Mission and Values

OUR MISSION
To develop and share knowledge that improves the care of patients around the world through innovative clinical research.

OUR VALUES
Integrity | Excellence | Respect | Innovation | Teamwork
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Welcome from the Interim Executive Director

I am delighted to share this year’s DCRI annual report, an especially meaningful edition for me as I complete more than a year as interim executive director. The stories and studies here reflect fully how the DCRI is advancing clinical research through groundbreaking studies led by exceptional teams of faculty and operational staff. Under the leadership of our research teams, we continue to introduce new methods and pursue innovative approaches in clinical research for the most pressing issues in patient care.

The past year has brought challenges and change, and also a deeply renewed commitment to our mission throughout the DCRI and across the Duke system. We completed a comprehensive strategic planning effort and launched transformation initiatives aimed at revitalizing our core offerings and advancing new ways of conducting clinical research. The DCRI is an undisputed leader in the areas of using pragmatic approaches and real-world data to improve clinical trial design—the future of clinical research. Our overarching goal is to ensure the DCRI remains distinct in its academic and operational expertise and its approaches—for the benefit of our sponsors, partners, collaborators, and the patients we serve. As expected, we opened a search for a new executive director. In the coming year, I am excited to be able to hand the reins of an invigorated and future-focused organization to a new leader.

I am honored to have led the DCRI. The progress we have made is due to so many—a sincere commitment to improvement from the DCRI operational teams and support from the Duke School of Medicine and my colleagues, both at the DCRI and the Department of Population Health Sciences.

I look forward to an exciting year ahead and many years of growth and contribution as the DCRI continues to achieve its mission to improve the care of patients around the world through innovative clinical research.

Lesley H. Curtis, PhD
Chair and Professor
Department of Population Health Sciences
Interim Executive Director,
Duke Clinical Research Institute
Duke University School of Medicine
Reflection from the Head of Research Operations

As a member of the DCRI team for more than 12 years, including as head of research operations now, I am especially proud to represent our operational teams in this year’s annual report. Inside, you will find a sampling of the hundreds of projects led by our dedicated clinical research project teams. Nowhere else will you find an academic research organization with the depth of operational expertise to translate thought leadership from the pages of a protocol through study start-up, recruitment, retention, and returning results to our valued study participants.

Whether it’s a traditional interventional trial such as ARISTOTLE, a DCRI-led study that was recognized by the New England Journal of Medicine as one of a dozen studies that have changed clinical practice, or DCRI-led ADAPTABLE, one of the first truly pragmatic clinical trials with direct-to-patient engagement, our operational teams approach their work each day with the following shared goals in mind:

- Developing new ways to engage patients;
- Delivering quality data;
- Fostering new ideas and innovative approaches;
- Improving efficiency;
- Sharing learning; and
- Partnering with DCRI faculty and collaborators.

We achieve these goals in collaboration with our many long-standing partnerships that extend our expertise around the world. In this annual report, I chat with one of our partners, Tracy Temple, Canadian VIGOUR Centre’s associate director of clinical trials, about how collaborations unite the best minds in thought leadership and operational expertise to advance clinical research around the world.

Whether working together with our partners or teaming up here at the DCRI, we all are motivated by our mission to improve care for patients. I know this is true for me, and I witness it in the work of so many colleagues. I am honored to lead the DCRI’s operational teams, and I’m looking forward to what comes next.

Ty Rorick
Head, Research Operations
DCRI at a Glance: Publications

The DCRI's mission is to develop and share knowledge that improves the care of patients around the world through innovative clinical research. One of the primary ways in which the DCRI shares knowledge is through scientific publications.

These publications are the result of successful collaborations with academic partners and government and industry sponsors. Through these strong relationships, we ensure that evidence moves forward, facilitating change through science that has a measurable impact on patients' lives.

The DCRI has produced **more than 15,000 publications** since 1996.

IN FY19, DCRI RESEARCHERS

- Published **more than 1,300 scholarly articles**, more than 260 of which appeared in top-tier journals; and
- Collaborated with **more than 6,500 co-authors** from nearly 1,900 institutions in 72 countries.

Our work has been cited in **more than 760,000 scientific articles**.
DCRI at a Glance: Key Stats

As part of the Duke University School of Medicine, the DCRI is known for conducting groundbreaking multinational clinical trials, managing major national 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.

The depth and breadth of DCRI’s collaborations reach around the globe to more than 40 countries. In the U.S. alone, the DCRI network touches every state with more than 1,520 sites.
Michael Felker, MD, MHS, a cardiologist at the DCRI, invited his colleague, fellow DCRI cardiologist Adrian Hernandez, MD, MHS, to discuss the evolving clinical research landscape and how the DCRI is responding by continuing to deliver traditional clinical trials while also incorporating pragmatic approaches.

MICHAEL: It seems like we’re at an inflection point in clinical research, from an era where we were focused on randomized clinical trials as the foundational way of generating evidence to now, where there are all these additional aspects of evidence generation, such as real-world data, pragmatic trials, and registry-based trials. I think it’s created interesting opportunities, as well as interesting challenges. Adrian, how do you view the current landscape?

ADRIAN: There are two things at play. The complexity and cost of trials have increased. On the other hand, we need more answers to important questions. Alongside that, we’ve seen a transformation in health care systems in terms of greater access to data and greater engagement of patients, which gives us the ability to take advantage of that for research purposes and hopefully make research simpler.

MICHAEL: Agreed. This transformation, particularly in terms of data access, is interesting. As you know well, the way we collect data clinically is often not structured for the data to be used for research. But it seems like a real opportunity, especially in a big health system like Duke, to have a learning health system where we’re actually testing questions and learning from the way we conduct clinical practice.

Sharing Knowledge, Changing Practice

The DCRI’s mission is to translate knowledge gained from research into clinical practice in order to improve patient outcomes. Our long tradition of delivering on this mission was recognized this year when one of our studies was honored by the New England Journal of Medicine.

Prior to his retirement, Jeffrey Drazen, the journal’s former editor-in-chief, reflected on the studies the journal had published since his tenure began in 2000—more than 80,000 submissions and nearly 4,000 published studies. He selected what he called Drazen’s Dozen: 12 studies that were “practice-changing and lifesaving,” and the ARISTOTLE trial was included in the list. ARISTOTLE, published in 2011, was led by a team at the DCRI and the Uppsala Clinical Research Center in Sweden.

The ARISTOTLE study, spanning 39 countries and including more than 18,000 patients with atrial fibrillation, was a clinical trial that randomized patients to either apixaban or warfarin. Results showed that apixaban was superior to warfarin; not only was apixaban more effective at preventing stroke, but it also caused less bleeding and resulted in fewer deaths.

Although use of warfarin was prevalent prior to these findings, apixaban is now the most commonly initiated oral anticoagulant drug for patients with atrial fibrillation, said Christopher Granger, MD, the DCRI lead investigator on the study. Apixaban is easier to use because warfarin is associated with several food and drug interactions and requires monitoring.

