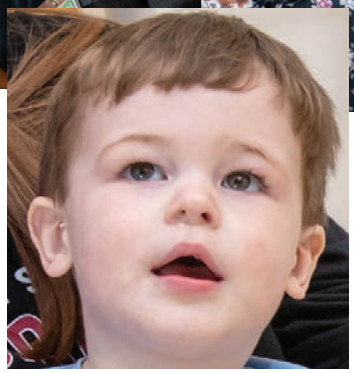
University of Arkansas for Medical Sciences (UAMS)

TRI

Translational Research Institute



2023

Annual Report

University of Arkansas for Medical Sciences (UAMS)

UAMS

Arkansas Children's

HOSPITALS • RESEARCH • FOUNDATION

THE TRANSLATIONAL RESEARCH INSTITUTE IS SUPPORTED BY THE NATIONAL INSTITUTES OF HEALTH (NIH) NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS), CLINICAL AND TRANSLATIONAL SCIENCE AWARDS (CTSA) PROGRAM UL1 TR003107, KL2 TR003108 AND TL1 TR003109.

Translational Research Institute (TRI)

TRI PROVIDES SERVICES AND RESOURCES TO ENSURE THE SWIFT TRANSLATION OF RESEARCH INTO HEALTH CARE ADVANCES. THIS SUPPORT IS AVAILABLE TO RESEARCHERS AT UAMS, ARKANSAS CHILDREN'S HOSPITAL AND ARKANSAS CHILDREN'S RESEARCH INSTITUTE, AND THE CENTRAL ARKANSAS VETERANS HEALTHCARE SYSTEM (TRI HUB PARTNERS).

Mission Statement

OUR MISSION IS TO DEVELOP NEW KNOWLEDGE AND NOVEL APPROACHES THAT WILL MEASURABLY ADDRESS THE COMPLEX HEALTH CHALLENGES OF RURAL AND UNDERREPRESENTED POPULATIONS.

Vision Statement

OUR VISION IS TO BE A THRIVING TRANSLATIONAL RESEARCH ECOSYSTEM THAT CATALYZES DISCOVERIES INTO HEALTH SOLUTIONS FOR RURAL AND UNDERREPRESENTED POPULATIONS.

This report is dedicated to the memory of **Susan Smyth, M.D., Ph.D.**, for her many contributions to translational research and for her remarkable leadership. She served as dean of the UAMS College of Medicine from June 2021 through December 2022. She was a longtime member of the CTSA family, serving on the NCATS-CTSA Steering Committee while at the University of Kentucky. She was also a nationally respected cardiologist and leader in academic medicine. At the time of her death, Dr. Smyth was actively involved in advising UAMS faculty on aspects of our 2023 CTSA renewal application.

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This report is produced by the UAMS Translational Research Institute (TRI). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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Message from the Director

DEAR READER,

My role as a translational research leader keeps me in a forward-thinking posture, but each year I have the pleasure of looking back as we compile our annual report. The past year has been marked by noteworthy achievements of our TRI-supported researchers, novel cross-CTSA collaborations, and innovations that will impact health and research across the United States.

TRI has also experienced unprecedented growth in clinical trials, helping launch and conduct 292 studies since receiving our CTSA in 2019, a seven-fold increase over that period. Importantly, we have expanded our research into rural areas of the state with the UAMS Rural Research Network, a TRI-supported program.

We have also seen a healthy return on investment from our programs to increase the breadth and depth of translational researchers at UAMS and at our partner institutions: Arkansas Children's Research Institute (ACRI) and the Central Arkansas Veterans Healthcare System (CAVHS).

One of our newest training programs, Strategies for Training and Advancing underrepresented Researchers (STARs), was an immediate help to participants in securing grants. For example, Bolni "Marius" Nagalo, Ph.D., said the STARs Program was vital to his obtaining a $300,000 American Association for Cancer Research (AACR) Career Development Award.

Meanwhile, TRI's more established programs, such as the premier KL2 Mentored Research Career Development Scholars Program, continue to draw strong, diverse fields of early-career researchers who are producing impactful research and becoming independently funded translational research leaders. We selected our largest-ever KL2 cohort in 2022, thanks to funding support from the UAMS College of Medicine, Winthrop P. Rockefeller Cancer Institute, Arkansas Children's Research Institute and CAVHS.

As you read through this 2023 Annual Report, you will see why we are so excited about our accomplishments. They weren't achieved in a vacuum; they required critical internal and external partnerships and all the resources and innovation we could bring to bear as a CTSA program.

I anticipate many more successes in the coming year, and I am already looking forward to looking back in 2024.

Laura James, M.D.
Director, Translational Research Institute
Associate Vice Chancellor for Clinical and Translational Research, UAMS

New Paths to Success

NOVEL TRI EFFORTS SPUR PUBLICATIONS AND FUNDING FOR JUNIOR FACULTY

KL2 scholars Cody Ashby, Ph.D. (left), and Jennifer Rumpel, M.D., say Mario Schootman, Ph.D. (center), has provided critical guidance that has helped advance their careers.

Applicants were two times more likely to receive a KL2 award if they received help from Mario Schootman, Ph.D., in the Path 2 K Grant Writing Program.

Continued on page 6

Two new programs supported by TRI quickly showed their value in 2022, helping researchers secure career development awards and publish their TRI-supported work: the Path 2 K Grant Writing Program and the Promoting Professional Publication Program (P4) (see story opposite page).

Path 2 K

Developed and directed in spring 2022 by Mario Schootman, Ph.D., a professor in the College of Medicine, Division of Community Health and Research, the Path 2 K Program is UAMS' first program devoted to helping junior faculty succeed as early-career award applicants for institutional KL2 awards and NIH K (career development) awards. The program is provided in partnership with the UAMS Winthrop P. Rockefeller Cancer Institute and modeled after similar successful programs at Duke University and the University of Alabama, Birmingham. After joining UAMS in January 2022, Schootman, aware of a fast-approaching KL2 application deadline, immediately started scheduling workshops and offering individualized support to early-career researchers. KL2 applicants who took advantage of his expertise were two times more likely to receive the training award that spring than other applicants.

"I really feel like Dr. Schootman has got my back and is committed to my success."

— Jenny Rumpel, M.D.

'Best Mentor'

Schootman, formerly a professor at Saint Louis University and Washington University, always enjoyed mentoring and is excited to be doing it full time at UAMS.

"I've written a lot of grants and papers, and all throughout my career I have helped junior faculty to be successful," he said. "Now at TRI I have a much more formalized opportunity for doing that."

He has quickly earned the admiration of applicants and TRI leadership.

Jenny Rumpel, M.D., and Cody Ashby, Ph.D., for example, credit Schootman's expert guidance in securing TRI KL2 Mentored Research Career Development Program Scholar Awards in 2022.

"Dr. Schootman is the best mentor I've ever had," said Rumpel, an assistant professor in the College of Medicine Department of Pediatrics. "I obtained the KL2 grant with his mentoring, and he became my primary mentor this year once I received that grant."

Rumpel's KL2 project is focused on how acute kidney injury contributes to infant mortality. She was on track to submit a K23 Mentored Patient-Oriented Research Career Development Award application in June 2023.

"Dr. Schootman always reviews my grants and manuscripts in a timely fashion and gives very helpful feedback," Rumpel said. "He is kind and makes time in his schedule for me. I really feel like he has got my back and is committed to my success."

In addition, Schootman has taught Rumpel valuable organizational skills and how to use certain tools to improve her efficiency, she said.

Ashby, an assistant professor in the College of Medicine Department of Biomedical Informatics, said Schootman provided a constructive critique that meaningfully improved his application.

"It was very nice having a grant-writing expert read through it with a different perspective," said Ashby, whose KL2 project is helping him acquire expertise in multiple myeloma risk classifications and identify rural and racial disparities in Arkansas as they relate to multiple myeloma risk. "Dr. Schootman was great at recognizing where I had too much detail and where I needed more detail."

TRI Associate Director John Arthur, M.D., Ph.D., also co-director of the KL2 program, said Schootman has substantially improved the quality of applications.

"I can't believe how lucky we are to have had Dr. Schootman fall in our lap. He has really made a big difference," said Arthur, a professor and chief of the Division of Nephrology in the College of Medicine Department of Internal Medicine. "As reviewers, it helps us do a better job of judging the applications. Sometimes we have to guess what an applicant is trying to say, but now they are actually saying it."

More Ks

The Path 2 K Program also aims to increase the number of external NIH career development awards such as the K01, K08 and K23 awards. Twice a year, Schootman provides four to six months of structured activities, including brief workshops and one-on-one support. His first cohort to go through the Path 2 K Program included seven junior faculty, and three submitted applications in October 2022. His second cohort of trainees included five junior faculty, and all were on track to submit K applications in June.

The program should help improve UAMS' showing among its peers in the number of NIH K awards per faculty, Schootman said. For example, the University of Nebraska has four times as many K awards per faculty as UAMS, and the University of Oklahoma has six times as many.

"I see this is a great opportunity for UAMS," Schootman said. "I believe the Path 2 K Program will help improve our position."

"A lot of times all I needed to do was listen and the solutions would reveal themselves."

— Kristie Hadden, Ph.D.

Using her P4 intervention, Kristie Hadden, Ph.D., helped nine TRI-supported researchers produce eight manuscripts and five publications in the program's first year.

Promoting Professional Publication Program (P4)

A promising intervention that helped produce eight manuscripts and five publications in its first year started with an informal conversation. Kristie Hadden, Ph.D., asked TRI Director Laura James, M.D., how she could help TRI.

"What we really need is more TRI-cited publications," James told the UAMS senior strategy associate and former TRI-supported researcher.

Hadden suggested a novel intervention in which she would work with TRI-supported researchers to identify and overcome barriers to producing and publishing manuscripts. With James' encouragement, the program was implemented in February 2022.

Formerly an NIH-funded researcher, Hadden is an associate professor in the College of Medicine Department of Medical Humanities and Bioethics and has interprofessional faculty appointments in all five UAMS colleges and the Graduate School.

In her first year leading P4, Hadden served as a consultant to 10 TRI-supported researchers from all faculty ranks, and nine completed the program.

Hadden's approach deliberately deviated from traditional manuscript writing programs that focus on time management for writing. Although time is the biggest barrier, she was more interested in other impediments to manuscript production.

"The publication pathway is not linear," Hadden said. "There are feedback cycles, and at each phase there are different kinds of micro-barriers. I asked each of the participants to identify those micro-barriers so we could determine what TRI resources could help or what I could do to help them progress to the next step."

After participants listed their barriers in a pre-assessment questionnaire, Hadden helped them overcome them through resources, networking, training, skills development, submission assistance, or brainstorming and motivation.

The needs of junior faculty were very different from senior faculty, she said. Junior faculty asked for more one-on-one time and wanted to build a trusting relationship, while senior faculty more often needed to find resources that could help them extend their capacity.

"A lot of times all I needed to do was listen and the solutions would reveal themselves," Hadden said. "Our researchers often just need the space to identify barriers and brainstorm solutions to whatever is standing in the way of their publication. P4 provides that space and access to the resources that they need to move their work toward publication."

Antiño Allen, Ph.D., joined four of his UAMS colleagues in completing mentorship facilitator training at the University of Wisconsin-Madison, the lead site for the mentor training core of the NIH-sponsored National Research Mentoring Network.

Mentoring comes with the job for researchers and now, for many at UAMS, it comes with evidence-based training and support.

Mentoring Evolution

TRI PROGRAMS NOW REQUIRE EVIDENCE-BASED MENTOR TRAINING

Learning something new about mentoring was a little unexpected for Fred Prior, Ph.D., a distinguished professor and department chair with decades of mentoring experience.

Prior, who leads the College of Medicine Department of Biomedical Informatics, was among 20 UAMS participants involved in field testing a TRI-led evidence-based mentorship training in October 2022.

"It was not only very good, it gave me important new perspective about the needs of our mentees, and I plan to adjust my approach as a result," he said.

All 20 participants in the training said it was a valuable use of their time and 18 said they are likely or very likely to recommend it to colleagues.

Past evidence-based mentorship trainings sponsored by TRI have been well attended, but optional. That will change this year for all primary mentors in TRI-funded career development programs. Mandatory training will ensure that all mentors have a strong foundation in quality, evidence-based practices.

TRI's Carolyn Greene, Ph.D., is spearheading the work along with John Arthur, M.D., Ph.D., Antiño Allen, Ph.D., Jessica Snowden, M.D., and Jennifer Vincenzo, Ph.D., MPH, PT. All have received facilitator training from the Center for the Improvement of Mentored Experiences in Research (CIMER) at the University of Wisconsin-Madison (UW) to lead mentorship trainings for UAMS faculty. UW is the lead site for the mentor training core of the NIH-sponsored National Research Mentoring Network.

