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Indiana CTSI sixth annual meeting put focus on the patient role in health care

Nov. 11, 2014

A good physician always bases treatment recommendations on all the available evidence. But how can a doctor know they are making the right decision when they simply don't have enough evidence?

A leader of the group created to fill those evidence gaps -- and to spearhead greater efficiency in medical care and delivery in general under the U.S. health care reform law -- struck the keynote at the sixth annual meeting of the Indiana Clinical and Translational Sciences Institute, "From Academic Centers to Population Health," Sept. 26 in the Hine Hall Auditorium at IUPUI.

[A complete video of the event and presenter slides are online.](#)

The **Indiana CTSI** is a statewide collaboration of IU, Purdue University and the University of Notre Dame to facilitate the translation of scientific discoveries in the lab into new patient treatments in Indiana and beyond. The director of the Indiana CTSI is Anantha Shekhar, M.D., Ph.D., associate vice president for university clinical affairs at IU and associate dean for translational research and Raymond E. Houk Professor of Psychiatry at the IU School of Medicine.

"Comparative effective research emphasizes the choices that are already available to people; the options that already exist," said David Hickam, M.D., director for the Clinical Effectiveness Research Team at the **Patient-Centered Outcomes Research Institute**, or PCORI, a non-government institute created as part of the Patient Protection and Affordable Care Act to provide support for comparative effectiveness research and other types of research that can help patients and providers to deliver high quality medical care.

"The United State spends a lot of money on health care compared to other nations but doesn't necessarily get the desired outcomes," he added. "This raises the question: Do we truly understanding the available evidence? Are we truly working to figure out what new information might improve our evidence base so the choices people make are based upon the best possible evidence?"

The approach flips the traditional model in which a physician prescribes a treatment based upon all available evidence. Comparative effectiveness research asks physicians what gaps exist in the available evidence and then designs studies to fill those gaps to improve the physicians' ability to make decisions with the greatest chance of generating positive results.

"PCORI also places a strong emphasis on the role of patients in their own care," according to Dr. Hickam. The organization, which has distributed over \$250 million since its creation in 2010, includes clinical stakeholders and patients -- as well as scientific experts -- on its review panels. All applicants are also required to explain not only the health impact and technical merits of the projects but also how the work will positively impact the lives of patients. The organization's whole philosophy revolves around the concept of "patient-centeredness."

The model represents a growing trend, according to Jay L. Hess, M.D., Ph.D., MHA, dean of the IU School of Medicine and vice president for university clinical affairs at IU, who also presented. Healthcare reform is shifting the health care model from a "volume based" model rewards physicians for prescribing treatments to a "value based" model that rewards physicians for successfully keeping a group of patients healthy to the point where they don't require as many treatments in the first place. The concept of population health management is shifting the focus to greater accessibility, strong prevention, fewer unnecessary procedures, and strong care coordination -- also known as the patient-centered medical home model. The ultimate goal -- and challenge



David Hickam, M.D., director for the Clinical Effectiveness Research Team at PCORI



Anantha Shekhar, M.D., Ph.D., director of the Indiana CTSI



Charles R. Bantz, Ph.D., Chancellor for IUPUI



Jay L. Hess, M.D., Ph.D., dean of the IU School of Medicine

-- is simultaneously strengthening patient care, improving the health of the community and lowering costs.

Other presenters included Paul K. Halverson, Dr.PH, dean of the IU Richard M. Fairbanks School of Public Health at IUPUI, and Brad N. Doebbeling, Ph.D., professor and chair of biohealth informatics at the IU School of Informatics and Computing and professor of medicine at the IU School of Medicine. "We're so proud to work with the Indiana CTSI," Dr. Halverson said. "They've got so many great things going on in community engagement... it's really an interaction that recognizes the importance and value of what everyone in the community brings to the table."

