ANSWERING TODAY’S QUESTIONS FOR TOMORROW’S WORLD

Duke Clinical Research Institute
Annual Report 2014–2015
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OUR MISSION

TO DEVELOP AND SHARE KNOWLEDGE THAT IMPROVES THE CARE OF PATIENTS AROUND THE WORLD THROUGH INNOVATIVE CLINICAL RESEARCH
Here at the Duke Clinical Research Institute, a cornerstone of the Duke University School of Medicine for more than 30 years, we are dedicated to advancing clinical research through innovative study design and operations, thoughtful interpretation of data, and a commitment to the rapid translation of knowledge into practice. We are addressing the challenges patients, clinicians, and sponsors face while offering insights, ideas, and direction for the future.

In this report, we show how our faculty members, operational staff, and fellows are actively reshaping the future of clinical research and medical care. Whether it’s transforming the way clinical trials enroll patients, analyzing enormous datasets to understand diseases, or developing novel tools for communicating treatment options to patients, the DCRI is leading the way to a healthier life for everyone.

We also believe that the best results come from working collaboratively, both among disciplines at the DCRI and with our external partners around the globe. Our teams bring an eagerness to listen and learn from peers, to consider new options, and to disseminate novel innovations in research.

By bringing an insightful perspective to complex healthcare challenges, we craft the right approach for today’s clinical research—advancing science for tomorrow’s world.

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

Project Portfolio: July 1, 2014–June 30, 2015

- **36.7%** Government
- **63.3%** Commercial

DCRI Publications

- High impact manuscripts published in journals with an impact factor greater than 10.0 (<2% of all indexed journals)

**Trials Experience by Phase and Size**

- **36%** Other/Registry
- **15%** Phase II
- **3%** Phase I
- **16%** Phase IV
- **49%** Small (1–499 patients)
- **27%** Mega (>5,000 patients)
- **6%** Large (2,000–4,999 patients)
- **30%** Medium (500–1,999 patients)
THE PROMISE OF PERSONALIZED MEDICINE:

What roles do our researchers play in advancing the promise of personalized medicine?

It’s a hot-button issue and a major focus of the scientific community. It goes by many names—personalized medicine, precision medicine, risk stratification—but regardless of the terms used, it translates to one question: *How can we collect and analyze individuals’ health data to find the right treatment for the right patient?* The applications surrounding more personalized approaches to prevention and treatment are endless, but collecting the necessary clinical data can present conceptual and practical challenges.

At the DCRI, researchers are collaboratively developing registries, research programs, and partnerships in service of personalized medicine.

One pioneering project is the MURDOCK Study, led by Dr. Kristin Newby. MURDOCK was launched in 2007 and has grown into a major platform for data collection and analysis.
“This is like team science on steroids,” says Dr. Newby, a DCRI faculty member and leader of several projects related to personalized medicine. “It really takes everybody participating to achieve the greater good for society.”

MURDOCK researchers have created a community registry and biorepository that gathers information from more than 12,000 participants who have shared health information and biological samples. When patients first join the study, they provide information about their health status, lifestyle habits, and family medical history, while study staff collect blood and urine samples and measure their vital signs. Participants also submit annual follow-up information so researchers can track their health status over time.

Because the registry includes more than just clinical information and biomedical samples, researchers can more accurately characterize participants based on environmental and lifestyle factors such as socioeconomic status and activity level. This leads to a deeper understanding of how different subgroups are affected by common chronic diseases, including diabetes and obesity.

“It really takes everybody participating to achieve the greater good for society.”

Kristin Newby, MD, MHS

As the study has evolved and the registry has expanded, so has the number of topics its data can help address. The MURDOCK Study’s flexible infrastructure means that researchers can use information from the registry and biorepository to answer a wide variety of questions about why some people develop specific diseases and others don’t, as well as how responses to therapies vary.
Data, however, do not become knowledge without careful analysis and interpretation. The DCRI’s biostatistics group is also focused on how to improve personalized medicine. Dr. Michael Pencina, director of biostatistics, is leading his team in the development of new methodologies to answer difficult questions.

For example, the DCRI’s Center for Predictive Medicine aims to advance personalized medicine through the development and application of novel approaches to quantify and communicate risk. The center’s biostatisticians recently partnered with the Duke University Health System on a new endeavor to develop a risk-based algorithm that will identify Duke hospital patients at risk of sepsis using data culled from Duke’s electronic health records (EHRs).

Today, Duke and other healthcare organizations use a generic risk prediction model to identify high-risk patients, but the most common model was developed in England and isn’t tailored to a specific patient population. The center aims to develop a more accurate algorithm by using Duke EHR data to identify high-risk Duke patients. Once the DCRI develops the Duke-specific algorithm, the teams will compare it to the generic model developed in England to assess which model has greater accuracy in identifying high-risk patients.

