CTSI Translational Impact: AGILITY AND EQUITY

Duke Clinical & Translational Science Institute

Equity in Science, Medicine, and Health

"CTSI is committed to fostering a truly diverse and equitable environment.
As an organization, we seek to improve the health and health equity of our community here in North Carolina and across the nation. We see our actions locally as critical enablers of this vision.

In a single year, society has been forever changed by simultaneous, acute crises. Never has the path of translational science been more complex to navigate than now, and rarely has scientific discovery been more urgently needed."

> **Ebony Boulware, MD, MPH** (she/her/hers) Director, Clinical and Translational Science Institute

Table of Contents

Message from the Director
Vision and Mission
Rapidly Responding to the COVID-19 Pandemic
Centering Equity, Diversity, and Inclusion
Catalyzing Discovery and Research
Accelerating Innovation 60
Strengthening Community Connections and Resilience
Transforming Education and Training
Building Access to Data with Integrity and Transparency 91

Message From the Director



At the Duke Clinical and Translational Science Institute, we support scientific discovery to improve the health and health equity of our communities. Agility and equity have always been central to our approach, and these principles have come very sharply into focus during the pandemic, which has amplified health inequities.

We are pleased to present our latest CTSI Impact Report, *CTSI Translational Impact: Agility and Equity in Action*. This report, spanning 2019 to 2021, highlights people and projects that exemplify the theme of agility and equity in action, and the great work we have achieved with our partners.

CTSI has partnered with innovative thinkers, researchers, and institutions to accelerate discovery around COVID-19 and bridge the translational space to improve health outcomes. We've also spent time reflecting deeply as a community on our culture of diversity, equity, and inclusion, as well as our role within larger systems of institutional inequality, our stake in community health equity, and the actions we will take to create new opportunities that address the health priorities of the future.

Thank you for your efforts to improve health and health equity locally, throughout North Carolina, and across the nation. I look forward to continuing our work to positively impact the lives of individuals and our communities.

Sincerely,

Ebony Boulware, MD, MPH (she/her/hers)

Nanaline Duke Distinguished Professor in the School of Medicine Chief, Division of General Internal Medicine in the Department of Medicine Director, Clinical and Translational Science Institute Associate Vice Chancellor for Translational Research Vice Dean for Translational Science Duke University School of Medicine

Our Vision

To catalyze science that improves health and achieves health equity—for individuals and communities—in our region and across the nation. We strive toward equity in science, medicine, and health.

Our Mission

- Accelerate scientific discovery, innovation, and translation;
- · Develop and sustain a vital and diverse translational science workforce;
- Foster a vibrant, transparent, and trustworthy research environment benefiting all;
- Create and promote a culture of equity, anti-bias, and anti-racism throughout all aspects of clinical and translational science at Duke.

Who We Are



bit.ly/wearectsi

Rapidly Responding to the COVID-19 Pandemic

Section Overview: Rapidly Responding to the COVID-19 Pandemic.	6
Duke's CTSA Responds Quickly to Dual Crises	8
TransPop Launches New MURDOCK Study Cohorts in Response to COVID-19	10
New Website for Duke COVID-19 Research Studies	12
CTSI Contributes to Duke-Led \$50 Million Study of COVID-19 Prevention in Healthcare Workers	13
CovIdentify Study Aims to Monitor COVID-19 Spread Through Wearable Smart Devices	15
MEDx, in Partnership with Duke CTSI, Announces COVID-19 Pilot Project Awardees	17
Duke Faculty Fight for Latinx Communities Hit Hard by COVID-19	18

Steps to Address Biomedical, Health Care, and Social Drivers	
of COVID-19 Disparities	24
COVID-19 Clinical Research Recruitment Best Practices	25

CTSI Takes Action on COVID-19	26
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CTSI quickly stood up COVID-19 research projects by leveraging the MURDOCK Study, Duke's groundbreaking longitudinal health research initiative based in Kannapolis, N.C.

Section Overview: Rapidly Responding to the COVID-19 Pandemic

he research landscape at Duke has evolved to meet the challenge of the pandemic. CTSI efforts have focused on empowering researchers to quickly launch projects to study the disease and facilitating community collaborations to address the societal impact of the pandemic.

As a far-reaching convener and resource within and beyond Duke, CTSI staff worked quickly in the early weeks of the pandemic to coordinate the development of the COVID-19 Research & Activities Registry, an online data collection tool, using MyResearchHome (a portal created by Duke's CTSA). Within one week, the registry had more than 100 responses.

In addition, with the launch of the national Healthcare Worker Exposure Response and Outcomes (HERO) registry to rapidly identify and enroll a large community of healthcare workers at high risk for COVID-19 infection, the CTSI's Clinical Data Research Networks program identified Deverick Anderson, MD, MPH, as the Principal Investigator at the Duke site.

In the midst of the pandemic, the Translational Population Health Research group launched two new cohorts of the MURDOCK Study: the MURDOCK C3PI Study to understand the community prevalence of COVID-19 and monitor the disease over time, and the MURDOCK COPE Study to understand how the responses, perceptions, and experiences of participants and their families changed due to the pandemic and associated regulations.

As COVID-19 cases continued to grow, the need to learn more about how the virus spreads and affects those recovering from the virus increased. CTSI personnel led the creation of a centralized DukeCovidStudies.org website at Duke to help the public participate in COVID-19 research and get information about testing.

Another participant-centered research effort, the CovIdentify study, was launched to predict early cases of COVID-19 infections in people and ultimately monitor the spread of the coronavirus by using data generated by wearable smart devices.

Two CTSI projects were awarded COVID-19 Pilot Project Awards by Medicine + Engineering at Duke (Duke MEDx) to support research that can only be conducted during the pandemic or support development of technologies that could benefit COVID-19 patients or Duke's return to campus efforts.

By the late spring of 2020 it was clear that

the COVID-19 pandemic was disproportionately affecting communities of color. CTSI faculty and staff mobilized quickly to convene working groups with both Duke and community grassroots stakeholders to address disparities, barriers, and challenges in the Latinx, Black, and African American communities.

CTSI faculty and staff joined forces to support the work of LATIN-19, a group of concerned stakeholders advocating for Hispanic and Latinx communities statewide, and with the African American COVID Taskforce Plus (AACT+), doing similar work in the Black and African American communities.

In May 2020, CTSI hosted or co-hosted a series of symposia and workshops to educate internal and external audience about anti-biased, anti-racism, and equity in research, including "A Call to Action: Identifying Next Steps to Address Biomedical, Health Care, and Social Drivers of COVID-19 Disparities" and "Strategies and Best Practices for Enrolling Black and Latinx Americans in COVID-19-related Clinical Research."

Like most groups across Duke, CTSI had to figure out how to work amid the COVID-19 pandemic. Our teams used this opportunity to explore innovative ways to support communities in Duke, Durham, and beyond.



COVID Dashboard on My RESEARCH Home portal

Duke's CTSA Responds Quickly to Dual Crises

n 2020, two events changed the world forever: the COVID-19 pandemic and the national reckoning of systemic racism. Both of these events served to highlight, among other things, the importance of programs like the Clinical and Translational Science Award (CTSA). As a far-reaching convener and resource within Duke and beyond, the CTSA program at Duke, managed by the CTSI, was called upon for coordination, resources, and leadership. Normal plans were upended with mandatory shutdowns of research laboratories, a sudden shift to remote working for nearly everyone, and a prioritization of COVID-related research. Immediate and unending attention to the issues of racial injustice is driving intrinsic changes in our personal, institutional, and cultural identities and practices. The Duke CTSA has supported all of these efforts and, in fact, has taken advantage of opportunities that were previously uncontemplated.

COVID-19 Response

The initial reaction to the pandemic at Duke was to identify people and resources that could be garnered to support COVID-19 related activities. The CTSI was deployed to serve as the clearinghouse for this information. Over a period of days, CTSI staff, working with University and School of Medicine leadership, disseminated a call to all researchers at Duke to identify specific projects, people, and resources that could be helpful to Duke's COVID-19 response. Using MyResearchHome (a tool created by the CTSA—see figure above), the CTSI developed an online data collection tool, the COVID-19 Research & Activities Registry, and within one week, we had over 100 responses. The system currently includes more than 575 projects from across the University.

In collaboration with School of Medicine leadership, the CTSA's Participant and Interactions Core (Duke Office of Clinical Research) implemented a system of tiered criteria for ongoing research studies to evaluate direct patient benefit, and established processes for transitioning to remote activities. CTSA teams reviewed and approved "Return to Research" plans for all studies following a phased approach with approved guidelines and training for conducting research on-site. In addition, we created processes for COVID patient triage, to ensure equitable distribution of participants to COVID studies; remote monitoring requests; and research PPE distribution.

Other essential tools, processes, and resources developed or provided by the CTSA include:

 A symptoms reporting database for on-site employees across the Duke Health Enterprise (developed in collaboration with Duke University Health System and Duke Health Technology Solutions).

- A shared effort pool to reallocate available effort for research staff idled by suspended studies.
- An intake and matching process for medical and graduate students to assist with COVID studies.
- A grant "SWAT" team to assist with the rapid development of COVID-related research grants.
- Staff support for the ACTT, Biorepository, and Community Watch studies at their inception.
- Communications outreach related to COVID with the SoM through newsletters, website and Town Hall meetings.



A participant completes a nasal swab test during a drive-through event, part of a study launched in response to the COVID-19 pandemic.

TransPop Launches New MURDOCK Study Cohorts in Response to COVID-19

n response to the pandemic, <u>Duke TransPop</u> launched the <u>MURDOCK Cabarrus County</u> <u>COVID-19 Prevalence and Immunity (C3PI)</u> <u>Study</u> in June 2020. This partnership with the N.C. Department of Health and Human Services aims to understand the prevalence of COVID-19 in the community and to monitor the disease over time.

The MURDOCK C3PI Study <u>follows the health</u> and <u>well-being</u> of more than 1,400 MURDOCK Study volunteers to examine how the COVID-19 pandemic affects them and their households. Researchers are especially interested in learning more about the behaviors of both symptomatic and asymptomatic people over time.

A sub-group of 300 volunteers are <u>regular-</u> ly tested for both COVID-19 infection and potential immunity to the novel coronavirus that causes the disease. Participants complete nasal swab tests at home every other week to detect COVID-19 infection, and serology testing is done at the Duke CTSI office in Kannapolis to detect antibodies that could indicate prior, potentially asymptomatic, exposure to the SARS-CoV-2 virus, and possible immunity. In December 2020, the MURDOCK C3PI Study also began a collaboration with the N.C. Wastewater Pathogen Tracking Research Network (WW PATH) and contributes data to the statewide research network monitoring the coronavirus in sewer systems, to help inform the public health response in North Carolina.

"We can quickly and efficiently engage the MURDOCK Study cohort and the team in Kannapolis to ask and answer important scientific



L. Kristin Newby, MD, Chris Woods, MD

questions, as in the case of COVID-19," said L. Kristin Newby, M.D., principal investigator for the MURDOCK C3PI Study. "Participants are highly committed to helping move research forward and to helping their community. The MURDOCK Study is uniquely suited to respond, recruit, and generate data during this kind of public health emergency."

Chris Woods, M.D., executive director for the Duke Hubert-Yeargan Center for Global Health, is co-principal investigator.

Volunteer Zenobia Fleming said she joined the study because she wants to help researchers better understand COVID-19 and feels that by participating, she is benefitting society.

"The more knowledgeable we are about what's really going on, the better," said Fleming.

"The only way we will know is that people will come forward to do things to try to help."

Fleming said she signed up for the study and committed to months of follow-up via testing and online surveys because she has lost friends and family members to COVID-19 and wants to be part of the solution.

Participant Aimy Steele expressed a similar desire. "My hope is that the research will help

us make better decisions about how we move forward. And about how we will be prepared the next time in case something like this happens again," Steele said.

In response to the pandemic, Duke TransPop also quickly stood up and managed the <u>MURDOCK COVID-19 Opinions</u>, <u>Perceptions & Experiences (COPE) Study</u>, a collaboration of Duke CTSI and the Duke Social Sciences Research Institute (SSRI).

The MURDOCK COPE Study surveyed more than 500 participants every other week for several months. The study followed how they felt in response to the COVID-19 pandemic and related events, how the pandemic and associated regulations affected them and their family, and how these perceptions and experiences changed over time. <u>Alexandra Cooper</u>, <u>Ph.D.</u> is the principal investigator, and <u>L. Kristin</u> <u>Newby, M.D.</u> is the co-principal investigator.

The MURDOCK C3PI and MURDOCK COPE studies are nested cohorts of the broader MUR-DOCK Study, a landmark community-based health research initiative in Cabarrus County with more than 12,500 participants. MURDOCK is an acronym that stands for the Measurement to Understand Reclassification of Disease Of Cabarrus and Kannapolis, and the study is based at the N.C. Research Campus in Kannapolis.



New website for Duke COVID-19 research studies

uke Health has launched a website to help the public participate in COVID-19 research studies, with opportunities for those who have, or have had, COVID-19, and healthy volunteers. The site provides basic information about each of the studies taking place at Duke, and guides users to enrollment information.

Duke CTSI personnel helped drive this effort to create a centralized resource for potential research participants to find Duke studies they might be eligible for, including leadership from Jamie Roberts, Senior Staff Director of Clinical Research Networks at Duke CTSI.

The site emphasizes that "our clinical trials and studies are open to the entire community, and we invite you to be part of the solution and help end the pandemic in our community and everywhere." Explore the Duke Covid Studies website at <u>www.dukecovidstudies.org</u>.

CTSI Contributes to Duke-Led \$50 Million Study of COVID-19 Prevention in Healthcare Workers

he <u>Patient-Centered Outcomes Research</u> <u>Institute</u> has funded up to \$50 million to evaluate hydroxychloroquine (HCQ) as a preventive drug for the novel coronavirus.

The funding creates a new rapid-response study designed and led by the Duke Clinical Research Institute (DCRI) which seeks to engage healthcare workers across the nation to understand the impact of COVID-19 on their health and to evaluate whether hydroxychloroquine can prevent COVID-19 infections in healthcare workers at high risk of contracting the coronavirus.

The launch of the Healthcare Worker Exposure Response and Outcomes (HERO) research program was announced today by the Patient-Centered Outcomes Research Institute (PCORI), whose Board of Governors today approved support for the program. The program will engage the powerful PCORI-funded



Adrian Hernandez, MD

PCORnet[®], the National Patient-Centered Clinical Research Network, which is an established health research network involving more than 850,000 clinicians and hundreds of health systems across the U.S. Study results will be shared widely with the healthcare community.

"Healthcare workers on the front lines are critical to the pandemic response," said Adrian



Healthcare Worker Exposure Response & Outcomes

Hernandez, M.D., a Duke professor of cardiology and member of the DCRI. "To address their needs, we need to do rapid-cycle research and clinical trials," said Hernandez, who originated the program and is serving as the administrative principal investigator.

"Although there has been discussion about hydroxychloroquine (HCQ) as a potential prevention method for COVID-19, we are lacking the data on safety and efficacy of this therapy," Hernandez said. "By conducting this study with healthcare workers, we are working directly with those who understand the importance of quickly getting answers into the hands of those on the front line."

"The HERO study offers an important opportunity for healthcare systems across the country to unite and use the national resources offered by PCORnet to answer some of the most critical questions facing our nation right now," said Judith Currier, M.D., a co-chair of the study's steering committee and chief of infectious diseases at UCLA Medical Center, Santa Monica.