Dr. Doebbeling is one of two IU faculty members whose has received support from PCORI. Dr. Doebbeling's project, "Improving Healthcare Systems for Access to Care by Underserved Patients," aims to develop patient-centered approaches to improving access to care among the poor, uninsured or underinsured through a simulation model that takes into account the major barriers to care, such as lack of transportation, inability to get off of work, missing documents, language barriers and months-long delays in Medicaid approval. The other IU faculty to receive support from PCORI is Michelle P. Salyers, Ph.D., professor of psychology in the IU College of Arts and Sciences at IUPUI, who is testing evidence-based approaches to fight burnout and improve well-being among doctors.

Additional investigators to present at the event also put a spotlight on patient-centered research. Sarah Wiehe, M.D., co-director of the Indiana CTSI CHEP and associate professor of pediatrics, discussed the Patient Engagement Core, a new service from the Indiana CTSI that borrows the "user-centered approach" concept from the field of design to develop hands-on and interactive activities that engage patients in their own care -- as well as improve study recruitment and disseminate research findings to the public. Nitesh Chawla, Ph.D., Frank Freimann Collegiate Associate Professor of Computer Science and Engineering and Director of the Interdisciplinary Center for Network Science & Applications (iCeNSA) at the University of Notre Dame, discussed iCeNSA's mission to advanced personalized medicine through customized smartphone and web-based applications that collect relevant health data from patients. Project examples included an obesity management program developed for high school students in South Bend and a diabetes management smartphone application receiving support from an Indiana CTSI CHEP seed grant.

A panel presentation on population health from representatives of three major research hospitals in Indiana closed the session. Presenters were Lisa Harris, M.D., CEO of Eskenazi Health and associate dean for Eskenazi Health Affairs and John F. Williams, Jr., M.D. Scholar at the IU School of Medicine; Chet Ho, M.D., director of the Population Health Office at IU Health and Michael Weiner, M.D., director of Health Services Research and Development at the Richard L. Roudebush Veterans Affairs Medical Center and associate professor of medicine and Department of Medicine Investigator in Health Services Research at the IU School of Medicine. William M. Tierney, M.D., president and CEO of the Regenstrief Institute and associate dean for clinical effectiveness research at the IU School of Medicine, served as the moderator.

The event also included a poster session with prizes for the top three posters in the both the Indiana CTSI-supported researcher and scholars and trainees categories. Each winner received \$1,000.

The winners in the Indiana CTSI-supported researcher category were:

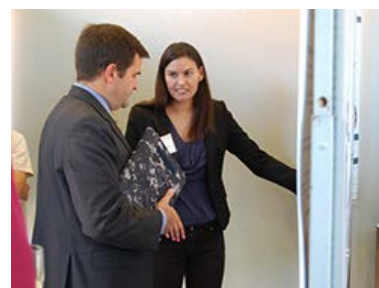
- Robin K. Fuchs, Ph.D., assistant professor of physical therapy in the IU School of Health and Rehabilitation Sciences at IUPUI, "Bone Health in Children with Cerebral Palsy."
- Laurie Littlepage, Ph.D., Campbell Family Assistant Professor of Cancer Research and a member of the Harper Cancer Research Institute at the University of Notre Dame, "The Oncogene ZNF217 Promotes Breast Cancer Chemoresistance."
- Janet E. Panoch, a research assistant in the Department of OB-GYN at



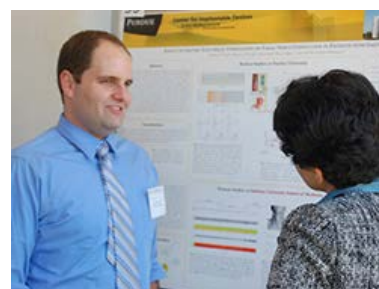
Poster presenters display their CTSI-supported research projects



A group discusses their work at the poster session.



Andrew Bullock, Ph.D, MBA, left, research navigator for the Indiana CTSI at Notre Dame, speaks with a poster presenter.



An investigator discusses his work at the poster session.



A sign leads conference-goers to their destination.

the IU School of Medicine, "Patient Communication Skills Training for High School Health and Wellness Classes."