Allen is a professor in the UAMS College of Pharmacy, associate dean of Pipeline and Career Development at the UAMS Graduate School, and TRI associate director of Diversity Initiatives, and its STARs Program.

Arthur is a professor and chief of the Division of Nephrology in the College of Medicine Department of Internal Medicine, and TRI associate director and co-director of the KL2 program.

Snowden is vice dean for Research in the UAMS College of Medicine; professor and chief of the Division of Pediatric Infectious Diseases, Department of Pediatrics; and TRI co-director of Translational Workforce Development.

Vincenzo is an associate professor in the College of Health Professions and former TRI KL2 program scholar.

By the end of February, dozens of research faculty at UAMS and Arkansas Children's had assisted TRI in field testing the nationally recognized mentor training program.

"Today we're seeing changes in the research landscape that make quality mentorship more important than ever."

— Carolyn Greene, Ph.D.

TRI's mentorship training efforts reflect a priority of the National Center for Advancing Translational Sciences (NCATS) at the NIH.

"It's almost impossible to be a successful researcher unless someone has shown you the ropes, and that is supported by a growing body of empirical evidence," said Greene, TRI associate director of Programmatic and Strategic Planning. "Today we're seeing changes in the research landscape that make quality mentorship more important than ever."

Capstones to Milestones

MASTER'S PROGRAM BUILDING COMMUNITY OF CLINICAL AND TRANSLATIONAL SCIENTISTS

After two years of study, the first class of early-career clinical researchers was set to deliver on the promise of the UAMS Clinical and Translational Science Master of Science (CTS-MS) program this summer.

As part of an update to the program, the first scholarships were offered to protect time for clinical researchers in 2021, and the capstone master's thesis was changed to a grant application for internal or external funding.

Each of the four faculty was poised to submit grant applications this spring/summer, said Shelley Crary, M.D., a professor in the College of Medicine Department of Pediatrics who co-led the program update with Jun Ying, Ph.D., a professor in the UAMS Department of Biostatistics.

"They have all been extremely successful so far in meeting TRI's goals for the program," Crary said.

One member of the class, Jenny Rumpel, M.D., had already secured a TRI KL2 Mentored Research Career Development Program Scholar Award. Rumpel was also planning to submit an NIH K23 career development award application this summer.

The other class members planning grant submissions were:

- **Harmeen Goraya, M.D.,** for a Cystic Fibrosis Foundation grant
- **Megha Sharma, M.D.,** for a TRI KL2 award
- **Tara Johnson, M.D.,** for a NIH R21 award

Crary said the CTS-MS program has revealed another important benefit – one she was hoping to see as she worked to update the program.

"They've started to develop their own community of clinical investigators, which was my dream when I got involved with the program," said Crary, who is also co-director of TRI's Pilot Award Program. "I really wanted it to be a catalyst for developing a supportive culture for physicians who want to do clinical research."

All four have become friends and talk outside of the program, creating bonds that will pay dividends for them as well as CTS-MS scholars coming behind them, she said.

"Now we have a second group of four who are going through it, and the program structure allows them to learn from one another and present their research to one another," Crary said. "I see that as the future, with our physicians benefiting from each other as they pursue clinical and translational research as an important part of their careers."

"They have all been extremely successful so far in meeting TRI's goals for the program."

— Shelley Crary, M.D.

Jennifer Andersen, Ph.D

Jennifer Andersen, Ph.D., has 40 publications (14 as first author and 26 co-authored) since joining UAMS in 2020.

Astounding Apprentice

KL2 SCHOLAR DOMINATES MANUSCRIPT WRITING CONTEST

Jennifer Andersen, Ph.D., claimed two victories in TRI's Summer 2022 Writing Challenge with seven manuscript submissions.

The impressive total earned her the Astounding Apprentice Award for the most submitted manuscripts by an assistant professor or instructor. For the second year in a row, she also won the category of Most Reflective of Community Engagement and Partnerships. No previous winners have had more than five manuscripts, including in last year's first Summer Writing Challenge.

"The summer is my writing time," said Andersen, an assistant professor in the College of Medicine Department of Internal Medicine, Division of Community Health & Research. "This year we had some new data come in at the right time, and it all coalesced into a really productive summer."

UAMS-affiliated researchers who have received TRI support submitted 77 research manuscripts as part of the Summer 2022 Writing Challenge.

Andersen's winning total accounts for only a fraction of her 40 publications (14 as first author and 26 co-authored) since joining UAMS in 2020.

Based at the UAMS Northwest Regional Campus, the topics of Andersen's publications have mostly covered family diabetes self-management and education in the Marshallese population and COVID-19-related studies in the Marshallese and general Arkansas population.

"The summer is my writing time."
— Jennifer Andersen, Ph.D.

She said her output has benefited from her 2022 KL2 Mentored Research Career Development Program Scholar Award.

"The additional protected time from the KL2 is very helpful, and I am 100% research – I don't teach," she said. "That gives me an advantage that others may not have."

Her KL2 work is testing the feasibility of remote monitoring of blood glucose for pregnant Marshallese women with diabetes.

She said the supportive research environment – from TRI to her colleagues at the Division of Community Health & Research – has been a critical component of her success.

"None of those papers would have been published if I didn't have the great co-authors and support staff that we have here," Andersen said.

In addition, she said her publishing proficiency has benefited from the book, *Writing Your Journal Article in Twelve Weeks: A Guide to Academic Publishing Success*, by Wendy Laura Belcher.

"Following the book's approaches is how I trained myself to write because it provides such good guidelines," she said.

INFORMED CONSENT BREAKTHROUGH

TRI ADVANCES HEALTH EQUITY WITH COMPUTER-GUIDED CONSENT FORMS

Members of TRI's Informed Consent Navigator team include (front, l-r) Mathias Brochhausen, Ph.D., Nicki Spencer, MHA, Alison Caballero, MPH, CHES, and Jonathan Bona, Ph.D.; (back row) Justin Whorton, Sarah Fountain, MPH, CPH, CHES, Jennifer Gan-Kemp, MBA, CRS, and Aaron Kemp, MBA.

The Informed Consent Navigator builds on years of work by the UAMS Center for Health Literacy, which created a plain-language consent form template and made it available to all researchers.

Continued on page 12

"This is a big win for health equity and a big achievement for UAMS."

— Mathias Brochhausen, Ph.D.

A new software tool developed by the TRI will help researchers quickly create consent documents in plain language for their prospective study volunteers.

Called the Informed Consent Navigator, the web-based tool breaks new ground with its ability to guide researchers through the creation of plain-language informed consent forms (eighth-grade reading level or below). The *Journal of Clinical and Translational Science* published the TRI team's work in December, drawing immediate interest from several research institutions across the United States.

"This is a big win for health equity and a big achievement for UAMS," said co-author Mathias Brochhausen, Ph.D., a professor in the College of Medicine Department of Biomedical Informatics.

Interdisciplinary Research

Led by first-author Jonathan Bona, Ph.D., the project involved interdisciplinary researchers including biomedical informaticists, software developers, research ethicists, and experts in community engagement, health literacy, health education, plain-language writing, clinical trials and informed consent. Bona is an assistant professor in the College of Medicine Department of Biomedical Informatics, with expertise in artificial intelligence, knowledge representation, biomedical ontologies and natural language processing.

The team was assembled and supported by TRI Director Laura James, M.D., a co-author.

"This project truly played to UAMS' strengths and is a testament to multidisciplinary team science and the vital support of TRI," said Brochhausen, who is an expert in knowledge representation, biomedical vocabularies and ontologies, and semantic web technologies in biology and medicine. "In addition to the institute's financial support, Dr. James and her team have been with us in the trenches, attending our meetings and helping connect us to key resources."

Ensuring Readability

Consent forms are often long, detailed, and introduce new concepts, said co-author Alison Caballero, MPH, CHES, director of the Center for Health Literacy. The forms can be a barrier to conducting research, especially with populations underrepresented in research and with limited health literacy.

"Using language that is readable, understandable and actionable is a challenge, but it is essential for truly informed consents and ensuring the greatest possible diversity in research," said Caballero, an associate professor.

While other institutions across the U.S. have been working on similar automated consent processes, UAMS appears to be first with its automated plain-language consents.

"We were able to get further than any other group with our tool's added health equity benefits," Brochhausen said.

The Informed Consent Navigator builds on years of work by a collaborative team including the UAMS Center for Health Literacy, which created a plain-language consent form template and made it available to all researchers. Now part of the navigator, the text is automatically populated in the informed consent form based on the user's answers to questions presented by the navigator.

Where researchers must write original text about their specific studies, the navigator provides instructional text, content examples and real-time feedback with readability scores and suggestions to improve readability.

The navigator also uses survey logic that helps tailor what researchers see as they are guided through the process, reducing the difficulty and eliminating errors often made when using print-based templates.

"The goal for this is not just to make it easier for researchers to build forms, but to do so in a way that checks and encourages — and in some cases enforces — that the forms are readable," Bona said.

Next Steps

The team's immediate plans are to pilot the Informed Consent Navigator at UAMS and other institutions. Longer term, the team will establish an electronic consenting platform (e-consent). It will also work toward artificial intelligence-powered management of consents to expand the navigator's functionality.

Bona said the team ultimately hopes to see the navigator deployed at research institutions across the U.S. and beyond with the ability to query the network's data.

Community Feedback Improves Consent Tool

Before introducing its novel plain-language, computer-guided Informed Consent Navigator, TRI assembled two Community Review Boards (CRBs) to assess its readability.

The CRB reviews complemented the work of the project's plain-language experts at the UAMS Center for Health Literacy, who developed the text for the navigator.

CRBs are typically one-time meetings of community members to provide feedback on a researcher's project, including aims and goals, promotional materials usually involving underrepresented populations.

For the navigator project, TRI's Community Engagement team put together one CRB with five community members who had never participated in research, and the other, with nine members, included former research participants and volunteers who have served on other TRI community boards.

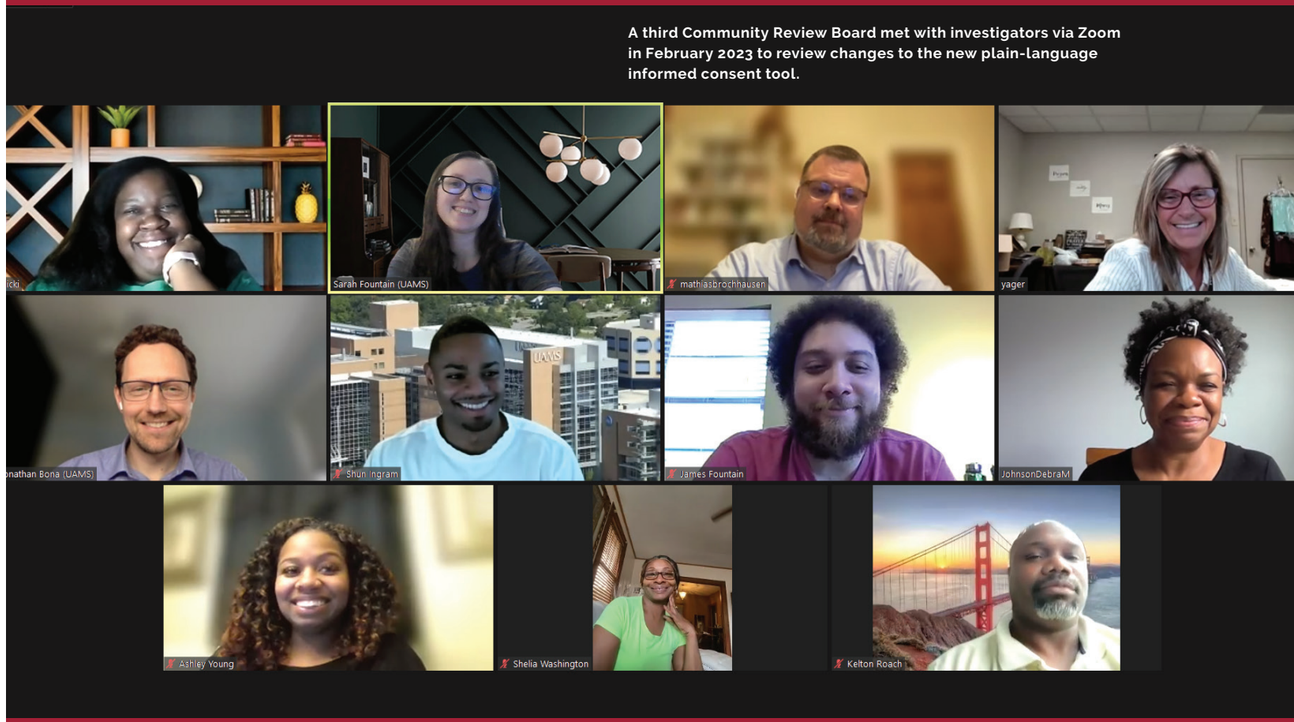
Also unique was a health literacy assessment of the CRB members, administered by Nicki Spencer, MHA, senior program manager for the TRI Community Engagement program, after training from the UAMS Center for Health Literacy.