"The urgency of the questions we are asking and the need for speed cannot be overstated, and it's heartening to see the dedication being poured into this effort," said study co-chair Russell Rothman, M.D., senior vice president for population and public health and Ingram professor of integrative and population health at Vanderbilt University.

The HERO registry of healthcare workers will ease study start-up times for future clinical trials that may be carried out for other prevention or treatment strategies.

— Susanna Naggie, MD

The HERO program will initially consist of two parts, a national registry and a randomized clinical trial.

The registry will be led by the DCRI's Emily O'Brien, Ph.D., an assistant professor in Duke's department of population health sciences. This effort will seek to rapidly identify and enroll a large community of healthcare workers at high risk for COVID-19 infection. Recruitment for the registry is expected to begin within the next two weeks. The registry will not only support recruitment into the clinical trial, but it will also assess the wellbeing of healthcare workers on issues such as workforce stress, burnout and other outcomes, and enable future trials. The randomized clinical trial, HERO-HCQ, will be led by the DCRI's Susanna Naggie, M.D., an associate professor of medicine at Duke. This trial will launch later in April, having identified about 15,000 healthcare workers from the registry to participate. The trial will ran-

domize participants to either one month of hydroxychloroquine or one month of placebo and then will examine whether hydroxychloroquine is effective in decreasing the rate of COVID-19 infection.

In addition to the benefits and risks of using hydroxychloroquine, the study also will explore how well the drug can prevent healthcare workers from unintentionally spreading the virus to others.

"It's important that we assess the effectiveness of this drug for prophylaxis treatment in healthcare workers, both for their safety and to prevent further spread of SARS-CoV-2 as they care for patients," Naggie said. "The HERO registry of healthcare workers will ease study start-up times for future clinical trials that may be carried out for other prevention or treatment strategies."

In addition to participant recruitment resources and support for this registry, the Duke CTSI <u>Clinical Data Research Networks program</u> moved swiftly to identify <u>Deverick J. Anderson</u>, <u>MD, MPH, FSHEA, FIDSA</u>, as site Principal Investigator. Anderson is the director of the Duke Center for Antimicrobial Stewardship and Infection Prevention and Professor of Medicine, Division of Infectious Diseases.

<u>Return to section start.</u>



CovIdentify Study Aims to Monitor COVID-19 Spread Through Wearable Smart Devices

new study by Duke researchers may help predict early cases of COVID-19 infections in people and ultimately monitor the spread of the coronavirus by using data generated by wearable smart devices.

The research project, called _ is led by co-Pls <u>Dr. Jessilyn Dunn</u> and <u>Dr. Ryan Shaw</u>. One of the challenges researchers and clinicians have noted with COVID-19 is the rate of unidentified infections circulating in the community and continuing the spread. According to the study's website, there are 60.5 million people in the U.S. using 117 million wearable devices, such as Fitbits. The CovIdentify team believes these devices could be used to develop digital biomarkers

for infectious disease.

Previously, Dr. Dunn had worked on a project that used data from wearable devices to detect influenza and other respiratory diseases. Dr. Shaw's work has focused on using data from wearable devices for patients with chronic illnesses such as diabetes and hypertension – risk factors associated with COVID-19. They believe their work ideally positions their team to tackle this project.

"Our goal is to be able to detect signals of COVID-19 in a person before they know they're even sick," Dr. Dunn said. "Using wearables, we are able to see signals for different illnesses. The more pronounced these physiological symptoms are, the better chance we'll have to detect them." Along with other Duke researchers and staff at <u>MEDx</u>, <u>the Pratt School of Engineering</u>, <u>the</u> <u>School of Nursing</u>, and <u>the Department of Bio-</u> <u>statistics and Bioinformatics</u>, Dr. Dunn, Dr. Shaw

This disease has strange trajectories that vary dramatically. Some patients seem to be doing better and then crash, some don't have many symptoms. We want to understand why and determine earlier signs for when someone is going downhill.

— Jessilyn Dunn, PhD

and their team have been working with the CT-SI's <u>Recruitment Innovation Center</u> and Mobile App Gateway teams to create a mobile platform for her study and recruit study participants. The first phase of the study officially launched the first week of April. Participants are asked to share their demographics and medical information and complete a daily sur-

> vey asking about people they've come in contact with and whether or not they feel sick. These data are stored on secure servers to protect participant privacy. Currently, the study can collect data directly from Fitbit and Garmin wearables, and users will soon be able to connect a multitude of other wearable devices in the coming weeks.

> "We want to prevent the spread of this illness," Dr. Dunn said. "This disease has strange trajectories that vary dramatically. Some patients seem to be doing better and then crash, some don't have many symptoms. We want

to understand why and determine earlier signs for when someone is going downhill."

Those interested in learning more and participating in the study can visit <u>covidentify.org</u>.

MEDx, in Partnership with Duke CTSI, Announces COVID-19 Pilot Project Awardees



Medicine + Engineering at Duke (Duke MEDx) has awarded four projects with COVID-19 Pilot Project Awards. To be considered, projects had to involve research that could only be conducted during the pandemic or support development of technologies that could benefit COVID-19 patients or Duke's return to campus efforts. One award, "CovIdentify: Using Wearable Devices and Smartphones to Detect and Monitor COVID-19," was given in partnership with Duke CTSI; another grant, "SARS-CoV-2 in Bioaerosols and Risk Assessment," follows seed funding from Duke CTSI.



Clockwise from top left: Dr. Gabriela Maradiaga Panayotti, Dr. Viviana Martinez-Bianchi, CERI co-director Dr. Leonor Corsino, CERI co-director Dr. Rosa Gonzalez-Guarda, and Michelle Carreño.

Duke Faculty Fight for Latinx Communities Hit Hard by COVID-19

he COVID-19 pandemic has wreaked havoc in every part of American life, but it has taken a disproportionately heavy toll on people of color, including the Latinx community. By June 2020, Latinx people in North Carolina accounted for more than 40 percent of the state's cases, despite comprising just 10 percent of the population, and they continue to be over-represented at the start of 2021, accounting for 23 percent of new cases, according to the North Carolina Department of Health and Human Services.

Last March, concerned local physicians, nurses, researchers, educators, and community advocates formed a group—"Latinx Advocacy Team & Interdisciplinary Network for COVID-19," or simply LATIN-19—to address these disparities and support the Latinx community. Numerous CTSI personnel have been involved in this work.

A diverse team has driven LATIN-19 from the beginning, including four Duke faculty members: Dr. Viviana Martinez-Bianchi, Dr. Gabriela Maradiaga Panayotti, Dr. Leonor Corsino, and Dr. Rosa Gonzalez-Guarda. (Corsino and Gonzalez-Guarda are co-directors of Duke CTSI's Community Engaged Research Initiative.)

They are swift to point out that many others from inside and outside of Duke have been vital leaders and contributors. "LATIN-19 exists not just because of our efforts," says Martinez-Bianchi. "We would not be successful without our colleagues and the community, without the people who show up at our meetings each Wednesday."

The group has been meeting weekly ever since March, with an average attendance between 70-100, hearing from the community about their lived experience with the pandemic and drawing on their collective knowledge, energy, and influence to create change. Among other accomplishments, LATIN-19 encouraged the state of North Carolina to distribute coronavirus information in Spanish, alerted health officials to a lack of accessible testing sites in Durham and has built an online forum for community members to safely and frankly express their concerns. LATIN-19's multi-sector, interdisciplinary collaboration is now seen as a model to replicate around the country, according to Martinez-Bianchi.

<u>Read the full story online</u>, and meet four Duke faculty members who have been instrumental in this effort as they talk about how their backgrounds, expertise, and passions positioned them to fight for Latinx health equity in a time of crisis.



Darius Russell (owner of Russell Pharmacy), Dr. Roosevelt Campbell, and Dr. Andrew Flynn at a testing and food distribution event.

Community Stakeholders Form Taskforce to Address the Devastating Effects of the Pandemic

arly in 2020, Duke Family Medicine residents Dr. Roosevelt Campbell and Dr. Andrew Flynn began noticing a disturbing trend in their clinics. The COVID-19 pandemic, wreaking havoc in every part of American life, seemed to be disproportionately hitting communities of color. In May, Black Durham residents were 40% less likely to be tested for COVID-19, yet more than twice as likely to test positive when compared to white residents.

"COVID testing sites were primarily in white neighborhoods and information about testing, medical care, and prevention was not equitably distributed through the city," said Flynn. "Most significantly, in the early stages of the pandemic and into the summer, Black people in North Carolina were dying of COVID at almost twice the rate of other people."

During his clinical rotation at Lincoln Community Health Center, Campbell and Dr. Holly Biola, Chief of Family Medicine at Lincoln, discussed the success of a group of local providers, researchers, educators, and community advocates who were meeting via Zoom to tackle similar disparities in the Latinx community. In fact, Campbell and Flynn had been attending the weekly calls with the Latinx Advocacy Team & Interdisciplinary Network for COVID-19, or LATIN-19 since its inception in March 2020.

"This group was tapping into grassroots community stakeholders to discuss barriers and challenges," said Biola, "and they were finding success with innovative ways to mitigate the overall impact of COVID-19." Through her connections, Dr. Biola would soon help Campbell and Flynn link to several members of the African American faith community.

According to Campbell, the LATIN-19 group was very effective at leveraging connections and knowledge about needs in the community and disseminating vital information about the virus and testing. "They were debunking myths about COVID-19 and how it was spread," said Campbell.

Dr. Viviana Martinez-Bianchi, former program director of Duke Family Medicine Residency and one of the founders of LATIN-19, advised that a similar group should form to address the needs of the African American community. She introduced Campbell during a Partnership for Healthy Durham Access to Care Committee meeting in June where he presented the idea.

We needed to pull together well-connected stakeholders within the African American community in Durham to discuss the immediate needs related to the pandemic and help to disseminate accurate information to the community members.

Roosevelt Campbell, MD, PhD

Members of the community expressed interest and with their approval, Campbell and Flynn set out to schedule the first meeting.

"We needed to pull together well-connected stakeholders within the African American community in Durham to discuss the immediate needs related to the pandemic and help to disseminate accurate information to the community members," said Campbell.

The first formal meeting of the AA/Black COVID Community Response group was held

AACT+ African American COVID Taskforce *Plus*

on June 17. Now named the African American COVID Taskforce Plus (AACT+), this diverse team has been meeting weekly with attendance between 40 and 60 people. Guest speakers from community organizations and Duke share stories about their firsthand experiences with the pandemic and draw on their collective knowl-

> edge, energy, and influence to create necessary change. These presentations from the community and frontline workers help to inform and guide planning efforts and action items for AACT+.

> "Dr. Campbell and Dr. Flynn started up a group that included members of Duke Health, Lincoln Community Health Center, the Durham County Department of Public Health, Community Health Coalition (CHC), Durham Together for Resilient Youth, Durham Academy for Physicians, Pharmacists and Dentists (DAMDP), Old

North State Medical Society (ONSS), and the Inter-Denominational Ministerial Alliance," said Biola. "From there it has grown to include representatives from Partnership Effort for the Advancement of Children's Health, Durham Public Schools, Senior PharmAssist, and GeriatRx, among others, and the number of participants just continues to grow."

While Campbell, Flynn, Martinez-Bianchi, and Biola inspired the creation of AACT+, they are quick to point out that many others inside Duke and beyond have been vital leaders and

Authentic community engagement is at the heart of this group — meeting people where they are, listening to their concerns, and taking action based on those concerns. It is important to meaningfully engage the people who have long been left out of the process — listened to, but not necessarily heard.

— Kimberly Monroe, Program Manager, Duke Office of Community Health

early stages of the pandemic and directly serve Black and Latinx communities."

Sabrena Mervin-Blake, Staff Director of the Community Engagement core for the Duke Clinical and Translational Science Institute (CTSI) and a founding member of AACT+, has dedicated

> resources to help sustain AACT+. Through Mervin-Blake's commitment of support, Leatrice Martin has become a highly valued resource for the group. Martin, who works for CTSI, provides logistical support for the weekly virtual meetings, manages the ever-growing mailing list of attendees, and invites a variety of community-based and clinical experts to present findings, updates, and resources to the meeting participants.

> "Without Leatrice's time and effort, it would have been very difficult for us to grow as much as we have," said Campbell. "She has extended our reach into the

contributors. "AACT+ exists because of the efforts and commitment of our colleagues and the community," said Campbell. "We would not be successful without the people who come each week to engage meaningfully on the needs of our communities."

"[AACT+] was key to dissemination and support for the testing held at African American churches and pharmacies in Durham through collaboration of DAMDP, CHC, and ONSS," said Dr. Maria Small, Duke Associate Professor Obstetrics & Gynecology and Medicine. "These events were key to early COVID testing as they focused on Black and Latinx communities and were unique because they were free walk-up/drive-up events that didn't require registration. AACT members mobilized to volunteer at these events during the local community to invite stakeholders and to share updates about COVID testing and vaccine sites with our group."

A newly formed AACT+ executive team helps define and oversee broad initiatives and workgroups for the coalition to address, including 1) information dissemination, 2) COVID testing, 3) community resources 4) advocacy, 5) grant and research funding opportunities, 6) physical and mental health, and now 7) information about and access to the COVID vaccine in traditionally underserved communities.

"Authentic community engagement is at the heart of this group — meeting people where they are, listening to their concerns, and taking action based on those concerns," said Kimberly Monroe, Program Manager with the Duke Office of Community Health. "It is important to meaningfully engage the people who have long been left out of the process—listened to, but not necessarily heard. Using the Principles of Community Engagement as a guide keeps us focused on building and establishing strong connections and a commitment to making the spaces and places where we work, live, and play better for everyone."

Over time, the composition of the group has evolved to include leaders from faith communities and community-based organizations focused on providing care and resources to underserved members of the community. AACT+ provides a safe space to discuss the needs of the community, to coordinate efforts and ideas, and to learn about services, resources, and opportunities that already exist.

"We don't want to reinvent the wheel," said DeLon Canterbury, Chief Executive Officer of GeriatRx and newest member of AACT+ executive committee. "We want to leverage what is being done by other organizations to make sure that these efforts to serve our communities have broader reach."

Addressing racism in health care and the need for patient advocacy are two specific areas of focus. Duke and other healthcare providers in the community are grappling with the impact of racism within the healthcare system and are looking to AACT+ for guidance, including more effective vaccination support in underserved communities.

As part of this work, Duke Health and Duke CTSI are committed to dismantling racism in health care and addressing health inequities. In the summer of 2020, CTSI formed the Equity in Research core to elevate, advance, and accelerate equitable, inclusive, anti-racist, and anti-bias research. "We look forward to working together with our community in authentic, mutually beneficial, bidirectional ways toward the goal of health equity," said Mervin-Blake, Staff Director for the Equity in Research core.

Among other accomplishments, AACT+ has worked to connect community stakeholders with resources and accurate information to help community members find out about COVID screenings and vaccines, health education, mental health services, clinical studies and research, and food.

"These community organizations have been incredibly receptive and responsive," said Martin. "They've made my job easier with their willingness to join, to offer resources, and to suggest stakeholders we should invite to the group. All I hear is 'Yes!' when I make a request. It has been so encouraging to be a part of this movement on behalf of the African American community in Durham."

