

THE TRIbune

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University of Arkansas for Medical Sciences

ACCELERATING DISCOVERIES TOWARD BETTER HEALTH

November 2015

One-Stop Shop

TRI Serves UAMS Clinical Trial Needs



(L-R) TRI Project Support Unit team members: Michael Bailey, Lisa Richardson, Suzan Blair, Ashley Sides, Shawna Owens, Angela Garland, Rita Vaughn, Cynthia Spinks, Sharon Sandria, Jonathan Young, Kennetha Newman and Mtonya Hunter-Lewis.

As he considered his needs for a large, multi-center clinical trial, UAMS' Everett "Pat" Magann, M.D., said the clear choice for professional assistance was the Translational Research Institute (TRI) Project Support Unit.



Dr. Magann

Magann, principal investigator of the industry-sponsored phase III trial evaluating the use of Antithrombin III in the management of pregnancies complicated by

preeclampsia, said his Obstetrics and Gynecology Department lacked the infrastructure to conduct it.

TRI's assistance to Magann demonstrates the full range of TRI clinical trial services by staff specializing in protocol development, regulatory support, budget reviews, Medicare/ insurance coverage analyses, and clinical research coordination.

TRI staff helped with study planning, site selection, and study initiation activities. They performed all work on regulatory startup and budget development, required institutional reviews, and assisted with budget negotiations. The team is also providing data management, laboratory specimen processing and shipping, study billing, invoicing, and all study monitoring visits.

In addition, TRI's professional staff mentored Magann, who is new to leading a clinical trial, and departmental staff on the many aspects of clinical trials, the UAMS clinical trials process, and various research computer systems.

"Shawna Owens and Rita Vaughn (TRI clinical research coordinators) have done an excellent job getting our project up and running," Magann said. "Without their help in getting this project through the IRB, helping us create a budget and then assisting us with the multiple tasks involved

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Message from Dr. James



Dear Colleagues,
One of the cornerstones of translational science is achieving a vibrant collaborative research environment not bound by colleges, professions or geography. It's our aim at

TRI to provide the resources that foster a strong culture of collaboration.

We recently launched UAMS Profiles, the online platform (TRI.uams.edu/Profiles) that connects researchers across the country. This month we're excited to announce the recipients of the 2015 Western States Consortium (WSC) Pilot Awards, designed to stimulate research among Clinical and Translational Science Award (CTSA) institutions.

In addition to UAMS, the WSC members include the University of Kansas Medical Center (KUMC), University of New Mexico Health Sciences Center (UNM HSC) and the University of Utah. Of the eight applications submitted, three one-year pilots of up to \$50,000 were awarded. Two of the three projects involve UAMS researchers as co-principal investigators:

- Sean Adams, Ph.D., with KUMC, "Metabolomics Signatures That Occur in Alzheimer's Disease (AD) Patients With and Without Type 2 Diabetes in Comparison to Controls (non-AD) With or Without Type 2 Diabetes," \$35,334
- Joshua Kennedy, M.D., with UNM HSC, "Host-Pathogen Genomic Determinants of Pediatric Respiratory Infection Severity," \$50,000

We are very proud of Dr. Adams and Dr. Kennedy and look forward to another productive year in 2016!

Laura James, M.D.
Director, TRI

Seminars Offer Practical Information for Commercializing Ideas



As a senior partner with a UAMS BioVentures startup, PinPoint Testing LLC, Nancy Rusch, Ph.D., knows how the commercialization of ideas contributes to the goals of translational science – and the bottom line.

Rusch, chair of the Department of Pharmacology and Toxicology and leader of TRI's Education and

Workforce Development Team, is using her knowledge to help expand commercialization training at UAMS, primarily for students and postdoctoral fellows.

Among her initial endeavors is a Health Sciences Innovation and Entrepreneurship (HSIE) training program, which began this fall with a seminar series. The seminar series is co-directed by BioVentures Director Nancy Gray, Ph.D., and Michael Owens, Ph.D., professor of pharmacology and toxicology and chief science officer for InterveXion Therapeutics, also a BioVentures startup.

The impetus for the seminar series is to address an entrepreneurial knowledge gap for students, postdocs and faculty who may want to pursue commercialization of their ideas.

“We’re providing some practical information about what it means to be an entrepreneur, and we want to break down barriers that may be preventing them

from turning their ideas into products or practices for patient care,” Rusch said. “We also want to make it part of the culture at UAMS – that being an entrepreneur is a positive thing.”

She also notes that when ideas are commercialized, it creates a source of revenue, a portion of which goes to UAMS, that is in addition to grant funds and clinical revenue.

Below are future HSIE seminars. Unless otherwise indicated, all are at 4 p.m. in the Cancer Institute, 10th floor, Walton Auditorium.