“It is gratifying to be able to generate evidence that prevents strokes and saves lives,” Granger said. “The honor of being selected as one of the 12 most lifesaving studies from such an important journal aligns nicely with the DCRI’s mission to develop and share knowledge that improves patient care around the world.”
ADRIAN: That's exactly right. As health care systems get smarter about care delivery, how do we embed research within the health care systems to power clinical trials? For certain outcomes, what we need as researchers is already available in the clinical care setting.

But there may be other things that we need to do more in a traditional mode or directly with patients to collect certain information that isn’t part of routine care. That’s where things have to be hybridized, combining traditional aspects with more pragmatic approaches that leverage what’s being done as part of clinical care.

MICHAEL: A lot of these more pragmatic approaches have the potential to address some of the challenges we’ve seen in traditional trials—expense, as you mentioned, slow enrollment, and very long timelines. Do you think the traditional Phase 3 randomized clinical trial is on its way out, or do you think there’s always going to be a role for that kind of evidence generation?

ADRIAN: I think one of the things we’ve learned is that one size does not fit all. There is a spectrum of discovery as we learn about a condition or a novel therapy, and we want to know everything about it before it reaches the public.

MICHAEL: I think we've realized it's not a strict dichotomy between traditional and pragmatic. Even for trials that are traditionally structured, there are a lot of opportunities to leverage other data sources to identify patients, conduct follow-up, or otherwise streamline trials so we can get answers more quickly for our patients.

This is a place where the DCRI can really add value because we have expertise across not only traditional clinical trials, but also a lot of these new technologies like wearables, real-world data, and learning health systems. The ability to bring all of that together in one place will be critical as clinical research moves forward.

“*The ability to bring [traditional and pragmatic approaches] together in one place will be critical as clinical research moves forward.*”
Michael Felker, MD

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**Reducing Risk, Changing Paradigms**

An ongoing DCRI clinical trial seeks to determine whether an experimental lipid treatment is effective in preventing a second cardiovascular event in patients who have already had a heart attack. Patients who have had a heart attack are at highest risk for stroke or a second heart attack in the months following their initial heart attack, said John Alexander, MD, DCRI’s investigator on the AEGIS-II trial. The study centers on whether an experimental lipid therapy called CSL112 could help reduce this risk.

CSL112, developed by CSL Behring, consists of apoA-1, a naturally occurring human protein that is part of high-density lipoprotein, also known as “good cholesterol” that removes cholesterol from plaques. In a 2016 DCRI coordinated study that proved the drug’s safety, CSL112 was found to reduce cholesterol buildup. AEGIS-II will enroll over 17,000 patients at about 1,000 sites worldwide and will examine the drug’s efficacy by determining whether this reduction in buildup also results in fewer recurrent cardiovascular events.

Participants in the study will receive four weekly infusions of CSL112 and will be followed for one year, the timeframe during which investigators expect to see maximum benefit. Patients will then be followed for a year to determine whether these effects are sustained.

The study is the next step in a partnership with CSL Behring and other academic collaborators that has been ongoing for almost a decade. Since initially discussing CSL Behring’s development program for the drug in 2010, the DCRI has partnered with them on three trials, all of which led to new discoveries that can improve clinical care.
The DCRI’s Robert Mentz, MD, is the co-principal investigator for a pragmatic clinical trial on heart failure called TRANSFORM-HF, which is funded by the National Heart, Lung, and Blood Institute (NHLBI). Mentz discussed features of the trial with Patrice Desvigne-Nickens, MD, a medical officer in the Heart Failure and Arrhythmias Branch of the NHLBI and project officer for TRANSFORM-HF.

ROB: Patrice, we met while working with the Heart Failure Research Network funded by the NHLBI, which was formed to run many small trials to answer key questions in heart failure. Many of the lessons learned from the network helped us fine-tune our approach to TRANSFORM-HF.

TRANSFORM is a real-world comparative effectiveness study that has many elements of pragmatism, including a broader population, streamlined trial conduct, and fewer requirements for patients in the follow-up period.

PATRICE: Yes, TRANSFORM looks at two active drugs to determine if one is more effective than the other in improving outcomes in a general population of patients with heart failure. Because it’s answering an important question using available drugs and tools, a pragmatic design is possible and preferred. Determining the kind of trial needed often depends on context, whether it’s a proof-of-concept trial or whether it’s a definitive trial seeking clinical outcomes that could change practice. Pragmatic trials are not new, although new emphasis may be placed on pursuing more pragmatic methods. In fact, the NHLBI has supported trials in the past that have involved a large number of patients with heart failure, clinically important outcomes, and minimal case report forms—all features of a pragmatic trial.

“As we improve patient outcomes and they live longer, they have other health issues that need more study, which leads to additional research questions.”

Patrice Desvigne-Nickens, MD

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The DCRI is partnering with Cerner, the world’s largest electronic health record (EHR) company, to conduct clinical research using Cerner’s cloud-based platform. The platform, called HealtheIntent, was originally developed for use in population health management. When DCRI researchers Ann Marie Navar, MD, PhD, and Eric Peterson, MD, MPH, learned about the platform, they saw an opportunity for clinical research. Although maintained by Cerner, the platform can incorporate data from a variety of EHR vendors and has the ability to link to other data sources such as health care claims and mortality indices. Together with Cerner, the DCRI is now among the first to pilot this platform for clinical research.

The DCRI has a strong history in leveraging real-world data from the EHR to power future research. To further the collaboration with Cerner, Navar and Peterson identified academic collaborators at both the University of Texas Dell Medical School and the University of Missouri to pilot the use of HealtheIntent to run an EHR-powered clinical registry. Funded by Janssen, the pilot project will explore treatment patterns for patients with cardiovascular disease while helping to identify the benefits and limitations of Cerner’s platform for clinical research. Evaluating and maximizing data quality is also of paramount importance; as part of the project, large numbers of chart reviews are being performed to verify the accuracy of the EHR-generated data and refine how key clinical conditions are defined.

The DCRI and Cerner hope to expand this partnership by recruiting other health systems to join their network of sites dedicated to using the EHR to power research in what they are calling the Learning Health Network. Through expansion of the network, Navar and Peterson hope to create a network that can be leveraged for other research purposes, from larger observational registries to pragmatic clinical trials, as well as studies on how to best drive the adoption of evidence into clinical practice.
ROB: Agreed. As both the DCRI and the NHLBI look toward the future of clinical research, TRANSFORM is a good step forward in an environment in which it’s become harder to recruit patients with heart failure. We’re learning how to do trials more efficiently and make the experience better for all stakeholders, although of course there is more work to be done to innovate direct-to-patient trials. Can you talk a bit about differences you’ve seen in TRANSFORM versus other heart failure trials you’ve worked on in your career?