Post-pandemic, AACT+ will evolve again, changing from African American COVID Taskforce to African American Community Taskforce. "The needs of our community beyond COVID still need to be addressed," said Dr. Angeloe Burch, Executive Director for the African American Dance Ensemble and Secretary of the Inter-Denominational Ministerial Alliance of Durham and Vicinity. "The pandemic highlighted the disparities and distrust, and helped us to pull together to create a better and more effective system for supporting our communities. We need to continue to meet, discuss, address, and evolve to better support and serve our communities."



Sheriff Clarence F. Birkhead presents during "A Call to Action: Identifying Next Steps to Address Biomedical, Health Care, and Social Drivers of COVID-19 Disparities."

Research Symposium—A Call to Action: Identifying Next Steps to Address Biomedical, Health Care, and Social Drivers of COVID-19 Disparities

n May 22, 2020, an online Duke University-wide symposium on COVID-19 Disparities and Health Equity sought to identify causes, consequences, and solutions as they related to COVID-19 and its impact on our community.

The symposium speakers and panelists, representing disciplines from lab science to community and population health science and included experts in environmental and social science as well as ethics and policy. Community leaders provided their perspectives and feet-on-the-ground knowledge of our community and its members. Meaningful content and dialogue were highlights from this event.

Recordings and slides from the symposium can be found at <u>https://bit.ly/covidcalltoaction</u>.



COVID-19 Clinical Research Recruitment Best Practices

he "Strategies and Best Practices for Enrolling Black and Latinx Americans in COVID 19-related Clinical Research" symposium, held in August 2020, featured overviews presented by Kimberly S. Johnson, MD, MHS, Director for the Duke Center for Research to Advance Healthcare Equity and Dean Mary Klotman, MD, the Dean and Vice Chancellor for Health Affairs for the Duke University School of Medicine.

The Keynotes were given by Nadine Barrett, PhD, an Assistant Professor in Family Medicine and Community Health, who addressed the lack of diversity in clinical research and proposed strategies to engage Black communities; and Rosa Gonzalez-Guarda, PhD, an Associate Professor at the Duke University School of Nursing, who shared strategies to effectively engage Latinx communities in research and the implications for COVID-19 research.

Individual Study Consultations were provided to those who requested consultation when registering for the workshop.

Dr. Barrett moderated an abbreviated Just Ask training that was focused on the impact of implicit bias in clinical research and trial recruitment. Participants discussed how personal beliefs and attitudes affect approaches to recruitment and practiced strategies to increase participant diversity.

View the Symposium recording at <u>https://</u> <u>bit.ly/3eWx4Wb</u>.



Duke TransPop supports recruitment and enrollment for multiple community-based CTSI research studies in Kannapolis at the N.C. Research Campus.

CTSI Takes Action on COVID-19

CTSI Teams Support Communities at Duke, in Durham, and Beyond

In the midst of the pandemic, most groups across Duke had to adjust to a new way of working. For the Duke Clinical and Translational Science Institute (CTSI), this time was spent exploring new ways to support communities in Duke, Durham, and beyond.

Working with the Duke Community

In May 2020, the CTSI sponsored "A Call to Action: Identifying next steps to address biomedical, health care, and social drivers of COVID-19 disparities" research symposium. This online university-wide discussion on COVID-19 disparities and health equity examined the causes, consequences, and solutions related to COVID-19 and its impact on our community.

The symposium speakers and panelists represented disciplines from lab science to community and population health science and included experts in environmental and social science as well as ethics and policy. Key representatives from the community, including leaders from local clinics and the Department of Social Security, as well as the Durham County Sheriff, offered their perspectives on the community's response to the pandemic and what can be done to recognize and repair the evident health disparities. The CTSI hosted another virtual symposium on July 9, "Research Resilience in the Age of COVID-19: Insights from Sponsors and Investigators." Resources from the symposium, including session recordings and PowerPoint slides, are available on the <u>CTSI website</u>.

Engaging the Durham Community

The Community Engaged Research Initiative (CERI) has developed a page on the Community-Engaged Research e-Library dedicated to COVID-19 resources. In May, CERI staff members presented the e-Library to the Community Engagement Brokers across the CTSAs. The e-Library's COVID-19 resources include health and safety guidelines, resources in English and Spanish, and research and volunteer opportunities.

CERI supported Durham's Partnership for Seniors' online COVID-19 Telephone Reassurance Training in early April and continues to be involved in a working group that is helping to write and provide COVID-19 health information to older adults in the Durham community. CERI also worked with the partnership to write a rapid response Duke Corporate Partnership for Durham' COVID-19 recovery grant proposal titled "Durham's Partnership for Seniors and More-COVID-19 Response: Making Connections While Distancing." The goal of the grant is to provide essential information and supplies to socially isolated older adults and to train existing community connectors/champions as community health workers to make connections with older adults. The Partnership received an award of \$50,000.

CERI has also been responding to a greater number of consultation requests since March: 23 consults were conducted in March, April, and May.

Supporting Health Research Studies

Leveraging the community-based MURDOCK Study and its highly engaged 12,500-plus participant cohort in Cabarrus County, Duke CTSI TransPop quickly stood up two new studies and supported recruitment for other initiatives in response to COVID-19.



The MURDOCK Study is CTSI's landmark longitudinal research initiative in Kannapolis.

Co-located in Kannapolis and Durham, the TransPop team during the summer of 2020 launched the MURDOCK Cabarrus County COVID-19 Prevalence and Immunity (C3PI) Study, a partnership with the State of North Carolina, and the MURDOCK COVID-19 Opinions, Perceptions & Experiences (COPE) Study, a partnership with the Duke Science Research Institute (SSRI).

Through the MURDOCK Study and the <u>Duke</u> <u>TransPop Volunteer Registry</u>, TransPop also supported recruitment for <u>CovIdentify</u>, COVID-19 research being led by Duke co-PIs Dr. Jessilyn Dunn and Dr. Ryan Shaw. This study may help predict early cases of COVID-19 infections in people and ultimately monitor the spread of the coronavirus by using data generated by wearable smart devices.

The Recruitment Innovation Center has worked to support the Healthcare Worker Exposure Response & Outcomes (HERO) Registry at Duke. The HERO Registry invites healthcare workers to share clinical and life experiences in order to understand the perspectives and problems faced by those on the COVID-19 pandemic front lines. HERO Registry participants may have the opportunity to participate in future research studies to improve our understanding of COVID-19 and beyond, generating evidence to help healthcare workers stay safe and healthy. Learn more about the HERO Registry at <u>https://heroesresearch.org/</u>.

Centering Equity, Diversity, and Inclusion

Section Overview: Centering Equity,	
Diversity, and Inclusion	
Duke CTSI Launches New Center Dedicated	
to Equity in Research	
New CTSI Core Dedicated to Integrating Equity	
Throughout Research Enterprise	
Duke CTSI Multidisciplinary Vision Program (MVP) Award	3
Duke CTSA KL2 Program Named a Top-Performing Hub40)
New Center Dedicated to Equity in Research Offers	
Expertise, Learning Opportunities42	2
Designing the Roadmap Toward Equity44	1
Surveys Reveal Attitudes and Experiences	
Regarding Racism and Discrimination46	5



A Durham family participates in a session with Duke researchers, giving feedback on study design.

Section Overview: Centering Equity, Diversity, and Inclusion

rom the beginning, CTSI's mission has included changing the paradigm in translational research by actively seeking to support scholarship, career development, and funding opportunities for underrepresented ethnic group (UREG) investigators. This commitment to diversity and inclusivity extends internally as well, as CTSI has worked to center equity in our institutional culture.

As part of its commitment to building a diverse and inclusive research environment at Duke, CTSI launched the Center for Equity in Research and its supporting Equity in Research core to provide infrastructure support for equity,

anti-bias, and anti-racism in research and shift the research culture toward proactive and robust planning for diversity, equity, and inclusion.

Many of CTSI's new and ongoing programs include a focus on diversity and equity, including a new pilot program, the Multidisciplinary Vision Program, to fund health equity research and continued support of the Duke CTSA KL2 program's goals in recruitment of UREG scholars for research opportunities and awards. The KL2 program exceeded its recruitment goals and was named a top-performing hub in the nation by the Center for Leading Innovation and Collaboration. Much of CTSI's attention was focused internally, both within the institute and across the Duke campus, as CTSI collaborated with Duke's Office for Diversity and Inclusion (ODI) in the School of Medicine to develop and implement our longitudinal equity strategy. Programs and activities included the execution of the CTSI Climate Survey, now adopted by Duke, and piloting the Teaching and Leading Equity Now curriculum for all staff, faculty, and learners.

CTSI leadership, in partnership with ODI and the Duke Center for Truth and Racial Healing and

Transformation, held an Equity Retreat and town halls to present CTSI Climate Survey findings, and foster shared language around anti-racism, anti-bias, and equity as an integral part of designing a roadmap toward equity.

Finally, a series of comprehensive surveys completed during the summer of 2020 helped CTSI leadership understand the attitudes, experiences, and concerns of CTSI personnel regarding racism, discrimination, and equity. The survey findings are informing key services and activities to promote a safe and equitable environment.

Duke CTSI Launches New Center Dedicated to Equity in Research

uke Clinical and Translational Science Institute has launched the Center for Equity in Research to address the profound challenges of the COVID-19 pandemic and racial

reckoning that unfolded during the summer of 2020. These challenges highlighted, among many things, a common thread around equity in health and research that has been a CTSI priority for years.

The new center is led by Nadine J. Barrett, PhD, an Assistant Professor in the Department of Family Medicine and Community Health at Duke University. She holds a joint senior leadership role as the Associate Director of Equity and Community and Stakeholder Strategy for the Duke Cancer Institute and the Duke CTSI. A medical sociologist by training, Dr. Barrett is a health

Nadine Barrett, PhD, Center Director

disparities researcher, expert equity strategist, and a nationally recognized leader in facilitating community/stakeholder and academic partnerships to advance health equity, as well as developing training and methods to address implicit bias and structural and systemic racism that limit diverse participation in biomedical research.

The vision for this new Center is to provide leadership, guidance, and resources to improve equity and thwart bias and racism in research. The Center will operationalize CTSI's longitudinal strategy to fully integrate equity at every level. This strategy applies an equity lens to existing services and infrastructure and will evolve as new initiatives and projects are launched and expanded.

Planning for the Center for Equity in Research was already underway before the devastating

events of 2020 prompted CTSI to quickly deploy a more organized initiative to integrate equity throughout the institute by creating the Equity in Research (EIR) core in July 2020. This core, led by Keisha Bentley-Edwards, PhD, and Dane Whicker, PhD, is focused on elevating, advancing, and accelerating equitable, inclusive, and anti-racist research.

The EIR core is at the heart of the work of the Center for Equity in Research. The new Center will leverage the recent work of EIR to promote diversity, inclusion, and equity throughout the research enterprise at Duke.

Important work last summer included the design of an assessment tool measuring the perception of anti-bias, anti- racism, and equity, with CTSI staff and leadership participating in a multi-part survey. Since then, the survey has been refined and shared with Duke leadership as part of a broader, campus-wide equity assessment initiative.

Initial Center priorities under Barrett's leadership will focus on creating accountability to ensure an anti-biased, anti-racist, and equitable research enterprise; developing and providing tools and resources to promote anti-racism, anti-bias, and equity for faculty, staff, and learners; providing consultations and resources to ensure diversity, equity, and inclusion in biomedical research studies within the CTSI and across the Schools of Medicine and Nursing, as well as other Duke entities; and reframing constructs around bias and race in research with interdisciplinary teams across Duke and our broader community.



Top row: Nadine Barrett, PhD; Keisha Bentley-Edwards, PhD; Pamela Maxson, PhD. Bottom row: Sabrena Mervin-Blake, Judy Seidenstein, Dane Whicker, PhD

New CTSI Core Dedicated to Integrating Equity Throughout Research Enterprise

s the COVID-19 pandemic and racial reckoning unfolded side-by-side during the summer of 2020, a common thread emerged that prompted an intentional shift at the Duke Clinical and Translational Science Institute (CTSI) and Clinical and Translational Science Award (CTSA).

"Although equity is something that Duke CTSA has always been interested in, during the summer of 2020, a more organized initiative to integrate equity throughout CTSI and CTSA was deemed necessary," said Keisha Bentley-Edwards, PhD, a Duke developmental psychologist and member of CTSI.

This call to intentionally incorporate equity throughout CTSI led to the creation of a new CTSA core. Inspired by CTSI Director L. Ebony Boulware, MD, with senior advisors Nadine J. Barrett, PhD, and Pamela Maxson, PhD, and in partnership with the School of Medicine's Chief Diversity Officer, Judy Seidenstein, the new Equity in Research (EIR) core launched in July 2020 and aims to elevate, advance, and accelerate equitable, inclusive, and anti-racist research.

With the profound challenges of 2020 still driving conversations, innovation, and necessary
change, CTSI has created a longitudinal strategy to fully integrate equity at every level. The strategy applies an equity lens to existing services and infrastructure, and builds as new initiatives and projects are launched and expanded.

"The whole focus of this is a comprehensive model of how we will address anti-bias and anti-racism and promote equity within anything that we do as CTSI," said Barrett, director of the new Center for Equity in Research, which is supported by the EIR core. "That includes our environment, our culture and how we engage with one another, and also the products that we put out."

The EIR core is at the heart of this work.

"Everyone will remember 2020 as the year of COVID and racial reckoning. We have everyone's attention. This is something that people are thinking about and talking about, a reckoning with not just racial bias but all forms of bias," said Bentley-Edwards, now co-director of EIR. "People want to be on the right side of history, including their research."

The new core provides infrastructure support for research teams and other CTSA cores to promote equity, anti-bias, and anti-racism across the research enterprise and environment. Services include ongoing and evolving development opportunities for staff, faculty, and researchers, as well as consultations with investigators and teams about the urgent need to increase diversity in clinical research.

"We want to help researchers from the very beginning of their projects think about equity, anti-bias, and anti-racism and how to incorporate these into a project, before they've even written the grant or developed research questions," said Dane Whicker, PhD, co-director of EIR.

These consultations will shift the culture toward proactive and robust planning for diversity, equity, and inclusion in research. The sessions will help research teams think strategically about diversifying clinical research participation using best practices and innovative solutions, and give them the tools to implement an equity lens across the lifecycle of a project from idea generation through dissemination.

Specific work accomplished thus far:

Developing and providing tools and resources:

- Anti-bias/anti-racism continuous learning environment: longitudinal curricula for all science trainees; curricula and tools for faculty, faculty mentors, and staff at Duke; featuring tailored learning tools and venues for various audiences
- Tools and resources to promote anti-bias and anti-racism culture in science teams: deepen the expertise and in anti-bias and anti-racism and to create change agents capable of generating an equitable, anti-biased/anti-racist research environment
- Consultations and resources to ensure diversity and cultural competency in biomedical research studies: direct engagement with CTSI cores as well as key school of medicine/school of nursing research resources to create tools and accountability around participant recruitment and engagement practices

Reframing constructs around bias and race in research:

 Convene biomedical researchers, social scientists and ethicists to deconstruct traditional uses of race and other harmful identifiers in research: a 'think-tank' for experts to discuss and develop new conceptual frameworks for scientists and to guide future research; promote new grants; fund pilots Develop cutting-edge anti-bias/anti-racism frameworks for researchers: advance the field through transdisciplinary collaborations that re-think scientific practices that may unwittingly reinforce racism or bias

Creating accountability to ensure an anti-biased/anti-racist research enterprise

- Evaluate and guide anti-bias/anti-racism research policies and practices: ongoing formal evaluation of policies and practices for research quality improvement
- Promote and support actions to dismantle biased and racist institutional practices in research: provide senior leadership with

strategic guidance and actionable recommendations to thwart bias and racism in research

Supporting efforts to establish an equity lens around clinical care

- Further a learning health system around equity, anti-bias/anti-racism. Develop ongoing collaborations with Duke Health leaders to establish equity lens around clinical care delivery and process improvement and clinical research: connect directly with Duke leaders focused on quality improvement with an equity lens
- Promote implementation research studies that focus on equity and anti-bias



Researchers Dennis Ko, PhD, and Raul Salinas in the Clinical and Research Laboratory Building on the Duke School of Medicine campus.

