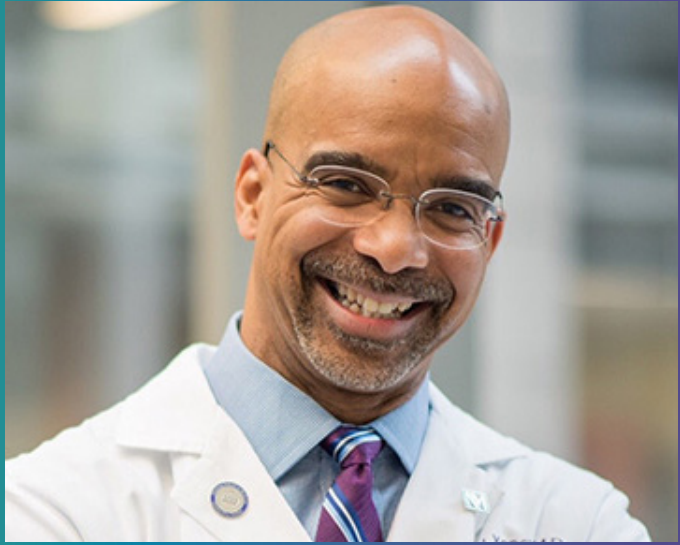


Northwestern University

NUCATS

Clinical and Translational Sciences Institute



IMPACT REPORT 2021

NUCATS is supported by the NIH's National Center for Advancing Translational Sciences, grant UL1TR001422, as well as Northwestern University's Feinberg School of Medicine and Office for Research

2021: A YEAR OF RESILIENCE, PERSEVERANCE AND EXCELLENCE

Throughout a global pandemic that has brought unprecedented challenges and altered our workflows and lives in dramatic ways, the NUCATS Institute continues to advance research from bench to bedside to population impact for all.

Following a dynamic and fast-paced reaction to the spread of COVID-19, the NUCATS Institute funded or supported numerous studies that highlight the breadth and scope of research at Northwestern and its affiliates.

Our 11 programs and centers support each step along the translational spectrum: from pre-clinical discovery and entrepreneurship; through clinical trials to assess efficacy; to implementation into widespread practice that improves public health. As one of 61 NIH National Center for Advancing Translational Science (NCATS) Clinical and Translational Science Award-funded hubs – with strong and generous institutional support from Northwestern University – we continue to strengthen resources and opportunities for our members.

This Impact Report details some of our accomplishments over the past year, which include:

- Multiple mechanisms to fund pilot research, as well as cross-disciplinary seminars and symposia to spark collaborations. We are proud of our many contributions to Northwestern's robust research response to the COVID-19 pandemic via these mechanisms.
- Our Center for Clinical Research expanded capacities and improved processes in the NM Clinical Research Unit. Our Applied Research Informatics Group enabled FDA-compliant electronic consenting. Applying artificial intelligence/machine learning to EMR data opened new research opportunities. The Center for Biomedical Informatics and Data

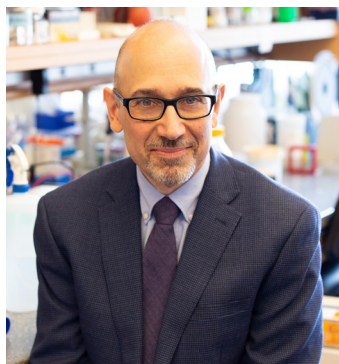


Photo by Eileen Molony

Sciences also contributed to the national CTSA consortium, including to the National COVID Cohort Collaborative.

- Our faculty career development programs (KL2 and TL1), as well as our TL1's Science Immersion Program for students, expanded and enhanced the diversity of their scholars. The Center for Education and Career Development added strong support for NIH Diversity Supplement applications, mentoring and clinical research coordinator education. An elective on anti-racism was added to the MSCI curriculum. Galter Library leadership gained national prominence, including an exciting award from NIH's National Library of Medicine to Galter's director, who also expertly leads evaluation for NUCATS.

Several additional initiatives were started this year that I expect to have impact in the coming months. These include more research support for our regional clinical affiliates; community engagement as well as diversity, equity and inclusion; stronger emphasis on the "science" of translational research (eg, how to improve processes applicable to all diseases/disciplines, including implementation science); and new hub and national CTSA consortium collaborations. If you have an idea how we can better accelerate YOUR impact on better health for all, please let me know.