PATRICE: One of the fundamental differences in running a pragmatic trial is that it requires broader eligibility criteria, which hopefully allows all patients with the condition to be included. Traditionally we must interview many patients before finding one who is eligible. A pragmatic trial like TRANSFORM is a tremendously different paradigm where we’re eager to enroll everyone affected by the disease we’re studying.

ROB: We’ve seen this difference impact TRANSFORM’s enrollment rates. Overall in the U.S., heart failure studies recruit about 0.2 patients per site per month. Our goal was to get that to three to five patients. Our average right now is just over two patients per site per month, which is higher than average but still not yet where we need it to be. Broadening the eligibility criteria has also resulted in important inclusion of women and minorities. Patrice, can you comment on what you see as the future for pragmatic trials and our work together?

PATRICE: As we improve patient outcomes and they live longer, they have other health issues that need more study, which leads to additional research questions. To address this paradox with limited resources, we’ll need to conduct trials with large numbers of patients, which is where pragmatic design is a good option. At the DCRI, which is a research tour de force in cardiology clinical trials, and at the NHLBI, we’re working toward bringing clinical research into the 21st century by embracing information technology to facilitate collection and analyses of traditional patient-reported outcomes and, when appropriate, administrative databases, which will enhance efficiency and lower costs. Because we share these goals, it makes sense to align forces to work on projects like TRANSFORM-HF.

A Pragmatic Approach to Benefit an Understudied Population

A new DCRI-led pragmatic clinical trial conducted in partnership with the Wake Forest School of Medicine will assess the effectiveness of statins in patients aged 75 or older. Statins are known to lower cholesterol and reduce the risk of cardiovascular events for secondary prevention, or patients with known coronary artery disease (CAD), as well as primary prevention, or those without CAD who are at high risk of future cardiovascular events. However, few statin studies in primary prevention populations have included older adults.

PREVENTABLE is the largest pragmatic clinical trial with placebo-controlled drug assignment to date. It is also the first statin trial with a non-cardiovascular primary outcome. Instead, investigators will study whether statins could prolong survival free of new dementia or physical disability—a critical consideration for older adults looking to maintain independence. The study’s secondary outcome will include cardiovascular events as well as mild cognitive impairment.

PREVENTABLE will partner with PCORnet®, the National Patient-Centered Clinical Research Network, and the National VA Network to identify and recruit 20,000 participants aged 75 years or older and without CAD at 100 U.S. sites. Utilization of these two national resources is expected to enable investigators to enroll participants and collect health data faster and more efficiently than a traditional trial. Investigators will also use electronic health records (EHRs) to help ascertain patient outcomes.

The study will be funded over seven years from the National Institute on Aging in partnership with the National Heart, Lung, and Blood Institute and will be led by the DCRI’s Karen Alexander, MD.

PREVENTABLE will use pragmatic elements throughout, including:

- Embedding research in the health care system by enrolling patients in their usual care settings and in partnership with their primary care clinicians;
- Engaging potential participants during screening and recruitment by using informational videos, panel discussions with research participants, and an e-consent platform;
- Pairing EHR data with other forms of follow-up, including calls and in-person visits for cognitive and functional assessments, to ensure complete collection of outcomes; and
- Simplifying study drug delivery by shipping directly to patients.
Laine Thomas, PhD, associate director of DCRI Biostatistics, sat down with David Page, PhD, chair of Duke Biostatistics & Bioinformatics, who is new to his role as of this year, for a discussion on the future of biomedical data science, as well as how machine learning techniques will be incorporated in this work.

**LAINE:** David, I’d like to talk about your vision for Duke Biostatistics & Bioinformatics in terms of where we’re going in some exciting new areas, like artificial intelligence and machine learning. Let’s start with a brief explanation of artificial intelligence and machine learning.

**DAVID:** Artificial intelligence is automating human thought and actions. Machine learning is the adaptation piece of that. I view machine learning as the creation of algorithms that will analyze data and give back insights. Those insights could be predictors of the future, better explanations of past events, or indicators of cause-and-effect relationships.

**LAINE:** Although I’m trained as a computer scientist, I see machine learning and data science emerging just as much from statistics as from computer science and engineering.

**LAINE:** Can you talk us through your vision for collaboration among different groups on campus doing work in biomedical data science?

**DAVID:** A tremendous opportunity is to use cross-campus partnerships to recruit new faculty and staff. I think the DCRI and Duke Biostatistics & Bioinformatics can be critical players here because we offer outstanding data access, as well as translational opportunities for people who want to make a real difference in society.

**Ensuring Data Quality**

Data are easily accessible, but not all data are well-suited to answer a given clinical research question. A team that includes DCRI faculty is working to build frameworks to assess whether data can be used in research studies.

It is important to assess data, the DCRI’s Keith Marsolo, PhD, explained, because data come from many different sources. For example, within PCORnet®, a national patient-centered distributed research network for which the DCRI serves as a coordinating center, real-world data come from health systems and health plans across the country. Variation in source systems and data collection practices can lead to data heterogeneity that is problematic for research.

Alongside its work in defining PCORnet’s common data model, a team led by Marsolo has developed routines to assess data quality—what Marsolo called “a foundational set of data checks.” This material has been made publicly accessible on the PCORnet website, which is novel, Marsolo said, because many other groups working with real-world evidence (RWE) do not publicize their data quality processes.

The data checks help determine whether available data is fit for purpose, or able to be used to answer the research question at hand. Although each study team will need to address study-specific questions, the checks developed by Marsolo’s team answer baseline questions of dataset fitness and shorten study start-up time.

Marsolo also leverages his expertise outside of PCORnet by collaborating with other organizations at Duke. He serves as a member of the data quality working group convened by the Duke-Margolis Center for Health Policy’s RWE Collaborative. By participating in this group, which includes researchers, industry representatives, patients, and other stakeholders, he helps translate complex data concepts so they can be viewed through a health policy lens. The group hopes to inform the Food and Drug Administration’s (FDA) work in the RWE space.
LAINE: Speaking of intersections on campus, I want to segue a bit into other intersections—those between machine learning and causal inference, just because that’s the area my work is in. Have you worked on any problems that sit in this intersection?

DAVID: For the last 10 years, I’ve been working on using machine learning for discovery of adverse drug events. That project is primarily focused on using observational data such as EHR data or claims data. We’ve tried to build on previous statistical and artificial intelligence methods, and our best results have come from algorithms that combine insights from both traditions.

LAINE: I’m working on a project where we are developing new methods to analyze the comparison of hysterectomy and myomectomy in the COMPARE-UF registry of women with uterine fibroids. This DCRI registry emphasizes personalized medicine, where we’re trying to estimate individual treatment effects while accounting for differences between groups. Our approach also combines both traditions. We have a machine learning element, but it’s currently a tool that’s separate from the causal inference. We’re fitting models using machine learning methods, then the causal inference phase occurs. I can imagine some ways to make them more integrated. In my mind, the next step is to make them actually interact with each other instead of treating them as pre- and post-processing.