“Identifying patients at risk of sepsis is just one example of how we can leverage EHR data to help save lives in a real-world setting, and it’s a model that can translate to other conditions as well,” says Dr. Pencina. “Our goal is to use data from EHRs to build more accurate predictive models that can help answer key clinical questions and identify high-risk patients who most need treatment. There is a tremendous need for big data to help support what is happening on the front lines of health care.”
Project Spotlight: Taking the Initiative

The Southeastern Diabetes Initiative (SEDI), led by the DCRI, the Duke Translational Medicine Institute, and the University of Michigan’s National Center for Geospatial Medicine, is taking a multi-tiered community approach to improving outcomes for high-risk patients with diabetes.

Diabetes is one of the biggest health epidemics facing the United States, and it increases the risk for many other serious health problems. The Centers for Medicare & Medicaid Services, in collaboration with Bristol-Myers Squibb Foundation, launched SEDI to improve patient outcomes in communities with high rates of uncontrolled diabetes. Traditional approaches to patient care have not been able to successfully reverse the epidemic.

This unique community intervention program is based in five diverse regions, including Durham and Cabarrus Counties in North Carolina; Camden, New Jersey; Mingo County in West Virginia; and Quitman County in Mississippi. These areas, despite being geographically diverse and having significantly different populations, all have epidemic rates of diabetes.

The program identifies people in the communities who have diabetes and other risk factors associated with poor clinical outcomes, such as high blood pressure and high cholesterol. Staff at Duke and the DCRI built a predictive algorithm that indicates which people are at the greatest risk, and the outreach efforts focus on those patients. Using a multi-tiered approach that includes home visits and educational outreach, the program aims to reduce the rates of stroke, heart attack, and other serious complications in this population.

The program is a true multidisciplinary, cross-institutional approach to treating diabetes. It involves community health workers, statisticians, cardiologists, nephrologists, internists, and information technology staff, as well as the geospatial mapping team at the University of Michigan. Geospatial mapping allows the researchers to identify particular neighborhoods with the highest-risk populations, where additional outreach can have the most impact. The goal is to expand the program further if SEDI can successfully improve outcomes in these communities with diabetes epidemics.
“There is a tremendous need for big data to help support what is happening on the front lines of health care.”

Michael Pencina, PhD
How are collaborative partnerships advancing clinical research methodology, statistical innovation, and knowledge dissemination?

Patient care improvements that grow out of DCRI research are invaluable, but there’s still a need for some traditional aspects of clinical research study design and operations to evolve.

“In every trial, we’re trying to figure out ways to do something better, and not just repeat the same recipe,” says Dr. Adrian Hernandez, director of Health Services and Outcomes Research at the DCRI.

Trials need to be more efficient and faster, so data can build insights and real-world solutions quickly. At the DCRI, faculty and staff are committed to improving methodology and advancing the field. Collaboration is at the heart of these efforts—partnering with sponsors, government, fellow research institutions, and, most importantly, patients themselves.

Within DCRI research teams, there’s meaningful partnership among clinical, statistical, and operational experts, or what DCRI Global Outcomes Commercial Megatrials Director Lisa Berdan calls a “mind meld.”

“A team works better than an individual,” Berdan says. “There’s so much more you can get done in a group than by yourself.”
Creating teams with so many different stakeholders, all of whom have opinions and perspectives shaped by personal experience, can be complicated, requiring everyone to approach key decisions about trial design and execution with flexibility and humility. This is an area where DCRI leaders excel.

The ADAPTABLE study, the first trial run by PCORnet, the National Patient-Centered Clinical Research Network, represents a new type of collaboration between patients, health system networks, researchers, and data scientists.

Patients have been involved in every aspect of the trial from the beginning, helping researchers choose the question—What dose of aspirin is better for cardiovascular health for patients with heart disease?—and develop the web tools that allow patients to sign up for the trial online. Throughout the trial, they will participate in data-monitoring and safety discussions, and they will help drive key decisions when issues arise.

“It’s an opportunity for us to put the patient at the center of everything,” says Tyrus Rorick, DCRI associate director of Megatrials.

Another innovative aspect of the trial is how it takes advantage of EHRs. During most trials, researchers need to find potential participants at their clinical sites, which is costly and complicated. In ADAPTABLE, they’re using data from patients’ EHRs to identify who could qualify for the study, and then inviting them to participate via an online patient portal, where they can learn about the study and give electronic consent to participate. The health networks participating in PCORnet and the ADAPTABLE study use a Common Data Model, so data already collected as part of routine patient care will be shared centrally, avoiding the traditional method of local data entry.