Richard D'Aquila
NUCATS Director

On the cover, clockwise from top left:

As a KL2 Scholar, **Rupal Mehta**, MD, Medicine, is working on a project to identify subclinical or early heart failure using advanced cardiac imaging and functional testing.

NUCATS Associate Director of Diversity and Inclusion **Clyde Yancy**, MD, MSc, Medicine, was named on Clarivate Analytics' annual list of highly cited researchers. Those named are selected for their "exceptional research performance, demonstrated by production of multiple highly cited papers" that were published from 2009 to 2019 and at the end of 2019 ranked in the top 1 percent by citations for field and year in Web of Science. Four other NUCATS investigators were also among the most highly cited for 2020.

Margaret Flanagan, MBBChBAO, Pathology and Neuropathology Core Leader of the Mesulam Center for Cognitive Neurology and Alzheimer's Disease, far right, received the inaugural Mark Rogovin Pilot Research Award in Neuroscience from the NUCATS Institute. Mark Rogovin, whose picture is being held by lab members, brought his artistic vision to the west side of Chicago in 1972 when he founded the Public Art Workshop. Flanagan is currently enrolled in the NUCATS-sponsored Master of Science in Clinical Investigation program.

NUCATS Community Partner **Melvin Thompson**, executive director of the Endealeo Institute, is also co-principal investigator of a project that aims to mitigate food deserts, as well as improve outcomes for patients with kidney disease in Black communities in Chicago.

Galter Health Sciences Library and Learning Center's **Karen Gutzman**, MSLS, MA, head of research assessment and communications, was honored this year with the Estelle Brodman Award for Academic Medical Librarian of the Year.

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NUCATS RESPONDS TO PANDEMIC WITH NEW GRANT INITIATIVES, RESEARCH SUPPORT

As part of the NUCATS Institute's efforts to promote critical research on the evolving pandemic, Northwestern University research teams led by [Daniel Batlle](#), MD; [Ramon Lorenzo-Redondo](#), PhD; and [Pinelopi Kapitsinou](#), MD, received COVID-19 Collaborative Innovation Awards. Each project was initiated at the NUCATS Institute's [COVID-19 Symposium](#), moderated by [Michael Ison](#), MD.

"It has been inspiring how our faculty, students and staff have stepped up to use their research skills and ideas to combat COVID-19," said [Rex Chisholm](#), PhD, vice dean for Scientific Affairs and Graduate Education.



PINELOPI KAPITSINO

Lorenzo-Redondo was joined by [Sasha Misharin](#), MD, PhD; [Judd Hultquist](#), PhD; [Egon Ozer](#), MD, PhD, and [Lacy Simons](#), BS, on a project that examined if changes in SARS-CoV2 — the virus that causes COVID-19 — occurring inside a patient's body during the infection can influence the severity of the disease itself. Kapitsinou,

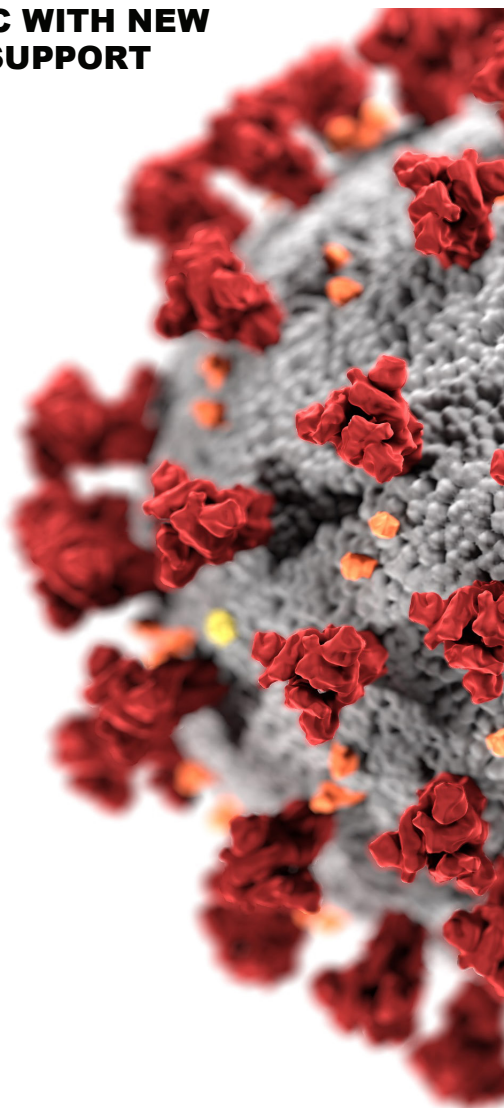
worked with collaborators [Anand Srivastava](#), MD, MPH; [Scott Budinger](#), MD; and [Richard Wunderink](#), MD, to learn more about the cross-talk between the kidney and lung in severe COVID-19 pneumonia. Batlle, explored a way to block the main entry point of SARS-CoV2 into humans.