DAVID: That’s really exciting. I’d love to hear from you about what other areas you see for future intersection between the two fields as we continue to seek collaboration opportunities.

LAINE: In the DCRI Biostatistics group, I see a number of potential areas where machine learning could improve how we approach problems in causal inference. One area is precision medicine. As our purpose in causal inference changes—instead of trying to estimate averages, we’re now trying to estimate individual treatment effects—we need to figure out how to do that better, and machine learning could help.

Another opportunity is hospital profiling. Because our work in this space is in demand from the patient perspective, I expect it will continue to expand and could integrate machine learning to improve our rating models.

DAVID: Thanks for those insights, Laine. Both of those sound like exciting opportunities to find the right hybrid approach that could improve how we do things across the board, and I look forward to working with you in these areas.

“The DCRI and Duke Biostatistics & Bioinformatics can be critical players [in recruitment] because we offer outstanding data access, as well as translational opportunities for people who want to make a real difference in society.”
David Page, PhD

Innovating Adjudication

As the DCRI’s Clinical Events Classification (CEC) group grows, its leaders are seeking innovations to make their work more efficient.

Traditionally, clinical events are reviewed by a group of adjudicators to determine whether they meet the definition outlined in the study protocol. Adjudication of events is important in securing FDA approval for new drugs and devices. The DCRI’s CEC group has about 50 faculty reviewers who dedicate time weekly to event adjudication. However, the work has expanded exponentially—CEC now performs about 30,000 adjudications per year, in comparison with 5,000 per year about five years ago.

Because of this growth, it is essential to enhance CEC’s processes, said Matt Wilson, RN, operations director of CEC. The group is working closely with machine learning experts at the DCRI and Duke to develop machine learning algorithms that are able to adjudicate the more straightforward cases.

The group plans to test the capabilities of these algorithms in a prospective study that will compare a pure machine learning approach to a hybrid approach that pairs the algorithms with human adjudication. Renato Lopes, MD, PhD, one of CEC’s faculty directors, said he believes the hybrid approach will be most accurate, as human adjudication will likely be necessary for complex cases.

As CEC looks forward to implementing these algorithms in real-time adjudication, it is also diversifying the therapeutic areas it serves. Three years ago, its portfolio was 70 percent cardiovascular. However, with this year’s additions of endocrinology, nephrology, neurology, infectious diseases, and pediatrics, it is now 49 percent cardiovascular—which suggests that other clinical areas are realizing the benefit of using CEC before seeking FDA approval.
Valuing Patients as Equal Stakeholders

Through the DCRI Research Together™ program, the DCRI strives to view study participants as partners in research rather than research subjects. The program was formed to help study sponsors meaningfully embed the patient perspective throughout the research process as clinical research becomes more patient-centered.

This engagement can take many forms. One approach is to assemble a panel of diverse patient advisors whose insights and experiences inform study teams and sponsors every step of the way. The Cardi-Yacks, a group of patients with heart failure, convened as patient advisors on the CONNECT-HF trial, worked on many components of the trial. They participated in end-user testing of a mobile app and provided feedback to developers before the app’s implementation in the trial. They also worked on developing a motivational enrollment game for sites, along with providing insights on study processes, materials, barriers, and retention.

The Cardi-Yacks’ contributions provided so much value that the group also advised a study team on maintaining patient centeredness for a separate grant that was submitted to the Patient-Centered Outcomes Research Institute® (PCORI). In addition, one of the members is now serving as a co-principal investigator for another grant.

The ADAPTABLE study has a diverse team of Adaptors, led and coordinated by the Heart Research Alliance at the University of California, San Francisco, that serve as patient partners and provide insight on all aspects of the study. Schuyler Jones, MD, co-principal investigator of ADAPTABLE, spoke with two Adaptors, Nadine Zemon and Greg Merritt, to discuss their experience and the importance of stakeholder engagement.

SCHUYLER: I can remember vividly when I met each of you, and I really look forward to revisiting some of your ideas that have helped the trial thus far. First, can you each talk about how you got involved with ADAPTABLE?

NADINE: I got involved with ADAPTABLE because I was part of the Citizen Scientist team at the University of Florida, and ADAPTABLE needed people to help with recruitment there.

GREG: I became a patient advocate partner after having a heart attack in 2012 that left me without a heartbeat for about 30 minutes. After that, I was looking for ways to give back and joined a couple of patient advisory councils at the University of Michigan, which ultimately connected me to ADAPTABLE.

“My connection with our Adaptor family has influenced how I practice medicine and think about clinical research.”

Schuyler Jones, MD

SCHUYLER: Nadine, can you tell us about some of your work in recruitment? For example, how you helped in transforming the plain invitations into lively materials?

NADINE: Initially they had this dull letter, and I was able to say, “This doesn’t really appeal to me.” My input helped make our invitations more attractive to capture people’s attention and explain difficult-to-understand concepts like big data.
SCHUYLER: Sites loved that idea. That experience, for me, drove home that we have to use ideas from everybody, especially from patient partners, to engage potential study participants. Greg, one of your early ideas involved engaging people in cardiac rehab clinics. Can you talk about your experience being an Adaptor?

GREG: I’ve found the process to be a true partnership, which is different from experiences I’d had in the past. I joined a different trial just after my heart attack, but in the end, I had no idea what role my participation played. In many projects when you work as a patient partner, it’s easy to ascertain whether you’re just a token patient trying to check some box. But back to the very first ADAPTABLE meeting I attended, I remember thinking, “Wow, this is different; they really want our opinion.” Through ADAPTABLE, I feel like I’ve had an impact right from the start.

“I remember thinking, ‘Wow, this is different; they really want our opinion.’ Through ADAPTABLE, I feel like I’ve had an impact right from the start.”
Greg Merritt, Adaptor

NADINE: I agree; I feel like our comments are not only heard, but also receive follow up. We met weekly and were integrated right from the beginning. We discussed everything from avoiding jargon to safety concerns. Having a venue to make our voices heard has established transparency and trust.

SCHUYLER: I’m glad you both can feel how much your perspective matters to us. From the get-go, we said that even though we haven’t done patient engagement at this scale before, we need to go all in. We decided to have Adaptors on the executive committee and the steering committee; we committed to meet in person so that you could review anything that touched our participants. In short, we decided that patient partners needed to be involved in every aspect of the trial.

GREG: It’s so important to involve patients because their lives are actually affected by the research question. I’d like to know which dose of aspirin is most effective. If the results say I could prevent another heart attack by switching doses, I’d like to change tomorrow. Researchers should be asking questions in partnership with the people who have the most at stake.

SCHUYLER: I agree. My connection with our Adaptor family has influenced how I practice medicine and think about clinical research. It’s made me realize that we need to continue to partner at every step, including at the planning phases. I think that we’ve now really embraced giving patients the opportunity to come in, get matched to their interests, and contribute meaningfully.