Duke CTSI Multidisciplinary Vision Program (MVP) Award

he Duke CTSI Multidisciplinary Vision Program (MVP) Award provides funding to support novel translational research focused on improving health and healthy equity. We anticipate awarding up to three grants and have a total of \$110,000 for awards. Award amounts vary based upon amount requested and budget evaluation by the Program Leadership Committee.

Duke CTSI supports translational research endeavors under the following domains:

• Methods/Processes: Scientific study of, and innovation in, the individual steps of the

translational process, and its integration into an efficient system of translation from discovery to community.

- Collaboration/Engagement: Research in the structures, rationales, operations, purposes, outcomes, and metrics of engagement with stakeholders at each step of the translational process to elucidate principles and practices that make translation maximally efficient, focused, and relevant.
- **Informatics:** Development, demonstration, and dissemination of informatics and Information

Technology (IT) innovations that accelerate both the science and operations of clinical translation.

- Integration Across the Lifespan: Development of scientific insights, and operational processes that will ensure that translational advances are realized in all populations, including children, pregnant and lactating women, the elderly, and other special populations, with particular emphasis on life stage transitions.
- Workforce Development: Innovations in the substance and culture of translational science workforce development, to create and sustain a robust, supported workforce with the skills, knowledge, and institutional environment necessary for continuous improvement in translational research and science.

The Duke Clinical and Translational Science Institute's mission is to accelerate scientific discoveries to improve health and health equity for patients and communities. Duke CTSI facilitates translational research by providing funding, promoting investigator collaboration, encouraging innovation, providing project management assistance, and providing access to resources/services in a collaborative and service-oriented fashion.

Translational research includes:

- Studies that address mechanisms contributing to human health and health equity, regardless of whether the context of the discovery is the laboratory, individuals, or communities.
- Studies that contribute to improvements in health or health equity by addressing barriers to clinical care or access to care in community or population settings.
- Research that contributes to improved health outcomes or health equity through changes in clinical practice or health policy.

Proposals from teams of investigators from different disciplines are encouraged. Collaborations that bring together ideas, theories, methods and approaches from disparate scientific disciplines are particularly encouraged.

Duke CTSA KL2 Program Named a Top-Performing Hub

he <u>Duke CTSA KL2 program</u> was recently identified as one of the top program hubs by the Center for Leading Innovation and

Collaboration (CLIC). The Duke KL2 program was a top performer in the KL2 education program—Underrepresented measure.

The CLIC evaluates programs using a Common Metrics Initiative. In alignment with the CLIC's current goals, the Duke KL2 program set a goal to increase the representation of underrepresented racial and ethnic groups (UREG) since

2013. <u>Laura Svetkey</u>, co-director of the Duke KL2 program, said the hub aimed to have at least 50 percent of funded KL2 scholars from underrepresented racial and ethnic groups.

"That's where it starts," she said. "Really having an intentional metric with institutional support to achieve it." Since 2013, 38 percent of Duke KL2 applications have been submitted by UREG investigators and more than 47 percent of scholars selected



Duke CTSA KL2 Co-Directors: Dr. Rasheed Gbadegesin, Dr. Kimberly Johnson, and Dr. Laura Svetkey

> for the program were UREG investigators. Compared to the national program average, Duke has 10 times as many Black/African American scholars participating in the KL2 program.

> In order to achieve this goal, leaders in the Duke KL2 program partnered with groups focused on UREG faculty development, including the School

> > of Medicine Office of Diversity and Inclusion and the Assistant Dean for Underrepresented Faculty. The group also worked with the Office of Research Mentoring to develop the KL2 Application Preparatory Program, designed to assist investigators with preparing their KL2 applications.

> > "It is important that the institution itself is committed to promoting diversity and inclusion," said <u>Kimberly Johnson</u>, Duke KL2 co-director. "Our program has been

Our program has been able to capitalize on Duke's commitment to both increasing the number of faculty from underrepresented racial and ethnic groups and providing resources to support their career development.

— Kimberly Johnson, MD

able to capitalize on Duke's commitment to both increasing the number of faculty from underrepresented racial and ethnic groups and providing resources to support their career development." Duke's achievements have also been featured on the <u>CLIC website</u>.

New Center Dedicated to Equity in Research Offers Expertise, Learning Opportunities

hrough the new Center for Equity in Research and a supporting core, CTSI has launched a range of initiatives to intentionally incorporate equity throughout the organization, including piloting a unique learning series for Duke employees called *Teaching and Leading Equity Now.*

Both the Center and the Equity in Research (EIR) core provide infrastructure support for research teams and other CTSA cores to promote equity, anti-bias, and anti-racism across the research enterprise and environment. Among others, services include ongoing and evolving development opportunities for staff, faculty, and researchers, as well as consultations with investigators and teams about the urgent need to increase diversity in clinical research.

Fueled by the pandemic and racial reckoning during the summer of 2020, CTSI accelerated work already underway to fully integrate equity at every level, beginning with a survey to understand the institution's baseline regarding equity, anti-racism, and anti-bias from three perspectives — interpersonal, intrapersonal, and systemic. The overarching themes of the survey results were shared during a highly interactive CTSI retreat, an event that helped launch the longitudinal journey by creating a shared language and vision to move the work forward.



Nadine Barrett, PhD

"We're not just thinking about our environment, but also the culture that builds our environment around these concepts," said Nadine J. Barrett, PhD, director of the Center for Equity in Research. "Equally importantly, we want to make sure that the products we create and the work we do within the CTSI really reflect the use of an an-



Keisha Bentley-Edwards, PhD; Dane Whicker, PhD; Sabrena Mervin-Blake

ti-bias, anti-racist, and equity lens."

The new EIR core features the interdisciplinary expertise necessary to foster an equitable, anti-biased, and anti-racist research environment throughout the entire Duke CTSI and CTSA enterprise, Barrett said. The core is led by co-directors Keisha Bentley-Edwards, PhD and Dane Whicker, PhD. Sabrena Mervin-Blake is staff director for the core. "This core will apply their great expertise to help our research become even more rigorous because we're increasing diversity, as well as framing our research questions within the context of equity," Barrett added.

The core will offer resource development including anti-racist and anti-bias curricula tailored to faculty, staff, and scholars, as well as providing equity-informed recruitment and retention resources and tools for research teams.

Future plans include creating a clearinghouse of best strategies for increasing diverse participation in clinical and translational research, and developing a network of champions integrated across the Duke School of Medicine to promote equity in research.

"CTSI is a trailblazer for Duke in this area," said Judy Seidenstein, chief diversity officer for the Duke University School of Medicine. "This intentional focus on longitudinal learning, instead of one-off training classes, has the potential to create a tipping point — a point when we reach a certain percentage of people who have a shared framework, language, and understanding which ultimately influences cultural transformation."

So far, about 200 people in the School of Medicine have gone through Teaching and Leading Equity Now, the in-depth, four-week development workshop piloted by CTSI. Employees will have the opportunity to participate in this interactive virtual learning platform, which serves as a model across Duke.

"Each person will process and embed this work in their own unique reality and in their particular work," Seidenstein said. "People will be able to



Judy Seidenstein

apply and engage this framework in ways that contribute to our long overdue cultural tipping point."

CTSI is partnering with institutional offices to provide training in equity and anti-racism for the entire health-related research enterprise at Duke (including the Schools of Medicine and Nursing). The four-part learning series consists of the following:

Workshop 1, Community Building & Defining Racism: This initial

workshop begins the task of building the learning community as it delves into defining racism as more than personal, as institutional, cultural, systemic and pervasive.

Workshop 2, History and Lessons for Today: Examines how our history brought us to this moment as well as what we can learn from that history in the form of racial equity principles to guide strong anti-racist practice.

Workshop 3, The Three Expressions of Racism: Offers an analytical framework for understanding how racism and white supremacy operate. This framework is also useful for considering how to collectively embed and apply a racial equity lens.

Workshop 4, Onward: Application for Dismantling Racism: The concluding workshop invites participants to raise questions and concerns as they apply what they have learned to their practice, teaching, mentoring and work environments by providing facilitated space for problem-solving and planning.



"White Coats for Black Lives" demonstration, June 2020 in Durham, NC.

Designing the Roadmap Toward Equity

he racially motivated violence, discrimination, and disenfranchisement in our nation, highlighted during the summer of 2020, laid bare our society's deep wounds emanating from long-standing systemic racism. For many in our community, this was and continues to be a time of tremendous sorrow, pain, outrage, and reflection. The concern, fear, and trauma experienced by so many must be recognized and honored.

CTSI's commitment to fostering a truly diverse and equitable environment must start with thwarting injustices against any individual, whether motivated by race or ethnicity, culture, sexual orientation, gender, or disability status. As an organization, we seek to improve the health and health equity of our community here in North Carolina and across the nation. We see our actions locally as critical enablers of this vision.

Throughout 2020, and continuing into 2021, opportunities for learning and self-reflection were made available to the members of the CTSI to help the organization as a whole work together to create an equitable and just community and environment—both from within and outside the institution. CTSI has committed to taking on the meaningful ongoing and sustained work to realize the vision for equity and inclusion.

Initial efforts included virtual conversations via CTSI town halls and staff meetings, along with a series of comprehensive surveys administered throughout the summer, helped CTSI leadership understand the attitudes, experiences, and concerns of CTSI personnel regarding racism, discrimination, and equity. The insights gleaned from these early conversations and feedback cycles helped the CTSI leadership team develop a longitudinal strategy for anti-racism, anti-bias, and equity that was presented to the entire CTSI staff and faculty during an Equity Retreat in the fall. The retreat included an overview of the roadmap toward equity and meaningful presentations by experts at Duke, and opportunities to interact and engage with each other.

These learnings and conversations have helped the members of CTSI to work collectively

to break down policies and practices that have resulted in inequities permeating our daily work and interactions. Understanding what implicit bias is and how it manifests in micro-aggressions will help individuals, teams, and entire organizations strive to disrupt the deep roots of systemic and structural racism.

Surveys Reveal Attitudes and Experiences Regarding Racism and Discrimination

uring the summer of 2020, CTSI team members participated in an assessment of the workplace culture, specifically in regards to anti-bias, anti-racism, and equity. The assessment was done via Qualtrics over a two-week period. The survey results, along with additional resources presented during the CTSI's Equity Retreat, were shared with CTSI members to provide foundational guidance for shaping a long-term, meaningful, and healing response to perceived and experienced racism and discrimination within our organization and the larger Duke community.

The initial CTSI survey was presented to Duke School of Medicine and University leadership teams to inform the design and planning of a larger Duke initiative to survey all members of the Duke community, including staff, faculty, and students. With appropriate editing and review to accommodate the variety of departments, organizations, and people, the final Duke Community Diversity, Equity, and Inclusion Survey was administered to the entire campus in the spring of 2021.

All Duke community members were invited to share their perspectives about important issues connected to their work and educational experience to track the effectiveness of current and planned programmatic and policy changes designed to help Duke become a more just and equitable community for all. Aggregate survey



CTSI created a workplace survey about equity and discrimination that Duke University adapted and implemented campus-wide.

results will be shared with senior and unit leaders, as well as all community members, during the summer of 2021. These results will inform leadership efforts moving forward.

Catalyzing Discovery and Research

Section Overview: Catalyzing Discovery and Research	47
First Ever Duke Golden Ticket Awarded to Dr. Eric Benner	
CTSI-Backed Startup Gets FDA Clearance for its Hernia Mesh Product	51
Duke/NCCU Collaborative Translational Research Awards	52
Duke-NCCU Collaboration Secures Follow-On Funding from NC Biotech Center	54
Duke Study Sheds New Light on Statin Therapy for High-Risk Patients	55
Duke-UNC Study Shows Women with High Blood Pressure During Pregnancy More Likely to Develop Heart Disease	57



Dr. Eric Benner receives the inaugural Duke Golden Ticket award at the Chesterfield Building in Durham, NC. The award was given to support Benner's groundbreaking therapy for treating and reversing infant brain injuries.

Section Overview: Catalyzing Discovery and Research

ven in the midst of the pandemic, CTSI maintained focus on its mission to advance scientific discovery that will improve human health and health equity by holistically supporting research from early stages in the lab all the way to patients and communities.

In early 2020, Dr. Eric Benner was awarded the first-ever Duke Golden Ticket to advance a groundbreaking brain injury therapy toward clinical trials. Despite the pandemic, the project remains on track for an accelerated timeline to clinical use.

In another translational success, a Duke startup, Deep Blue Medical, received FDA clearance to take its hernia mesh product to market after receiving CTSI funding in the development phase.

CTSI's collaborative pilot funding program with North Carolina Central University (NCCU) has yielded six new inter-institutional research teams studying cancer treatment, drug delivery, population health, and other domains.

One of the funded Duke-NCCU collaborative research teams secured follow-on funding from NC Biotech Center for their drug delivery innovation.

Duke investigators Tina Tailor, MD and Melissa Daubert, MD used CTSI's Clinical Data Research Networks to conduct multi-site studies illuminating little-known health disparities in cardiology and OBGYN care. Their findings could inform changes in care and policy.

Each of these successes is a testament to the vision of Duke researchers and the spirit of collaborative exploration fostered by CTSI.



Dr. Eric Benner (second from left) and his team with the Duke Golden Ticket award at the Invented at Duke Celebration in November 2019.

First Ever Duke Golden Ticket Awarded to Dr. Eric Benner

uke Clinical & Translational Science Institute and <u>BioLabs North Carolina</u> have awarded the first ever Duke Golden Ticket to <u>Dr. Eric Benner</u>, Assistant Professor of Pediatrics in the Duke School of Medicine, and co-founder of <u>Tellus Therapeutics</u>.

The award includes the <u>\$500,000 Transfor-</u> mative Funding Agreement from <u>Duke CTSI</u> <u>Accelerator</u> and one year of lab space in Bio-Labs NC's facility at the Chesterfield Building in downtown Durham, NC.

"With this inaugural Duke Golden Ticket, we have created a public-private partnership between Duke CTSI and NC BioLabs that represents a profoundly different model to support enterprise," said <u>Dr. Barry Myers</u>, Director of Innovation at Duke CTSI and Professor of Biomedical Engineering in the Duke Pratt School of Engineering.

Myers highlighted the ecosystem that helps translate exciting research from the lab to the commercial space: "The <u>Duke Office of Licens-</u> <u>ing and Ventures</u> provides guidance to Dr. Benner through experts in technology transfer along with assigned Experts and Mentors In Residence. Duke CTSI awarded Dr. Benner our Transformative award, which provides Project Management support along with \$500K of financial support. The Duke Golden Ticket provided by BioLabs NC completes the bridge from academics into an operational enterprise."