"We always benefit from community feedback, and the screenings confirmed that we were including a variety of health literacy levels in those reviews," said Alison Caballero, MPH, CHES, director of the Center for Health Literacy.

After reviewing the nine-page consent form, the CRB members largely agreed the language was readable, but they expressed concern that the form was too long and redundant in places. They also suggested using images to aid comprehension of the text.

In February 2023, a third CRB was generally positive about the revisions researchers made based on its previous feedback.

"The CRBs did a fantastic job of identifying needed improvements, and we are very grateful for their work," said Jonathan Bona, Ph.D., who led the navigator's software development.



A third Community Review Board met with investigators via Zoom in February 2023 to review changes to the new plain-language informed consent tool.

"The Rural Research Network has become a very important resource for helping UAMS improve health equity."
— Pearl McElfish, Ph.D., MBA

Challenge Accepted

RURAL RESEARCH NETWORK RECRUITS 1,100 ARKANSANS FOR DIABETES INTERVENTION TRIAL

A UAMS study coordinated by the Rural Research Network achieved a major milestone in October 2022 when it met the enrollment goal for its trial comparing two diabetes interventions.

The research team and TRI-supported Rural Research Network, which began operation in 2020 and includes eight UAMS regional campuses, overcame challenges and delays associated with COVID-19 to recruit 1,100 participants in the randomized controlled trial.

"What excites me most is that we were able to implement this trial across rural Arkansas, and it was one of the very first large, randomized controlled implementation trials to use the Rural Research Network," said Pearl A. McElfish, Ph.D., MBA, the study's principal investigator. "Whether it is cancer clinical trials or diabetes trials, this achievement demonstrates how UAMS is making research accessible to all Arkansans. The Rural Research Network has become a very important resource for helping UAMS improve health equity."

The study will show whether involving family members improves outcomes more than another effective diabetes intervention.

The Study

McElfish's team is comparing the effectiveness of two diabetes intervention models: family diabetes self-management education (FDSME) and diabetes self-management education (DSME). Funded by the Patient-Centered Outcomes Research Institute (PCORI), the trial recruited 550 pairs of family members to participate, with one person being the primary Type 2 diabetes study participant.

The randomly assigned pairs in either the FDSME or DSME study groups attended 10 one-hour weekly group sessions conducted by certified diabetes educators. The family model sessions required both family members to attend the education sessions and encouraged the family support of the primary study participant. The DSME model, a well-known diabetes intervention, does not encourage the participation of the family member.

Participants' hemoglobin A1c (HbA1c) levels were tested when they joined the study and at six, 12 and 18 months after they have attended the education classes. An HbA1c blood test measures the average blood sugar levels over the past three months.

The study will determine whether involving family members in the intervention improves outcomes beyond the standard DSME, which is known to be an effective intervention.

Initial Results

Data are still being collected as the research team tracks participants, comparing their hemoglobin A1c and other biometric, behavioral and psychosocial outcomes with their pretrial baseline measures.

Research coordinators for the Rural Research Network have observed enthusiastic responses from participants and improved outcomes in their follow-up HbA1c tests. McElfish said the preliminary data support the anecdotal reports.

"The initial results show that the interventions have produced a clinically and statistically significant reduction in HbA1c levels, which has improved patient outcomes for the rural clinics," said McElfish, professor and director of the UAMS Office of Community Health & Research. "Final analysis will examine if one of the interventions was more effective than the other and what intervention is best for different populations."

Team Science

The study has drawn on a strong interdisciplinary team involving clinical endocrinologists, implementation scientists, biostatisticians, clinical dietitians, behavioral scientists, pharmacists, research coordinators and diabetes educators.

"This is the type of project that by necessity has to involve a range of expertise from different investigators to be successful," McElfish said. "The faculty at the regional sites were essential partners, providing diabetes education and helping us meet our enrollment goal."

The diabetes study was the first large-scale randomized controlled intervention trial to use the **TRI-supported UAMS Rural Research Network**.

CO-INVESTIGATORS ON THE RESEARCH TEAM ARE:

Jennifer Andersen, Ph.D., assistant professor, College of Medicine Department of Internal Medicine, Division of Community Health & Research

Geoffrey Curran, Ph.D., director, UAMS Center for Implementation Research; professor, College of Pharmacy

Holly Felix, Ph.D., MPA, professor, Department of Health Policy and Management, UAMS Fay W. Boozman College of Public Health; and College of Medicine Division of Community Health & Research

Joseph A. Henske, M.D., clinical endocrinologist and director, UAMS Diabetes Program

Jonell Hudson, Pharm.D., associate professor, College of Pharmacy Department of Pharmacy Practice

Jennifer Callaghan-Koru, Ph.D., associate professor, UAMS College of Medicine Department of Internal Medicine, Division of Community Health & Research

Lindsay Mayberry, M.S., Ph.D., associate professor, medicine, Vanderbilt University Medical Center; director, Vanderbilt Effective Health Communication Core

James Selig, Ph.D., associate professor, UAMS Department of Biostatistics

Benjamin Teeter, Ph.D., associate professor, UAMS College of Pharmacy and Center for Implementation Research

THE STUDY'S PRINCIPAL INVESTIGATORS AT THE UAMS REGIONAL CAMPUSES ARE:

Amber K. Norris, M.D., medical director, UAMS East in Helena West Helena

Matthew Nix, M.D., medical and residency director, UAMS Southwest in Texarkana

Ronald Brimberry, M.D., medical director, and Michael Macechko, M.D., residency director, UAMS Northwest in Fayetteville and Springdale

Darrell R. Over, M.D., medical director, and Toni Middleton, M.D., residency director, UAMS South Central in Pine Bluff

Tabasum Imran, M.D., medical director, and Katherine A. Irish-Clardy, M.D., residency director, UAMS West in Fort Smith

IN ADDITION TO TRI, SUPPORT FOR THE RURAL RESEARCH NETWORK IS PROVIDED BY:

UAMS Regional Campuses — **Richard Turnage, M.D.,** vice chancellor, and **Shashank Kraleti, M.D.,** chair, Department of Family and Preventive Medicine

UAMS Office of Community Health & Research — **Pearl McElfish, Ph.D., MBA,** director

UAMS Winthrop P. Rockefeller Cancer Institute — **Michael Birrer, M.D., Ph.D.,** vice chancellor and director

Pilot Leverage

NIH, NSF FUND STUDY OF RAPID GENOMIC TESTING OF INFECTIONS

A study that began with a TRI pilot award is developing real-time and accurate genomic methods that can be used routinely to deliver life-saving information to doctors treating antibiotic-resistant infections.

Led by UAMS' Se-Ran Jun, Ph.D., the study received a two-year, $418,000 NIH National Institute of Allergy and Infectious Diseases (NIAID) grant in 2022, and this year received a two-year $254,929 National Science Foundation grant.

The funding is supporting Jun's effort to harness now-affordable real-time sequencing technology for everyday use in hospitals.

In addition to helping doctors optimize antibiotic therapy, genome-based information could help hospitals identify and prevent hospital-acquired infections and their transmission.

"Current genomic methods do not have fast enough turnaround times and accuracy to serve as an effective epidemiology tool," said Jun, an assistant professor of the Department of Biomedical Informatics in the College of Medicine. "Establishing an accurate real-time genomic pathogen surveillance system for routine use would be revolutionary in clinical medicine and help make hospitals safer places."

Jun is focusing her study on a group of six highly virulent and antibiotic-resistant bacterial pathogens: *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa and Enterobacter* species. The group is known by the acronym ESKAPE.

Antibiotic resistance occurs when bacterial and fungal infections develop the ability to defeat the drugs used to kill them. According to the Centers for Disease Control and Prevention (CDC), it is a top threat to the public's health and a priority across the globe. In the United States alone, it causes more than 2.8 million infections and 35,000 deaths per year. Immunocompromised cancer patients are especially at risk of acquiring antibiotic-resistant infections.

Jun's research builds on data she gathered using a translational biomedical informatics-focused pilot grant from TRI.

The team's preliminary data shows that its experimental protocol could obtain antibiotic resistance profiles of Klebsiella pneumoniae isolates within six hours with real-time Nanopore data. Additionally, she has preliminary data with Klebsiella pneumoniae isolates in which she could observe a specific antibiotic resistance gene within two hours.

The NSF grant was approved by the Board of Directors of the Arkansas Economic Development Commission Division of Science and Technology. It enables Jun to implement data governance in pathogen surveillance with the ESKAPE project.

"We will create a multi-layered data governance plan for sequencing and analyzing bacterial pathogens collected in Arkansas," Jun said.

The governance plan has five sections, each with its own unique data types and data governance needs: genomic sequencing, assembly and functional enrichment, data analysis pipelines, integrative analysis, and public health, clinical impact, and scientific outcomes. A standardized pipeline for collecting and storing the data as well as its associated metadata will be created for each section.

"This is a great example of translational biomedical informatics — leveraging the latest sequencing technology for a critical application in patient care," said TRI Director Laura James, M.D.

If she is able to confirm her hypothesis, Jun said the genomic surveillance system would accurately and swiftly identify pathogen and transmission routes. It would also measure how vulnerable microbes are to antibiotics along with clinical microbiology laboratory tests.

"I am so excited because the output we generate could be translated directly into medical practice."
— Se-Ran Jun, Ph.D.

"I am so excited because the output we generate could be translated directly into medical practice," she said.

Jun, a data scientist whose doctorate is in mathematics, is using her expertise of real-time Nanopore sequencing, genomics, microbiomics and computer science to conduct the study.

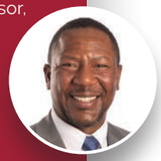
The team's preliminary data shows that its experimental protocol could obtain antibiotic resistance profiles of Klebsiella pneumoniae isolates within **six hours with real-time Nanopore data.**

Se-Ran Jun, Ph.D., discusses her TRI pilot award-supported findings with Fred Prior, Ph.D., distinguished professor and chair of the Department of Biomedical Informatics, at TRI Research Day 2022.

Five UAMS Researchers Receive TRI Pilot Awards in 2022

TRI pilot grants for studies that impact rural health went to five UAMS researchers in October 2022.

The one-year awards of up to $50,000 went to projects led by researchers in the College of Medicine, College of Pharmacy and Fay W. Boozman College of Public Health. They are:



STANLEY K. ELLIS, ED.D., M.S., associate professor, College of Medicine Department of Obstetrics and Gynecology; director of education for the Institute for Digital Health & Innovation.
PROJECT: School-Based Tele-counseling Feasibility Pilot

SUSAN EMMETT, M.D., MPH, associate professor, College of Medicine Department of Otolaryngology-Head and Neck Surgery, and director of the Center for Hearing Health Equity
PROJECT: Achieving Hearing Health Equity for Rural Children: Optimization of a Novel Mobile Health Tympanometer for Community-Based Hearing Screening

MEGAN SMITH, PHARM.D., BCACP, assistant professor, College of Pharmacy Department of Pharmacy Practice
PROJECT: Evaluation of the Integration of Community Health Workers (CHW) into Rural Community Pharmacies

MICHAEL THOMSEN, PH.D., professor, Governor Sidney S. McMath Chair in Obesity Prevention, director of the Center for the Study of Obesity, Fay W. Boozman College of Public Health
PROJECT: Understanding Rural Disparities in Severe Obesity through the Arkansas Childhood Body Mass Index Panel

LINDSEY WOLF, M.D., assistant professor, College of Medicine Department of Surgery, Division of Pediatric Surgery
PROJECT: A Pilot Program to Evaluate the Feasibility of Telemedicine Pediatric Surgical Consultations in Referring Emergency Departments

Kate Stewart, M.D., MPH

As people began to understand what community engagement is, to see how it works in practice, then they began to value it more."

— Kate Stewart, M.D., MPH

Sustainable Legacy

COMMUNITY ENGAGEMENT PIONEER KATE STEWART, M.D., MPH, RETIRES

Anna Huff Davis was distrustful of academic researchers until she met a professor in 2001 from the then new UAMS Fay W. Boozman College of Public Health.