ADAPTABLE is “the single most transformative thing we’re doing in clinical research at the DCRI right now,” says Berdan. Already, the collaborative work that has led to the creation
of a Common Data Model and the online patient recruitment and consent “will push forward how research is done today.”

Collaboration often begins with project sponsors and government partners, who are asking the same questions as researchers and are equally committed to developing new ways to answer them.

Collaboration is also fueling much of the work that the DCRI’s biostatistics group is doing. DCRI biostatisticians are collaborating with a number of partners outside of Duke. For example, a team of DCRI researchers, in concert with the University of Washington and the National Institutes of Health (NIH), have identified the best statistical method to use in group or cluster-randomized trials.

Other researchers have been working with the Radiological Society of North America and the National Institute of Biomedical Imaging and Bioengineering to answer questions about terminology and methodology. And in keeping with the DCRI’s long tradition of excellence in collaboration on clinical trials, DCRI faculty statisticians have been providing leadership for the statistical and data coordinating centers for a number of high profile NIH-sponsored studies, including PROMISE, CABANA, STICH, and BRIDGE.

By modeling how different organizations and stakeholders can effectively work together to develop and conduct these innovative trials, these projects demonstrate the power of collaboration. Helping patients get the right care is a compelling and motivating example of the whole being greater than the sum of its parts.
Another DCRI project, the Clinical Trials Transformation Initiative (CTTI), is also working hard to speed the transition of data into patient care. Co-founded by Duke University and the FDA and hosted by Duke, CTTI develops recommendations, tools, and resources to enable a high-quality, efficient clinical trial system. The organization, which is co-chaired by the DCRI’s Dr. John Alexander, studies current clinical trials processes, identifies impediments to beneficial change, and develops consensus-driven, evidence-based recommendations and solutions to improve clinical trials.

This summer, CTTI was honored with a Regional Inspire Award for the Americas at the annual meeting of the Drug Information Association (DIA) in Washington, D.C. The Regional Inspire Awards program recognizes DIA’s outstanding volunteers for their leadership, level of excellence, and commitment to service. CTTI received the Outstanding Contribution to Health Award, which is presented to an organization that has made significant and innovative contributions to advancing health throughout the region.

“We’re honored to receive this award. It is a testament to CTTI’s dedicated membership and staff, who come together as equal partners to develop evidence-based solutions that improve the clinical trials process,” says CTTI’s executive director Pamela Tenaerts. “CTTI’s recommendations and implementation tools are having a true impact as demonstrated by changes in the clinical trial enterprise and by this award.”
“In every trial, we’re trying to figure out ways to do something better, and not just repeat the same recipe.”

Adrian Hernandez, MD, MHS
Just as several DCRI studies are pushing clinical research methodologies and study operations forward, so too is the DCRI changing how real-world outcomes are studied, and how findings from those studies are implemented and brought into routine care. Advances in how the DCRI works with data are shaping that process; by rethinking data gathering, data sources, and data sharing, researchers are helping to bring their findings to bear on patient care more quickly and effectively.

Innovation can start with a simple question: Which kinds of outcomes data should be analyzed? Two DCRI studies funded by the Patient-Centered Outcomes Research Institute (PCORI) examining the effectiveness of stroke therapies and post-acute care options began by posing that question to patients, to find out which outcomes matter most to them. Researchers learned that while key clinical outcomes like re-hospitalization are important, many patients cared even more about “home time” — the number of days they were able to spend in their homes and out of an institution after a stroke.
Dr. Emily O’Brien is one of the DCRI faculty members leading the study and working with the information technology department to develop the website where the results will be shared with patients.

“It’s really important to have the perspective of people who don’t work in the research environments where this terminology is used all the time, but who are really interested in this information and could very much use it in their decision-making process,” she says.

To make the website as accessible and engaging as possible, the PROSPER team is including infographics that display how many additional days at home are associated with each treatment option. Even in situations where a formalized decision tool may not be helpful, the DCRI sees opportunities to bring a by-patients, for-patients approach to how study information and results are shared.

PROSPER also engaged three stroke survivors as patient co-investigators throughout the study. In addition to shedding light on the importance of measuring home time as a key outcome, the patient co-investigators helped shape how researchers gather data—which survey questions would be easy for stroke patients to complete—and how researchers would share that data. They also collaborated on the design of a web portal to simply visualize study results for easy risk, cost, and outcome comparison across stroke therapies.

Lesley Maisch, one of the patient co-investigators, says that the researchers’ receptiveness to patient feedback was refreshing. As surveys evolved and the language used to describe the difference between treatments changed, she was able to see the impact of her suggestions firsthand.