Benner is a neonatologist specializing in the care of high-risk infants in the Neonatal Intensive Care Unit, and his research focuses on perinatal brain injuries. The Duke Golden Ticket will enable him to advance a highly promising, novel therapy that uses molecules derived from human breast milk to treat and reverse white-matter brain injuries, which are most common among premature babies and can lead to lifelong conditions such as cerebral palsy. Learn more about Dr. Benner's work at <u>https://ctsi.</u> <u>duke.edu/news/personal-quest-reverse-neonatal-brain-cell-damage</u>.

"The Duke Golden Ticket gives the awardee free access to fully equipped wet lab space in BioLabs NC for one year," said Ed Field, President of BioLabs NC. "The goal of this Duke Golden Ticket is to allow the awardee access to a facility to continue to perform additional proof of concept experiments that will eventually attract licensing partners or capital for a new company. Additionally, the BioLabs NC ecosystem provides the awardee access to a rich scientific and entrepreneurial environment and connections to multiple potential pharmaceutical licensing partners and investors, including BioInnovation Capital."

Previously, Duke CTSI Accelerator supported this research with its <u>Translational Accelerator</u> <u>Funding Award</u> and by providing project management through its team of Project Leaders.



T-Line[®] Hernia Mesh product created by Dr. Howard Levinson, with support from the Duke CTSA Transformative Research award.

CTSI-Backed Startup Gets FDA Clearance for its Hernia Mesh Product

Duke startup, <u>Deep Blue Medical Ad-</u> vances, has received FDA clearance to start selling its patented T-Line[®] Hernia Mesh product, which "solves the issue of failure of mesh at fixation sites in ventral hernia repair," according to the company's website.

The company was founded in 2014 by <u>Dr.</u> <u>Howard Levinson</u>, Associate Professor of Surgery in the Duke School of Medicine.

In 2016, <u>Levinson received a Transformative</u> <u>Research award</u> from <u>Duke CTSI Accelerator</u> to complete benchtop and in vivo studies of the hernia mesh—an early investment that is now paying off as the product can begin to improve the lives of patients. <u>From WRAL TechWire</u>: The T-Line Hernia Mesh "provides superior anchoring strength and eliminates a key point of failure for conventional mesh fixation," the Durham-based company says. It is designed to counter "mesh migration, contraction and eventual failure."

Millions of hernia surgeries are done globally at billions in clinical costs and support a \$1.1 billion hernia device market.

In addition to funding and project management from CTSI Accelerator, Deep Blue benefitted from Duke's translational research pipeline, receiving commercialization support through the <u>Duke Office of Licensing and Ventures</u>.



The Biomanufacturing Research Institute and Technology Enterprise (BRITE) at North Carolina Central University facilitates high-throughput screening, drug discovery, and other advanced research needs, with over 30,000 square feet of laboratory space.

Duke/NCCU Collaborative Translational Research Awards

he Duke Clinical and Translational Science Institute, the academic home of the National Institutes of Health's Clinical and Translational Science Awards (CTSA) pilot funding programs at Duke University, is partnering with North Carolina Central University (NCCU) to support new inter-institutional collaborative research projects.

This pilot program is designed to facilitate novel clinical, population, and translational research that applies or accelerates discovery into testing in clinical or population settings. Projects must demonstrate stakeholder engagement and a high translational potential with a clear path for continued development to move into clinical practice, generate new clinical guidelines, or other applications via subsequent grant support, new company formation, licensing, not-for-profit partnering, an evidence base that changes practice or other channels.

Duke CTSI and NCCU are interested in the following types of translational research projects:

- Projects developing new collaborative science teams with investigators from both Duke and NCCU.
- Development and/or evaluation of the evidence base that **changes clinical practice**.
- Research that investigates how practice improves health policy, health outcomes, and the health of populations.

Funded Research Teams

Jan 2019 – Dec 2019

Engineering smart injectable drug delivery theranostics for uterine fibroids Duke PI: <u>Frederike Jayes, DVM, PhD</u> NCCU PI: Darlene Taylor, PhD

Jan 2019 – Dec 2019

Identification of existing drugs and drug combinations that are synthetic lethal for PTEN-deficient cancer cells Duke PI: <u>Kris Wood, PhD</u> NCCU PI: John Scott, PhD

Jan 2019 – Dec 2019

SPLUNC1 mediated myoepithelial cell calcium signaling in airway regeneration and asthma Duke PI: <u>Purushothama Rao Tata, PhD</u> NCCU PI: Tongde Wu, PhD

July 2019 – June 2020 Impact of disproportionate minority contact (DMC) and race-related stressors on mental health and well-being of rural African-American Transition-Age Youth (AA-TAY) Duke PI: <u>Ann Brewster</u> NCCU PI: Lorraine Taylor July 2019 – June 2020

Heart Healthy U: A multimedia campaign pilot study to promote heart healthy behaviors among college students Duke PI: <u>Helene Vilme, MPH, DrPH</u> NCCU PI: LaShawn Wordlaw, PhD

July 2019 – June 2020

Characterization of genomic determinants for disparities in African-American patients with non-small cell lung cancer (NSCLC) Duke PI: Jennifer Freedman, PhD NCCU PI: Kevin Williams, PhD



The North Carolina Biotechnology Center, located in Research Triangle Park, helps bring scientific ideas to market.

Duke-NCCU collaboration secures follow-on funding from NC Biotech Center

collaborative research team supported by Duke CTSI has secured follow-on funding from the North Carolina Biotechnology Center for their work in drug delivery.

The project, "Engineering smart injectable drug delivery theranostics for uterine fibroids", is led by Frederike Jayes, DVM, PhD as the Duke Principal Investigator (PI) on the project, and Darlene Taylor, PhD as the NCCU PI.

The team's funding period from NC Biotech Center runs from February 2021 to February 2022, and will advance research on a hydrogel for controlled release of drugs used in uterine fibroid therapy.



Representative lung cancer screening CT examination showing coronary artery calcification (arrows).

Duke study sheds new light on statin therapy for high-risk patients

or people who are at high risk for lung cancer— particularly individuals with a longtime smoking history—annual screenings are essential. Radiologists conduct these screenings by using a low-dose CT scan to get a detailed image of the lungs. But these screenings sometimes reveal more than just lung health.

"The negative effects of smoking extend beyond just lung cancer," says <u>Tina Tailor, MD</u>, Assistant Professor of Radiology in the Duke School of Medicine. "Cardiovascular disease is actually the leading cause of death in patients screened for lung cancer."

Coronary artery calcification (CAC), which is the build-up of calcium on the heart's arteries, is visible on a CT scan, and is a known predictor of cardiovascular disease. It's not unusual to find CAC in the lung cancer screening group—many people are at risk for both. Statins, a class of drugs that lower cholesterol levels, are a common therapy used to prevent serious adverse cardiovascular events down the road. The American Heart Association has certain clinical criteria to determine if a patient should be on a statin.

However, a collaborative study led by Tailor and colleagues at UNC-Chapel Hill and Wake Forest University has found that most lung cancer screening patients who are statin eligible are not on a statin at the time of their screening. They also found that if CAC was reported by the radiologist, those patients were more likely to be prescribed a statin later on.

From reporting to prevention

"Lung cancer screening is a relatively new recommendation," says Tailor, who acted as the co-principal investigator on the study. She was joined by co-Pls <u>Caroline Chiles, MD</u>, of Wake Forest Baptist Hospital, and <u>Louise Henderson, PhD</u>, of UNC-Chapel Hill.

"Through lung cancer screening, we may be able to look for markers of cardiovascular disease, and CAC is one of these."

Tailor and her collaborators studied a cohort of over 5,000 lung cancer screening patients, finding that the vast majority of them met the criteria for preventative statin therapy. At the same time, most of those patients were not prescribed a statin when they came in for their screening exam.

"The knowledge gap that we were interested in here is, 'How does the reporting of CAC at a screening exam affect downstream preventative statin therapy?" she explains.

If the radiologist reported CAC, the study found that that the patient was more likely to be prescribed a statin afterward—a link that had not before been robustly established. The team plans to share the details of these findings in forthcoming publications and presentations.

The power of data

To make this data-heavy, multi-site collaboration work, the team relied on funding and data from the Carolinas Collaborative and project management from Duke CTSI Accelerator.

"CTSI provided us with an ideal opportunity for this group of researchers to bring in three clinical sites [Duke, UNC, and Wake Forest] with a high volume of lung cancer screening," says Tailor. "It was the first time I had collaborated in this way."

Tailor worked directly with <u>Lisa Davis</u>, Director of Special Projects at Duke CTSI, and <u>Janis Curtis</u>, Associate Director of Duke's <u>Clinical Data Research Networks (CDRN)</u> program. Data teams at all three sites extracted massive amounts of electronic health record (EHR) data from the Carolinas Collaborative datamart, creating datasets that were securely and effectively shared across institutions.

"Dr. Tailor's collaborative study is a great example of how the CDRNs in which Duke participates can support clinical research," says Curtis. "The availability of large amounts of coded EHR data in an electronic format makes it significantly easier to work with very large numbers of patient records."

Davis, in her role as Project Leader with <u>Duke</u> <u>CTSI Accelerator</u>, provided project management, helping the team complete their study across a one-year timeline despite the complexities of having multiple sites.

"Project leadership and connections to resources can really go a long way in helping study teams advance important research," Davis says. "It was truly an honor to work with Dr. Tailor and team to help move the work forward efficiently."

The collaborative nature of the project was essential, according to Tailor. "With a study like this that is retrospective, the ability to have data from multiple centers gave us more statistical power to answer our questions."

Armed with their new findings, the multi-institutional team will explore ways to improve the guidelines for lung cancer screening, and work toward developing recommendations for radiologists to report CAC in a standardized manner.

"We've shown that when we do report these findings, they lead to changes downstream," Tailor says—changes that could help prevent adverse cardiovascular events for patients.

For more information about translational funding and project management, visit <u>CTSI Accelerator</u>. For more information about using Clinical Data Research Networks to conduct multisite research using well-curated EHR, visit the <u>CDRN Program</u>.



Care providers at Duke Health conduct a pregnancy ultrasound.

Duke-UNC study shows women with high blood pressure during pregnancy more likely to develop heart disease

magine a 25-year-old woman who is pregnant with her first child and living in Chapel Hill, North Carolina. Let's say that during her pregnancy, the woman develops pre-eclampsia—a condition marked by high blood pressure. There's a good chance she's receiving her obstetric (OB) care in the UNC Health system, where her providers will monitor the condition and deliver the baby at the appropriate time.

Now imagine that five years later, that woman moves down the road to Durham, NC. At a routine checkup with her new doctor in the Duke Health system, she's found to have high blood pressure. Unless the woman thinks to tell her doctor about the pre-eclampsia, or the doctor takes the non-routine step of reviewing her OB records, this important part of her medical history may go unnoticed.

A knowledge gap like this is not unique to Duke and UNC.

"It's not unusual for women to give birth in one health system and later receive hypertensive care in another system," says <u>Melissa</u> <u>Daubert, MD</u>, a Duke cardiologist who specializes in women's cardiovascular health and the burgeoning field of Cardio-OB.

But this kind of knowledge gap could have serious consequences, according to the results

of a study led by Daubert as Principal Investigator, in collaboration with researchers at UNC-Chapel Hill.

The study has revealed that women with hypertensive complications in pregnancy (such as pre-eclampsia) are at far higher risk for heart disease later in life, and that the current guidelines for postpartum blood pressure screening are inconsistent.

"Our question was, 'How are these women being cared for?' That's an area that hasn't been

Dr. Daubert's study reflects some of the key benefits of leveraging electronic health record data to address important clinical questions.

> — Janis Curtis, Associate Chief Information Officer, Duke CTSI

well studied," says Daubert, who is an Associate Professor in the Duke School of Medicine.

She and her team collaborated with a UNC-Chapel Hill team led by <u>Rachel Urrutia</u>, <u>MD</u>, <u>MSCR</u>, aided by funding and data resources from the <u>Carolinas Collaborative</u> and support from <u>Duke CTSI</u>. They analyzed more than a decade's worth of medical record information to find out if women who experienced hypertensive complications during pregnancy received blood pressure screening postpartum, to assess the long-term risk to their cardiovascular health, and glean insights that could help improve the guidelines for care.

High risks, not enough information

Utilizing data from both Duke and UNC, made shareable by the Carolinas Collaborative, one

of the <u>Clinical Data Research Networks (CDRN)</u> in which Duke participates, Daubert and Urrutia found that nearly 46% of the women in their study cohort—all of whom experienced hypertensive pregnancy complications—had developed high blood pressure, prediabetes, diabetes, or another cardiovascular risk factor within five years.

They also found that only one-third of the women had a blood pressure check within a year of giving birth.

> "These are really eye-opening findings," Daubert says. "Women who have hypertensive complications of pregnancy develop heart disease later in life at a much higher rate than other women, and a significant portion of these high-risk women develop heart disease risk factors as early as 5 years after giving birth, which makes screening and close monitoring critical. Unfortunately, only a

fraction of these women are getting screened in the in the first year after giving birth."

The data also uncovered racial health disparities: Non-white women, particularly Black and Latinx women, were at higher risk for cardiovascular events.

"Dr. Daubert's study reflects some of the key benefits of leveraging electronic health record data to address important clinical questions," according to Janis Curtis, Associate Director of the CDRN program at Duke CTSI. "This includes the ability to identify potential gaps and differences in treatment patterns for various racial groups."

Curtis also noted that through the Carolinas Collaborative CDRN, the study was able to find more than 7,000 Duke patients who met the inclusion criteria—a crucial dataset. (This data was de-identified, meaning all information that could distinguish an individual had been removed.)

The study crystallized a major issue Daubert had come to suspect as a practicing cardiologist: Despite a clear link between pregnancy complications and heart disease, there is a lack of robust guidelines and systems for screening and following-up with women in this high-risk group.

Lifting the burden

Daubert and Urrutia plan to publish their findings soon, and use them as a springboard to explore interventions that can fill the gaps they've identified.

Given the hectic nature of parenthood, especially in the first few months, one of the key goals is taking the burden off of individual women to track their cardiovascular health, and instead make it systematic process, leveraging the electronic medical record.

"We need to automate and facilitate the follow-up care of these women," Daubert says. "It should be codified in the guidelines that women should have at least one blood pressure check within a year postpartum. We hope that the Duke and UNC health systems can be a model for this preventive care." They also hope to influence policy, such as extended postpartum insurance coverage, and work to educate both patients and providers on the importance of knowing the full Cardio-OB health picture, which includes knowing the implications of the hypertensive complications of pregnancy on future cardiovascular risk.

"There is now more recognition that this is a problem and this study moves us closer to solutions," Daubert says. "The goal is to prevent or reduce the long-term consequences of the hypertensive disorders of pregnancy."

Crossing the finish line

A retrospective study like this needs more than funding and data to succeed. As a Carolinas Collaborative awardee, Daubert also received expert project management from <u>CTSI Acceler-</u> ator to shepherd this work from initial design to IRB approval, data analysis, and completion.

For more information about translational funding and project management, visit <u>CTSI Accelerator</u>. For more information about using Clinical Data Research Networks to conduct multisite research using well-curated EHR, visit the <u>CDRN Program</u>.