RAPID RESPONSE TO COVID-19

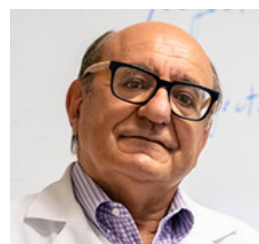
With support from the NUCATS Institute and a supplement from the University of Chicago's Center for Clinical and Translational Science, Northwestern researchers developed a technique that requires just a few drops of blood to determine if an individual has anti-SARS-CoV-2 antibodies. Working with a group of multidisciplinary investigators that includes [Thomas McDade](#), PhD, Anthropology; [Alexis Demonbreun](#), PhD, Pharmacology; [Brian Mustanski](#), PhD, Medical Social Sciences; and [Rich D'Aquila](#), MD, Medicine: Infectious Diseases, [Elizabeth McNally](#), MD, PhD, Medicine, helped devise a first-of-its-kind dried blood spot test that people could take at home.

Early in its pandemic response, the Institute also held a highly successful competition for a pair of [Rapid Response grants](#). Funding was awarded to a project to better understand virus-host interaction through the creation of a COVID-19 BioBank and another exploring the effect of COVID-19 on individuals with serious pneumonia. The grants were supported by NUCATS and the Feinberg School of Medicine Office for Research.

NUCATS and the Feinberg Office for Research also worked to ensure support for five additional COVID-19 research proposals through various funding sources. One of those projects was a study by Hultquist, which led to a successful R21 grant in 2021.



ABOVE: CCR DIRECTOR MICHAEL ISON ALEXIS DEMONBREUN (L) AND DAN BATLLE





75%

THREE IN FOUR INVESTIGATORS WHO HAVE PARTICIPATED IN A NUCATS STUDIO HAVE HAD THEIR GRANT **FUNDED**

13

THE NUMBER OF NUCATS GRANT DEVELOPMENT AND IMPLEMENTATION **STUDIO** CONSULTATIONS IN FY 21

\$1M

NUCATS ANNUALLY SUPPORTS MORE THAN \$1M IN **PILOT RESEARCH FUNDING** THAT SEEDS NEW NIH APPLICATIONS

\$600M

IN THE PAST 2 YEARS, BCC AND NUDACC BIOSTATISTICIANS HAVE HELPED SUBMIT MORE THAN 250 PROPOSALS TOTALING MORE THAN \$600 MILLION IN **POTENTIAL FUNDING**

359

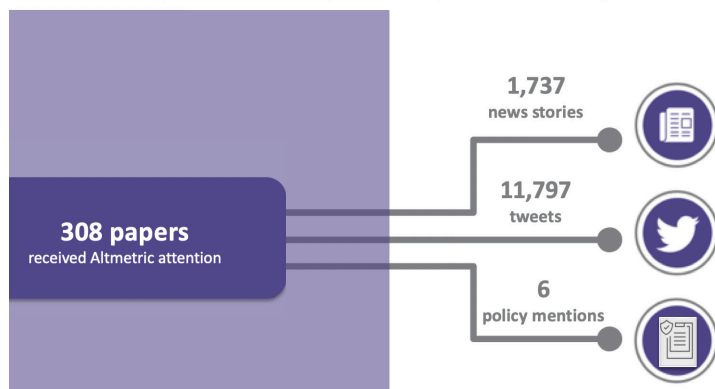
MORE THAN 350 SCIENTIFIC **PAPERS** WERE SUPPORTED BY NUCATS IN FY21

2,500

SINCE LAUNCHING IN 2008, NUCATS HAS SUPPORTED MORE THAN 2,500 **PUBLICATIONS**, WHICH HAVE BEEN CITED BY ACADEMICS AND POLICY EXPERTS THROUGHOUT THE WORLD