The winners in the scholars and trainees category were:

- David W. McIlwain, a predoctoral researcher in the Department of Pharmacology and Toxicology at the IU School of Medicine, "APE1/Ref-1 Regulates Survivin-Mediated Drug Resistance in Prostate Cancer Cells."
- Eric Orman, M.D., a postdoctoral researcher in the Department of Medicine at the IU School of Medicine, "Delirium is Associated with Poor Outcomes in Patients with Cirrhosis."
- Emily K. Sims, M.D., a postdoctoral researcher in the Department of Pediatrics at the IU School of Medicine, "Beta Cell Derived miR-21 as an Intrinsic Protective Response and Biomarker in Type 1 Diabetes Mellitus."

McIlwain is also a recipient of the Indiana CTSI Predoctoral (Trainee) Award. Drs. Orman and Sims are also the recipients of the Indiana CTSI Postdoctoral (Young Investigator) Award. Drs. Fuchs, Littlepage and Panoch have also received support from the Indiana CTSI.

By Kevin Fryling

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Indiana CTSI director, scientist's startup earns innovation grant, venture competition award

Nov. 11, 2014

A company founded by two Indiana Clinical and Translational Sciences Institute-affiliated scientists was recently named the recipient of [Phase I Small Business Innovation Research grant](#) from the National Institutes of Health as well as the [winner of the 2014 BioCrossroads New Venture Competition](#).

Anagin, founded by Anantha Shekhar, M.D., Ph.D., director of the Indiana CTSI, and Yvonne Lai, Ph.D., an Indiana CTSI research navigator and senior scientist in the Department of Psychological and Brain Sciences at IU Bloomington, aims to revolutionize post-traumatic stress disorder treatment with a first-of-its-kind therapeutic to battle PTSD.

The company's NIH grant will provide \$692,706 in startup funds. The BioCrossroads award, received Oct. 14 as part of a contest held in conjunction with the 2014 Indiana Life Sciences Summit at the JW Marriott hotel in Indianapolis, will provide an additional boost to the project with \$25,000 cash prize on as well as business planning and early strategic support from the Indiana Seed Fund II, as well as the opportunity for more exposure by making a presentation to the fund's investment committee.

One in seven Americans -- in cases that range from child abuse, domestic abuse, and sexual assault to the trauma faced by soldiers, police, and firefighters -- will battle post-traumatic stress disorder at some point in their lives, said Dr. Shekhar, who is also associate vice president for university clinical affairs at IU and Raymond E. Houk Professor of Psychiatry and a professor of neurobiology and of pharmacology and toxicology at the IU School of Medicine.

Yet current medicines work for only half of the 24.4 million Americans who suffer from the disorder at any given time these individuals will see only 30 to 60 percent improvement in their symptoms, he added. Anagin aims to developing drugs that block the target mechanism of PTSD without triggering others that cause crippling side effects, such as agitation, irritability, sexual dysfunction, drowsiness, memory and motor skill problems and addiction.

"Current medications work on brain chemicals such as GABA and glutamate, which affect many brain functions such as thinking, motor coordination, memory and alertness," said Dr. Shekhar. Since (our) drugs do not directly block the normal brain chemical message mechanisms, they will not cause sedation, memory problems and motor difficulties such as balance, walking and driving. So we think the effectiveness of these medications will be much greater."

Launched in 2013, Anagin is a product of the Spin Up program created by the IU Research and Technology Corp. IURTC brings promising technologies to market by helping IU researchers form startup companies. Spin Up specifically aids companies like Anagin, whose technologies are promising but at early stages of development.

With Spin Up's help, Anagin has had little trouble getting support from early-stage funding agencies. Along with its NIH grant and New Venture funding, Anagin will receive \$50,000 in matching funds from Elevate Ventures, a nonprofit organization that provides state dollars to promising, early-stage entrepreneurs who have received funding through small business grants.

