DCRI has produced over 16,000 publications. In keeping with our mission, we disseminate scientific publications in order to share knowledge gained through our clinical research activities. These publications are the result of successful collaborations with academic partners as well as government and industry sponsors. Through these strong relationships, we ensure that evidence moves forward, facilitating change through science that has a measurable impact on the health of people around the world.



# New Faculty and DCRI Fellowship Program

## New Faculty

### **Hrishikesh Chakraborty, DrPH**

Associate Professor of Biostatistics and Bioinformatics

### **Marat Fudim, MD, MHS**

Assistant Professor of Medicine, Division of Cardiology

### **Stephen Greene, MD**

Assistant Professor of Medicine, Division of Cardiology

### **Jennifer Rymer, MD, MBA**

Assistant Professor of Medicine, Division of Cardiology

## Leadership Team

### **Sana Al-Khatib, MD, MHS**

Fellowship Program Director  
Professor of Medicine, Cardiology

### **Janelle Burner**

Administrative Coordinator

### **Adam Goode, PhD, DPT**

Fellowship Program Associate Director  
Associate Professor of Orthopaedic Surgery

### **June Loveday Clement**

Program Coordinator

### **Neha Pagidipati, MD, MPH**

Fellowship Program Associate Director  
Assistant Professor of Medicine, Cardiology

### **Kristen Tuminski**

Director, Academic Affairs

### **Zach Wegermann, MD**

Co-Chief Fellow

### **E. Hope Weissler, MD**

Co-Chief Fellow

## Second-Year Fellows

### **Anthony Carnicelli, MD**

Cardiology

### **Derek Chew, MD**

Cardiology

### **Sarah Commander, MD**

Pediatric Surgery

### **Rahul Loungani, MD**

Cardiology

### **Marc Samsky, MD**

Cardiology

### **Matthew Sinclair, MD**

Nephrology

### **Zach Wegermann, MD**

Cardiology

### **E. Hope Weissler, MD**

Cardiology, Vascular Surgery

### **Jedrek Wosik, MD**

Cardiology

## First-Year Fellows

### **Anne Friedland, MD**

Infectious Diseases

### **Michelle Kelsey, MD**

Cardiology

### **Caitlin King, MD**

Pediatrics

### **Rachel Randell, MD**

Pediatrics

### **Vishal Rao, MD**

Cardiology

### **Isaac Smith, MD**

Rheumatology

### **Andrew Vekstein, MD**

Surgery

### **Jonathan Young, MD**

Psychiatry

# Leadership

## Senior Management Team

**Adrian Hernandez, MD, MHS**

Executive Director, DCRI

Vice Dean, Duke University School of Medicine

**Danny Benjamin, MD, PhD, MPH**

Deputy Executive Director, DCRI

Distinguished Professor of Pediatrics,  
Duke University

**Michael (Micky) Cohen-Wolkowicz, MD, PhD**

Kiser-Arena Distinguished Professor of Pediatrics

DCRI Therapeutic Area Lead, Pediatrics Research

**G. Michael Felker, MD**

Professor of Medicine, Division of Cardiology

Vice Chief of Cardiology for Clinical Research

DCRI Therapeutic Area Lead, Cardiovascular Research

**Susan P. Landis**

Head, Strategic Communications

**Dana McDonald**

Director, Human Resources

**Shelby D. Reed, PhD**

Professor in Population Health Sciences

DCRI Therapeutic Area Lead, Population Health  
Sciences Research

**Ty Rorick**

Head, Research Operations

**Aimee L. Turner, CPA**

Chief Financial Officer

## Operations Management Team

**Kevin J. Anstrom, PhD**

Professor, Department of Biostatistics

DCRI Therapeutic Area Lead, Statistics and

Data Science

**Carolyn Moore Arias, MPH**

Director, Strategic Engagement

**Elizabeth (Beth) Fraulo, RN, BSN**

Director of Operations, Health Services Research

**Linda Lillis, MS**

Director, Industry Trials

**Brian McCourt**

Senior Director, Technology and Data Solutions

**Dana McDonald**

Director, Human Resources

**Tom Mullen, MBA**

Associate Director, Operational Excellence

**Donna Parker, MPH**

Operational Lead, Transformation Team

**Suzanne Pfeifer, MPH**

Director, Grants and Proposals Services

**Renée L. Pridgen, MHA**

Director, Government Trials and Networks

**Ty Rorick**

Head, Research Operations

**Lindsay Singler, MPH**

Associate Director, Research Communications  
and Engagement

**Lauren E. Tochacek, MS**

Assistant Director, Quality Assurance

**Aimee L. Turner, CPA**

Chief Financial Officer

**Matt Wilson, RN**

Director of Operations, Clinical Events

Classification-Safety Surveillance (CEC-SS)

Director of Operations, Imaging

**Sybil Wilson, RN**

Director, Operations



**Duke** Clinical Research Institute

FROM THOUGHT LEADERSHIP  
TO CLINICAL PRACTICE

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Mailing address

P.O. Box 17969, Durham, NC 27715

[dcri.org](http://dcri.org)



**Duke** University School of Medicine