Attention in News and Social Media

Based on publications collected from PubMed from June 2020 to May 2021



243K

NEARLY 250,000 RESEARCH PARTICIPANTS ENROLLED IN **CLINICAL TRIALS** AT NORTHWESTERN IN FY20

13,500

SINCE 2017, MORE THAN 13,500 PEOPLE HAVE ENGAGED WITH WEB-BASED **TEAM SCIENCE** TRAININGS

85

NUCATS HAS **SUPPORTED** 35 KL2 SCHOLARS, 25 TL1 FELLOWS AND 35 SCIENCE IMMERSION PROGRAM TRAINEES



COVID TRIALS ACCELERATED, NEW RESEARCH HUB ANCHORED BY NM CLINICAL RESEARCH UNIT

The Northwestern Medicine Clinical Research Unit (CRU) was integral to supporting COVID studies throughout the pandemic. A significant contribution came from the CRU's involvement in a monoclonal antibody infusion trial in which the CRU — which is a program within the NUCATS Institute's [Center for Clinical Research](#) — contributed to expediting the approval of the clinical trial within a 4-week timeframe. The CRU also assisted with the transition of the monoclonal antibody infusion from research to standard of care after emergency

use authorization (EUA) approval. The CRU trained NMH infusion nurses in the care of these patients so that the treatment could occur in an observational unit. The CRU successfully evaluated 23 study participants during the phase II clinical trial, and treated an additional 136 patients under the resulting EUA. It is important to note that the typical time for a clinical trial from start to market is 6-7 years. For this treatment, it took 5 months to get approval for EUA.

As Northwestern investigators continue to increase the breadth

and widen the impact of clinical research, Northwestern Medicine opened a new 10,000 square foot Clinical Research Hub to enhance investigative scope and infrastructure while improving participant experiences.

Following a ceremonial ribbon cutting on January 31, 2020, the dedicated outpatient research space on the 15th floor of Northwestern Memorial Hospital's Galter Pavilion now includes an expansion of the outpatient location of the CRU, which also maintains an inpatient unit in Feinberg Pavilion.

STUDY MANAGEMENT IMPROVED BY INFORMATICS GROUP

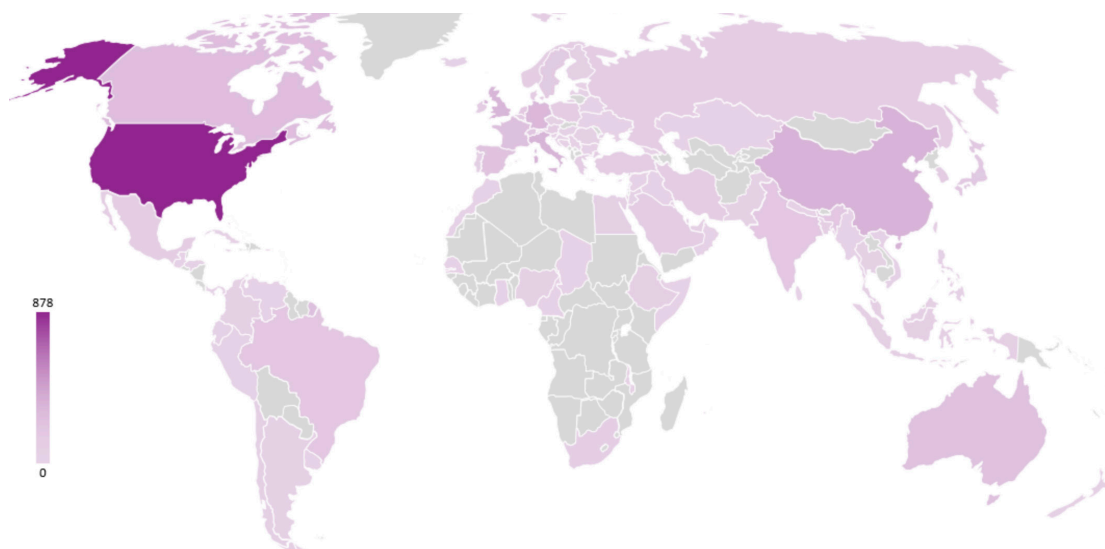
Study Tracker, which was developed entirely in-house at NUCATS, has improved and evolved over a decade to become a premium Clinical Trial Management System with integrations to many of Northwestern's partnering systems, including Epic and eIRB+. Ann & Robert H. Lurie Children's Hospital of Chicago tapped the NUCATS [Applied Research Informatics Group](#) to build a version of Study Tracker exclusively configured for their specific workflows and policies. Launched in FY21, the