"Anagin was funded in its first application to the NIH, which is rare," said Joe Trebley, who heads startup support and promotion for IURTC and the Spin Up program. "Part of the reason is the strength of the development team. You have two people in Dr. Shekhar and Dr. Lai who are very renowned in their field."



Shekhar, M.D., Ph.D.

Anantha



Lai, Ph.D.

Yvonne

Another factor is the tremendous market opportunities that Anagin's drugs, if successful, may provide for future PTSD treatment.

"It's an enormous market and a critical unmet need in some of our most vulnerable populations," Trebley said. "We're talking about drugs that can help a wide variety of people such as veterans, victims of violent crime ... any sufferer of PTSD who feels the effects of anxiety, depression or chronic pain."

The prospect of lower health care costs also is a consideration. According to a 1999 study published in the Journal of Clinical Psychiatry and cited by the Centers for Disease Control and Prevention, the annual cost of anxiety disorders in the U.S. was estimated at \$42.3 billion -- a figure Dr. Shekhar and the CDC view as conservative 15 years later.

"This estimate focused on short-term effects and did not include the effect of outcomes such as the increased risk of other disorders," the CDC said on a section of its website that lists statistics on the burden of mental illness.

A Crippling Disease

Through more than 25 years as a psychiatrist and neuroscientist, Dr. Shekhar has seen more than his share of the ravages that PTSD sufferers endure.

"There was a young man who served for two years in Vietnam but has since been isolated from society, depressed and unable to function for 35 years," Dr. Shekhar said. "There was a young woman who was assaulted, developed severe PTSD and then committed suicide within a year. There was a child that was attacked severely by a dog while waiting for the school bus and has not been able to attend school.

"There have been hundreds of patients that I have tried to help with this problem," he added. "But I have been frustrated with the lack of effective interventions."

Dr. Shekhar's encounters offer a brief glimpse into a wide window of how PTSD affects everyday Americans.

According to PTSD United, a California-based nonprofit support organization for PTSD sufferers, about 44.7 million Americans -- roughly one in seven -- either have the disorder or previously struggled with it.

About 24.4 million Americans, a figure nearly equal to the population of Texas, have PTSD at any given time. Although military personnel -- particularly after protracted tours in combat zones such as Vietnam, Iraq and Afghanistan -- are commonly viewed as primary sufferers of PTSD, figures provided by Dr. Shekhar suggest otherwise.

They indicate nearly half of abused children develop some form of PTSD, while 45 percent of domestic violence victims and 36 percent of sexual assault victims suffer the disease. About 30 percent of military veterans deal with PTSD, along with 15 percent of firefighters and 13 percent of suburban police officers.

Women are particularly susceptible to PTSD. According to 2014 study published in JAMA Psychiatry, researchers at Columbia and Harvard universities found that one in nine females -- about twice the rate of men -- develop PTSD sometime in their life. According to a 2009 study also cited by the CDC, anxiety disorders -- which include PTSD, panic disorder, generalized anxiety disorder, phobias and separation anxiety disorder -- are the most common class of mental illness.

Dr. Shekhar said about 40 percent of PTSD sufferers become "completely disabled" by its symptoms, with 20 percent becoming suicide risks and 60 percent developing drug or alcohol addiction.

"Patients can become extremely withdrawn, avoid society, become unable to work and have severe sleep problems," he said.

Even when treatment drugs work, the side effects often create other problems.

"With antidepressants, it can be agitation, irritability and sexual side effects," Dr. Shekhar said. "With anticonvulsants, you have sedation, dulling of thinking, motor coordination problems and memory disruptions. With anti-anxiety medications, it involves sedation, motor problems, memory problems and addiction problems."

Next Steps

With Lai directing early development of Anagin's lead drug, pre-clinical tests on rats showed that nitrous oxide production associated with neural receptors -- a key process in forming fearful memories -- can be disrupted without triggering mechanisms that cause side effects.

So far, the drug appears to have no sedative, memory or motor effects, Dr. Shekhar said.

