

MAY 2023

## Quest for Quality

### TRI, UC Irvine Test Collaboration to Improve Study Designs



*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 the Translational Research Institute (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.

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Dear Colleagues,  
In this issue of The TRIBune, we feature our first test of a new approach for improving clinical trials. Called Quality by Design, the initiative focuses on academic medical centers and is led by Dan M. Cooper, M.D., director of the Institute for Clinical and Translational Sciences at UC Irvine.

The Quality by Design framework includes a panel of research experts who review a study and have 90 minutes to question the principal investigator in a Critical to Quality Studio.

We are excited to participate in the program because high quality translational research demands clinical trials that address relevant health challenges, produce accurate, reproducible data, minimize risk to participants, and are inclusive of underrepresented populations.

In our test case, a cross-section of 15 relevant faculty and staff representing UAMS and UC Irvine considered a pediatric clinical trial proposed by Tara Johnson, M.D., a TRI KL2 scholar graduate and a Master of Science in

Clinical and Translational Science scholarship recipient who graduates this month.

Ours was one of the first Quality by Design, Critical to Quality Studios across universities. The collaboration with UC Irvine is a great opportunity to help evaluate its innovative approach while also providing a larger pool of experts who can help us assess clinical trials, particularly those involving vulnerable populations of children.

Sincerely,

A handwritten signature in black ink, reading "Laura James, M.D." with a stylized flourish at the end.

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

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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, research nurse practitioner, recruitment coordinator, clinical trial manager, and an expert in predictive analytics in neuroimaging.

### 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.”

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 pediatric 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.”



**Jessica  
Snowden, M.D.**

# Christi Madden, MPA, Joins TRI as Executive Director



Christi Madden, MPA, has joined the Translational Research Institute (TRI) as its executive director.

Madden, a leader with more than two decades of research programmatic management experience, spent most of her career

in her home state of Oklahoma at the University of Oklahoma Health Sciences Center (OUHSC), where she worked in the Department of Pediatrics and at the Oklahoma Clinical and Translational Science Institute.

As executive director, Madden oversees all TRI staff and services to UAMS researchers. She also serves as a liaison to the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH), which funds TRI with a Clinical and Translational Science Award (CTSA).

“We are thrilled to have Christi on our team,” said TRI Director Laura James, M.D. “In her roles at

OUHSC, she managed several highly impactful public health research and quality improvement programs. Her skillset and research leadership experience will help our institute provide the highest quality service to our researchers and to our research participants.”

Madden’s management experience includes the IDeA States Pediatric Clinical Trials Network, the Oklahoma Primary Healthcare Improvement Cooperative, the Oklahoma Child Health Research Network and the Healthy Hearts for Oklahoma project.

She has also worked on several projects with rural communities across Oklahoma to implement community-driven initiatives to improve cardiovascular health, increase access to health care and mental health resources, and implement COVID-19-related research.

In 2022, she was recognized by the Public Health Institute of Oklahoma as one of the County Health Improvement Organization’s Top Ten People of the Decade.

[Read the full story here.](#)

## TRI Study of the Month

**UAMS Principal Investigator:** Johnathan Goree, M.D., associate professor and director, Division of Chronic Pain, College of Medicine Department of Anesthesiology.

**Summary:** The Sequenced Strategy for Improving Outcomes in People with Knee Osteoarthritis (SKOAP) Study is a two-phase multi-site clinical trial comparing non-opioid pain management strategies. Phase 1 compares non-surgical treatments, including best practices, web-based pain-coping skills, and the use of duloxetine, an FDA-approved drug for joint pain. Phase 2 compares joint injections, nerve blocks and nerve ablations to treat participants’ knee osteoarthritis.

**Significance:** Researchers hope the study of non-surgical, non-opioid pain treatments will reveal the best way to reduce knee osteoarthritis pain and improve function.

**TRI Services:** Medicare coverage analysis, study budget development, administration

of Clinical Trial Management System, clinical research coordinator support, and post-award financial management.

**Sponsor:** Johns Hopkins University; funding by the Helping to End Addiction Long-term® (HEAL) Initiative; administered by the CTSA Trial Innovation Network.



*Clinical Research Financial Analyst Ty Stacey, B.A., CRS, CCRP (left), is assisting Johnathan Goree, M.D., on the study's budget development.*



# Six UAMS-Community Scholar Teams Selected to Compete for TRI Pilot Awards

The TRI Community Engagement program recently kicked off its Community-Based Participatory Research (CBPR) Scholars program with six teams pursuing health-related projects.

CBPR scholars and their UAMS academic research partners can apply for a TRI pilot award of \$25,000 or \$50,000. This year's UAMS-community partner teams are:

- Alexandra Marshall, Ph.D., MPH, UAMS Fay W. Boozman College of Public Health; and Engaging Arkansas Communities, represented by:
  - Danny "Eric" Harris, executive director
  - Bobby Pierce, community engagement director and human resources manager
  - Jeff Walker, grants and communications director
  - Whitley Hopkins, community health worker program coordinator
- Jaimi "Mimi" Allen, Ph.D., M.S., and Ben C. Amick, Ph.D., College of Public Health, and Arkansas Cancer Coalition, represented by:
  - Miriam Karanja, MBA - director of programs
  - Trina Mitchell, MA - executive director
  - Wonder Lowe, MPA - health program specialist
- Suzanne J. Dhall, Dr.P.H., MSPH, College of Medicine; and Giving. Others. Ambition. Together (GOAT), Kelvin Parker, CEO and founder
- Tiffany Miles, Ph.D., and Taren Swindle, Ph.D., College of Medicine; and Greater Powerhouse Church of God in Christ, Kim Smith, pastor
- Tracie Harrison, Ph.D., RN, College of Nursing; and Difference Makers of Hot Springs, Rev. Willie Wade, founder and president; and Diamonds in the Rough, Esther Dixon, founder and president



*Representatives of community groups partnering with UAMS researchers attended a program orientation in April.*