Accelerating Innovation

Section Overview: Accelerating Innovation	61
2020 SciTS Conference Focuses on Education, Convergence, and the Future6	53
Duke CTSI Doubles Space at NC Research Campus	
for Translational Population Health Research,	
Home of MURDOCK Study	56
Introducing myRESEARCHpath, the Institution-Wide	20
Interactive Research Roadmap	DO
Mobile App Gateway Provides Critical Support	
for Award-Winning App6	59
Mobile App Gateway supports award-winning	
child healthcare app	/1
Machine Learning and Augmented Intelligence	
Cross the Chasm in Health Care	72



Dr. L. Kristin Newby and Dr. Ebony Boulware celebrate with the TransPop team and community stakeholders during the ribbon-cutting ceremony for Duke CTSI's space expansion at the NC Research Campus.

Section Overview: Accelerating Innovation

he future of translational science will require highly collaborative inter-disciplinary research teams and flexible tools to support those teams. In recent years, CTSI has ramped up its efforts to build infrastructure, capacity, and knowledge to lead the next era of research.

In June 2020, a team of CTSI faculty and staff designed and hosted the 2020 International Science of Team Science Conference, presenting a robust program of cutting-edge scholarship in the Team Science field while setting records for attendance as one of the first science conferences to pivot online due to the pandemic.

CTSI doubled its space at the NC Research

Campus in Kannapolis, home of our Translational Population Health Research group. The new state-of-the-art facility has increased capacity for high-impact, community-engaged research.

CTSI supported the creation and launch of MyResearchPath, an innovative online roadmap to conducting research at Duke, expanding the functionality of the MyResearch suite of tools. MyResearchPath is now being used by investigators across Duke to navigate the research landscape.

CTSI's Mobile App Gateway group helped produce two award-winning apps: The Talk, which promotes sexual health among Black male adolescents in the South, and Caremap, which helps families coordinate their children's healthcare needs.

CTSI investigators partnered with the Duke Institute for Health Innovation to pioneer machine learning algorithms that help identify hospital inpatients at risk of sepsis. Since 2019, active dashboards have been used by hospital care teams in the Duke Health system.

These are just a few examples of how CTSI leverages new fields of knowledge, new technologies, and a health equity lens to advance translational science.

2020 SciTS Conference Focuses on Education, Convergence, and the Future

his year, Duke University and the Duke CTSI, along with the International Network for the Science of Team Science (INSciTS), hosted the 11th Annual International Science of Team Science (SciTS) Conference. The conference, which took place entirely online due to the COVID-19 pandemic, exists to share and advance the evidence base for effective team collaboration, transdisciplinary science, and working across boundaries (disciplinary, sectoral, geographical, e.g.) to solve complex problems.

Building off over a decade of establishing the SciTS field, the 2020 conference focused on highlighting and pursuing excellence in studying, doing, and teaching team science. Daily virtual interactive workshops, panel discussions and Q&A sessions hosted by leading experts in the field focused on the basics of team science, critical collaboration skills, scientometrics and data analysis, and more. The conference also featured two novel interaction modalities, created in the transition to the virtual platform, to recre-



ate important aspects of in-person gatherings,

namely opportunities for informal networking, identification of collaborators and feedback on presented work.

Keynote: The Collaborative Era of Science

The keynote address was delivered by Dr. Caroline Wagner, Associate Professor and Milton



The SciTS 2020 virtual keynote was delivered by Caroline Wagner, PhD, of The Ohio State University (top right), and included a discussion with international experts on Team Science.

& Roslyn Wolf Chair in International Affairs at The Ohio State University and author of *The Collaborative Era in Science: Governing the Network*. Dr. Wagner spoke about the contribution of teams to what she dubs, "the collaborative era of science."

"Deep knowledge is needed in each field in a team or a group in order to find complementary ways of knowing," she said. "The broader the frontier, the more you need teams. The greater the need for creativity and recombination, the more you need diverse teams."

Convergence and Team Science

One of the plenary panels focused on the meaning and importance of convergence science in the context of team science. The panel included experts from Duke, the University of Birmingham, and the University of Virginia.

When it comes to convergence in team science, the panelists discussed the difficulties of getting interdisciplinary research off the ground, particularly at an academic institution. Dr. Missy Cummings, Professor in the Department of Electrical and Computer Engineering at the Pratt School of Engineering, recounted her challenge transitioning from working as one of the Navy's first female fighter pilots to a researcher at the Massachusetts Institute of Technology (MIT).

Dr. Cummings said that when she began her academic career, "interdisciplinary research was definitely not rewarded. So I had to play the game to get tenure and get to the point that I was doing more interdisciplinary work."

Now, she believes that inter- and trans-disciplinary teamwork is essential to scientific research. "There is no problem you can present to me anymore that does not require people from more than one domain."

When actually getting to work in an interdisciplinary team, the panel also discussed the challenge of getting researchers to look at the work and contributions of team members with expertise outside of their own concentration.

"It is difficult to talk about other people's research, particularly when it's out of your comfort zone," said Iseult Lynch, Professor in the School of Geography, Earth and Environmental Science at the University of Birmingham. "But for team science and for convergence, I think that humility and that ability to learn how to present other people's work with as much passion as you do your own are very critical components."

Excellence in SciTS Education

The conference's final plenary panel explored multiple models for excellence in team science education across a range of career stages, including the undergraduate, graduate, and early career researcher levels. Panelists from Duke, the University of Waterloo, and the University of Florida shared their experiences working with students and trainees at these different levels.

Dr. Claudia Gunsch, the Theodore Kennedy Associate Professor in Civil & Environmental Engineering at the Pratt School of Engineering, spoke about the importance of showing her graduate students how to work in a team setting before asking them to work together.

"For our engineering students, there's been so much of a focus on the technical skills, and there hasn't been much of an emphasis pushed really on learning those types of collaborative skills," Dr. Gunsch said. "We put you in the team and we expect you to know how to function in that team without really teaching you. I am seeing an evolution; I do think a lot of universities are adapting their curricula to start incorporating more of this."

The panelists noted that some students, particularly students from professional backgrounds in business or law, have more of a background in team-based approaches through their programs. The challenge, then, is to determine how to adapt the curriculum to be meaningful to students coming in with different skillsets.



A virtual plenary panel session at SciTS 2020 included Duke Vice Provost for Interdisciplinary Studies Ed Balleisen, PhD (bottom row left).

"We need to not just provide them with a safe space to collaborate with one another and take risks, but also show them how to create those spaces and cultivate psychological safety for others," said Dr. Kathryn Plaisance, Associate Professor in the Department of Knowledge Integration at the University of Waterloo.

Panelist and Vice Provost for Interdisciplinary Studies at Duke <u>Dr. Edward J. Balleisen</u> oversees and provides strategic guidance for <u>Bass</u> <u>Connections</u>, a program that brings together faculty, postdocs, graduate students, undergraduates and external partners to tackle complex societal challenges in interdisciplinary research teams. Reflecting on the impact of these experiential, team-based learning programs, he and students of the program have been able to see the value of team science beyond the academy.

"These team-based experiences end up being what employers want to ask about in interviews," Dr. Balleisen said. "It is getting people fellowships, and it is getting people internships, and it is getting people jobs. It is in many ways launching a growing number of our students on their career trajectory."

To learn more about the Science of Team Science, visit <u>www.inscits.org</u>.



Duke CTSI leaders and staff gather with community stakeholders to celebrate the space expansion in Kannapolis, N.C.

Duke CTSI Doubles Space at NC Research Campus for Translational Population Health Research, Home of MURDOCK Study

ith a grateful nod to the past and a bright eye on the future, the Duke Clinical and Translational Science Institute (CTSI) officially opened its expanded space Wednesday on the North Carolina Research Campus in Kannapolis.

Duke doubled its presence on the campus to 10,100 square feet, all of it home to the Translational Population Health Research group, or "TransPop."

"As Duke enters the second decade of the foundational MURDOCK Study, CTSI has doubled the TransPop office space to accommodate even larger and more complex studies," said L. Kristin Newby, M.D., the founding faculty director of Duke TransPop who led the evolution of the MURDOCK Study. "Everyone is looking forward to new collaborations that leverage the MURDOCK Study asset, as well as other projects based in Kannapolis that seek to improve health."

From Duke's expansive office suite on the third floor of the NCRC Medical Plaza, the crowd at the grand opening enjoyed a wonderful view of the new Kannapolis Sports and Entertainment Venue — the future home of the Kannapolis Cannon Ballers baseball team.

"Duke and the MURDOCK Study have helped put us on the map as a city where groundbreaking, community-based research is taking place," Kannapolis Mayor Darrell Hinnant said. "Kannapolis is proud to be the home of the MUR-DOCK Study, and we look forward to upcoming studies made possible by Duke's expansion on the North Carolina Research Campus."

From humble beginnings in 2007 in a former downtown retail shop with one employee, Duke CTSI now has 27 employees in Kannapolis and 12,526 volunteers in the MURDOCK Study, plus hundreds more in other studies. Duke studies aim to better understand the transition between health and disease at the clinical, community, and molecular level, and ultimately contribute to improved diagnosis and treatment.

"I'm so pleased to see Duke expanding. In doubling their space, Duke joins the seven UNC System universities that have expanded their campus footprint within the past year," said Mark Spitzer, president of Castle & Cooke NC, developer of the NC Research Campus. "Duke's MURDOCK Study and other longitudinal health studies are particularly important to the overall mission of the North Carolina Research Campus, and Duke's community-based research is vital as the campus grows through the increasing participation of each entity toward improving human health."

Many Duke researchers and leaders arrived from Durham for the event, including Dr. Ebony Boulware, director of Duke CTSI, who congratulated the TransPop team on what they have built in Kannapolis.

"Not only is vital clinical research taking place here, but TransPop always places study participants at the center of everything they do," Boulware said. "This community-based approach is the gold standard, and investigator after investigator tells me of their remarkable experience working with this team on grants, projects, and



L. Kristin Newby, MD

initiatives. Thank you for the important work you do for Duke CTSI and for Duke University as a whole. TransPop ensures that clinical research continues to flourish at Duke and in our North Carolina communities, and that the knowledge gained through research at Duke will improve the health of our communities."



Introducing myRESEARCHpath, the Institution-Wide Interactive Research Roadmap

ith support from Duke CTSI and the Duke Office of Research, a new tool is now available through <u>myRESEARCH</u>home to guide Duke's research community to policy, process, and helpful resources throughout a research project lifecycle.

This new tool, <u>myRESEARCHpath</u>, brings together information from over 35 research support offices across the institution so researchers can easily access the information they need to navigate tasks from idea generation to project closeout. Access this <u>brief tutorial video</u> to learn more about the features and functionality of myRESEARCHpath.

myRESEARCHpath is intended to support faculty, scientific staff, research administrators, and trainees throughout Duke University and the Duke University Health System.

Duke Mobile App Gateway

Mobile App Gateway provides critical support for award-winning app

ith the help of the Duke CTSI Mobile App Gateway (MAG), Dr. Schenita Randolph received an award for her app, The TALK: A Novel Mobile Application marketed in Barbershops and Beauty Salons for Black Fathers and Mothers to promote sexual health among Black male adolescents living in the United States South.

Dr. Randolph's award was her proposal to the <u>Betty Irene Moore Fellowships for Nurse Lead-</u> <u>ers and Innovators</u>, a new fellowship program funded by a five-year, \$37.5 million grant from the <u>Gordon and Betty Moore Foundation</u> to recognize early- to mid-career nursing scholars and innovators with a high potential to accelerate leadership in nursing research, practice, education, policy and entrepreneurship.

Through an initial consultation, the MAG assisted in the navigation in the develop of the app for Dr. Randolph. Initially she received a grant for \$50,000 to develop the app. Through its collaborative structure, the MAG team was able to assist in securing a developer Onyx Ocean Technologist and worked with Office of Research Contracts for solidify an agreement.

As part of the three-year <u>fellowship program</u>, fellows receive \$450,000 to conduct an innovative project or study with the potential to address a gap in knowledge, meet a vital need, alter care delivery or design a new solution to advance health. Dr. Randolph's project focuses on the development of a nurse-led mobile application (The TALK) to promote healthy sexual behaviors among Black adolescent males, integrating fathers and mothers as health educators. Marketed in community barbershops and beauty salons, the app will have a community widespread impact in promoting health among Black male adolescents. Dr. Randolph's program started on July 1, 2020.

Proposal Abstract

Black male youth ages 13 through 17 have eight times the rate of human immunodeficiency virus compared to White male youth, accounting for over half of all HIV infections in this age group in the United States, predominantly in the South. Black male youth tend to have multiple sexual partners, use condoms inconsistently and if HIV infected, are unaware of their infection. Just 34.5% of young adults aged 18-25 have ever been tested for HIV and 60% of infected young adults are unaware of their infection. In general, Blacks test less frequently than Whites and Latinos. Thus, reaching Black male youth before their risks increase is critical in ending the HIV epidemic. Parents are important as sexual health educators for their adolescent males'. Evidence supports that interventions engaging mothers are effective in delaying sexual debut and promoting condom use among adolescent males. Although there are fewer interventions that focus on fathers, especially Black fathers, there is ample evidence to show that fathers are as equally important in delaying sexual debut and increasing condom use among sexually active youth. A majority of parent-adolescent interventions focused on male adolescents engage mothers and sons or fathers and sons. However, what is missing from adolescent sexual health interventions are interventions that engage both the mother and father as a family unit regardless of their marital or residential status (living in or outside of the home). Family interventions that are culturally and socially relevant and sustainable are needed to improve adolescent male sexual health.
Duke Mobile App Gateway

Mobile App Gateway supports award-winning child healthcare app

he Caremap app, developed and tested by a multidisciplinary team from National Family Voices, Boston Children's Hospital, and Duke Health, won the Care Coordination for Children with Special Health Care Needs (CSHCN) Challenge. The team received a \$130,000 cash prize.

Caremap is a software solution that helps families of CSHCN coordinate the care their children receive from a variety of health care professionals, including medical, behavioral, social, educational, and developmental specialists. The patient-facing mobile-app leverages open standards and has an associated Clinician Dashboard enabling communication with care team members across settings and over time.

The app was developed with the support of the Mobile App Gateway, a collaborative effort designed to help Duke faculty and students who are interested in digital health development.

This winning solution is a culmination of more than two years of creative and innovative work. HRSA's MCHB launched this Challenge as one of four Grand Challenges in 2018, and each one addresses critical maternal and child health issues.

Challenge entrants included multidisciplinary teams of academics, health professionals, tech

companies, IT designers, as well as individuals, community groups, and startups. The innovations aim to improve quality of care, enhance family engagement, reduce disparities in access and outcomes, and positively impact health care outcomes with the potential of saving costs to



families, society, and to the health care system.

The Maternal and Child Health Bureau is part of the Health Resources and Services Administration, an agency of the U.S. Department of Health and Human Services. These Challenges are designed to inspire innovation, promote partnerships, and help families and care providers address some of today's most important health issues.

For more information about the MCHB Grand Challenges, visit the website. Please send questions to MCHBGrandChallenges@hrsa.gov or contact the Caremap Team directly.

Machine Learning and Augmented Intelligence Cross the Chasm in Health Care

achine Learning (ML) and Augmented Intelligence (AI) crossed the chasm at Duke Health in 2019. The technologies Amidst the pilot success, five ML/AI projects were selected for funding through the DIHI RFA, including projects led by multiple clinical stake-

and clinical integrations are now mainstream with great expectations to improve care delivery and outcomes.