The Science of Appreciation

The DCRI is working to develop the science behind the best way to say thank you.

In conjunction with DCRI Research Together™, The Bioethics and Stakeholder Engagement (BASE) Lab housed in Duke’s Department of Population Health Sciences, DCRI Communications, and the Pediatric Trials Network (PTN) are developing lay summaries to share research results with study participants, as well as notes to thank them for their participation.

The DCRI serves as the coordinating center for the PTN, a research network focused on making drugs safer and more effective for children. Several DCRI researchers also act as PTN investigators, including the DCRI’s Kanecia Zimmerman, MD, MPH. Developing and studying thank you materials is especially important in the trials Zimmerman conducts as part of PTN because people participate not necessarily for personal benefit, but to advance science to help future critically ill infants.

This study is one example of how The BASE Lab partners with clinical investigators to gather stakeholder input in order to improve the clinical research process, Corneli said. Although there are federal requirements for returning research results, few entities have run studies to consider how to do this affordably and thoughtfully.

The team hopes that providing the lay summaries and thank you will have lasting impacts, helping to bolster retention and inspiring current participants to consider additional participation in research.

The BASE Lab:
• Identifies areas critical to the successful implementation of clinical research that can be strengthened with data from key research stakeholder groups;
• Gathers essential data through social science research with patients, research participants, and other key stakeholders; and
• Demonstrates how data can inform the planning, conduct, interpretation, and reporting of clinical research.
IMPLEMENTATION SCIENCE

The DCRI’s Neha Pagidipati, MD, MPH, is the faculty lead for the COORDINATE-Diabetes trial, along with the DCRI’s Christopher Granger, MD. Diabetes is increasing in epidemic proportion, and the most devastating consequence is cardiovascular disease. It is possible to prevent death, heart attack, and stroke in patients with diabetes, but only a small percentage of patients in the U.S. are getting the necessary treatments.

To achieve the DCRI’s mission of improving patient care with innovative research, COORDINATE-Diabetes seeks to ensure that people with diabetes and cardiovascular disease receive these life-saving, evidence-based therapies. Pagidipati discussed the work with Monica Reed, MHA, a clinical research associate and quality improvement specialist at the DCRI who is helping to lead the intervention arm of the trial.

NEHA: Implementation science is an important and growing field. Even though we have medications that help make patients healthier, many patients aren’t receiving the evidence-based therapies they should be. We need rigorous scientific methods to help us understand how we can improve in clinical practice, and implementation science will guide that.

MONICA: Completely agreed. Through the COORDINATE trial, we are focusing on intensive education, which starts with our faculty, both at the DCRI and from external partner institutions. We assemble teams of three experts—a cardiologist, an endocrinologist, and a quality improvement specialist—who visit sites to talk about the guidelines, care pathways, and what the sites are doing that is working, as well as what isn’t.

Improving Quality for Better Outcomes

A DCRI-led pragmatic clinical trial is focusing on improving quality initiatives so that patients with heart failure receive better care and spend less time in the hospital.

CONNECT-HF, led by the DCRI’s Adam DeVore, MD, MHS, focuses on encouraging patients to connect with their outpatient doctors to optimize their care. The study will work with 161 sites to enroll high-risk patients and follow them for 12 months.

There are two major quality improvement initiatives delivered by CONNECT-HF. One is the return of feedback, ensuring that each site has data on its performance and progress associated with heart failure care and outcomes. This is paired with mentorship and coaching from the study team so that each site can improve adherence to evidence-based therapies available for patients with heart failure. The study team will leverage existing infrastructure by partnering with hospitals that are already engaged and making an effort to improve patient care.

“Anything that improves implementation of evidence-based therapies, and in turn patient care, will include a lot of different levers,” DeVore said. “Each site has the freedom to decide how to improve patient outcomes, but when their work is bolstered by the support of data and coaching provided by CONNECT-HF, I am confident we will see some real progress and keep more patients out of the hospital for longer.”

Adam DeVore, MD, MHS

CONNECT-HF will measure its progress by tracking time to first readmission to the hospital or death within the 12-month follow-up period after hospital discharge. The study team has also developed a composite score that each patient will receive based on adherence to quality metrics, which includes taking medication, as well as other factors like cardiac rehabilitation and exercise.

“I am confident we will see some real progress and keep more patients out of the hospital for longer.”

Adam DeVore, MD, MHS
Each site has different challenges because each one is unique, from smaller community-based sites to larger sites based in academic centers. Our team helps identify both opportunities and challenges, as well as strategies to address them. We have created a toolbox of resources that our sites can use in clinic, such as a set of pathway examples and a learning module system based on the guidelines.

After our site visit, we also deliver a comprehensive analysis tailored to each clinic that the sites can use to create an action plan. As sites implement their strategies, we continue to work with each one-on-one. We also invite sites to collaborate with each other; it’s exciting to see clinicians in the real world partnering to share ideas that work.

“Being able to have peer-to-peer conversations at the clinic level that are open and collaborative is key, and at each site visit we learn something new.”

Monica Reed, MHA

NEHA: Agreed. This collaboration has been really inspiring to see. Some of our greatest advances have come from brainstorming with sites, as they can share real examples of the roadblocks they are seeing and we can work together to find solutions.

MONICA: Right. Being able to have peer-to-peer conversations at the clinic level that are open and collaborative is key, and at each site visit we learn something new.

NEHA: COORDINATE is a team-based approach to bettering patient care. There’s a great partnership at the DCRI between clinical faculty, quality improvement experts, and operational experts who know how to work with sites to achieve shared goals.

MONICA: It’s also important that our deliverables to these sites are sustainable over time. These collaborations are key so that we can continue to share concepts and make improvements in patient outcomes as we move forward.

Stakeholders Share Ideas

The DCRI convenes DCRI Think Tanks on a regular basis to inspire collaboration around solving the most critical gaps in clinical research. At its most recent event, participants discussed implementation science.

Although more than $100 billion is spent on biomedical research each year, it can take over a decade for study results to be adopted in clinical practice. To address this challenge, the DCRI hosted a DCRI Think Tank entitled “Fast-tracking Research Results into Practice: Designing and Testing Effective Strategies for Implementing Evidence-Based Medicine,” which was directed by Tracy Wang, MD, MHS, MSc, director of the DCRI’s Health Services and Outcomes Research, and Amy Kilbourne, PhD, MPH, director of the VA Quality Enhancement Research Initiative (QUERI) at the University of Michigan. The meeting brought together numerous stakeholders, including academic researchers, health care practitioners, pharmaceuticals representatives, FDA leaders, and patients, for a discussion on how best to implement findings from research.

Members of the diverse group shared their perspectives and eventually came to a consensus about how to define implementation research. They defined it as the study of methods to promote the systematic uptake of research findings and other evidence-based practice into routine practice. Participants also agreed that the ultimate goal of implementation research is to improve the delivery and effectiveness of health care.