“It’s been a really eye-opening and pleasant experience to realize I could make a difference,” Maisch says.

Adding new data variables can also reshape how information is interpreted, and ultimately transform clinical practice. That was the result of a study led by DCRI faculty
member Dr. Julie Ann Sosa, which examined surgical options to remove tumors in thyroid cancer patients. A previous study had indicated a 31 percent improvement in survival rates when surgeons removed all of the thyroid gland rather than just half.

Dr. Sosa and her team re-created the study using information from the same database, but looked at a broader range of data variables and made important statistical adjustments for additional patient demographic, clinical, and pathological variables. By doing so, they discovered that the survival rates associated with the two surgery options were comparable—a victory for patients, given that the partial removal carries fewer surgical risks.

There are certainly opportunities that remain untapped: In a follow-up to the thyroid cancer surgery study, Dr. Sosa and her team learned that nearly a fourth of patients received an inappropriate radioactive iodine treatment after thyroid surgery for very small thyroid cancers, leading to up to $16 million in unnecessary healthcare spending.

Dr. Sosa’s conclusion was that clinical research organizations like the DCRI have more opportunities to think through “how we can do a better job educating patients and communities, and how we can do a better job educating providers about contemporary data so they too can practice evidence-based medicine.”

As the DCRI continues to evolve its approach to data gathering, sourcing, and sharing, the potential influence on the speed with which findings make it into clinical practice, and the percentage of patients those findings impact, continues to grow.

The success of these projects shows a promising path forward, one that marries a rigorous approach to data gathering with deep stakeholder engagement. It’s a path leading to findings that can be shared with patients and providers in the modes and mediums that are most intuitive and helpful, driving meaningful impact on clinical practice.
Project Spotlight: Weighing the Costs of Care

The ongoing ARTEMIS trial demonstrates how the DCRI and its partners are making an impact in innovative trial design.

ARTEMIS goes beyond the usual research question of “which therapy to use?” to answer the question of “how can we help patients and providers choose the most effective therapies?” It’s a groundbreaking practical policy trial that examines whether reducing patients’ medication copayment burden will help them choose the most effective therapy and stay on it for the duration recommended by practice guidelines.

Two simple aspects set ARTEMIS apart. First, it’s a cluster randomized trial, meaning that hospitals are assigned to be either one of the “intervention arm” sites, which will distribute a voucher that equalizes copayments between generic and brand treatment options before patients and providers are asked to make treatment decisions, or one of the “control arm” sites, which will go about care as usual. It’s a straightforward approach that simplifies patient consent and permits observation of provider care practices in a real-world setting.

Second, the DCRI will collect patient data for 15 months via phone or web portal, rather than asking patients to return to the hospital, making the process easier and more appealing to patients and hospitals. Using a combination of medical bills, hospital records, and blood samples, ARTEMIS will help answer not only the question of whether cost influences patients’ care decisions, but also whether removing the cost barrier leads to better outcomes and lower healthcare costs.

“ARTEMIS is launching the next phase of integrated clinical research by incorporating clinical data with patient-reported outcomes through the innovative medium of technology,” says Linda Davidson-Ray, project leader.
“It’s really important to have the perspective of people who don’t work in the research environments where this terminology is used all the time, but who are really interested in this information.”

Emily O’Brien, PhD
DATA DRIVEN, PATIENT CENTERED:

How do we make better use of data and improve care for patients?

The DCRI has made a commitment to become the first academic institution to make its study data public. Several initiatives led by DCRI faculty members have already made the jump. One is the Pediatric Trials Network (PTN), led by principal investigator and DCRI associate director Dr. Danny Benjamin.

The PTN is an alliance of clinical research sites that design and conduct trials to study the proper dosages of drugs for infants. Its recently completed study of meropenem, an anti-microbial drug used to treat intra-abdominal infections in infants, led the FDA to re-label the drug with the updated dosing recommendations. Because intra-abdominal infections are the second most common cause of death for infants in the intensive care unit, this change will help ensure the safety of some of the youngest patients.

The meropenem study’s key documents, including details about the data system used to analyze the results and the meta-data itself, are publicly available on the PTN website. This transparency will give more researchers access to work that can be used to further improve care for infants.

Simply making results available, though, doesn’t necessarily lead to use beyond the academic community. Education and partnerships with clinician and patient resources will close that particular data divide. The PTN, for example, has partnered with Pediatric Medical Group to bring its
dosing recommendations directly to doctors, making personal contact with the editors of the reference textbooks and providing copies of abstracts and manuscripts so that information could be immediately updated in online sources.