version of Study Tracker for Lurie Children's Hospital includes all of the valuable modules that exist at Northwestern to aid in crucial study components like recruitment and budget-building. Lurie Children's currently has more than 500 studies and 2,500 research participants.

To enhance support for FDA regulated clinical trials, NUCATS partnered with the Feinberg Medical School Dean's Office and a third-party vendor in FY21 to certify a Title 21 CFR Part 11-compliant

remote eConsent solution for the medical school's REDCap system. Part 11 compliance is a nuanced and time-consuming part of FDA regulated clinical trial workflows, and the REDCap system can now help lift some of this burden from study teams by providing a prescribed and pre-built instrument set focused on remote eConsent collection. While each team brings their own consent language and needs to consider their specific workflow needs, this resource is offered as a largely turn-key solution.

MEMBERS CITED 1,882 TIMES IN 101 NATIONS LAST YEAR



NUCATS Institute members continue to make a global impact. During the past year (June 20-21), NUCATS-supported research discoveries were published in 359 peer-reviewed journals — work that received 1,882 citations. Those citations occurred in 11 languages and in 101 nations (see figure).

RESEARCH WORKFORCE ENHANCED BY NEW MSCI COURSE, MENTORSHIP OPPORTUNITIES, EDUCATION PROGRAMS

The Center for Education and Career Development's mentoring programs provide tools for investigators to develop strong relationships through the ["NUCATS Series for Developing and Enhancing Mentoring Relationships."](#) Throughout the past year, the series had 100 individual participants representing 80 percent of all Feinberg School of Medicine departments. This mentorship initiative was complemented by an innovative program that launched [mentoring circles](#) comprised of new clinical research coordinators (CRC) and CRCs who are further along in their careers to develop a network of research staff across Feinberg.

In FY21, the Institute launched a number of diversity, equity and inclusion initiatives, including a new Master of Science in Clinical Investigation course, ["Antiracist Strategies for Clinical and Translational Research,"](#) which provides an overview of how anti-Black racism can be perpetuated in clinical research, how to spot these patterns and how students can actively address them as they conduct research projects. The course was led by [Nia Heard-Garris, MD, MSc](#), top-right, and [Susanna McColley, MD](#), right. NUCATS also secured two NIH Diversity Supplements on its UL1 grant for the first time in the Institute's history.

To support the creation of a clinical research workforce that is highly-skilled, competent and efficient in facilitating the speedy translation of scientific discoveries, the NUCATS Institute facilitates the successful [CRC Basic Training](#) course and [Clinical Research Workforce Excellence \(CRewe\)](#) Program. In FY21, the NUCATS Institute launched a new



comprehensive [CRC Toolkit](#) intended to support and complement departmental efforts to standardize onboarding and training initiatives.

Over four weeks in May and June, the 2021 [Enhancing Quality in the Translational Research Workforce Conference](#) welcomed 400 clinical and translational research professionals from throughout the nation.

NEW USES FOR EHR DATA

More than a quarter-million American women will be diagnosed with breast cancer this year. A new dataset — the result of a collaborative project between **Seema Khan, MD**, the Bluhm Family Professor of Cancer Research and a member of the NUCATS Institute and Robert H. Lurie Comprehensive Cancer Center of Northwestern University, and NUCATS Institute Chief AI Officer **Yuan Luo, PhD** — has made the process of reviewing thousands of patient histories increasingly possible. The process relies on machine learning to mine the electronic health records of nearly 10,000 breast cancer cases in an effort to deliver new data to researchers. The dataset has led to numerous publications, including "Identifying Breast Cancer Distant Recurrences from Electronic Health Records Using Machine Learning" in the *Journal of Healthcare Informatics Research* in 2019.