- Introduction to Methods of Financing a Startup, Mike Smith/Ted Dickey, Dec. 8
- NIH SBIR/STTR Program, Lenka Fedorkova, Ph.D., Jan. 12
- FDA 101, William Slikker, Ph.D., Feb. 9
- Developing Your Business Plan, Leslie Lane, March 8
- Career Roundtable – LeRoy LeNarz, M.D. (UAMS alumnus, working at Eli Lilly); Joe Underwood, Ph.D., and Misty Stevens, Ph.D., April 8, Rayford Auditorium, 1-3 p.m.
- Managing Conflict of Interest and Conflict of Commitment, TBD, May 10

One-Stop Shop (continued from page 1)

in actually running this trial, we would have been unable to participate in the trial.”

Alison Oliveto, Ph.D., the faculty team leader who oversees TRI's Project Support Unit, said TRI has taken up the mantle of clinical trials support for UAMS researchers.

“How are we providing researchers with value-added services? We have all the nuts and bolts to really help people navigate the clinical trials process,” Oliveto said. “Many individual investigators do not have the support staff needed to perform clinical trials. Our team has the capability to support investigators in this important component of UAMS’ research portfolio.”

In the last six months, TRI has been coordinating 22 studies and recently began work on six new clinical trials requests for its coordinator services.

As an administrative hub for clinical trials, the Project Support Unit can help industry and other sponsors identify potential investigators, facilitate the clinical trials process, help implement clinical trials on campus, and consult with investigators who do not have staff support.

“We are truly a providing a complete service for UAMS investigators from startup to completion of their clinical trials,” said Jonathan Young, senior project leader for the Project Support Unit. “We are also able to assist investigators in developing recruitment plans for clinical trials.”

Requests for TRI services can be made at tri.uams.edu by clicking the Request Services button and filling out the form. Or you may email your request to TRIServices@uams.edu.



Dr. Oliveto

TRIBUTARY

TRI KL2 Recipient Ling Gao, M.D., Ph.D., Published in NEJM

Identifying a patient's genetic mutation led TRI KL2 Award Scholar Ling Gao, M.D., Ph.D., to an existing drug that eliminated the patient's stage IV Merkel-cell carcinoma. Gao's findings, made in collaboration with two other UAMS researchers, were published in the Oct. 15, 2015, *New England Journal of Medicine*.

Gao is a recipient of TRI's KL2 Mentored Research Career Development Scholar Award, which provided two years of research funding and translational research training.

Metastatic Merkel-cell carcinoma is often fatal and there is no effective treatment. Gao's 86-year-old female patient was diagnosed in 2013 with stage IIIB Merkel-cell carcinoma of the right temple. She had surgery and received radiation therapy in May 2013 and additional surgery in July 2014. In November 2014, doctors confirmed that the cancer had metastasized. Gao, a dermatologist, performed genetics tests on the tumor that revealed multiple mutations, including PI3Kδ.

Gao was aware that the drug idelalisib is a novel PI3K pathway inhibitor approved by the FDA for treatment of B-cell lymphoma, a cancer of the blood. She was also aware of recent studies showing that disruption of the PI3Kδ mutation allows the body to mount an effective antitumor immune response.

Gao began treatment of the patient with the drug on Feb. 6, 2015. Three months after administering the idelalisib, there was



no sign of the tumor in the patient's liver. Her findings were published in the *Journal* in a letter to the editor.

Based on what she's learned, Gao said the case can be made for further study of PI3Kδ inhibitors like idelalisib in solid tumors, not just blood cancers. "The efficacy of idelalisib in our patient provides initial clinical evidence that the targeting of PI3Kδ in Merkel-cell carcinoma is warranted," Gao said in the letter, which was also signed by UAMS' Fade Mahmoud, M.D., and Mallory B. Shiver, M.D.

View the article and accompanying PET-CT findings at <http://tri.uams.edu/files/2015/10/NEJM-Letter-Gao.pdf>.



Mary Aitken, M.D., M.P.H.,
Co-Director, TRI KL2
Mentored Research Career
Development Scholar
Award Program; Professor,
Department of Pediatrics;
Director, Center for Applied
Research and Evaluation.

"As KL2 co-director, I see TRI as filling a critical need in the development of junior research faculty here at UAMS. By providing promising researchers with protected time, training and support we're ensuring they can be as successful as possible. That's absolutely critical, and in the program's six-year history we've seen our KL2 scholars earn

career promotions, obtain research funding and become highly productive. TRI has also provided vital support to me as a researcher, helping me acquire data necessary to successfully apply for a 5-year NIH National Institute of Child Health and Human Development RO1, which is testing interventions promoting safe sleep of infants of teen mothers."

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Website
TRI.uams.edu
Email: TRI@uams.edu

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David Robinson
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Leslie Norris
TRI Director
Laura James, M.D.

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The following UAMS researchers cited the Translational Research Institute (TRI) in publications after utilizing TRI resources or funding:

Bose C, Megyesi JK, Shah SV, Hiatt KM, Hall KA, Karaduta O, Swaminathan S. Evidence suggesting a role of iron in a mouse model of nephrogenic systemic fibrosis. *PLoS One*. 2015 Aug 25;10(8):e0136563. doi: 10.1371/journal.pone.0136563. eCollection 2015.