The discussion also focused on challenges currently impeding implementation of research findings. Takeaways included the importance of emphasizing implementation throughout the product development pipeline. Participants brainstormed approaches to streamline the path from discovery to application, including designing innovative trials that reflect real-world populations and health care delivery environments as well as incorporating various perspectives from clinicians and patients throughout the process.
COLLABORATIONS

Transforming Clinical Trials

No single stakeholder can successfully address the challenges in clinical research. Because of this, the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the FDA in 2007, brings together stakeholders from across the clinical research ecosystem to create new solutions for better, more efficient clinical trials.

With representation from academia, clinical investigators, government and regulatory agencies, industry, institutional review boards, patient advocacy groups, and others, CTTI has created over 20 recommendations and associated resources that address current challenges and opportunities in clinical research. Organizations have implemented these recommendations and resources to improve their clinical trials, and regulatory agencies have cited the work in developing new policies. Led by Executive Director Pamela Tenaerts, MD, MBA, CTTI works to determine strategies to accomplish its mission. The DCRI, which serves as the host of CTTI, and Duke University more broadly play a critical role in this collaboration. The DCRI’s John Alexander, MD, MHS, is CTTI co-chair and sits on the executive committee, which is chaired by Mark McClellan, MD, PhD, director of the Duke-Margolis Center for Health Policy.

Recent CTTI work includes creating a comprehensive set of recommendations and resources to drive the appropriate use of mobile technologies in clinical trials. Additionally, CTTI announced new resources to facilitate the implementation of single institutional review boards (sIRBs) in multicenter trials, building on many years of leading the culture shift around the use of sIRBs. This work is especially important given the 2018 Common Rule, which requires that all U.S. institutions involved in U.S.-based cooperative research use a sIRB by January 20, 2020. And, closing out 2019, CTTI also announced recommendations, resources, and case studies detailing how to leverage real-world data to plan trial eligibility criteria and recruit participants in clinical research. Looking ahead, CTTI will continue this momentum and embark on new areas of work.

The DCRI often partners with other academic research organizations around the world, such as the Canadian VIGOUR Centre (CVC), in their work to deliver clinical trials. The DCRI’s head of research operations, Ty Rorick, sat down to discuss the success of these collaborations with Tracy Temple, associate director of clinical trials at the CVC.

TY: The DCRI’s partnership with the CVC is longstanding and is built on trust and openness, quality delivery of work, and the relationships we’ve developed with Dr. Paul Armstrong, other CVC faculty, statisticians, and with you, Tracy. There’s been little turnover on both sides, so we’ve gotten to work side-by-side in a completely integrated partnership.

TRACY: I would echo that. Our collaboration started with Drs. Paul Armstrong and Robert Califf during the GUSTO-I trial in the 1990s. It was the beginning of a strong partnership and friendship that has continued to grow over time. These relationships have been nourished by visits to each other’s organizations and face-to-face meetings at international meetings, CME events, and trial-related activities. An important milestone was the construction of an overarching master agreement between the CVC and the DCRI, which was supported by former DCRI Director Robert Harrington. Having worked on many trials together over nearly three decades, our academic thought leadership, as well as our statistics, population health, operations, and business teams, have been well aligned. Openly sharing SOPs, databases, and other tools and templates over the years has ensured a seamless experience for the study sponsor.

“We want our sites to know both the CVC and the DCRI and to be open to ongoing collaborations and new ways of working together.”

Ty Rorick
TY: That’s right. We spend time helping the sponsor understand that the experience will be seamless because of our long-standing partnership. From their perspective, it looks as though the entire North America piece of their study was conducted by a single entity, and together, we bring incredible academic and operational value to their project. We also learn from each other. The depth of experience on both sides has been invaluable to this learning.

TRACY: I agree that the shared learning has been beneficial across both of our organizations. For example, you and your team were able to walk us through your experiences hosting FDA inspections, which helped us work with our sites to be better prepared for FDA, Health Canada, and sponsor inspections.

TY: One way we learn from the CVC is to watch how your faculty and operations teams work together. Our faculty values our operations staff and they work together well, but it is always interesting to see how others do it outside of the DCRI and find areas where we may be able to improve. Another strength of the CVC is site engagement. The CVC has maintained strong connections with their sites, which promotes consistency in being able to go back to the same sites and personnel for new studies. We want our sites to know both the CVC and the DCRI and to be open to ongoing collaborations and new ways of working together. Speaking of the future, I’ll segue into a question I want to ask you, Tracy. What do you envision for the future of the partnership between our two organizations?

“Openly sharing SOPs, databases, and other tools and templates over the years has ensured a seamless experience for the study sponsor.”

Tracy Temple

TRACY: I expect we will continue to explore opportunities to strengthen our partnership in the years ahead. There are many new ideas emerging in research as it relates to the use of technology, alternate trial designs, and use of big data, which we are uniquely positioned to be a part of. The cross-border collaboration also offers a unique opportunity for Canadian/American comparisons related to health care and health economics. Thinking about how we can not only increase efficiency but also be innovative and creative in future projects will be important. Our collaboration has been built over many years and has been fostered by a mutual respect, established relationships, similar research interests and approaches, and producing high-quality deliverables—all of which will undoubtedly be key pillars as we continue working together.

Fostering Collaboration to Improve Pragmatic Trials

The DCRI’s Myles Wolf, MD, MMSc, is exploring how to best manage blood phosphate levels in patients receiving dialysis through the HiLo trial—one of six large-scale pragmatic clinical trials from across the U.S. that were added to the portfolio of innovative Demonstration Projects this year by the NIH Health Care Systems Research Collaboratory program (NIH Collaboratory).

Since becoming the coordinating center for the NIH Collaboratory at its inception in 2012, the DCRI has been working with the NIH to advance pragmatic clinical trials embedded in health care systems. The Demonstration Projects supported by the Collaboratory have access to support and resources, as well as a network of investigators conducting other pragmatic trials who share pitfalls and solutions during regular meetings.

The Collaboratory was formed to offer a testing ground for pragmatic trials and to create a new infrastructure for collaborative research within health systems. Developed by the NIH Common Fund and administered by the National Center for Complementary and Integrative Health (NCCIH) and the National Institute on Aging (NIA), the Collaboratory has delivered on its mission by supporting 15 innovative Demonstration Projects. Six of these awards were announced over the past year, including the DCRI-led HiLo. The Demonstration Projects encompass 1,200 clinical sites across 90 percent of the U.S. and include more than 752,000 active subjects.

The DCRI shares the Collaboratory’s activities via methods including publications, Grand Rounds, training workshops, and an innovative website called the Living Textbook of Pragmatic Clinical Trials. The Living Textbook offers a growing and continually updated set of resources to guide stakeholders in research that engages health care delivery organizations as partners.