CCH STRENGTHENS COMMUNITY BONDS

As part of its efforts to support local communities, the [Center for Community Health \(CCH\)](#) launched a Response and Recovery Fund, which provided financial support to 28 community organizations serving low- and moderate-income neighborhoods who are at the center of their community's response to the COVID-19 pandemic.



SHEHARA WAAS

Named ARCC Community Co-director in 2021

The newly created [Dissemination and Implementation \(D&I\) Program](#) within CCH continues to establish itself and held a virtual workshop in collaboration with the University of Illinois at Chicago Center for Translational Science. The workshop introduced key D&I terminology, methods and outcomes, with an emphasis on the value of involving community stakeholders.

In February, CCH Director [Darius Tandon, PhD](#), and Alliance for Research in Chicagoland Communities Co-director [Jen Brown, MPH](#), co-authored an important article: "It should not require a pandemic to make community engagement in research leadership essential, not optional" in the *Journal of Clinical and Translational Sciences*. The paper called on research funders and research institutions to take decisive action to make community engagement obligatory, not optional, in all clinical and translational research.

NEW PROGRAMS BOLSTER ENTREPRENEURSHIP

Six Northwestern-based teams took part in Northwestern's inaugural [I-Corps@NCATS](#) program, a six-week short course that combined business model training with the customer discovery process. The course was supported by the NUCATS Center for Translational Innovation and Northwestern's Innovation and New Ventures Office.

The primary focus of participating teams was to define and test the value proposition of their technology/service in the marketplace by conducting interviews of potential customers, partners and competitors. The curriculum focused on customer development, guided by the Business Model Canvas, to help each team better understand whether their innovation effectively addresses unmet needs.

[INVOForward Therapeutics: Building a Data Package](#), is a new mentorship program launched for faculty who are interested in translating their academic research into a potential therapeutic. In this program, faculty teams work with Northwestern professional staff experienced in the drug development process to map out a strategy for developing potential therapeutics. The objective of the program is to equip faculty teams with an improved understanding of the elements required for creating a compelling data package, and to help make projects competitive to various Northwestern accelerator/incubator opportunities as well as attract potential external partners or investors.

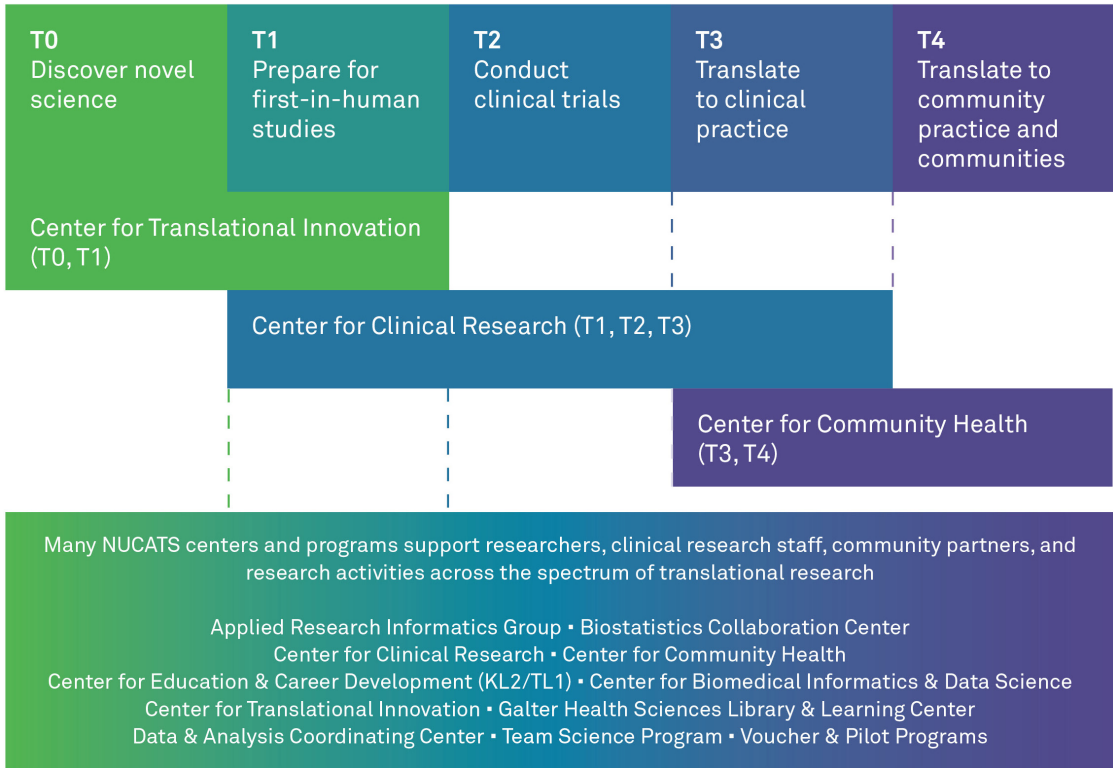
For several teams, the opportunity to showcase their data packages led to follow-up conversations to explore potential partnerships and funding. In particular, one team that was led by [Huiping Liu, MD, PhD](#), and [Deyu Fang, PhD](#), subsequently applied for and was awarded a \$100,000 Accelerator Award from the Chicago Biomedical Consortium. They also participated in an inaugural Polsky-Northwestern SBIR Sprint Workshop which should help position their future company's quest to secure SBIR grants.