Davis, a community advocate from Marvell, realized that Kate Stewart, M.D., MPH, was a game changer.

"I could tell right away that she had an understanding of community that I had never seen before," Davis said, reflecting on Stewart's retirement this year. "It wasn't just me. People could sense her passion for the work as well as her compassion. Then there's her desire for there to be equity, her social justice perspective and academic expertise. I could go on and on, and all of it has made her very effective in developing community-academic partnerships."

Today, Davis chairs the TRI Community Advisory Board and is a voice for underserved populations as a community liaison for TRI and the College of Public Health.

Despite Stewart's retirement this year, the future looks bright for her pioneering TRI programs in community engagement and community-based participatory research (CBPR), Davis said.

"Kate has made sure that there's capacity for the programs to continue," she added.

"I could tell right away that she had an understanding of community that I had never seen before."

— Anna Huff Davis

Stewart started the CBPR research program with Davis at her side when the College of Public Health was founded in 2001. Since then, she has witnessed a sea change in how the research world views her field.

"CBPR was not being funded at all at that point, and community engagement was not a mainstream idea," said Stewart, a professor in the college's Department of Health Policy and Management before her retirement.

A key development came in 2009 when Stewart was asked to lead TRI's Community Engagement Program with support from UAMS' first Clinical and Translational Science Award (CTSA). While she was excited for the support, she still had work to do helping the UAMS research community understand the significance of community engagement.

"People didn't know what community engagement is. And when you don't understand something, you may value it less," she said.

Over the years, she and her team have worked to expand the narrow view of community engagement as a tool for recruiting research participants to that of a catalyst for academic partnerships with communities and patients to influence research, to focus on issues important to them, and to work more effectively.

Several signature programs have been launched under Stewart's leadership with a team the TRI's External Advisory Committee recently described as "small but mighty" and guidance from TRI's Community Advisory Board. They include:

- The Community Scientist Academy, which aims to demystify research and increase community understanding of the research process and offer research decision-making opportunities to communities, patients and other stakeholders.
- Community Review Boards, a one-time meeting of community volunteers that provides feedback on a researcher's project, including aims and goals, promotional materials, potential partners, and plans for recruiting participants, usually involving underrepresented populations.
- Community Partner Celebration, an annual event that recognizes the contributions of community groups that have partnered with UAMS researchers.
- Community Partners Educated as Arkansas Research Leaders (CPEARL), a research leadership program for grassroots community organizations.
- Community-Based Participatory Research Scholars Program, which provides training and grant development support to UAMS researchers and their community partners.

"There are so many things that I think have gotten better," Stewart said. "We're not where we need to be, but the new leaders of TRI's community engagement team are doing incredible work and are going to take these efforts to a whole other level. The Community Engagement Program is in very capable hands."

Tiffany Haynes, Ph.D., an associate professor in the College of Public Health, now serves as director of TRI's Community Engagement Program, and Keneshia Bryant-Moore, Ph.D., APRN, FNP-BC, a professor in the college, is associate director.

Stewart is currently working part time on another of her passions — helping to grow and sustain Arkansas' community health worker workforce and the Arkansas Community Health Workers Association (ARCHWA).

"ARCHWA is a very beneficial resource to the work TRI is doing and Mrs. Davis will be key to growing that partnership," she said.

NEW COMMUNITY PARTNERS

FOUR COMMUNITY GROUPS SELECTED FOR 2022-2023 RESEARCH LEADERSHIP PROGRAM

Representatives of four community groups became trainees in TRI's 2022-2023 Community Partners Educated as Arkansas Research Leaders (CPEARL) Program.

Led by TRI's Community Engagement Program, CPEARL targets leaders and emerging leaders within community-based organizations (CBOs) in Arkansas. It aims to foster research partnerships and program development competencies within CBOs.

This year's CBOs, representatives and their project titles are:.

- **Engaging Arkansas Communities; Denise Alanis, Bobby Pierce and Jeff Walker**
  PROJECT: "E-P-I-C Food Pantry" HIV Food Pantry Pilot Project
- **Giving, Others, Ambition, Together (GOAT); Kelvin Parker**
  PROJECT: G.O.A.T Health Initiative
- **Marshallese Educational Initiative; Trina Marty and Marcina Langrine**
  PROJECT: "Oncological Frontiers and the Role of Cultural Stereotypes"
- **The Confess Project; Dimika Nelson and Darnell Rice**
  PROJECT: Barbers as Community Gatekeepers

As part of the CPEARL Program, the CBO representatives attend a three-day in-person workshop at UAMS in Little Rock, plus two virtual trainings.

Academic, practice and community experts provide didactic learning sessions during the training. UAMS researchers serve as mentors to the CBOs throughout the program year.

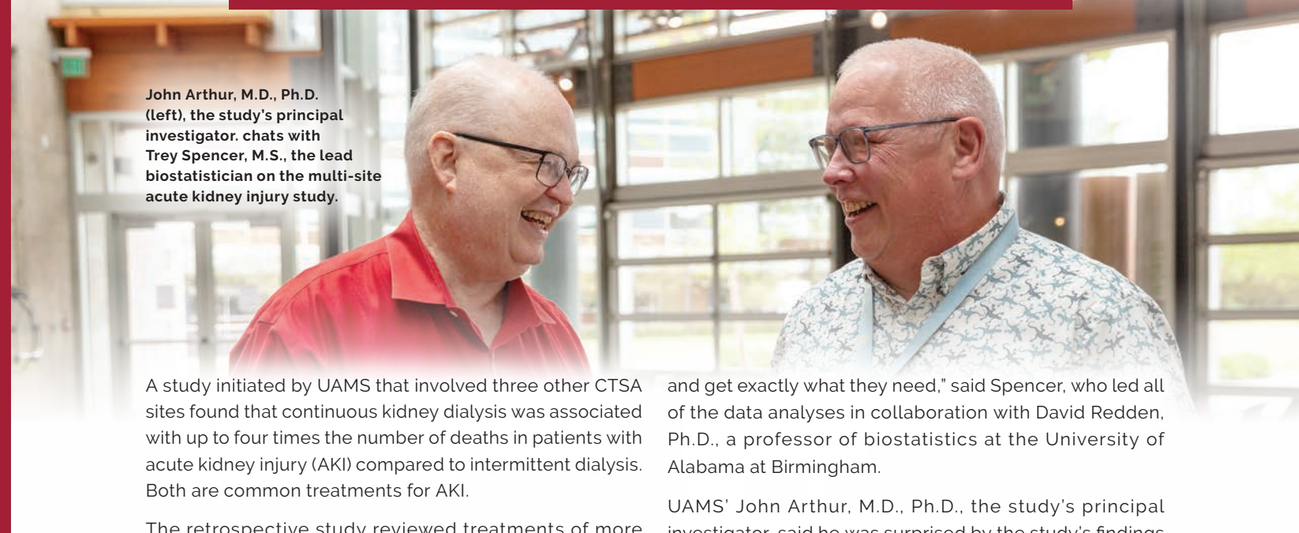
The participants receive up to $2,500 in seed funding to implement a real-world project.

Participants also have the opportunity to apply to participate in the TRI Community-Based Participatory Research (CBPR) Scholars Program. CBPR scholars and their UAMS academic research partners can apply for a TRI pilot award of $25,000 or $50,000.

The 2022-2023 CPEARL class includes, (front row. l-r): Trina Marty and Marcina Langrine (Marshallese Educational Initiative), and Kelvin Parker (Giving, Others, Ambition, Together (GOAT)); (back row): Bobby Pierce, Jeff Walker and Denise Alanis (Engaging Arkansas Communities), and Darnell Rice and Dimika Nelson (The Confess Project).

CTSA Collaboration

UAMS, THREE OTHER SITES HARMONIZE PATIENT DATA, MAKE SURPRISING DIALYSIS FINDING



John Arthur, M.D., Ph.D. (left), the study's principal investigator. chats with Trey Spencer, M.S., the lead biostatistician on the multi-site acute kidney injury study.

A study initiated by UAMS that involved three other CTSA sites found that continuous kidney dialysis was associated with up to four times the number of deaths in patients with acute kidney injury (AKI) compared to intermittent dialysis. Both are common treatments for AKI.

The retrospective study reviewed treatments of more than 4,000 ICU patients from UAMS, the University of Alabama at Birmingham, Medical University of South Carolina and the University of Kentucky — members of the CTSA Southeastern Shared Health Research Informatics Network (SE-SHRINE).

The study took nearly five years to complete, challenging TRI's Biostatistics, Epidemiology and Research Design (BERD) program and Comprehensive Informatics Resource Center (CIRC) program.

"When you have more than one site it always gets more complex," said Trey Spencer, M.S., the lead biostatistician on the study.

Because the sites have different electronic medical records systems, the study required significant coordination, harmonization of the data, checking and resolving discrepancies.

"There was a lot of back and forth — that's what took a lot of time," Spencer said.

Kim Gates, a project manager and part of TRI's CIRC team in the College of Medicine Department of Biomedical Informatics, spearheaded the successful coordination of the project. TRI Research Program Manager Michael Bailey oversaw the myriad of regulatory issues that involved the Institutional Review Board (IRB) at each institution.

"We were able to ensure the definitions were precise so that teams at each institution can query their database and get exactly what they need," said Spencer, who led all of the data analyses in collaboration with David Redden, Ph.D., a professor of biostatistics at the University of Alabama at Birmingham.

UAMS' John Arthur, M.D., Ph.D., the study's principal investigator, said he was surprised by the study's findings that AKI patients who received continuous dialysis (requiring a 24-hour session) were three-to-four times as likely to die as those on intermittent dialysis (four hours per session).

"The mortality rate was high for continuous dialysis even after we adjusted for every factor we could think of," said Arthur, TRI associate director and professor and chief of the Division of Nephrology in the College of Medicine Department of Internal Medicine. "Continuous dialysis is a more gentle procedure that we think should be better, and yet the mortality rate is higher."

"We made a lot of contacts with other sites, and those connections are important."

— Trey Spencer, M.S.

The question is why? Arthur said the research team has some theories, such as that the longer dialysis may be removing antibiotics or essential vitamins and minerals.

"We'll need to conduct a randomized clinical trial to make sense of our findings," Arthur said.

A manuscript was submitted for publication in April 2023.

In addition to providing robust data, Spencer said the experience working with multiple institutions fostered productive relationships.

"We made a lot of contacts with other sites, and those connections are important," he said. "We have and I expect we'll continue to share our expertise and learn from each other."

Peer Power

IMPLEMENTATION SCIENCE SCHOLAR ACHIEVES 20% REDUCTION IN OPIOID DOSING FOR UAMS SURGERY PATIENTS ON VENTILATORS

UAMS surgeon Kyle J. Kalkwarf, M.D., wanted to address opioid prescribing practices in the surgical intensive care unit (SICU) after hypothesizing that some patients were receiving higher doses than necessary. As an initial step, he conducted a study that found a 45% difference between the highest and lowest prescribing physicians from January 2019 to June 2020.

He believed that with the right approach, his group of SICU surgical intensivists could significantly reduce opioid prescribing, and they would do it by choice.

He was right. Kalkwarf's novel approach, developed in the TRI Implementation Science Scholars Program, produced a 20% reduction in opioid use for surgery patients on a ventilator — well above his initial 10% goal.

"The implementation science program gave me a structure and a way to think about the problem. It also allowed me to look at all the ways to ensure buy-in," said Kalkwarf, who was named UAMS trauma medical director in February 2023.

Quality Mentorship

He was mentored by Geoffrey Curran, Ph.D., who leads the TRI program and directs the UAMS Center for Implementation Research.

"The project evolved quite a bit from my original idea, and I think with TRI's support and Dr. Curran's mentorship, we improved its impact," he said.

Kalkwarf's goals, based on Centers for Disease Control and Prevention guidelines, are to treat pain using the minimum required dosage and duration in order to decrease the risk of harmful side effects associated with opioid use, such as tolerance and dependence.

"It is not about making patients endure more pain," said Kalkwarf, an associate professor in the College of Medicine Department of Surgery, Division of Acute Care Surgery. "There are other pain medications that work just as well with few side effects, but the myth is that opioids are better."

Potency Primer

His two-year project began with a survey of UAMS physicians and nurses, which identified knowledge gaps about opioid potency and morphine milligram equivalents (MME) of different opioids. One way he addressed the lack of transparency with opioid potency was by putting the MME for different opioids on an information card that he provided to SICU residents.

> **"This is really great work. I know it has helped me change my practice for the better."**
> **— Katie Kimbrough, M.D.**

The card shows, for example, how potent fentanyl is compared to oxycodone. A physician can quickly see that the most potent prescribed oral opioid is 10 mg of oxycodone every four hours, or 90 MME per day, while intravenous infusions of fentanyl were commonly ordered at a rate of 960 MME per day.