Many studies follow patients over a period of time that can span from several months to several years, and many require patients to make return visits simply to share basic data. It’s expensive, time-consuming, and a burden on sites and patients. Dr. Matthew Brennan, in collaboration with the Centers for Medicare and Medicaid Services (CMS) and other partners, is asking a provocative question: Can we use claims data to track patient outcomes over time to make trials more efficient?

By using a DCRI-developed method that links clinical data from patient registries to claims data from Medicare billing, Dr. Brennan can see whether the medical data “validates” the billing data by tracking whether they record the same patient medical events. Dr. Brennan has discovered that while there are differences, in the most important ways, they’re very similar. Both types of data record similar “event rates”—in other words, they record similar numbers of medical issues that lead to unfavorable changes in the patient’s health. These encouraging results are an important step forward for gauging the usefulness of claims data for clinical trials.

For clinical research findings to make an impact on patient treatment, doctors and patients need access to study results. The public and private institutions that sponsor research have both a legal and an ethical responsibility to share their findings. Ethically, it’s important that patients who participate in trials understand their contributions and that other patients have access to findings that may be pertinent to them. Legally, researchers are bound by a 2007 FDA amendment that requires most trials to register on, and submit summary results to, ClinicalTrials.gov, the official registry and results database for clinical studies.

“A lot of trials never go to completion, and some trials never get published, so it’s important to have one place to know what’s going on,” says Dr. Monique Anderson,
a DCRI faculty member whose recent work has examined results reporting compliance.

Dr. Anderson recently published a study that found that despite ethical and legal mandates, only 13.4 percent of eligible studies’ results were reported to ClinicalTrials.gov within a year of study completion. What’s more, only 38.8 percent had reported results at any point during the five years in which the reporting mandate for ClinicalTrials.gov had been in effect.

While several proposals to change FDA policy are currently being considered, it is likely that even more trials will be required to post results (including trials that involve a therapy that didn’t end up getting approved), and that the penalties for not reporting results will be a reality (up to $10,000 a day). Dr. Anderson also aims to motivate academic institutions in particular to make their own internal changes.

“My hope is that academic institutions will create their own policies,” Dr. Anderson says. “It’s made me much more aware of the need to get my data out there in a timely manner.”

The DCRI is also taking advantage of opportunities to build on the broader landscape of data-gathering innovations. One of those is Apple ResearchKit, which provides a platform for researchers to directly reach out to patients and engage them in outcomes research. Dr. Zubin Eapen, the faculty leader of the DCRI Innovation Team, spearheaded an event that asked faculty to develop ideas for studies that could use ResearchKit. The Innovation Team then connected faculty members with developers and engineers who could help them prototype their apps and bring their studies to fruition through this exciting new platform.

Dr. Eapen is hopeful that the Innovation Team can “help seed and accelerate ideas,” showing faculty members that even ideas that start small can be quickly scaled up via technologies like apps and web-based educational tools.

“You can’t just have four or five people brainstorming on behalf of a 1,400-member organization,” Dr. Eapen says. “We want everyone to put forth their best ideas.”
Project Spotlight: Data on Demand

In addition to considering how to make study results more transparent, the DCRI is also looking at opportunities to share entire study data sets. The Institute of Medicine recently published a report laying out data-sharing best practices and recommending that sponsors share full results, including metadata sets, within 18 months of study completion. Supporting Open Access to clinical trials data for Researchers (SOAR), a new partnership between the DCRI and Bristol-Myers Squibb (BMS), will help make that recommendation a reality. BMS has committed to making studies completed in 2008 and later available to researchers who want to leverage the data in their studies.

Dr. Peterson and Dr. Pencina will lead an independent scientific review process for the data requests. They will offer feedback on the scientific merit and methodology of proposals to help ensure that the right data are used to answer the right questions.

Dr. Pencina thinks that the DCRI can play an important role in the process because of its access to clinical and biostatistical leaders from across the university.

“We bring the science and the scale of science to be able to help researchers from all walks of life,” Dr. Pencina says. “The big hope is that there will be more research happening. If you have the data available, everyone with reasonable ideas can use it and analyze it.”

As data transparency initiatives continue to expand, the DCRI hopes to drive long-lasting cultural change within the research community. Dr. Pencina and Dr. Peterson are thinking big. They envision a universal public portal for data collection and aggregation. As more of these data get shared, the DCRI can play a key role in helping scientists identify and use the right biostatistical methods to conduct high-quality research.
“A lot of trials never go to completion, and some trials never get published, so it’s important to have one place to know what’s going on.”

Monique Anderson, MD
Improving patient care is the driving force behind every DCRI study, but in the current clinical research environment, there’s often a frustrating gap between generating knowledge and acting on it.

“There is often a huge time lag between when research findings are presented in journals or at conferences and when they actually influence practice,” says Rebecca Ortega, director of DCRI Education.