Culp WC, Brown AT, Lowery JD, Arthur MC, Roberson PK, Skinner RD. Dodecafluoropentane emulsion extends window for tPA therapy in a rabbit stroke model. *Mol Neurobiol*. 2015 Jun 9 [Epub ahead of print].

Engelen MP, Com G, Anderson PJ, Deutz NE. New stable isotope method to measure protein digestibility and response to pancreatic enzyme intake in cystic fibrosis. *Clin Nutr*. 2013 Nov 9. pii: S0261-5614(13)00305-1. doi: 10.1016/j.clnu.2013.11.004.

Erickson SW, Stephens OW, Chavan SS, Tian E, Epstein J, Barlogie B, Heuck CJ, Vangsted AJ Common genetic variants in 11q13.3 and 9q22.33 are associated with molecular subgroups of multiple myeloma. *Leukemia*. 2015 Aug 26. doi: 10.1038/leu.2015.238.

Garimalla S, Kieber-Emmons T, Pashov AD. The Patterns of Coevolution in Clade B HIV Envelope's N-Glycosylation Sites. *PLoS One*. 2015 Jun 25;10(6):e0128664. doi: 10.1371/journal.pone.0128664. eCollection 2015.

Hayes CJ, Hudson TJ, Phillips MM, Bursac Z, Williams JS, Austin MA, Edlund MJ, Martin BC. The influence of propoxyphene withdrawal on opioid use in veterans. *Pharmacoepidemiol Drug Saf*. 2015 Aug 6. doi: 10.1002/pds.3851.

Jeffus SK, Gehlot A, Holthoff E, Stone R, Spencer H, Kelly T, Post SR, Quick CM. A fibromyxoid stromal response is associated with an infiltrative tumor morphology, perineural invasion, and lymph node metastasis in squamous cell carcinoma of the vulva. *Am J Surg Pathol*. 2015 Sep;39(9):1226-1233.

Johnston MJ, Ntambi JA, Hilliard N, Spencer HJ, Vaughn R, Owens SS, Myrick RS, Parker LD, Garner DA, Yarbrough TL. Reducing perceived pain levels during nonbreast lymphoscintigraphy. *Clin Nucl Med*. 2015 Jul 28.

Kenchaiah S, Vasan RS. Heart failure in women - insights from the Framingham Heart Study. *Cardiovasc Drugs Ther*. 2015 Aug 7.

Kim HN, Han L, Iyer S, de Cabo R, Zhao H, O'Brien CA, Manolagas SC, Almeida M. Sirtuin1 suppresses osteoclastogenesis by deacetylating FoxOs. *Mol Endocrinol*. 2015 Aug 19;me20151133.

Malik S, Bird TM, Jaquiss RD, Morrow WR, Robbins JM. Comparison of in-hospital and longer-term outcomes of hybrid and Norwood stage 1 palliation of hypoplastic left heart syndrome. *J Thorac Cardiovasc Surg*. 2015 Jul 4. pii: S0022-5223(15)01195-2. doi: 10.1016/j.jtcvs.2015.06.071.

Miousse IR, Chalbot MC, Lumen A, Ferguson A, Kavouras IG, Koturbash I. Response of transposable elements to environmental stressors. *Mutat Res Rev Mutat Res*. 2015 Jul-Sep;765:19-39. doi: 10.1016/j.mrrev.2015.05.003.

Snellgrove S, Beck C, Green A, McSweeney JC. Putting Residents First: Strategies developed by CNAs to prevent and manage resident-to-resident violence in nursing homes. *Gerontologist*. 2015 Jun;55 Suppl 1:S99-S107. doi: 10.1093/geront/gnu161.

Stewart MK, Felix HC, Olson M, Cottoms N, Bachelder A, Smith J, Ford T, Dawson LC, Greene PG. Community Engagement in Health-Related Research: A case study of a community-linked research infrastructure, Jefferson County, Arkansas, 2011-2013. *Prev Chronic Dis*. 2015 Jul 23;12:E115. doi: 10.5888/pcd12.140564.

Stupnikov A, Glazko GV, Emmert-Streib F. Effects of subsampling on characteristics of RNA-seq data from triple-negative breast cancer patients. *Chin J Cancer*. 2015 Aug 8;34:36. doi: 10.1186/s40880-015-0040-8.

Tsai PF, Chang JY, Beck C, Kuo YF, Keefe FJ, Rosengren K. A supplemental report to a randomized cluster trial of a 20-week Sun-style Tai Chi for osteoarthritic knee pain in elders with cognitive impairment. *Complement Ther Med*. 2015 Aug;23(4):570-6. doi: 10.1016/j.ctim.2015.06.001.

Vuong TD, Wei F, Beverly CJ. Absenteeism due to functional limitations caused by seven common chronic diseases in US workers. *J Occup Environ Med*. 2015 Jul;57(7):779-84. doi: 10.1097/JOM.0000000000000452.

Thank you for remembering to cite TRI in your publications resulting from studies that receive TRI support.