RENOWNED KELLOGG FACULTY LEND EXPERTISE

After successfully piloting a collaboration with Northwestern's Kellogg School of Management in 2020, NUCATS launched a week-long workshop on leadership in May 2021. "[Leadership, Management, and Fiscal Strategies for Clinical Investigators](#)" is designed to help teach clinical investigators strategies to improve management and leadership skills.

The program offers clinical investigators an opportunity to focus and work with peers in a Kellogg-led course to learn practical and effective approaches to topics including organizational culture, strategic time management, financial management, fundraising and influence and persuasion strategies. Forty-one faculty members have completed the course thus far.

FULL SPECTRUM OF CLINICAL, TRANSLATIONAL RESEARCH SUPPORTED BY NUCATS INSTITUTE CENTERS AND PROGRAMS

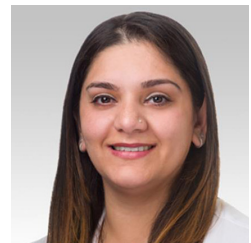


RESOURCE ACCESS BOOSTED BY NAVIGATOR PROGRAM

The NUCATS Institute is comprised of 11 centers and programs, each designed to provide scientists with consultative resources and expertise in order to accelerate how quickly transformative scientific discoveries make their way to patients and the community. Our team of NUCATS Navigators, led by [Toddie Hays](#), pictured, acts as a frontline for service by providing critical subject matter expertise. The Navigator program helped expand access to our 62-page Facilities and Other Resources document, institutional letters of support, and Grant Development and Implementation Studio Consultations. These consultations come at a critical time ahead of grant submissions and 3 out of 4 principal investigators who take advantage of the hour-long workshops are successfully funded.

NUCATS MEMBERS AMONG MOST CITED IN WORLD

NUCATS members continually find new ways to improve human health for all, while also contributing their scholarship by publishing scientific discoveries in high-impact, peer-reviewed publications.



SADIYA KHAN

Each year, Clarivate Analytics releases a list of highly cited researchers. Five NUCATS investigators were among the most highly cited for 2020, including [Robert Bonow](#), MD; [David Cella](#), PhD; [Mark Hersam](#), PhD; [Donald Lloyd-Jones](#), MD, ScM; and [Clyde Yancy](#), MD, MSc.

Many discoveries also make their way into the media. In May, COVID-19 seed grant awardee [Egon Ozer](#), MD, PhD, was featured in news articles that reached more than 4 million people. In July, a finding by former KL2 Scholar [Sadiya Khan](#), MD, MSc, that revealed heart health before a woman becomes pregnant is strongly related to complications, was featured in nearly 150 articles throughout the world. In August, faculty including NUCATS members [Michael Wolf](#), PhD, MPH, and Khan, reached more than 8 million people with discussions on COVID-19 vaccinations.