"This is the first-ever drug to work on this target in the brain," he said. "This treatment, if given in the early stages -- soon after trauma -- specifically disrupts the key molecular step in developing crippling fears and fear memories that are the core problem with PTSD. If the trauma is in the past and PTSD is already fully established, then the treatment also enhances more rapidly overcoming -- extinguishing -- the symptoms."

Although other new treatments involving inhibitors, antagonists and modulators of neural receptors are entering the market, Trebley said Anagin's strategy to specifically target PTSD sets it apart.

"We anticipate that the Anagin platform will significantly disrupt and grow the PTSD market," he said.

Armed with nearly \$800,000 in seed money, Anagin's next steps involve ramping up its own research and development, and beginning collaborations with Indiana University and Northeastern University-Boston to supplement its efforts. Part of that work involves optimizing bioavailability -- the rate and extent to which a drug reaches a patient's systemic circulation -- and other pharmacological characteristics to validate safety and ensure success at the clinical stage.

With IURTC's assistance, Anagin is seeking patent protection for its drug composition and treatment methods for PTSD and related diseases.

Within four years, Anagin -- named after Dr. Shekhar's daughter, Ana, and his wife, Gina -- hopes to complete an investigational new drug.

"We just hired our first two employees at this stage, and we are supporting work by several talented researchers in Indiana and across the country," Dr. Shekhar said. "But if successful, we see expanding to more than a half-dozen in the next (development) stage, and then we will scale even further. We see a lot of opportunity in this space."

BioCrossroads is an Indianapolis-based, public-private collaboration that provides money and support to budding life-science businesses in Indiana. Since 2012, its New Venture Competition has awarded more than \$120,000 to nine startups that attracted nearly \$5 million in subsequent funding.

By Bill Hornaday

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Teaching teens to talk to their doctor is goal of CTSI poster award winner

Nov. 11, 2014

Janet Panoch will soon deliver two presentations at the 100th Annual National Communication Association Conference in Chicago. It's a position the research assistant and graduate student never expected to be in only a few short years after a 15 year break from academia to homeschool her children.

The trip from Nov. 20 to 23 will be funded in part by a \$1,000 poster presentation award from the Indiana Clinical and Translational Sciences Institute, one of six awarded during the [sixth annual meeting of the Indiana CTSI](#) on Sept. 26.

The recipient of a master's in communication and former faculty member at Indiana University-Purdue University Fort Wayne, Panoch developed an interest in health care communication during her own daughter's fight against bone cancer. Now a research assistant in the Department of OB-GYN at the IU School of Medicine and graduate student in the Medical Humanities & Health Studies at IUPUI, Panoch is currently leading a project designed to help adolescents learn how they can more effectively talk to their doctor. The project will launch as a pilot in local classrooms starting this spring.

"For the past seven or eight years -- after my daughter Zoe's cancer diagnosis at age 12 -- I was just thrown into the world of healthcare," said Panoch, who recalled the confusion and frustration she encountered trying to navigating the health care system -- an overwhelming position for a parent, let alone a teen. "When students are as young as 18, they're legally expected to take over management of their health care -- parents can't speak to their doctors without consent -- it comes as a real shock to some of them."

"My idea is to create a health education module about patient-doctor communication that can be embedded into existing health and wellness curriculum at the high school level," she added. "Health education is required by the state so you've got a captive audience. Unfortunately almost everything that's currently being done with patient communication skills training starts after people are already sick; I want to educate teens before they reach that point."

The curriculum for the project, "Patient Communication Training Skills for High School Health and Wellness Classes," is modeled after an influential doctor-patient communication model called the [PACE system](#), will launch as a pilot project in late March or early April at Herron High School in Indianapolis, the same school previously attended by Zoe, who is now a sophomore studying biomedical engineering at Purdue University. The primary investigator on the project, which is funded by an [IU Health Values Grant](#), is Zoe's prior oncologist, Kenneth Lazarus, M.D., former director of pediatric hematology/oncology at IU Health Hospital North and currently a fellow and visiting academic specialist in curriculum implementation in the Office of Undergraduate Medical Education at the IU School of Medicine.