First was the launch of **Sepsis Watch** on November 5, 2018, after the DIHI team spent two and a half years developing and validating a deep learning model and building infrastructure to support real-time model integrations. This milestone marked the first time a deep learning technology was integrated into routine clinical care in the United

States. The six-month pilot brought Duke University Hospital to the top decile in performance for the Centers for Medicare and Medicaid Services sepsis measure.

Mark Sendak, MD, MPP

holders involved in the Sepsis Watch program. In June 2019, the team at DIHI, in partnership with the emergency departments at Duke Regional Hospital and Duke Raleigh Hospital, implemented Sepsis Watch. In parallel, DIHI integrated two new ML/AI models for predicting steroid-induced hyperglycemia and inpatient mortality into clinical care.

The ecosystem at Duke Health and Duke University is coalescing around the opportunity to lead the nation in de-

veloping and integrating ML/Al into clinical care. Ai.health, announced in June 2019, will harness talent, energy, and resources to scale high impact collaborations to improve health care.

Strengthening Community Connections and Resilience

Section Overview: Strengthening Community Connections and Resilience	. 74
NCCU, CERI Host Diabetes Ethnodrama Screening for AME Zion Parishioners	. 76
MURDOCK Study celebrates 10th anniversary	. 78
Community Engagement Core Oversees Organized Response to COVID-19	. 80
NCCU Partnership Focuses on Mind-Body-Spirit-Soul Practices to Improve Health	. 82
Community Engagement Vital to New Duke CTSI Core Dedicated to Equity in Research	. 83



CTSI works to foster and strengthen collaboration between community members, community-based organizations, and academic researchers.

Section Overview: Strengthening Community Connections and Resilience

ommunity engagement and input has always been crucial to successful health interventions, but in a time of enforced isolation, building connections was more important than ever. CTSI is committed to facilitating equitable and robust community-engaged health research by connecting academic stakeholders with community partners locally, regionally, and nationally.

CTSI partnered with North Carolina Central University (NCCU) on a number of projects to advance translational research and strengthen ties with the community. One such initiative, NCCU ethnodramas, are designed to educate community members about important health topics, including diabetes and COVID-19.

The Kannapolis-based MURDOCK Study celebrated its 10th anniversary in 2019. In that time, the study's Community Registry and Biorepository grew to more than 12,500 participants and 450,000 biological samples, and has made the community a partner in research designed to benefit the community.

The Community Engaged Research Initiative (CERI) has put their expertise and close partnerships with community members, communitybased organizations, and academic researchers to work, disseminating information about the latest evidence-based research regarding COVID-19 and the different vaccines in order to help alleviate the disproportionate negative effects of the virus in local communities.

CERI has also facilitated community engagement in COVID-19 research at Duke, helping to promote scientific equity for historically marginalized populations.

The partnership between NCCU and CTSI is designed to leverage the strengths of both institutions to advance translational science and improve health outcomes, particularly for those health issues that disproportionately impact underserved and underrepresented communities. With the onset of the COVID-19 pandemic, researchers at Duke and NCCU have worked together to address new health challenges that have intensified as a result of the pandemic.

Community engagement is vital to the new Equity in Research core, which is working to identify and anticipate community barriers to access while creating sustainable change throughout the research enterprise at Duke.

Going forward, CTSI's commitment to partnering with our local and regional communities to improve health for all has only been strengthened by the challenges of the pandemic, systemic racism, and health inequity.



Kenisha Bethea, MPH, (standing, left) of the Duke CTSI Community Engaged Research Initiative, in discussion with an ethnodrama attendee at St. Mark AME Zion Church in Durham.

NCCU, CERI Host Diabetes Ethnodrama Screening for AME Zion Parishioners

n February 19, 2020, the <u>Communi-</u> ty <u>Engaged Research Initiative (CERI)</u> and North Carolina Central University (NCCU) hosted a screening of the ethnodrama, "A Touch of Sugga," at St. Mark African Methodist Episcopal (AME) Zion Church. This screening was designed to stimulate discussions and raise awareness of diabetes self-management.

An ethnodrama is a written transformation and adaptation of ethnographic research data into a dramatic play script and staged as a live, public, theatrical performance. The screening was also part of CERI's <u>AME Zion Health Equity</u> <u>Advocates & Liaisons (HEAL) partnership</u>, which works with AME Zion clergymen to increase and diversify clinical trials recruitment efforts.

"A Touch of Sugga" focuses on an African-American family and their struggle to support the patriarch of the family. The patriarch is a man living with diabetes who is unwilling to come to grips with the seriousness of his chronic illness. Thus, he is resistant to making the lifestyle modifications necessary to manage his diabetes as he feels is "just a touch of sugga."

Following the screening of the ethnodrama, Drs. Bryan Batch and Iris Padilla moderated a Q&A session with attendees. The clinicians answered audience questions a ethnodramas, related to workforce development, pilot projects, and community engagement. In 2019, the partnership hosted the ethnodrama, "Write Now, We Will Heal," about cervical cancer prevention and treatment.

"It was truly an honor to join community members from Durham and surrounding counties," said <u>Kenisha Bethea, MPH</u>, research program leader for CERI. "This collaboration between academic institutions and community leaders is a wonderful example of how to creatively convey the importance of including and engaging communities, particularly African Americans, in research to improve health outcomes."

The next ethnodrama in the series will focus on opioid addiction and is slated to be performed June 2020 in Durham. To learn more about community-engaged research or how to incorporate community stakeholders into a health outcomes project, visit the <u>CTSI website</u>.



The first two participants enrolled in the MURDOCK Study reminisce with Dr. Newby at the 10th anniversary event in 2019.

MURDOCK Study Celebrates 10th Anniversary

en years to the day after she became the first participant in the <u>MURDOCK Study</u>, Bobbie Beam returned to the North Carolina Research Campus in Kannapolis on Saturday, Feb. 16, 2019 to celebrate the first decade of the landmark Duke CTSI study.

"It's a wonderful thing," said Beam, a retired nurse who joined hundreds of MURDOCK Study participants and community partners at the celebration. "I'm happy to be back."

From humble beginnings in a former dress shop with one Duke employee, the MURDOCK Study paved the way for Duke's presence in Kannapolis today — 5,000-square-feet of clinical office space and a team of more than 30 Duke employees co-located in Kannapolis and Durham. <u>Duke CTSI</u> manages the MURDOCK Study and a dozen nested cohorts, as well as other clinical research projects based in Kannapolis and built on the foundation that has been created by the MURDOCK Study since 2009.

In 10 years, the MURDOCK Study Community Registry and Biorepository has grown to more than 12,500 participants and 450,000 biological samples. The community-based longitudinal cohort recruited participants from 20 zip codes in and around Kannapolis and Cabarrus County. The study has more than 50 collaborations, including 150 collaborators across 21 institutions, and 45 peer reviewed publications. More than 100 Duke faculty members have used MURDOCK Study samples and data to explore



L. Kristin Newby, M.D., celebrates the 10th anniversary of the MURDOCK Study with TransPop staff.

a broad range of research questions to better understand health and the transition to disease.

L. Kristin Newby, M.D., was the founding faculty director of Duke TransPop and led the evolution of the MURDOCK Study. The MURDOCK Study and TransPop offer a range of assets and capabilities to <u>investigators and collaborators</u>.

As the MURDOCK Study began its second decade, TransPop launched two new cohorts

— the <u>MURDOCK Fractures and Falls Study</u>, focused on understanding bone fracture risk in older adults with diabetes, and the <u>MURDOCK</u> <u>Kidney Health Study</u>, which aims to understand factors that prevent kidney disease in people at risk. In response to the COVID-19 pandemic, TransPop also quickly stood up the <u>MURDOCK</u> <u>C3PI Study</u> and <u>MURDOCK COPE Study</u>, both focused on longitudinal, community-based COVID-19 research.

The 10th anniversary MURDOCK Study celebration in Kannapolis also featured the second MURDOCK Study participant, Ed Tyson, who joked that he would have been the first to enroll if Beam had not beaten him to it. Tyson said he joined the study because he wanted it to become a success for his hometown, which had suffered the loss of a large textile mill several years before the North Carolina Research Campus opened and the MURDOCK Study began.

"I have a great love for the community," said Tyson, a retired Kannapolis City Schools superintendent and former UNC-Charlotte professor. "If someone back then had said to us, 'The mill is going to close, what is your dream for the future of Kannapolis?' none of us could have had a dream this big."

MURDOCK is an acronym that stands for the Measurement to Understand Reclassification of Disease Of Cabarrus and Kannapolis. Duke University School of Medicine received a \$35 million gift from David H. Murdock, chairman of Dole Food Company, to establish the MURDOCK Study in September 2007.



A virtual meeting of the LATIN-19 leadership committee, including Rosa Gonzalez-Guarda, top left, and Leonor Corsino, middle row right, co-directors of CERI.

Community Engagement Core Oversees Organized Response to COVID-19

he CTSI's community engagement core, the Community Engaged Research Initiative (CERI), has been working with community members, community-based organizations, and academic researchers to disseminate information the community at large on the latest evidence-based research regarding the virus in order to help alleviate its disproportionate negative effects. CERI's signature programs have all moved to the virtual realm but this has given the Core the ability to forge even stronger ties with the Durham community and to report community-engaged research efforts back to stakeholders on a continual basis. CERI has reinforced internal and external communication plans to ensure that the Durham and Duke communities are informed and engaged with regard to COVID-19 clinical trials, best PPE practices, vaccine roll-out efforts, etc.

CERI has worked with community leaders and Duke staff and clinicians to form three Durham COVID-19 coalitions groups: LATIN-19, African American COVID-19 Taskforce (AACT+), and Durham's Partnership for Seniors and More, in which bi-directional communication is robust thanks to embedded staff and faculty supporting these efforts. Coalition members comprise leaders from community-rooted organizations, community members, healthcare providers and agencies, community health workers, local government representatives, and other key citizen stakeholders with connections to local, regional, and national resources.

CERI areas of focus in recent months include:

Health Disparities: Our Community Engagement programs have helped advance NIH's priorities to address health disparities research by: 1) supporting research that directly examines causes and solutions to community-identified health disparities through CTSI's Population Health Improvement Awards, and 2) enhancing the capacity of Duke investigators and their community partners to conduct health disparities research through the CEnR consultation service, e-library, expanded partnerships with the Special Populations Core and Duke's REACH Equity Center, trainings, and partnership with North Carolina Central University (an HBCU co-located with Duke in Durham).

COVID-19: 1) Supporting COVID-19 research that directly examines causes and solutions to community-identified health disparities through our PHI Awards; 2) Disseminating trusted information related to the COVID-19 pandemic in response to community requests for vetted information; 3) Providing direct and meaningful leadership and administrative support for local COVID-19 Community Coalition groups; 4) Facilitating community partner opportunities for meaningful engagement in COVID research efforts throughout the CERI portfolio of programs.

Increasing Participation of Women and Minorities in Research: CTSI is addressing imperatives from NIH to increase the participation of women and minorities in research as both subjects and leaders of research. CERI's partnership with the AME Zion Health Equity Advocates & Liaisons (HEAL) program is largely focused on increasing participation of minorities in clinical research, especially African Americans in North Carolina. The clergy in the AME Zion HEAL partnership are trained as ambassadors for clinical research and with CERI have been engaging in community events that address trust and transparency in clinical research and promote participation. These events have reached 17 clergy and hundreds of community members. Additionally, many of CTSI's Population Health Improvement Awardees are engaging women and minorities as research subjects in their research projects, and the vast majority of the Principal Investigators supported in both the academic and community partner side are women or underrepresented minorities in the biomedical and behavioral sciences.

Patients and Community Members as Partners in Research: CERI's programs and services are grounded in improving the clinical research enterprise's ability (at Duke and beyond) to engage patients and communities as partners in research. CERI's signature programs facilitate this engagement. For example, the Community Consultation Studios feature community experts whose lived experience help shape research study design. AME Zion HEAL partners are instrumental in providing the patient perspective for research protocols to Duke investigators, with a strong focus on advising on effective ways to better reach and engage patients and communities.

NCCU Partnership Focuses on Mind-Body-Spirit-Soul Practices to Improve Health

Since 2018, the Duke Clinical and Translational Science Institute (CTSI) has partnered with <u>North Carolina Central University</u> (NCCU) on a number of community health initiatives. The partnership is designed to leverage the strengths of both institutions to advance translational science and improve health outcomes,

particularly for those health issues that disproportionately impact underserved and underrepresented communities.

With the onset of the COVID-19 pandemic, researchers at Duke and NCCU have had to redesign some of their programs, as well as work together to address new health challenges that have intensified as a result of the pandemic. <u>Undi N. Hoffler, PhD</u>, director of research compliance and technology transfer at NCCU, has been focusing on how mind-body-spirit-soul practices can benefit people at this time.

Dr. Hoffler and members of the CTSI <u>Community Engaged</u>

<u>Research Initiative (CERI)</u> have partnered with local churches to educate community members about the importance of mental and spiritual health, as well as physical health. Specifically, Dr. Hoffler offers activities that will allow people to better manage their stress levels.

"Stressischronic, and it can exacerbate pre-existing conditions in people," Dr. Hoffler said. "With everything going on—COVID-19, social justice issues—these are events of significant intensity we have been experiencing. I want to help people take care of their wellness holistically."

Dr. Hoffler worked with CERI's <u>AME Zion Health</u> <u>Equity Advocates & Liaisons (HEAL) partnership</u> to reach out to these churches. She has held her

> workshops at Trinity Church in Greensboro and St. Mark AME Zion Church in Durham, and plans to expand to more church communities in the coming months.

> Some of the exercises Dr. Hoffler recommends to the community include mindful meditation, yoga, and gratitude journaling. In her own life, Dr. Hoffler has seen how critical these practices can be; she starts her day with either a brisk walk in her neighborhood or a virtual yoga practice, and ends it by praying and journaling about all of the things she has been grateful for during these last few months.

"It is truly vital to do these prac-

tices," Dr. Hoffler said. "Everything is so different now compared to how we were moving around a few months ago. Many people are trying to assess, "how do I not only make it through this time, but thrive?" If we can provide practices to people about how they can do that, we can help people effectively manage stress and lead people toward long-term health benefits."

Return to section start.



Dr. Undi Hoffler, North

Carolina Central University

Community Engagement Vital to New Duke CTSI Core Dedicated to Equity in Research

he Equity in Research (EIR) core at the Duke Clinical and Translational Research Institute (CTSI) is working to identify and anticipate community barriers to access, while creating sustainable and enduring change throughout the research enterprise at Duke.

Community engagement is a crucial part of the work of EIR, which supports the new CTSI Center for Equity in Research.

"We need to engage the community members' perspective within our research. Their voices need to be heard," said Dane Whicker, PhD, "People are talking about where we have been and where we are going," said Keisha Bentley-Edwards, PhD, co-director of EIR. "It's important to identify barriers to access, but also then to come up with practical solutions to eliminate those barriers. Those are some of the ongoing conversations that are happening across CTSA cores. We need a combination of awareness, reflection, and action."

The core, as well as the Center for Equity in Research that it supports, provide strategic leadership and expertise for anti-bias, anti-racism and



Keisha Bentley-Edwards, PhD; Dane Whicker, PhD; Sabrena Mervin-Blake

co-director of EIR. "We need to bring down the ivory tower and make people feel welcome by building trust and making genuine connections and relationships."