This year, a new group of Demonstration Projects will be added to the NIH Collaboratory portfolio. The projects, which will explore pain management and opioid prescribing, will be supported by a project called Resource Coordinating Center for Pragmatic and Implementation Studies to Reduce Opioid Prescribing (PRISM), which is funded by the NIH’s Helping to End Addiction Long-Term Initiative (NIH HEAL Initiative). The work of the Collaboratory will continue to be led by three DCRI co-investigators: Adrian Hernandez, MD, MHS; Lesley Curtis, PhD; and Kevin Weinfurt, PhD.

NIH Collaboratory
Health Care Systems Research Collaboratory
DCRI Service Offerings

As an academic research organization, our researchers and operational teams have the independence to challenge the status quo and think beyond traditional methods. From design to implementation to publication, the DCRI manages every stage of clinical research, giving our sponsors the confidence that their studies are being managed thoughtfully and seamlessly. Our project teams are made up of practicing physicians and operational staff who bring expertise to their roles in fields such as project management, life sciences, chemistry, nursing, and public health, to name a few.

**CLINICAL TRIAL PROGRAMS**

Having the expertise, technology, and resources to successfully conduct studies can lead to results that impact care sooner. By managing every facet of clinical research, studies at the DCRI are managed seamlessly throughout all clinical research phases by practicing physicians and data and operational experts who know exactly what's at stake. Clinical trial services provided by the DCRI include:

- Duke Early Phase Clinical Research (Phase I)
- Phase II/III Development
- MegaTrials (>5,000 patients)
- Device Trials
- Post-Marketing Surveillance/Late-Phase

**TRIAL DESIGN**

The DCRI excels at every facet of trial design required for an efficient and effective research project. By combining scientific leadership, clinical research expertise, and operational know-how, the DCRI is exceptionally qualified to:

- Provide expert support for clinical program development plans at FDA and international regulatory meetings;
- Develop ideas and protocols for clinical research projects designed to be implemented in the current practice setting; and
- Act as principal investigators for DCRI projects, providing access to the resources and expertise available within a large academic medical institution.

**HEALTH SERVICES RESEARCH AND OUTCOMES**

Every year, more than 35 million patients walk through the doors of hospitals and clinics with questions about their health and their care. Questions range from medication dosing to treatment expectations to paying the bill. At the DCRI, finding answers is a commitment we’re making through our Health Services Research capabilities in:

- Behavioral Research Intervention Science
- Comparative Effectiveness Studies
- Disease Registries
- Evidence Synthesis
- Health Economics
- Health Policy
- Outcomes Call Center
- Patient-Reported Outcomes
- Pragmatic Health Systems Research
- Quality Improvement
- Stated Preference Research
TRIAL SUPPORT SERVICES

The DCRI provides comprehensive trial support services, led by faculty, biostatisticians, and operational teams who work together to ensure the validity and integrity of a trial, resulting in the best chance of success with minimal risk to patients. Trial support services include:

• Clinical Events Classification and Safety Surveillance
• Independent Data Monitoring Committee
• Pharmacometrics Center
• Precision Imaging
• Study Communications

ANALYTICS AND DATA SCIENCE

The DCRI pushes beyond what’s most apparent. By tapping the experience of Duke faculty statisticians and the real-world insights of practicing physicians, we find the fullest potential in the datasets our research generates. The result is meaningful decisions reached more quickly and efficiently, evidence that has more immediate impact on patient care, and datasets with value beyond the immediate analyses.

Ushering in New Services: Motivating Behavior Change

Offering well-designed incentives to study participants can improve study recruitment and retention, as well as the health of individuals and communities, say the co-directors of the DCRI’s new Behavioral Research Intervention Science Center (BRISC).

Pediatrician Charlene Wong, MD, MSHP, and urologist Chuck Scales, MD, MSHS, teamed up to found and lead BRISC, which advances the science of applying behavioral incentives in clinical research. Through various financial, social, and informational incentives built into studies, BRISC is helping its researchers encourage behavior change in study participants.

In one ongoing study, Wong and Scales are using real-world data from the Duke Health System to generate monthly reports on individual providers’ opioid-prescribing patterns. The investigators expect that the reports will be a social incentive by enabling providers to compare their prescribing behaviors with those of their peers. The study team will compare baseline prescribing behaviors with behaviors six months after providers begin receiving the reports.

BRISC is also engaging the community and other experts both across Duke and beyond. It recently held a colloquium that convened thought leaders in behavioral economics and health care.

“The colloquium was an inspiring and successful first event for BRISC,” Wong said. “I believe I speak for many of the attendees when I say that I am now encouraged that we will be able to break down silos and continue to work together to conduct more high-impact work, achieving behavior change and more efficient clinical research that will help people become healthier.”

“I am now encouraged that we will be able to break down silos and continue to work together to conduct more high-impact work, achieving behavior change and more efficient clinical research that will help people become healthier.”

Charlene Wong, MD, MSHP
DCRI Therapeutic Areas

From its founding as the Duke Databank for Cardiovascular Disease, the DCRI has been known for its long history and expertise in cardiology. However, our investigators also pursue groundbreaking research in many other specialty areas, from pediatrics to neurosciences medicine. The breadth of our work is matched by the depth of our knowledge, which enables our researchers to collaborate across therapeutic areas to find answers about conditions that meet at the intersection—such as our cardiologists and nephrologists working together to tackle kidney disease.

As an academic research organization, all of the DCRI’s investigators are also physicians who care for patients day in and day out. Inspired to pursue problems they see in the clinic, DCRI faculty bring insight to their research that is grounded in real-world practice.

CARDIOVASCULAR

The world looks to the DCRI as the definitive leader in cardiovascular clinical research, science implementation, and education. Our cardiovascular expertise covers all research phases, from proof-of-concept studies to multinational late-phase trials. We also work with post-approval registries sponsored by industry, government, and professional societies. Most importantly, everything we learn is shared openly so that others can take our findings and build upon them, ensuring that the best answers to the hardest cardiovascular questions are found.

GASTROENTEROLOGY

Digestive disorders and diseases of the liver vary widely but share one common feature: the devastating impact they can have on a person’s health and quality of life. In the DCRI’s Gastrointestinal (GI) research program, clinical and basic science experts come together to seek out bold and creative innovations in the treatment of these complex conditions. This partnership positions Duke University and the DCRI as one of the leading GI and hepatology research centers in the world.

INFECTIOUS DISEASES

There is no room for uncertainty in identifying infectious diseases and finding effective treatment solutions. Success requires the confidence that comes with the experience derived from clinical practice and the deep understanding gained from repeatedly navigating the complexities of infectious disease research. With an attentive network of thought leaders, site investigators, and faculty who are practicing infectious disease physicians, we stand ready with insights and innovative research methods needed to understand and defeat infectious diseases.