"When Janet Panoch came to me with the idea of developing a program to help teenagers better understand how to interact with the medical care team in a positive and mutually beneficial manner, I jumped at the chance," Dr. Lazarus said. "With her daughter, she has gone through the frustrations and difficulties associated with a significant family medical illness. I am hoping that this program that we are developing will make that journey for teenagers and their families easier and more straightforward."

The project has also attracted several "heavy hitters" in the world of health care communications. Additional investigators on the grant include Donald J. Cegala, Ph.D., professor of communication and family medicine at the Ohio State University, who is creator of the communication system upon which the curriculum is based; Peter Anderson, M.D., past director of pediatric/oncology



Janet

Panoch with her award-winning poster at the Sixth Annual Indiana CTSI Meeting.

at the MD Anderson Cancer Center, who now serves as medical director in Charlotte, NC; Mark J. Di Corcia, Ph.D., assistant professor and vice chair of education in the IU School of Medicine Department of OB-GYN; and Jennifer Bute, PhD., graduate program director of communication studies at the IU School of Liberal Arts at IUPUI. Dr. Anderson, a leading expert in osteosarcoma, first encountered Panoch as a member of a national advocacy group for her daughter's cancer type.

"I think we're the only ones doing work with adolescents and patient communications right now; I'm not seeing anyone else doing anything similar in the United States," Panoch said. "It's amazing when you think about the personal responsibility they're about to take on at age 18. I was honestly a bit surprised to discover no one's tried to put together a class like this already."

The curriculum under development will be a week-long, video-based module produced in collaboration with the IU Health Learning Solutions Team. Video-based curriculum was selected partly in a response to a series of focus groups at Indianapolis' Todd Academy, many of whom cited the popularity of the YouTube "[Crash Course](#)" video series, produced by Indianapolis-based author John Green. In addition to working closely with the producers on the video, Panoch will be involved in the selection of on-screen presenters and writing scripts.

Video presenters include a colleague from Ivy tech, where Panoch serves as an adjunct professor, who will provide voice-over narration, as well as Fatima McKenzie, a research coordinator in the Department of OB-GYN at the IU School of Medicine. Younger actors include an Ivy Tech student and an 18-year-old known to Panoch from the local homeschool community.

"Remarkably, some of our two-year goals for this project are already happening," she said. "It's very exciting we're being invited to publish and present this material so early in the game. I never anticipated in writing the grant that we would need budget for travel and conferences so early -- the Indiana CTSI' support is really making it possible for us to quickly advance this work by providing means to spread the word."

Although the final phase of the curriculum pilot project won't wrap until the final participating health course concludes in spring 2016, Panoch has ambitious goals for the project, which she passionately believes has the potential to benefit the personal health of millions of young people across the country.

"There currently isn't anything about patient communication training in the Indiana Education Standards, and they're only going to teach what's in the standards," she said. "My ultimate goal would be change that -- to one day have this material taught in every high school in the state."

By Kevin Fryling

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Industry Collaboration Portal hosts first external advisory board meeting

Nov. 11, 2014

The Industry Collaboration Portal (ICP), a recently established program to promote collaboration between investigators at the IU School of Medicine and research at private industries, held its first external advisory board meeting on Oct. 21 in the Health Informatics and Translational Sciences (HITS) Building.

The event was the first leadership meeting [since the establishment of the portal](#) sixth months ago through support from the IUSM Transforming Research Initiative and Indiana Clinical and Translational Sciences Institute.

Jaipal Singh, Ph.D., director of the ICP, and Anantha Shekhar, M.D., Ph.D., director of the Indiana CTSI, associate dean of research at the IU School of Medicine and associate vice president of university clinical affairs at IU, led the meeting with an overview of the research enterprise at the IU School of Medicine and goals of the ICP. A welcome was delivered by Jay L. Hess, M.D., Ph.D., dean of the IU School of Medicine and vice president for university clinical affairs at IU.