The most influential piece of his project was a prospectively collected review of opioid prescribing practices for all attending physicians. In collaboration with UAMS data experts, Kalkwarf built a database showing how the physicians compared with their SICU peers. The database allows a prescribing physician to see their prescribing history while maintaining the anonymity of the colleagues to whom they are being compared.

Powerful Motivator

After Kalkwarf determined that his colleagues were confident in the accuracy of the data being collected, he let them know their prescribing practices would be tracked in the coming months by an "audit and feedback" system he developed with UAMS pharmacist Brett Bailey, Pharm.D. Between February 2022 and December 2022, the highest prescribers decreased their MME prescriptions to within the rest of the group's range, and the overall opioid prescribing for patients on a ventilator decreased by 20%

"That was a major goal, to decrease the variance," he said. "It gets us to a more appropriate level to reduce the high tolerance for opioids and avoid withdrawal."

Kalkwarf believes that allowing his colleagues to see how they compared with their peers was a powerful motivator.

"Surgeons are competitive by nature, so I'm not surprised," he said.

His colleagues have responded positively. Katie Kimbrough, M.D., an associate professor in the Division of Acute Care Surgery, expressed her gratitude in an email.

"This is really great work," she said. "I know it has helped me change my practice for the better."

Kyle Kalkwarf, M.D.

Kyle Kalkwarf, M.D., used a novel approach to produce a **20% reduction in opioids** prescribed for surgery patients on ventilators.

TRI Announces Five Implementation Science Scholars

TRI and the UAMS Center for Implementation Research (CIR) selected five clinical faculty as 2023 Implementation Science Scholars. CIR faculty use the principles of implementation science to guide the scholars through 10 didactic sessions per year and provide oversight and mentoring for their experiential implementation science projects. The two-year program provides 20% salary support (up to salary cap).

The scholars and their project titles are:

Stephen Foster, M.D., assistant professor, College of Medicine Department of Family and Preventive Medicine, UAMS Northeast Regional Campus
PROJECT: Improving Outcomes for Patients with Chronic Obstructive Pulmonary Disease in the Primary Care Setting through Electronic Health Record Optimization

Chelsea Mathews, M.D., assistant professor, College of Medicine Department of Orthopaedic Surgery, UAMS and Arkansas Children's Hospital
PROJECT: Improving the Patient Experience through Journey Mapping at The Orthopaedic and Spine Hospital

Veronica M. Raney, M.D., assistant professor, College of Medicine Department of Psychiatry; interim director, Division of Child and Adolescent Psychiatry; medical director, Child Study Center, UAMS
PROJECT: Implementation of Specialized Mental Health Services to Address Gaps in Care for Transitional Age Youth (TAY)

Jarna Shah, M.D., assistant professor, College of Medicine Department of Anesthesia, Chronic Pain Division, UAMS
PROJECT: Implementation of Nutrition Screening in Patients Undergoing Elective Joint Replacement Surgery

Shruti Tewar, M.D., MPH, associate professor, College of Medicine Department of Pediatrics, Division of Developmental and Rehabilitative Medicine, UAMS
PROJECT: Implementation of Guidelines for Medication Management of Complex ADHD in Children

QUEST FOR QUALITY

TRI, UC IRVINE TEST COLLABORATION TO IMPROVE STUDY DESIGNS

Although new to academic research centers, the Quality by Design concept has been used in the pharmaceutical industry since 2006, and its principles have been adopted by the U.S. Food and Drug Administration.

Tara Johnson, M.D., hopes the magnetoencephalography (MEG) device at Arkansas Children's Hospital will identify neurodevelopmental disabilities in children with congenital heart disease more quickly than existing methods.

UAMS' Tara Johnson, M.D., carefully designed a study involving infants with congenital heart disease. Then the pediatric neurologist and TRI invited subject-matter experts from UAMS and the University of California, Irvine, to pick it apart.

They did, with Johnson fielding questions and suggestions from the 15-member panel for 90 minutes, helping test a Quality by Design (QbD) program for academic research centers. The purpose of such panel reviews — called Critical-to-Quality (CtQ) Studios — is to prevent potential problems that could imperil a clinical trial.

The panel members included the leader of the QbD initiative, Dan M. Cooper, M.D., a pediatric pulmonologist and director of the Institute for Clinical and Translational Sciences at UC Irvine. He led a QbD study that was published in the Journal of Clinical and Translational Science in 2021. The study concluded that, "Quality by Design principles can be implemented to inform the design and conduct of clinical research at an academic health center using multidisciplinary design studios aimed at identifying and prioritizing Critical to Quality elements."

Other panelists included biostatisticians, a neonatologist, pediatric hospitalist, bioethicist, NICU clinical coordinator, a research nurse practitioner, experts in predictive analytics in neuroimaging, participant recruitment and retention, and clinical trial management.

High Risk

Johnson, a TRI-supported UAMS Clinical and Translational Science Master of Science scholar and former KL2 Mentored Research Career Development Program scholar, began by summarizing her novel study proposal. It aims to use magnetoencephalography (MEG) to identify neurodevelopmental disabilities in children with congenital heart disease more quickly than existing methods. Arkansas Children's Hospital, where Johnson is based, is one of only 20 hospitals with a MEG, a noninvasive biomagnetic device that provides functional imaging to characterize brain activity.

Congenital heart disease is one of the most common birth defects, affecting 1% of the population. Children with single ventricle physiology lack two fully functional ventricles, and the infants' hearts are unable to pump blood and oxygen needed for typical brain development. The condition was 100% fatal until sophisticated surgical techniques were developed only a few decades ago.

Today, while the infants' lives are spared, they are at high risk for a number of neurodevelopmental disabilities such as developmental delay, cerebral palsy, intellectual disability, and speech and language disorders.

"Early detection is crucial," Johnson said. "If we can identify these children early based on their brain waves, and we can say, for example, that our findings are highly predictive of language delay, we could start interventions much earlier than usual."

Constructive and Productive

The panel responded positively to the proposal but also had numerous questions and suggestions.

When the session was over, moderator Jessica Snowden, M.D., vice dean for research in the College of Medicine and chief of the Division of Pediatric Infectious Diseases, offered Johnson encouragement.

"I hope this felt constructive and productive for you, not punitive, because I think you could tell we're all very excited about the idea and what would come from this," said Snowden, who is also co-director of TRI's Translational Workforce Development Program.

Cooper was also enthusiastic, telling the group that it was one of the first QbD/CtQ Studios involving two universities. "This was a fantastic session; what a great group," he said. "Great study, Tara, thank you."

Johnson thanked the panel for its input, noting the many challenges that come with a complex project involving newborns at high risk for poor health outcomes.

"The panel was very helpful," said Johnson, an assistant professor in the College of Medicine Department of Pediatrics. "I want to make sure the study is bullet proof because we have a great opportunity to do something very impactful. And if it's successful here, we can move the research to other centers."

> **"This is a history-making event as one of the first Quality by Design, Critical to Quality Studios across universities."**
>
> **— Dan M. Cooper, M.D., University of California, Irvine**

The CtQ Studio was followed a few weeks later with a report detailing the reviewers' questions and suggestions to improve the likelihood of a successful clinical trial.

TRI Director Laura James, M.D., sees QbD/CtQ Studios being used in future clinical trials, especially pediatrics studies.

"This collaboration with UC Irvine provides us a greater pool of experts to weigh in on the development of cutting-edge trials in pediatrics," said James, a professor in the Department of Pediatrics. "Because children are a vulnerable population and given the complexity of conducting pediatric trials, it's imperative that we ensure the highest level of research quality."

Research Day

Nakita Lovelady, Ph.D., discusses her poster with Melissa Zielinski, Ph.D., at TRI Research Day 2023.

Translational Triumphs

RESEARCH DAY 2023 SHOWCASES SUCCESS, INSPIRES INVESTIGATORS

As a junior faculty researcher, Nakita Lovelady, Ph.D., discovered that TRI Research Day 2023 was an inspiring experience, starting with breakfast.

Lovelady and about a dozen of her peers met the morning of April 4 at Heifer International headquarters with Duane A. Mitchell M.D., Ph.D., an esteemed clinical researcher from the University of Florida (UF), and the Research Day keynote speaker.

"Dr. Mitchell had some great career advice for us as junior faculty who are trying to grow and become independent researchers," said Lovelady, a KL2 Mentored Research Career Development Award Program scholar and assistant professor in the Fay W. Boozman College of Public Health.

The second annual Research Day drew about 150 research faculty and staff and featured TRI-supported projects with eight oral presentations and a poster competition involving 33 posters.

Lovelady said Mitchell, a pioneer in brain tumor immunotherapies, told the group about the importance of focusing, developing good mentoring relationships, and figuring out what to prioritize in their careers so they can reach the necessary benchmarks.

"Hearing his stories about starting out as a researcher was also very inspiring and helpful," she said.

Mitchell, director of the UF Clinical and Translational Science Institute, included similar advice in his keynote presentation and discussed his work developing novel brain tumor immunotherapies that have been translated into first-in-human clinical trials and multi-center phase-two studies. The Phyllis Kottler Friedman Professor in the Department of Neurosurgery has been recognized nationally for his achievements, including this year's inaugural Louis W. Sullivan, M.D. Award from the American Society for Clinical Investigation.

Duane A. Mitchell, M.D., Ph.D., a pioneer in brain tumor immunotherapies at the University of Florida, was the keynote speaker.

Research Day drew about 150 research faculty and staff and featured TRI-supported projects with oral presentations and a poster competition.

Fred Prior, Ph.D., listens to keynote speaker Duane A. Mitchell, M.D., Ph.D.

Bolni Nagalo, Ph.D., takes notes at Research Day.

IN THEIR OWN WORDS

Research Day was an opportunity for researchers to network, gather ideas and feed off the enthusiasm of their UAMS peers – many they saw in person for the first time.

Here is what some had to say:

"As a junior faculty, taking part in TRI Research Day is almost like exposure therapy—being exposed to multiple researchers' projects, wins and barriers always gets my creative juices flowing with future health services research ideas." — **Leah Tobey, PT, DPT, MBA,** *an instructor and academic detailer at the Center for Health Services Research, UAMS College of Medicine Department of Psychiatry, and a clinician at the UAMS Chronic Pain Clinic.*

"Research Day was extremely interesting, and it was quite useful for me hearing about the discoveries that were presented and having the opportunity to meet new people, including potential new collaborators." — **Oleg Karaduta, M.D.,** *director of research and assistant professor, College of Health Professions Department of Physician Assistant Studies*

"The presentations were really good. It shows how much TRI funding has been helping so many young researchers, and even established researchers, to extend their research. It's exciting to see all of the wonderful work that researchers have done at UAMS." — **Chenghui Li, Ph.D.,** *associate professor, College of Pharmacy*

"It's really nice to see how enthusiastic everyone is about translational research. Last year I was here, but totally fresh and green having just graduated from the Department of Biomedical Informatics. This year I'm excited to be here to network, learn and present on behalf of the College of Pharmacy." — **Adrian Williams, M.S.,** *research program manager, College of Pharmacy*

"Today is a great way to see what kind of research initiatives are happening around the institution that I would never have known about otherwise." — **Kristen Alexander, MPH, MPS,** *Brain Injury Program, Institute for Digital Health & Innovation*

"I enjoy attending TRI Research Day because it promotes idea generation for future research projects and potential collaborations. Hearing about the ongoing and completed projects provides great role models for clinical researchers to understand various ways they can get involved and utilize the different TRI opportunities." — **Meghan Breckling, Pharm.D., BCACP,** *academic detailing pharmacist, and clinical pharmacy specialist, ambulatory care.*

"I enjoyed seeing everyone and learning about all the different research projects that are supported by TRI. Being a KL2 scholar, it was great seeing all of the other scholars in person and to hear everyone talk about their research." — **Nakita Lovelady, Ph.D.,** *assistant professor, Fay W. Boozman College of Public Health.*

TRI Director Laura James, M.D., presents the Overall Impact poster award to Eva Woodward, Ph.D., and Irenia Ball.