CTSI launched the core in the spring of 2020 at a pivotal time for Duke, the broader community, and the nation overall—a time when the COVID-19 pandemic and racial reckoning converged to reveal in new and profound ways longstanding issues of inequity and inaccessibility. equity training programs, resources, services, and tools to support established research investigators, trainees, and research teams as they integrate an equity framework in all aspects of the research process. This includes developing and sustaining demographically diverse research teams to maximize the impact.

That impact will become evident not only in more equitable research, but also in relationship building within CTSI and beyond, with the

community as a whole, said Sabrena Mervin-Blake, staff director for both EIR and the Community Engagement core, also part of CTSI. The work comes as Duke Health and CTSI have committed to dismantling racism in health care and addressing health inequities.

"We look forward to working together with our community in authentic, mutually beneficial, bidirectional ways toward the goal of health equity," Mervin-Blake said.

Transforming Education and Training

Section Overview: Transforming Education and Training	85
Duke NCSP Welcomes Inaugural Cohort, Second Cohort	87
Engagement, Recruitment, and Retention Certificate Program	89
Clinical Research Sciences Certificate	90



Duke's National Clinician Scholars Program (NCSP) welcomed its first cohort of scholars on July 1, 2019. The NCSP currently comprises six sites at institutions across the nation, offering unparalleled training for clinicians as change agents driving policy-relevant research and partnerships to improve health and health care.

Section Overview: Transforming Education and Training

TSI supports the advancement of the next generation of interdisciplinary research leaders, offering an evolving portfolio of educational and training opportunities to address the needs of Duke staff, students, and faculty.

In 2019, Duke became a site for the National Clinician Scholars Program (NCSP). Since its inception, the Duke NCSP program has welcomed three cohorts of students focused on policy-relevant research and partnerships to improve health and health care. CTSI began supporting the Engagement, Recruitment, and Retention Certificate Program, a skills-building program designed for clinical research study teams to help staff develop and expand competency in participant engagement, recruitment, and retention.

CTSI supported North Carolina Central University in the successful launch of its clinical research certificate program in spring 2020, graduating 9 students as of spring 2021; all 9 of those graduates have since become employed in clinical research. CTSI continues to provide

assistance in course development and content and is exploring means for facilitating the placement of NCCU students in clinical research internships at Duke as part of their degree program.

In 2021, CTSI announced the Center for Pathway Programs, a first-of-its-kind group at Duke. The Center's mission is to bring a cohesive approach to Duke's 30+ pathway programs, which enhance career opportunities for underrepresented students and early-career trainees.

CTSI's education and training portfolio emphasizes diversity, opportunity, and rigor to continue building an outstanding clinical & translational workforce that represents the people it serves.



The second cohort of Duke NCSP scholars (L to R): Kamal Golla, MD, MPH; Melissa Harris, BSN, RN, PhDc; Jennifer May, MSN, RN, ANP-BC, PhDc; and Karen Scherr, MD, PhD

Duke NCSP Welcomes Inaugural Cohort, Second Cohort

uke's <u>National Clinician Scholars Program</u> (NCSP) welcomed its <u>first cohort of scholars</u> on July 1, 2019. The NCSP currently comprises six sites at institutions across the nation, offering unparalleled training for clinicians as change agents driving policy-relevant research and partnerships to improve health and health care. A <u>second cohort</u> was announced in December of 2020.

The overarching goal of the <u>national program</u> is to cultivate health equity, eliminate health disparities, invent new models of care, and achieve higher quality health care at lower cost. Duke's NCSP is building upon this objective by training inter-professional clinician scholars in data-driven inquiry, rigorous investigation, sensitive community-based participatory research, and the transformation of the health care practice. With proximity to key federal and state policy stakeholders, Duke NCSP has joined resources from the Schools of Medicine and Nursing and the Durham VA Medical Center to create a unique training experience that prepares Scholars for leadership in clinical research and health policy locally, regionally, and nationally.

One of the scholars' first assignments on campus is to engage in a community immersion experience allowing them to apply guiding principles of community engagement and community-engaged research in health-related research and health improvement activities. The experience involves gathering preliminary data for the upcoming <u>Healthy Opportunities Pilots</u> to evaluate the impact of providing select evidence-based, non-medical interventions related to housing, food, transportation and interpersonal safety to high-needs Medicaid enrollees.

"This experience allows the scholars to gain a better understanding of Medicaid Transformation in North Carolina, learn more about Durham and the surrounding communities as well as introduce them to various stakeholders from local community organizations," said Devon Noonan, PhD, associate program director for Duke NCSP. "This project fits exceptionally well with the goals of NCSP training program allowing the scholars to play a key role in improving the health and wellbeing our patients and our community." Please visit the <u>national program website</u> for further details on the overall scope of this program.



Engagement, Recruitment, and Retention Certificate Program

The <u>Engagement, Recruitment, and Retention Certificate Program</u> is a certificate and skills-building program designed for Clinical Research study teams. The intention of the program is to help staff develop and expand competency in participant engagement, recruitment, and retention.

Program Goals

- Develop a cohort of engagement, recruitment, and retention specialists who can serve as a resource for their clinical research units, departments, and divisions.
- Bolster the skills that are necessary for both meaningful and inclusive engagement, recruitment, and retention engagement practices.
- Help study teams think critically about participant engagement and recruitment and participant engagement from perspectives other than their own.

Learn more about the Certificate program at http://bit.ly/errcert.



NCCU Clinical Research Sciences Certificate

he clinical research industry is a rapidly growing field, contributing more than \$1 billion to North Carolina's economy. Clinical Research Sciences is a branch of health science focused on studying the safety and effectiveness of medication, devices, diagnostic products and treatment regimens intended for human use.

The Clinical Research Sciences Program (CRSP) in the North Carolina Central University's Department of Pharmaceutical Sciences was established in the Fall of 2018 in partnership with Duke University in a National Institutes of Health Clinical Translational Science Award. The program's vision is to build a clinical research workforce of the future with a strong focus on health equity and community engagement. NCCU's Clinical Research Sciences Certificate program focuses specifically on workforce development for careers in clinical research.

The CRSP offers both didactic course work and a clinical rotation at the Duke Clinical Research Institute or another partnering organization. Graduates of this program are prepared for jobs in clinical research organizations or to pursue other opportunities to advance their clinical research education in an academic institution.

Building Access to Data with Integrity and Transparency

Section Overview: Building Access to Data with Integrity and Transparency92
Informatics Core Creates COVID-19 Data Repository
Duke Joins National Centralized Data Collaborative for COVID-19 Research95
Clinical Research Data Mart Enables Better Understanding of Patient Health97
1,000 Patient Project Enables Easier Access to Research Participant Data98
Data Services Catalog
Data Mapping Initiatives 100
Data Repositories Offer Best Datasets for Research Question or Projects



The Durham Neighborhood Compass is a primary community resource that allows users to track changes in the community with data.

Section Overview: Building Access to Data with Integrity and Transparency

ata science increasingly drives decision-making in health care and translational science, bringing with it both new possibilities for better care and new concerns about issues such as algorithmic bias. CTSI is supporting innovative work in this field to ensure that cutting-edge data science also advances health equity.

In the early months of the COVID-19 pandemic, the CTSI's Data Science and Informatics Cores created an Integrated Data Repository for COVID-19-related research to help make more genomic data available to the research community.

Guided by CTSI leadership, Duke joined a larger collaborative run by the NIH's National Center for Advancing Translational Science that attempts to make COVID-19 research at institutions like Duke easier. The National COVID Cohort Collaborative (N3C) has EHR data from more than 40 institutions available for Duke faculty to study COVID-19.

The creation of Duke's Clinical Research Data Mart (CRDM) now provides researchers with a set of consistently defined data elements to better understand the health and well-being of patients served by DUHS and Lincoln Community Health Center.

The first-of-its-kind 1000 Patient Project (1KP) at Duke aggregates clinical, sample, and assay data that enables researchers to quickly find a cohort of participants with readily available data for analysis.

The Duke Data and Analysis Resource Center (DARC) maintains a catalog of data resources to enable Duke researchers to find the appropriate data from entities across the School of Medicine, Duke Health, and Duke University.

In partnership with the Center for Community and Population Health Initiative, CTSI has developed a population health data mart and data mapping initiative to promote the understanding of community health, build collaborative partnerships within our communities, share data with stakeholders, and work together to improve the health and wellbeing of our communities.

CTSI teams led the campus-wide Discover Data @ Duke collaborative effort to provide a one-stop shop for Duke investigators to learn about and access a wealth of data resources.

CTSI's continued commitment to innovative data science solutions supports necessary and meaningful advances in health and health equity.



Informatics Core Creates COVID-19 Data Repository

he CTSI's Informatics Core created an Integrated Data Repository (IDR) for COVID-19 related research to help ensure that data is collected, stored, and used in accordance with Duke Health data quality controls and compliance.

The design enabled long term use, data sharing, harmonization, quality and security. In addition, a dashboard was developed to expose the information contained in the repository. The dashboard is now used to deliver self-service access to de-identified, COVID patient demographics, diagnosis, and specimen data. Duke researchers can build a cohort based on a subset of data and identify available samples. The creation of the IDR continues to advance the vision of making more genomic data available to the research community.

Duke Joins National Centralized Data Collaborative for COVID-19 Research

Since the beginning of the pandemic, the research landscape at Duke has evolved. Many teams at Duke, including the CTSI's <u>MURDOCK Study</u>, have launched research projects specifically focused on COVID-19. Now, Duke has joined a larger collaborative run by the NIH's <u>National Center for Advancing Translational Science (NCATS)</u> that attempts to make COVID-19 research at institutions like Duke easier.

The National COVID Cohort Collaborative (N3C) aims to build a centralized national data resource that the research community can use to study COVID-19 and identify potential treatments. Specifically, the N3C will enable the rapid collection and analysis of clinical, laboratory and diagnostic data from hospitals and health care plans.

Along with NCATS, many other <u>Clinical and</u> <u>Translational Science Awards (CTSA) Program</u> hubs – including Duke – and the <u>National Center</u> groups; anyone who receives approval for a Data Use Request (DUR) can access N3C data to help with their research projects. Visit the <u>N3C website</u> to apply for access and submit a DUR.



One of the difficulties of COVID-19 research at this time is that many sites do not have enough research participants who have contracted the virus or meet all of the qualifications for the study. With access to more research sites and variables, researchers can have the ability to in-

> crease the size of their cohorts and conduct COVID-19 research more readily. Sites are also asked to update patient-level clinical data twice a week, giving researchers access to the most up-to-date information.

> "Through N3C, COVID data is coming from the electronic health records of more than 15 sites, and more than 60 are in the process of submitting data to N3C," said Warren Kibbe, PhD,

No site has enough data to research COVID-19 on its own. The enclave gives us the ability to power up and do research on COVID-19.

> — Anthony Leiro, CTSA Informatics Operations Lead, Duke CTSI

<u>for Data to Health (CD2H)</u>, will contribute and use COVID-19 clinical data to answer critical research questions to address the pandemic. However, access to this data is not limited to participating director of the Duke CTSI Biomedical Informatics Core. "As of the end of September, there is data on more than 75,000 COVID positive patients and 650,000 patients with flu-like symptoms or diagnostic tests for SARS-CoV-2. There are also multiple active COVID-19 projects that span from investigating acute kidney injury to using machine learning to predict disease severity. These active projects are looking for additional team members and have already gone through the DUR process. This is a very low-barrier way to get involved in N3C without having to create your own protocol, IRB submission, and DUR approval."

Researchers interested in applying for N3C Data Access need to first <u>register with the N3C</u> and complete the NIH "Information Security,

Counterintelligence, Privacy Awareness, Records Management Refresher, Emergency Preparedness Refresher" course. Once completed, researchers must submit a DUR through the N3C Data Enclave. More information is available on the NCATS website.

"The data enclave is about power," said <u>An-</u> <u>thony Leiro</u>, IT consultant and CTSA informatics operations lead. "No site has enough data to research COVID-19 on its own. The enclave gives us the ability to power up and do research on COVID-19."



Clinical Research Data Mart Enables Better Understanding of Patient Health

he Duke Clinical Research Data Mart (CRDM) provides access to curated and characterized Duke patient data that can be accessed and analyzed using standardized methods that preserve data provenance and reproducibility. The CRDM is a set of consistently defined data elements (using the PCORnet Common Data Model) that can be used to investigate intrinsic and extrinsic factors that affect the health and well-being of pediatric and adult patients served by DUHS and Lincoln Community Health Center. In addition, an accompanying phenotype and code repository will facilitate efficiency and access to clinical research across Duke.

The CRDM will enable cost-effective, standardized access to data which can improve our understanding of population-level factors that influence early and lifelong health and aid in the identification of populations affected by racial and socioeconomic disparities in health outcomes, quality of life, and healthcare delivery.



A research participant during a study visit at Duke CTSI's Kannapolis, NC research campus.

1,000 Patient Project Enables Easier Access to Research Participant Data

he 1,000 Patient Project (1KP) is the first of its kind at Duke that aggregates clinical, sample, and assay data presented through an easy-to-use query interface that does not require training.

With the platform, researchers can quickly find a cohort of participants with readily available data for analysis. The searchable repository for all enrolled patients provides researchers the ability to query de-identified data for 1,000 patients to determine a potential cohort of participants for a research or QI study. This tool enables labs the ability to submit assay data that is loaded into durable storage along with necessary metadata. Data management can now finalize a target participant list generated by the researcher's query and export requested clinical data and assays to a secure environment for analysis.



Data Services Catalog

ithin the School of Medicine and across the entire University and its Health System, Duke is rich with intellectual, data and technological resources to further biomedical discovery. Key elements —IT, data, analysis, education, and partnerships—are aligned, designed and deployed in intentional, efficient, and sustainable ways to advance the School's mission of teaching and research.

Duke's Office of the Vice Dean for Data Science & Information Technology promotes open, secure, and appropriate access to data under Duke's stewardship and beyond by helping Duke researchers navigate and find the right data resources from entities across the School of Medicine, Duke Health, and the University. The Duke Data and Analysis Resource Center maintains this catalog of clinical and research data services that includes data resources managed by the CTSI.

<u>Return to section start.</u>



The Durham Neighborhood Compass mapping tool visualizes data about the Durham community, including demographics, health, economics, education, and more.

Data Mapping Initiatives

Clinical Research Datamart (CRDM)

- Accessible, curated EHR datamart (Duke and Lincoln)
- Phenotype bank
- · Linkable to other data resources
- Facilitates use (less time/\$)
- Encourages standardization
- Reduces barriers
- Increases collaboration

The Neighborhood Compass

Center for Community and Population Health Improvement (CCPHI)

Promote research to improve community and population health through academic, community, and health system partnerships.

- Mapping Durham County Health
- Democratizing data, including social drivers of health
- Convening stakeholders on health equity

A primary community resource that allows you to track changes in your community with data that is regularly updated. This updated information often deepens your understanding that the character of Durham's neighborhoods is changing.

<u>https://compass.durhamnc.gov/en</u>



Data services offered by CTSI span both Duke University and the School of Medicine campuses, and include datasets specific to Duke as well as regional and national resources.

Data Repositories Offer Best Datasets for Research Question or Projects

iscover Data @ Duke is a collaborative effort to provide a one-stop shop for Duke investigators to learn about and access a wealth of data resources.

CTSI and the DHTS Analytics Center of Excellence Research Solutions Team have partnered to connect investigators to local, regional, and national datasets that are crucial for scientific and clinical research.

Interested in learning more or starting a project using clinical data? <u>Get in touch with our</u> <u>data experts</u>.



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