To ensure providers have access to the novel therapies and methods that have the power to enhance care, it is critical to accelerate the research-to-practice timeline. The DCRI is in a unique position to bring clinical education into real-world provider and patient settings.

“While we are leading the research, most of us are also frontline practicing clinicians,” says Dr. Tracy Wang, faculty director of DCRI Education. “Our research originates from observed clinical needs, so naturally, we are motivated to translate our results into practice as quickly as possible.”
Although education has long been thought of as the vehicle for closing the gap between research and practice, the impact of traditional educational methods, such as didactic lectures, has largely been unmeasured.

Leveraging the DCRI’s world-class faculty and research infrastructure, Dr. Wang and Ortega are introducing a more hands-on approach to education that moves research beyond the podium and into clinicians’ day-to-day practices. DCRI Education works directly with healthcare providers to implement data-driven educational interventions. It’s an opportunity to contextualize the use of new methods and tools in real-world practice settings, and then use the DCRI’s data analytics capabilities to track how successfully those methods are implemented in real time.

The DCRI’s broad commitment to expanding how research is used in practice can be seen in interdisciplinary initiatives like the DCRI Innovation Team. In addition to helping develop apps that allow the DCRI to harness the power of data in exciting new ways, the team has led projects like Education Gateway, which has gathered a library of over 4,000 hours of medical education videos that share up-to-date treatment approaches across a range of clinical areas. The videos can complement direct education at hospitals and more traditional classroom education to help introduce new therapies and approaches to doctors.

The DCRI’s educational initiatives are making research insights more accessible and tangible for researchers, providers, and patients; taking the reams of data and
paragraphs of findings generated in DCRI studies and translating them into real-world patient care improvements.

“There is often a huge time lag between when research findings are presented in journals or at conferences and when they actually influence practice.”

Rebecca Ortega, MHA

The opportunity at the DCRI is to play existing and future educational formats off of each other, creating a more robust and synergistic education ecosystem. Dr. Wang is optimistic about the long-term and far-reaching potential of DCRI education platforms.

“Ultimately, we’re improving not only our clinical practice, and not only how our patients do over time, but also population health on a greater scale,” she says.
Project Spotlight: The Next Generation

The DCRI has a long-standing commitment to train fellows and junior faculty in order to develop the next generation of clinical researchers. This commitment has evolved into the creation of the DCRI Research Fellowship Training Program.

The philosophy of the training program is that the most successful investigators will be able to combine superior knowledge in their field of clinical specialty with quantitative principles in an interactive, teamwork-oriented environment.

One current DCRI fellow has already put her training to use with a study that questioned the conventional wisdom about current cholesterol medication guidelines.

In 2013, the American Heart Association released new guidelines that changed the way cholesterol-lowering medication was prescribed in the United States. Dr. Ann Marie Navar and a team of DCRI researchers discovered that meant nearly 12 million Americans were newly eligible for statin medication. She was concerned that the new guidelines might not accurately take into account the different needs of certain subgroups within the broader population, and that as a result, the relaxed guidelines could actually increase the risk of heart disease for those groups.

Using data from the Framingham Heart Study, which began collecting data about participants’ cardiovascular health in 1948, she and her team were able to demonstrate that adults in their 30s and 40s with even slightly elevated cholesterol levels were at risk of developing heart disease, thereby demonstrating the need to refine the risk threshold for different age groups.

“We’re using population-level data to help inform providers and patients so they can make more informed decisions about their care,” Dr. Navar says.
“Our research originates from observed clinical needs, so naturally, we are motivated to translate our results into practice as quickly as possible.”

Tracy Wang, MD, MHS, MSc
POPULATION HEALTH—THINKING GLOBALLY, ACTING LOCALLY:

What lessons learned from advancements in community-based health programs can be translated to global population health?

Across clinical research institutions and the broader healthcare community, there is a mutual commitment to answering the shared questions that will propel global population health forward. But it’s the differences that are essential to developing long-lasting solutions that can make an impact on a global scale.

Connecting these diverging perspectives begins with developing relationships with individuals and institutions. At the DCRI, a variety of partnerships within the local Durham community, with hospital sites around the country and world, and with fellow academic research institutions, helped to shape the grassroots strategies and programs that are poised to make a difference globally.

“Collaboration is in our genetic framework,” says Dr. Matt Roe, faculty director of Global Outcomes Commercial Megatrials and
a leader of the DCRI’s partnerships with other academic research organizations.

“We don’t have to be in the front seat,” he says. “What’s important is the impact on patient care.”