MUSCULOSKELETAL

Musculoskeletal conditions are the leading contributor to disability worldwide, according to the World Health Organization (WHO). Because of their frequency and interference with the ability to perform critical tasks of daily living, musculoskeletal disorders are a major determinant of health for both individuals and populations. The DCRI’s Musculoskeletal research program seeks to transform musculoskeletal practice and improve the delivery of patient care around the world.
NEPHROLOGY

Chronic kidney disease is a global public health threat that confers high risks of end-stage renal disease, cardiovascular disease, and premature death. Our DCRI team of nephrologists and urologists has years of collective experience in conducting federally-funded and industry-supported trials as well as observational clinical research. Backed by the unparalleled clinical research infrastructure at the DCRI, we are ideally positioned and committed to advancing clinical trials of all types in nephrology.

NEUROSCIENCES MEDICINE

From epilepsy to depression to Alzheimer’s disease and ADHD, neurological disorders affect up to one billion people worldwide, according to the WHO. The Neurosciences Medicine research program at the DCRI, led by more than 40 psychiatry and neurology faculty, is dedicated to taking bold action to find solutions for those affected. Our program develops, conducts, and supports innovative Phase I-IV clinical trials addressing neurological and psychiatric conditions for pediatric, adolescent, adult, and geriatric patient populations.

PEDIATRICS

The safety and well-being of children must be at the center of all pediatric clinical research. The commitment of the DCRI’s pediatrics faculty to advance the scientific investigation of safe medical therapies in children begins at the bedside. We know firsthand the limits and risks of providing treatments based on evidence generated through studies conducted in adults. Our faculty use innovative design methods and data monitoring in order to lead the effort to expand the prevalence and impact of pediatric research.

RESPIRATORY MEDICINE

Respiratory diseases are increasing in prevalence and today are the third-leading cause of death in the U.S. The DCRI’s Respiratory research program includes physicians with firsthand experience treating patients with diverse respiratory problems as well as expertise in conducting clinical and translational research in these patient populations. At the DCRI, we’re working with sponsors to apply new approaches to respiratory research—approaches that will lead to better and more effective therapies that offer both relief and hope.
### DCRI Leadership

#### Senior Management Team

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<th>Name</th>
<th>Title and Notes</th>
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<tr>
<td>LESLEY H. CURTIS, PHD</td>
<td>Interim Executive Director, DCRI</td>
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<tr>
<td></td>
<td>Chair and Professor, Department of Population Health Sciences</td>
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<tr>
<td>JOHN H. ALEXANDER, MD, MHS</td>
<td>Director, Cardiovascular Research, DCRI</td>
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<td>Professor of Medicine, Cardiology</td>
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<td></td>
<td>Vice Chief for Clinical Research, Cardiology</td>
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<td>DANIEL K. BENJAMIN, JR., MD, PHD, MPH</td>
<td>Faculty Associate Director, DCRI</td>
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<td></td>
<td>Kiser-Arena Distinguished Professor of Pediatrics</td>
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<td>Principal Investigator and Chair, National Institute of Child Health and Human Development’s Pediatric Trials Network</td>
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<td>LISA BERDAN, PA-C</td>
<td>Senior Director, Global Outcomes</td>
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<td>Commercial MegaTrials</td>
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<td>SUSAN P. LANDIS</td>
<td>Head, Strategic Engagement and Communications</td>
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<tr>
<td>DANA MCDONAL</td>
<td>Interim Head, Human Resources</td>
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<tr>
<td>TY RORICK</td>
<td>Head, Research Operations</td>
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<td>AIMEE L. TURNER, CPA</td>
<td>Chief Financial Officer</td>
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<tr>
<td>TRACY Y. WANG, MD, MHS, MSC</td>
<td>Director, Health Services Research, DCRI</td>
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<td></td>
<td>Associate Professor of Medicine, Cardiology</td>
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#### Operations Management Team

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<tr>
<td>KEVIN J. ANSTROM, PHD</td>
<td>Director of Biostatistics, DCRI</td>
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<td></td>
<td>Professor, Department of Biostatistics and Bioinformatics</td>
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<td>ELIZABETH FRAULO</td>
<td>Senior Director, Health Services Research</td>
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<td>BRIAN MCCOURT</td>
<td>Senior Director, Technology &amp; Data Solutions</td>
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<td>DONNA PARKER, MPH</td>
<td>Operational Lead, Transformation Team</td>
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<tr>
<td>SUZANNE PFEIFER, MPH</td>
<td>Director, Grants and Proposals Services Director, Contracts Management</td>
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<td>RENÉE PRIDGEN, MHA</td>
<td>Director, Government Trials and Networks</td>
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<tr>
<td>CRAIG REIST, PHD</td>
<td>Interim Director, MegaTrials</td>
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<td>TY RORICK</td>
<td>Head, Research Operations</td>
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<tr>
<td>LINDSAY SINGLER, MPH</td>
<td>Associate Director, Study and Project Engagement</td>
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<tr>
<td>LAUREN TOCHACEK, MS</td>
<td>Assistant Director, Quality Assurance</td>
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<tr>
<td>AIMEE L. TURNER, CPA</td>
<td>Chief Financial Officer</td>
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<tr>
<td>MATT WILSON, RN</td>
<td>Director of Operations, Clinical Events Classification-Safety Surveillance (CEC-SS) Director of Operations, Imaging</td>
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<tr>
<td>SYBIL WILSON, RN</td>
<td>Director, Site Management and Monitoring</td>
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New DCRI Faculty

MARA BECKER, MD
Department of Pediatrics

JESSilyn DUNN, PHD
Department of Biomedical Engineering
Department of Biostatistics
& Bioinformatics

DANIEL EDMONSTON, MD
Department of Medicine, Nephrology

CHRISTINE GOERTZ, DC, PHD
Department of Orthopaedic Surgery

DEBORAH KAYE, MD, MS
Department of Surgery, Division of Urology

KARAN KUMAR, MD, MS
Department of Pediatrics

TREVOR LENTZ, PT, PHD, MPH
Department of Orthopaedic Surgery
DCRI Fellows

Second Year

SAMIA ALEEM, MD

ZAK LORING, MD

ADAM NELSON, MD

SARAH GOLDSTEIN, MD

GUILLAUME MARQUIS-GRAVEL, MD

DAVID WILLIAMS, MD

ANNA HUNG, PHD

CHRISTOPHER MOSHER, MD

MICHEL ZEITOUNI, MD

OLIVER JAWITZ, MD

MICHAEL NANNA, MD

First Year

ERIC BLACK-MAIER, MD

RAHUL LOUNGANI, MD

E. HOPE WEISSLER, MD

ANTHONY CARNICELLI, MD

MARC SAMSKY, MD

JEDREK WOSIK, MD

DEREK CHEW, MD

MATTHEW SINCLAIR, MD

SARAH COMMANDER, MD

ZACH WEGERMANN, MD
BRINGING ORIGINAL THINKING TO PATHWAYS ALREADY EXPLORED AND NEW PERSPECTIVES YET TO BE FORGED