RESEARCH DAY 2023 POSTER CONTEST WINNERS

Poster awards were presented in five categories, judged by five faculty leaders. The winners, prizes and posters titles are:

OVERALL CONTENT

Cody Ashby, Ph.D., assistant professor, College of Medicine Department of Biomedical Informatics; prize – paid manuscript submission fee
Investigating the Landscape of Alternative Splicing in Multiple Myeloma

OVERALL DISCUSSION

Akilah Jefferson, M.D., assistant professor, College of Medicine Department of Pediatrics; prize – paid manuscript submission fee
Relationships Between Geospatial Factors and Adverse Outcomes in Medicaid-enrolled Children with Asthma

OVERALL VISUAL

Jennifer Rumpel, M.D., assistant professor, College of Medicine Department of Pediatrics; prize – free statistical consultation for study planning
ADVANCE: Advancing Care of Neonates with Acute Kidney Injury Utilizing the Children's Hospitals Neonatal Consortium Database

OVERALL IMPACT

Eva Woodward, Ph.D., assistant professor, College of Medicine Department of Psychiatry; prize – manuscript submission
Adapting Suicide Safety Planning Intervention for Veterans to be Delivered Outside Healthcare Settings in Rural Areas

Poster judge Peter Mourani, M.D., listens as Yong-Chen Lu, Ph.D., discusses his work.

Samjhana Shakya, Ph.D., discusses her poster with Duane Mitchell, M.D., Ph.D.

Akilah Jefferson, M.D., presents on her KL2-supported research.

Tiffany Miles, Ph.D., a TRI Health Sciences Innovation and Entrepreneurship trainee, presents her work.

Cody Ashby, Ph.D., presents on his KL2 project.

ORAL PRESENTATIONS HIGHLIGHT WORK IN TRI-SUPPORTED PROGRAMS

Research Day 2023 included oral presentations from eight researchers in four TRI-supported programs, listed below with their presentation titles:

KL2 Mentored Research Career Development Scholars

Akilah Jefferson, M.D., assistant professor, College of Medicine Department of Pediatrics, Division of Allergy and Immunology
Assessing Risk, Outcomes, and Disparities in Pediatric Asthma

Cody Ashby, Ph.D., assistant professor, College of Medicine Department of Biomedical Informatics
The Impact of Race and Location on Multiple Myeloma Outcomes in Arkansas

TL1 Health Sciences Innovation and Entrepreneurship Trainees

Tiffany Miles, Ph.D., postdoctoral fellow, College of Medicine Department of Neurobiology & Developmental Sciences
A HSIE Scholar's Pursuit Toward Translational Research

Julia Tobacyk, Ph.D., postdoctoral fellow, College of Medicine Department of Pharmacology & Toxicology
Treatment Strategies for Opioid Use Disorder in Pregnant Women

Pilot Awardees

Nick Zaller, Ph.D., professor, Fay W. Boozman College of Public Health Department of Health Behavior & Health Education
Proposed Development of the Criminal Justice Translation and Clinical Science (CJ-TRACS) Network

Eva Woodward, Ph.D., assistant professor, College of Medicine Department of Psychiatry; clinical psychologist and investigator, Central Arkansas Veterans Healthcare System
Adapting Safety Planning Intervention for Veterans to Be Delivered Peer-to-Peer Outside Healthcare Settings in Rural Areas

Implementation Science Scholars

Johnathan Goree, M.D., associate professor and director, Division of Chronic Pain, College of Medicine Department of Anesthesiology
Implementation of Safe Opioid Prescribing

Elizabeth Riley, DNP, APRN, CPNP-AC, PED-BC, RNC-NIC-CNE, ANEF, clinical associate professor, College of Nursing, Neonatal Intensive Care Unit
Bedside Interprofessional Rounding (IPR) in the NICU

Maryam Garza, Ph.D., and Tremaine Williams, Ed.D., share a laugh during a meeting.

"We are going to grow old together as collaborators. And who knows, maybe we'll win the Nobel Prize."
— Maryam Garza, Ph.D.

Complementary Talents

KL2 MEETING SPARKS JUNIOR INVESTIGATORS' COLLABORATION, THREE PUBLICATIONS

A routine monthly meeting, a comment and a question were the genesis for three publications in 2022 by two TRI KL2 Mentored Research Career Development Program scholars.

Maryam Garza, Ph.D., MPH, MMCi, and Tremaine Williams, Ed.D., who became KL2 scholars in 2021, are co-authors on papers in *BMC Medical Research Methodology, the Journal of Multimorbidity* and *Comorbidity, and the Journal of the American Medical Informatics Association.* By March 2023, they had three additional manuscripts under review and a poster accepted to the ACTS Translational Science 2023 Conference in Washington, D.C.

Carolyn Greene, Ph.D.

Elisabet Borsheim, Ph.D.

John Arthur, M.D., Ph.D.

For Garza and Williams, assistant professors in the College of Medicine Department of Biomedical Informatics, their early success speaks to the testimonies they have heard about the power of collaboration and team science.

"As early career investigators and KL2 scholars, we're trying to carry out our research, write papers and grants, and it's a lot to get done by yourself," Garza said. "So collaboration is really helpful to get you out of any holes and elevate the quality of the work. It is also much more enjoyable to not be alone in this work."

Williams agreed. "When I've taken a project as far as I can, I know I can go to Maryam, and she will have some questions, suggestions or substantial contributions to guide the direction of the work."

The two realized the opportunity for collaboration during a regular monthly meeting of the KL2 scholars as Williams gave his status report. He heard Garza say, "Ooh, I didn't realize how much our worlds intersect."

Her comment prompted him to ask the group if anyone was interested in collaborating. "Maryam was the first person to say, 'Yes, I would love to collaborate,' so it went from there," he said.

Both are working in the area of data quality, and their worlds intersect at how to streamline processes of getting that data from point A to point B.

Garza's work is focused on overcoming data-related barriers that slow the search for cures and vaccines.

Williams' work has focused on expanding the informatics capacity of the electronic health record to support patients with two or more chronic conditions, referred to as multimorbidity patients.

Williams said their collaboration was enabled in large part because of the tone set by the KL2 Program leaders, John Arthur, M.D., Ph.D., Elisabet Borsheim, Ph.D., and Carolyn Greene, Ph.D.

"The environment in the monthly KL2 meetings is very warm, very supportive," Williams said.

"The environment in the monthly KL2 meetings is very warm, very supportive."
— Tremaine Williams, Ed.D.

Hoping to capitalize on their efforts, Garza and Williams plan to resubmit an NIH R01 grant application this summer. And beyond that, they are dreaming big.

"We are going to grow old together as collaborators," Garza said, "and who knows, maybe we'll win the Nobel Prize."

Beyond Conception

KL2'S WORK YEILDS NIH GRANT TO STUDY URGENT HEALTH NEEDS OF PREGNANT MARSHALLESE WOMEN

KL2 Scholar Britni Ayers, Ph.D., and a team in northwest Arkansas are implementing a novel clinical study that aims to address the urgent health needs of pregnant Marshallese women.

Ayers, who completed TRI's two-year KL2 Mentored Research Career Development Scholar Award program in 2022, used the protected time to prepare her unique intervention for adoption on a larger scale. She was rewarded with a two-year, $420,750 R21 grant from the National Institute of Nursing Research at the National Institutes of Health (NIH).

"The KL2 program was a wonderful experience," Ayers said. "I learned a lot and it gave me time to really focus on fine tuning the implementation of my study. My publications also doubled when I had the KL2."

Since receiving the award, Ayers has been first author on eight publications and co-author of seven.

High Infant Mortality

Ayers hopes the study involving small groups of pregnant women, known as CenteringPregnancy, will show that it is effective, can be expanded further and sustained well into the future.

"Pregnant Marshallese women in Arkansas are experiencing urgent health needs, and we have the potential to move the needle tremendously with this type of concept," she said.

Pacific Islanders/Marshallese living in the United States have almost twice the infant mortality rate as non-Hispanic whites. Arkansas is home to the country's largest population of Marshallese, about 14,000 residents, mostly in the northwestern part of the state.

Ayers' preliminary research found that 15% of Marshallese women in Arkansas received no prenatal care (compared to 1.6% of women nationally); 19% of Marshallese infants were born preterm (compared to 9.6% nationally); and 15% were low birthweight (compared to 8.3% nationally).

Arkansas is home to the country's largest population of Marshallese, about 14,000 residents.

Overcoming Fear

Marshallese women face a number of barriers to medical care, including language, transportation and lack of information to help navigate the medical system and access resources.

"They are fearful of the medical system," said Ayers, an assistant professor at UAMS Office of Community Health & Research in Springdale. "It's ubiquitious — Marshellese women have expressed fear of the prenatal care process in all of our focus group interviews."

CenteringPregnancy programs have proved effective in other areas of the United States, but it has not been tried with Pacific Islanders/Marshallese women. It should be a good fit for the population, Ayers said.

"The Marshallese culture is collectivist. They value the group more than the individual, so I think any sort of group health care will be a better way to reach this population," she said.

Ayers is recruiting 40 Marshallese women to take part in 90-minute small-group sessions. The sessions include a bilingual CenteringPregnancy-trained Marshallese registered nurse and other prenatal health professionals providing brief one-on-one examinations and leading discussion of pregnancy topics at each of the 10 prenatal sessions. Additionally, all participants are provided a bilingual Marshallese care navigator to aid in assessment and enrollment in social support services.

Britni Ayers, Ph.D. (center), is leading the study with bilingual CenteringPregnancy-trained Marshallese team members who include Lynda Riklon, program coordinator (left), and Merely Mack, outreach associate.

KL2 SCHOLAR RECEIVES PRESTIGIOUS NATIONAL AWARD, $1 MILLION TO SUPPORT FALLS RESEARCH IN OLDER ADULTS

Jennifer L. Vincenzo, Ph.D.

Jennifer L. Vincenzo, Ph.D., MPH, PT, became the first UAMS researcher to receive the national Paul B. Beeson Emerging Leaders Career Development Award in Aging, which comes with $1 million over five years.

The award supports Vincenzo's work implementing a falls prevention strategy as a standard of care for all older adults attending outpatient physical therapy clinics. She established her fall prevention self-management plan through work supported by a UAMS Translational Research Institute KL2 Mentored Research Career Development Award. She credits the KL2 support that began in 2019 as a key to her success.

The Beeson award stems from an initiative by the National Institute on Aging (NIA) at the National Institutes of Health (NIH), the American Federation for Aging Research, and the John A. Hartford Foundation. Their aim is "to develop a cadre of talented scientists prepared and willing to take an active leadership role in transformative change that will lead to improved health care outcomes," according to the American Federation for Aging Research website.

Vincenzo is only the third physical therapist to receive the award, which typically goes to medical doctors.

Nine KL2 Scholars Named for 2022-2023

TRI's KL2 Mentored Research Career Development Scholars Program named nine new scholars for 2022-2023, its largest class.

The program selects promising early-career researchers through a competitive application process and provides two years of funded support (75% salary support and up to $25,000 a year for research, tuition, travel and education), plus mentored translational research training.

Additional scholars were selected this cycle thanks to funding support from the College of Medicine, Winthrop P. Rockefeller Cancer Institute, Arkansas Children's Research Institute and Central Arkansas Veterans Healthcare System.

The new scholars are:

JENNIFER ANDERSEN, PH.D., assistant professor, Northwest Regional Campus, Office of Community Health & Research

TIMOTHY "CODY" ASHBY, PH.D., M.S., assistant professor, College of Medicine Department of Biomedical Informatics

NISHANK JAIN, M.D., assistant professor, College of Medicine Department of Internal Medicine, Division of Nephrology

AKILAH JEFFERSON, M.D., M.SC., assistant professor, College of Medicine Department of Pediatrics, Division of Allergy and Immunology

NAKITA LOVELADY, PH.D., MPH, assistant professor, Fay W. Boozman College of Public Health Department of Health Behavior and Health Education

SAYEM MIAH, PH.D., assistant professor, College of Medicine Department of Biochemistry and Molecular Biology

DEEPA RAGHAVAN, M.D., assistant professor, College of Medicine Department of Internal Medicine, Division of Pulmonary and Critical Care; medical director, VA Medical ICU

JENNIFER RUMPEL, M.D., assistant professor, College of Medicine Department of Pediatrics, Neonatology Section

AMY SATO, PH.D., assistant professor, College of Medicine Department of Physiology and Cell Biology

"The TRI grant was enough to open doors, and I was able to meet new people, recruit new collaborators and develop new ideas."
— Bolni "Marius" Nagalo, Ph.D.

SPARKLING STARs

TRI PROGRAM NURTURES DEVELOPMENT OF UNDERREPRESENTED FACULTY

STARs participant Bolni "Marius" Nagalo, Ph.D., said the grant-writing program was a "fantastic experience."

Bolni "Marius" Nagalo, Ph.D., seized on every opportunity that came with the inaugural Strategies for Training and Advancing underrepresented Researchers (STARs) Program.

As a new researcher focused on drug development at the Winthrop P. Rockefeller Cancer Institute, he thought the fall 2021 program would be a good way to improve his grant-writing skills, learn more about UAMS and TRI, and meet colleagues.