Dr. Roe and Lisa Berdan recently collaborated with faculty and operational leaders at the DCRI and with two long-term partners, the Stanford Center for Clinical Research and the Canadian VIGOUR Center-University of Alberta, on a paper that articulates how the organizations have built grassroots relationships in the past and how they hope to expand them in the future to overcome some of the challenges facing research and to guide the future of cardiovascular clinical research.

The partnerships stretch back nearly 25 years, to the GUSTO trial, an international collaboration that enrolled more than 42,500 patients around the world and helped to uncover a key agent for treating a particular type of heart attack. It also showed clinicians how to incorporate clinical research into their daily practice.

A key finding from that study, and from subsequent trials completed in partnership with Stanford and VIGOUR, is the importance of creating meaningful roles for participants at every level of the study—particularly the physicians, nurses, and other healthcare personnel working at individual research sites around the world.

Their involvement is essential to developing research protocols that can be effective
across different countries and communities, and to ensuring that research findings are implemented after the study has concluded. To bolster these relationships, the DCRI and its partners are always looking for more opportunities to involve these diverse stakeholders in the study design process and to work with them afterward to promote data-sharing and educational opportunities.

Participating in the creation of a research question, and seeing the answer grow out of your own backyard, is powerful. Berdan says it makes the process more believable—“It’s not someone else’s work being imposed.” In turn, she says, that encourages people to be “the adopters as well as the creators.”

The DCRI is also committed to teaching the next generation of researchers about the power of collaborating with stakeholders of all perspectives at all stages of the research process. Approaching collaboration from a more practical angle will help researchers incorporate collaboration into their work from the very beginning of their careers. Teaching researchers how to cultivate connections, whether with one local patient or an entire organization halfway around the world, will bring the DCRI’s collaborative approach to more global research.
Project Spotlight: Community Building

The global perspective of the DCRI’s partnerships is complemented by an ever-expanding local presence in the Durham community. In March 2015, the DCRI announced the formation of the Duke Center for Community and Population Health Improvement. Although the formal center is new, it grew out of Duke’s longstanding engagement with academic, community, and health system partners in North Carolina.

The center’s goal is to “improve the health of our community locally, regionally, and beyond,” says Dr. Ebony Boulware, director. “I think there are a lot of forces helping people realize that health is not determined just by individual behaviors, but also by how people live and the context in which they live.”

The center is an opportunity to build on DCRI research that seeks to understand the interdisciplinary causes of health disparities—expanding partnerships that bring local patients, community leaders, community representatives, and community advisory boards into the research process. Dr. Boulware will turn to them to help develop the questions the center seeks to answer, so that projects really matter to community members and make a difference in their lives.

The center will also leverage Duke’s health system and resources to make a broader local impact. It is already working with the city of Durham on the Community Health Indicators project, which will map local health needs using data about care patients receive from Duke Medicine. The information will be publically available so that residents can understand the health of their individual neighborhoods.
“...health is not determined just by individual behaviors, but also by how people live and the context in which they live.”

Ebony Boulware, MD, MPH
DCRI CAPABILITIES

TRANSFORMATIONAL CLINICAL TRIALS

- Phase I to Phase III
- Thought leadership
- Clinical trial design
- Project management
- Regulatory services
- Site startup, site management
- Data management
- Statistics
- Clinical monitoring
- Safety surveillance
- Clinical events review
- Clinical hotline
- Pharmacometrics
- Biomarkers
- Image analysis lab
- Manuscripts

HEALTH SERVICES RESEARCH

- Outcomes research
- Quality improvement
- Implementation science
- Comparative effectiveness research
- Medical decision making
- Cluster randomized trials
- Empirical bioethics
- Drug and device safety
- Health economics
- Health policy
- Methods development
- Patient-reported outcomes
- Decision modeling
- Pharmacoepidemiology

EDUCATION PLATFORM OF THE FUTURE

- Evidence to Practice Series
- Fellows Education
- DCRI Learning Lab
- Site Network Education
EXECUTIVE TEAM

1 Eric Peterson, MD, MPH
   Executive Director, Duke Clinical Research Institute
   Professor of Medicine, Cardiology
   Fred Cobb, MD, Distinguished Professor of Medicine

2 John Alexander, MD, MHS
   Faculty Associate Director, Director, DCRI CV Research
   Professor of Medicine, Cardiology

3 Daniel Benjamin, Jr., MD, MPH, PhD
   Faculty Associate Director
   Kiser-Arena Distinguished Professor of Pediatrics

4 Lisa Berdan, PA, MHS*
   Director, Global Outcomes Commercial Megatrials

5 Lesley Curtis, PhD
   Director, Data Solutions for Health Services Research
   Director, Center for Pragmatic Health Systems Research
   Professor of Medicine, General Internal Medicine