"It was a fantastic experience," said Nagalo, an assistant professor in the College of Medicine Department of Pathology, who was recruited to UAMS last year from the Mayo Clinic.

The three-month program, a partnership with the UAMS Division for Diversity, Equity and Inclusion, offers grant-writing training, mentoring support and $10,000 in Equity, Diversity, and Grantsmanship Expertise (EDGE) funding. Underrepresented faculty participants may include racial and ethnic groups, individuals with disabilities, and those from disadvantaged backgrounds.

In addition to honing his grant-writing skills, Nagalo received a $10,000 STARs grant that helped him secure a recent three-year $300,000 American Association for Cancer Research (AACR) Career Development Award. He also found a collaborator and mentor in STARs Program lecturer Alexei Basnakian, M.D., Ph.D. Together they have published three papers and submitted an NIH R01 application. Basnakian is a professor in the College of Medicine Department of Pharmacology and Toxicology.

"The TRI grant was enough to open doors, and I was able to meet new people, recruit new collaborators and develop new ideas," Nagalo said.

He credits the grant-writing sessions and the data produced with the grant support for improving the competitiveness of his AACR application as well as strengthening his NIH R01 application. He also successfully applied for Cancer Institute's $100,000 Team Science Award.

The awards will help Nagalo further his novel research on virotherapy to treat advanced pancreatic ductal adenocarcinoma.

Other STARs participants also significantly advanced their research in 2022.

Michael Bauer, Ph.D., a multiple myeloma researcher, credits the STARs program for helping him secure a two-year $336,314 NIH National Cancer Institute Research Supplement to Promote Diversity in Health-Related Research, as well as this year's $50,000 Seeds of Science grant from the Cancer Institute.

Bauer's NCI grant is a supplement to an NCI R01 award led by Fenghuang Zhan, M.D., Ph.D., a professor in the College of Medicine Department of Internal Medicine based at the Winthrop P. Rockefeller Cancer Institute.

"The STARs program was a tremendous help to improving my grant-writing skills."
— Michael Bauer, Ph.D.


Michael Bauer, Ph.D.


Dina Jones, Ph.D.


Jennifer Andersen, Ph.D.

Zhan's grant is supporting research of NEK2, a gene with a key role in myeloma cell survival, drug resistance and overall disease progression. Bauer's supplement aims to complement Zhan's work by using third-generation sequencing and a multi-omic approach to identify genomic structural aberrations, changes in downstream gene/transcript expression and methylation patterns that can be attributed to high NEK2 expression.

"The STARs program was a tremendous help to improving my grant-writing skills," said Bauer, an assistant professor in the College of Medicine Department Biomedical Informatics. "The ability to go through writing a grant line by line with constructive critiques from the instructors was invaluable. I am much more confident in my grant writing now."

STARs participant Dina Jones, Ph.D., recently received a five-year, $733,000 K01 career development award from the NIH National Institute on Drug Abuse. Her research is focused on better understanding the social factors and role of tobacco product characteristics, particularly with Black/African American menthol cigarette smokers, and developing interventions to help disadvantaged populations quit tobacco.

Although she submitted her successful K01 application prior to her STARs participation, Jones said, "The feedback that I got on my proposal and the refinement of my grant writing skills during the STARs program will benefit me well into the future."

Jones, an assistant professor in the Fay W. Boozman College of Public Health, is using the $10,000 STARs seed funding to partially support a pilot study of Black and white smokers who will attempt to quit smoking. The resulting data will help her develop interventions to prevent relapse.

Jennifer Andersen, Ph.D., whose research is focused on addressing the health needs of underserved and minority communities using digital health technologies, also secured a $10,000 STARs grant in 2021.

The funding helped her successfully apply for a TRI KL2 Mentored Research Career Development Program Award. An assistant professor based at the UAMS Office of Community Health & Research in Springdale, Andersen is using the KL2 award to explore the feasibility and acceptability of a remote glucose monitoring program for Marshallese women whose pregnancies are complicated by pre-gestational and gestational diabetes.

FOUR RECEIVE STARS TRAINING, SEED FUNDS IN 2022

The Strategies for Training and Advancing underrepresented Researchers (STARs) Program provided training and seed funding to four recipients in 2022. Supported by TRI and the UAMS Division for Diversity, Equity and Inclusion (DDEI), the program offers grant-writing training, mentoring support, and $10,000 in Equity, Diversity, and Grantsmanship Expertise (EDGE) funding.

Following the three-month training program, scholars receive ongoing mentoring during their EDGE project. The STARs awardees and their project summaries are:

JAIMI "MIMI" ALLEN, PH.D., instructor, College of Public Health
PROJECT: Exploring work disparities and the potential role of physical activity in addressing work outcomes in cancer survivors through reduction in fatigue and improved cognitive functioning.

DAVID CHURCH, PH.D., assistant professor, College of Medicine Department of Geriatrics
PROJECT: Characterizing the muscle phenotype of patients with head and neck cancer with stable isotope tracers (D3-creatine) and an oral amino acid challenge curative treatment process in patients with head and neck cancer.

MARIE RACHELLE NARCISSE, PH.D., assistant professor, College of Medicine, Office of Community Health and Research
PROJECT: Using data on ambient light exposure and blood serum vitamin D levels to determine associations between these two factors and depression among cancer survivors.

RAMONA RHODES, M.D., associate professor, College of Medicine Department of Geriatrics
PROJECT: Describing the natural history of dementia care among veterans who receive their care within the South Central VA Health Care Network to identify racial, ethnic and geographic disparities with the ultimate goal of designing multi-level interventions to address barriers to care for rural and underrepresented populations.

'Secret Sauce'

HSIE TRAINING AIDS STTR-FUNDED DIAGNOSTIC FOR RARE KIDNEY DISEASE

Aaron Storey, Ph.D., hopes to commercialize a mass spectrometry-based workflow as a service that can identify and classify all the antigens associated with membranous nephropathy.

A project that Aaron Storey, Ph.D., started as a postdoctoral fellow and TRI Health Sciences Innovation and Entrepreneurship (HSIE) trainee in 2019 has helped secure NIH Small Business Technology Transfer (STTR) funding totaling more than $2 million.

The funding is supporting development of a precision medicine-based diagnostic tool for membranous nephropathy, an autoimmune disorder in which immune complexes in the blood build up in the kidney and impair renal function.

Storey's work with Chris Larsen, M.D., executive director of Arkana Laboratories and co-principal investigator on the project, led to a one-year, $250,000 phase 1 STTR contract (1R41DK130702) in 2021, followed by a $1.9 million phase 2 contract (2R44DK130702-02) in 2022. Arkana processes about a third of all kidney biopsies in the United States, enabling it to provide tissue samples for the study.

Storey is also co-author of an article featured on the March 2023 cover of the journal *Kidney International*, titled, "Discovery of Seven Novel Putative Antigens in Membranous Nephropathy and Membranous Lupus Nephritis Identified by Mass Spectrometry." The work was supported in part by the 2021 STTR funding.

As an HSIE trainee, Storey built an interactive computer dashboard to help make sense of vast amounts of proteomics data. The dashboard, he said, has been the "secret sauce" for development of the diagnostic tool — a mass spectrometry-based assay for typing membranous nephropathy from renal biopsies. Custom-designed for the membranous nephropathy project, it has helped identify several of the antigens responsible for the condition, which affects about 30,000 adults in the United States each year.

"The dashboard has paid dividends because I can organize the proteomics data analysis in a way that's much more efficient for identifying and drawing insights from these large proteomics datasets," said Storey, an assistant professor in the College of Medicine Department of Biochemistry and Molecular Biology.

"We've used the dashboard and our workflow to identify and study several novel antigens associated with membranous nephropathy," he said.

The team's goal is to commercialize its mass spectrometry-based workflow as a service that can identify and classify all the antigens. Storey hopes it will translate to personalized treatments that reduce the need for multiple kidney biopsies.

Samir Jenkins, Ph.D., Amanda Stolarz, Pharm.D., Ph.D., and Aaron Storey, Ph.D., are advancing translational research using their TRI-supported entrepreneurship training and NIH small business funding.

ENTREPRENEURSHIP TRAINEES TEAM UP, PURSUE NOVEL CHEMOTHERAPY

For Amanda Stolarz, Pharm.D., Ph.D., inspiration as a postdoctoral fellow from a UAMS Entrepreneurship Boot Camp in 2016 has led to new opportunities and success.

Now an assistant professor in the College of Pharmacy Department of Pharmaceutical Sciences, Stolarz said the training inspired her to co-found Rejuvenics Technologies LLC (doing business as Rejuvenix), which has made strides advancing a patented technique for delivering chemotherapy drugs to tumor cells.

The boot camp training program, supported by TRI, was the foundation for TRI's Health Sciences Innovation and Entrepreneurship (HSIE) Program, a two-year program established in 2019. It continues the boot camp's key partnership with the University of Arkansas Sam M. Walton College of Business, and it includes coursework and opportunities for collaboration and business team development.

Thanks in part to a collaboration that began in 2019 with then-HSIE trainee Samir Jenkins, Ph.D., Rejuvenix secured a $438,213 NIH Small Business Innovation Research (SBIR) contract (75N91020C00054).

Robert Griffin, Ph.D.

UAMS' Robert Griffin, Ph.D., Rejuvenix's vice president of Research and Development, led the successful SBIR application process in 2020. Griffin is a professor and radiation biologist in the College of Medicine Department of Radiation Oncology. He is also Jenkins' mentor and manages the research projects.

The team co-authored the paper, "Liposome Formulation for Tumor-Targeted Drug Delivery Using Radiation Therapy," in the *International Journal of Molecular Sciences* in October 2022.

Jenkins, now a research instructor, found in 2019 that his knowledge of nanomaterials and chemical science was a good fit for the Rejuvenix project, which aims to reduce the side effects of chemotherapy by delivering and releasing the drugs directly to the tumor.

A key to the project is development of a liposome (microscopic bubble made from lipids) that can release its drug payload inside the tumor only when hit by precision-focused radiation.

A key to the project is development of a liposome (microscopic bubble made from lipids) that can release its drug payload inside the tumor only when hit by precision-focused radiation.

The team wrapped up work on the first SBIR contract in 2022, establishing a proof of concept with animal data, and has applied for a phase 2 SBIR.

New Researchers Find Valuable Resources at Research Expo 2022

Zhong Su, Ph.D., MBA, visits with Nancy Rusch, Ph.D., and Pam Kahler, representing TRI's Health Sciences Innovation and Entrepreneurship Training Program for postdoctoral fellows.

Research Expo 2022 arrived at a great time for Lisa Jansen, Ph.D., and more than 100 other researchers wanting to learn about and leverage the numerous research resources available at UAMS, Arkansas Children's Research Institute (ACRI) and the Central Arkansas Veterans Healthcare System (CAVHS).

"I am a new researcher, so I came to the Expo today to learn about all the options and possibilities that are out there," said Jansen, who joined UAMS in January 2022 as an assistant professor in the College of Health Professions Department of Dietetics and Nutrition. "I love being able to directly ask questions to the representatives of these services. It's better than just clicking on a website."

Sponsored by TRI and the Division of Research and Innovation, the Research Expo promoted at least 47 research services and resources. The late afternoon event included food, beverages and door prizes. The event has grown from its origins six years ago to include research resources from UAMS, ACRI and CAVHS.

Nadim Nicolas Ghanem, M.D., a first-year fellow in the TRI-supported UAMS/Arkansas Children's Clinical Informatics Fellowship Program, is new to the United States, so having face-to-face conversations with people at the expo was especially valuable, he said.

"Seeing all the available resources for research was great for someone like me coming from abroad," Ghanem said. "It was a great day to meet new people and to learn more about the different tools I can potentially use in research."

Jansen pointed to the Center for Implementation Research and Center for Health Literacy as examples of newly discovered beneficial resources.

"They can help me with clinical trials as I am setting them up to ensure that they go smoothly and the methodology is sound," Jansen said.

Lisa Jansen, Ph.D

"I love being able to directly ask questions to the representatives of these services. It's better than just clicking on a website."

— Lisa Jansen, Ph.D.

"It was a great day to meet new people and to learn more about the different tools I can potentially use in research."

— Nadim Nicolas Ghanem, M.D.

The Research Expo promoted at least 47 research services and resources.

Nadim Nicolas Ghanem, M.D. (right), visits with Joe Schaffner of the Institute for Digital Health & Innovation.

Better, Faster

NEW SOFTWARE STREAMLINES TRI GRANT APPLICATIONS

"We want to be a world-class research institution at every level, and this new software program is one exciting way to up our game."