6 Nicole Hedrick*
   Chief Human Resources Officer

7 Adrian Hernandez, MD, MHS
   Director, Health Services and Outcomes Research
   Faculty Associate Director
   Associate Professor of Medicine, Cardiology

8 Sara Holleran, MPH*
   Senior Strategist

9 Walter Kwiatek
   Executive Director of Information Technology

10 Susan Landis*
    Head of Strategic Communications

11 Kristen O’Berry*
    Director, Academic Affairs

12 Michael Pencina, PhD*
   Faculty Associate Director
   Director of Biostatistics
   Professor of Biostatistics and Bioinformatics

13 Kevin Schulman, MD, MBA
   Faculty Associate Director
   Director, Center for Clinical and Genetic Economics
   Professor of Medicine, General Internal Medicine
   Gregory Mario and Jeremy Mario Professor of Business Administration

14 Michael Sledge*
   Chief Financial Officer

* member, Executive Operational Team
OPERATIONAL LEADERSHIP

1 Pamela Buchholz  
Senior Director, Clinical Trials Domain

2 Maureen Cunningham, RN, PMP  
Director, Clinical Operations

3 Elizabeth Fraulo  
Director, Outcomes Research

4 Debra Harris  
Associate Director, Pragmatic Health Systems Research

5 Cristine Karasek  
Director, Facility Services

6 Clare Matti  
Assistant Director, Regulatory Services

7 Brian McCourt  
Director, Clinical Research Informatics

8 Uduak Ndoh, MBA  
Director, Information Technology

9 Rebecca Ortega, MHA  
Director, DCRI Education

10 Suzanne Pfeifer, MPH  
Director, Business Development and Contracts Management

11 Damon Seils  
Managing Director, Center for Clinical and Genetic Economics Research Operations

12 Bill Shannon, M.Ed  
Director, Organizational Learning

13 Kristina Sigmon, MA  
Director, Statistical Operations

14 David Tillotson  
Senior Director, Finance

15 Jamie Young  
Director, Sponsored Projects Administration
NEW FACULTY

1 Jeff Clough, MD, MBA
   Department of Medicine, General Internal Medicine

2 Amy Corneli, PhD, MPH
   Department of Medicine, General Internal Medicine

3 Michael Durheim, MD
   Department of Medicine; Pulmonary, Allergy, and Critical Care Medicine

4 Benjamin Goldstein, PhD
   Department of Biostatistics and Bioinformatics

5 Thomas Holland, MD, MSc-GH
   Department of Medicine, Infectious Diseases

6 Reed Johnson, PhD
   Center for Clinical and Genetic Economics

7 Stuart Knechtle, MD
   Department of Surgery, Abdominal Transplant Surgery

8 Scott Kollins, PhD
   Department of Psychiatry and Behavioral Sciences

9 Roland Matsouaka, PhD
   Department of Biostatistics and Bioinformatics

10 Patrick H. Pun, MD, MHS
    Department of Medicine, Nephrology

11 Linmarie Sikich, MD
    Department of Psychiatry and Behavioral Sciences

12 Don Taylor, PhD
    Sanford School of Public Policy

13 Kanecia Zimmerman, MD, MPH
    Department of Pediatrics, Critical Care Medicine
# DCRI Fellows

## Second-year Fellows

1. Lauren Cooper, MD  
   Cardiology
2. Christopher Fordyce, MD, MSc  
   Cardiology
3. Patricia Guimaraes, MD  
   Cardiology
4. Kathryn Hudson, MD  
   Oncology
5. Jacob Kelly, MD  
   Cardiology
6. Julia Messina, MD, MSc  
   Infectious Diseases
7. Yi Pi, MD  
   Cardiology
8. Tiffany Randolph, MD  
   Cardiology
9. Amit Vora, MD  
   Cardiology
10. Melissa Wells, MD  
    Rheumatology
11. Nick Wysham, MD  
    Pulmonary
12. Linda Youngwirth, MD  
    Endocrinology
13. Emily Zeitler, MD  
    Cardiology

## First-year Fellows

1. Austin Chan, MD  
   Infectious Diseases
2. Meredith Clement, MD  
   Infectious Diseases
3. Daniel Friedman, MD  
   Cardiology
4. Nancy Luo, MD  
   Cardiology
5. Ann Marie Navar, MD, MHS, PhD  
   Cardiology
6. Robert Olivo, MD  
   Nephrology
7. Neha Pagidipati, MD, MPH  
   Cardiology
8. Kishan Parikh, MD  
   Cardiology
9. Abhinav Sharma, MD  
   Cardiology
10. John Stanifer, MD, MSc  
    Nephrology
11. Alice Wang, MD  
    General Surgery
12. Tunde Yerokun, MD  
    General Surgery
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