— Carolyn Greene, Ph.D.

TRI's Paul Duguid, MPH, and Carolyn Greene, Ph.D., have led TRI's acquisition and rollout of the Apply software.

This year, researchers applying for any of six TRI funding opportunities began using a new software program that vastly improves and simplifies the process for applicants, reviewers and TRI administrators.

The software program, called Apply, standardizes processes across the board, delivering an array of short- and long-term benefits, including a functional system that is comparable to the NIH review process.

It was time for an upgrade, said TRI's Carolyn Greene, Ph.D., associate director of Programmatic and Strategic Planning.

"We want to be a world-class research institution at every level, and this new software program is one exciting way to up our game," she said.

The number of TRI funding opportunities has grown substantially since UAMS became a National Institutes of Health (NIH) Clinical and Translational Science Awards (CTSA) Program site in 2009. Staff in multiple TRI programs have managed the grant programs with Research Electronic Data Capture (REDCap), Excel spreadsheets and Outlook email to coordinate and track applications, reviews and post-award reports. A single application cycle typically involves about 10 applicants and 10 reviewers.

"This is another example of how TRI uses innovative processes to make our research enterprise better, more efficient."

— Paul Duguid, MPH

With the Apply program, TRI now has a tool that not only streamlines processes but also ensures that its funding programs are equitable, fair and transparent, said Paul Duguid, MPH, assistant director of TRI Funding Programs.

"This is another example of how TRI uses innovative processes to make our research enterprise better, more efficient," Duguid said.

Researchers will encounter an application form that quickly determines their eligibility and lets them know what is required to complete their submissions. It allows applicants to add collaborators, to upload a variety of file types, including videos, and to request blinded recommendations. For researchers who apply for more than one funding opportunity, the form prepopulates their information where appropriate.

"It is going to increase the comfort level of the investigator who is applying for TRI funding," Duguid said. "No matter what they are applying for, they will have a clear picture of what we're asking for and what it's going to look like when they apply."

Reviewers of the applications also have a more streamlined experience, including an automated email when applications are submitted, and an option to download the form and materials for offline review.

Reviewers can also use an analytical process to help them strengthen their own critiques. Once a review is complete, the program sends an auto-generated email to a TRI administrator for the next stage in the workflow.

The Apply software provides administrators a customizable, automated way of tracking all parts of the application and review process, as well as post-award reports.

Apply's data tracking capability is one of the more exciting aspects of the new program, Greene and Duguid said, with an enhanced ability to keep better records and learn over time what makes a project successful and what red flags there may be.

"We can build a history with researchers, understanding what they're doing and what kind of support they need," Greene said. "For example, we can find opportunities for people to collaborate because we'll have an easy way of knowing who is doing what and more ways that we can find commonalities."

Duane Mitchell, M.D., Ph.D. and Laura James, M.D.

TRI Director Laura James, M.D., here with Duane Mitchell, M.D., Ph.D., at TRI Research Day, served as co-chair of the **CTSA Steering Committee** in 2022. Mitchell became co-chair earlier this year.

CTSA Leadership Post 'Invaluable' for TRI Director

TRI Director Laura James, M.D., recently concluded a year's national service as the co-chair for the Clinical and Translational Science Awards (CTSA) Steering Committee.

Her committee membership continues through Dec. 31, 2023, although her role shifted this year to supporting 2023 Co-Chair Duane Mitchell, M.D., Ph.D., principal investigator for the University of Florida CTSA.

"The experience has been invaluable," said James, UAMS associate vice chancellor of Clinical and Translational Research and the first to represent Arkansas on the Steering Committee.

She shared co-chair duties in 2022 with Michael Kurilla, M.D., Ph.D., who oversees the CTSA Program as director of the Division of Clinical Innovation at the NIH National Center for Advancing Translational Sciences (NCATS).

As one of 10 CTSA principal investigators (PIs) on the committee, James said the experience was rich with relationship building and information and idea sharing among her peers and NCATS leadership.

"I learned a lot listening to their unique perspectives and hearing about their successful approaches," she said. "It has benefited me as a CTSA leader, and it benefits our CTSA at UAMS."

UAMS is one of about 60 CTSAs across the U.S., and one of the few representing a rural southern state.

"I learned a lot listening to their unique perspectives and hearing about their successful approaches. It has benefited me as a CTSA leader, and it benefits our CTSA at UAMS."

— Laura James, M.D.

"Our CTSA offers the unique perspective of a rural state with tremendous health disparities," James said.

"At TRI, we have multiple nationally recognized programs that are providing research solutions to address the health care needs of populations underrepresented in research and that are likely to experience health disparities.

"The great promise of clinical and translational research is that the findings are relatable to individuals here in Arkansas. Faculty and staff members at TRI have worked to ensure that our research is meaningful to Arkansans. We are also finding that our successes connect with the needs of multiple groups across the U.S."

As an example, she cited a TRI-supported COVID-19 study led by Pearl McElfish, Ph.D., MBA. Published by the journal Clinical and Translational Science, the paper on vaccine hesitancy became the publication's most downloaded article in 2021 and 2022 and the top-cited paper in 2022.

"This illustrates that our CTSA-supported programs are influencing investigators across the U.S. and impacting how we as researchers are addressing unmet health challenges," James said.

Turnkey Trials

TRI OVERSEES UNPRECENDENTED INCREASE IN CLINICAL TRIALS

Recent growth in TRI-supported clinical trials is unparalleled in its 14-year history. Since receiving its five-year CTSA in July 2019, TRI has helped launch and conduct 292 studies, a seven-fold increase over the period.

"Our trials have really grown dramatically; last year we had over 1,600 individuals enrolled in clinical trials around our state," said TRI Director Laura James, M.D. "The thing I'm proudest of is that our research participants reflect the demographics of Arkansas' population."

"The thing I'm proudest of is that our research participants reflect the demographics of Arkansas' population."

— Laura James, M.D.

Many factors have contributed to the increase, including COVID-19 and the inspired research to combat it, innovations to speed the pace of clinical trial implementation, and the 2020 establishment of the Rural Research Network, James said.

"The pandemic brought challenges as well as new opportunities in clinical and translational science," she said. "A lot of clinicians volunteered to conduct COVID-19 trials, and that experience has helped increase the number of clinical trialists at UAMS."

TRI has also expanded its clinical trial infrastructure and streamlined its processes, automating many of them. The improvements helped spur clinical trials growth, aiding investigators locally and across the CTSA consortium.

"Clinical trials have become more of a turnkey operation, which has significantly reduced the burden for researchers, and our systems are more efficient for staff, as well," James said.

TRI's suite of software tools integrates multiple clinical trial-related functions including institutional review board (IRB) submission, budget development and accounting, and study-specific research activities.

"We provide everything an investigator needs to conduct a clinical trial," James said.

The addition of the TRI-supported Rural Research Network in 2020 has enlarged UAMS' research footprint across Arkansas. The network was on track to begin its 14th research project by June 30, 2023.

"We're very proud of the fact that we are taking UAMS research beyond Little Rock and extending it out into the state," James said.

In addition to increasing rural research participation, TRI has significantly improved diversity in other areas. For example, by fiscal year 2022, the number of Black/African Americans enrolled in trials surpassed that of whites.

"We highly value inclusiveness in clinical trial enrollment because this means that the knowledge we gain from trials has broader application to more individuals in Arkansas," James said. "It is important that our trials ultimately support improving the health of all Arkansans, not just a subset of our population."

The CTIU oversaw a **seven-fold increase in clinical trials** from the beginning of its CTSA funding cycle on July 1, 2019, to Dec. 31, 2022.

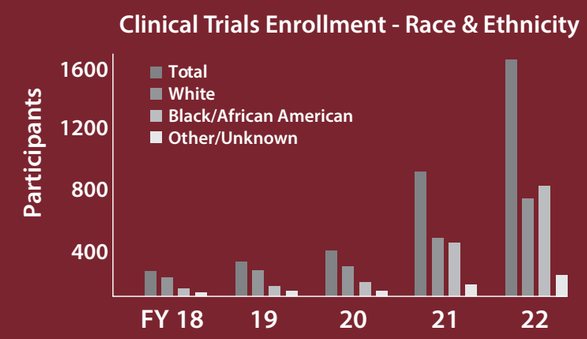
292 studies supported (2022)

123 unique principal investigators

141 new studies activated

494 protocol support requests

In 2022, clinical trials supported by the TRI Clinical Trials Innovation Unit (CTIU) enrolled more than **1,600 new participants.**



Pilot Lessons

TRI INSPIRES NICU HOSPITALIST TO TACKLE NATIONAL OPIOID WEANING TRIAL

UAMS was the **fourth-ranked site** as of February for enrolling participants in the 27-site Neonatal Opioid Withdrawal Syndrome (NOWS) weaning clinical trial.

Psychologist Brooke Yancey-Ward (far right) is joined by research team leaders Allyson Cheatham (far left), and Clare Nesmith, following the assessment of a child who is part of the NOWS weaning study.

The research team includes (front, l-r), TRI Research Coordinator Shellah Rogers, B.S.N., RN, Brooke Yancey-Ward, Psy.D., Principal Investigator Clare Nesmith, M.D., and TRI Research Coordinator Vallon Williams, DNP; (back, l-r) lead Research Coordinator Allyson Cheathem, B.S.N., RN, Co-Investigator Tara Venable, M.D., and TRI Research Coordinator Diana Gregory, RN.

As a hospitalist in the UAMS Neonatal Intensive Care Unit (NICU), Clare Nesmith, M.D., is excited about the potential outcome of a national clinical trial testing the potential of weaning infants more quickly from their dependence on opioids.

If not for her experience with a TRI pilot award four years ago, she would likely be cheering from the sidelines. Instead, she is the UAMS principal investigator for the NIH-funded, 27-site neonatal opioid withdrawal syndrome (NOWS) study. Under her leadership, UAMS is among the top four enrolling sites for the study.

Nesmith, an associate professor in the College of Medicine Department of Pediatrics, remembers being unsure about taking on a research project when first approached five years ago by TRI Director Laura James, M.D.

"My first reaction was, 'I'm a clinician; I don't know anything about research.' And Dr. James said, 'Well, we have the resources to help you, and I'll be glad to mentor you.' That's how it started," Nesmith said.

She received a TRI pilot award in 2019 that supported her study of blood opioid levels in infants with NOWS. Nesmith's study focused on newborns of women receiving buprenorphine as maintenance for opioid dependency. Buprenorphine and its primary metabolite norbuprenorphine levels were quantified in neonatal cord and infant blood samples to compare the relationship of these levels to whether or not infants needed treatment with morphine for opioid drug withdrawal. The study enrolled 44 mother-infant pairs. Among the 44 infants, 21 required treatment with morphine for symptoms of opioid withdrawal. Norbuprenophine was more commonly detected than buprenorphine, but the levels of norbuprenorphine did not associate with withdrawal symptoms or the requirement for treatment.

"I knew that we had TRI behind us with its outstanding team of research coordinators, regulatory experts, and other TRI resources we could call on."

— Clare Nesmith, M.D.

The important thing about the pilot study, said James, is that Nesmith met with many stakeholders in its planning, including mothers of patients, nursing staff and obstetricians to collect their opinions about best approaches to conduct the study.

"Dr. Nesmith intuitively knew that this buy-in was essential to the success of the study," James said. "She then recruited her colleagues to join her. Her study also used many components of TRI's services that we view to be essential to developing and conducting a study."

The successful pilot experience gave Nesmith the confidence to conduct the national NOWS weaning clinical trial as the UAMS principal investigator.

"I knew that we had TRI behind us with its outstanding team of research coordinators, regulatory experts, and other TRI resources we could call on, so we felt like we could do it," Nesmith said. Other NICU pediatricians joined her as co-investigators: Tara Venable, M.D., and Gwenevere White, M.D., both assistant professors in the Department of Pediatrics.

The multi-site trial, which concludes at UAMS at the end of 2023 and at remaining sites in 2025, is comparing a rapid-wean intervention to a slow-wean intervention to determine whether rapid weaning will reduce the number of treatment days among infants receiving morphine or methadone. Rapid weaning decreases each dose by 15% compared to 10% for the slow-wean group. The standard practice at UAMS is a 10% per dose reduction.

The UAMS NICU treats about 40 opioid-exposed newborns each year.

"This study is exciting to me because it's clinically relevant," Nesmith said. "If the trial determines a faster weaning time is best and your baby gets to go home three days earlier, that's amazing."

The study is supported by the NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development and the NIH-supported Data Coordinating and Operations Center (DCOC) for the Institutional Development Award (IDeA) States Pediatric Clinical Trials Network (ISPCTN), which is led by UAMS.

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