Topics under discussion included trends in industry R&D with respect to public-private partnerships and emerging best practices; trends in venture investment in academic innovation and emerging investment models; and organizational steps the IU School of Medicine should take to become a top-tier translational research and industry partnering organization.

The chair of the external advisory board of the Industry Collaboration Portal is Richard DiMarchi, Ph.D., Standiford H. Cox Professor of Chemistry and the Linda & Jack Gill Chair in Biomolecular Sciences at IU. Additional external advisory board members, who were also in attendance, are:

- Jamie Dananberg, Ph.D., executive vice president and director of therapeutic areas at Takeda Pharmaceuticals
- John D. Diekman, Ph.D., founder and managing partner at 5AM Ventures
- Ron Laufer, M.D., senior managing director at Medimmune Ventures
- Alan D. Palkowitz, Ph.D., vice president for discovery chemistry research and technologies at Eli Lilly and Company
- Franklyn G. Prendergast, M.D., Ph.D., director of the Center for Individualized Medicine at the Mayo Clinic
- Darryle D. Schoepp, Ph.D., senior vice President for preclinical discovery at Merck Research Laboratories
- Brian Sweet, executive director at AstraZeneca

Established in April, the ICP aims to catalyze partnership development with biomedical industry by identifying faculty members producing innovative technologies, providing guidance to enhance suitability for industry partnership, and connecting investigators to corporate partners and venture capital groups for discovery, development and commercialization.

The ICP advisory board consists of highly experienced industry and venture capital leaders. The portal also maintains a data base of innovative projects, subject matter experts and industry collaborative activities at the IU School of Medicine and has developed a unique institutional implementation structure -- modeled on the Indiana CTSI Project Development Teams -- that networks across the IU system to identify innovations, expertise and capabilities for industry collaboration.

Members of the executive team for the ICP are Dr. Hess, Dr. Wilkes, Dr. Shekhar, Dr. Singh and Mervin C. Yoder, M.D., associate dean for entrepreneurial research and Distinguished Professor and Richard and Pauline Klingler Professor of Pediatrics at the IU School of Medicine, who also serves as the chair of the ICP Industry Collaboration Team. Additional team members are Timothy W. Corson, Ph.D.; Elaine G. Cox, M.D.; Tatiana M.



IU School of Medicine Dean Jay L. Hess, M.D., Ph.D., addresses the Industry Collaboration Portal External Advisory Board.



Malaz Boustani, M.D., center, director of the Center for Health Innovation and Implementation.



Jaipal Singh, Ph.D., right, director of the ICP, chats with an invitee during the reception.



Timothy W. Corson, Ph.D.; Padma Portonovo, Ph.D.; and Yvonne Li, Ph.D.

Foroud, Ph.D.; Melissa Kacena, M.D.; Padma Portonovo, Ph.D.; R. Mark Payne, M.D.; David P. Basile, Ph.D.; Debbie C. Thurmond, Ph.D.; and Milan Radovich, Ph.D., all of the IU School of Medicine.

In addition to his role as ICP director, Dr. Singh, who has many years of experience in pharmaceuticals and medical device development and commercialization, serves as a member of the ICP team and as a visiting professor of cellular and integrative physiology at the IU School of Medicine.

"We believe that strong science at IUSM and partnership with Indiana companies will lead to innovative healthcare solutions for patients in Indiana and around the world," Dr. Singh said.

A reception on the third floor of the HITS Building followed the external advisory board meeting.

For more information about the ICP, contact Dr. Portonovo, ICP project manager, at pportno@iupui.edu.

By Kevin Fryling

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Translational master's degree graduate credits program for career success, "clarity of purpose"

Nov. 11, 2014

When Mona Selej, M.D., a native of Jordan, recently landed a job with a cutting-edge biotech firm in California, she could draw a line straight through the IU School of Medicine from her hometown to her new employer's headquarters on San Francisco Bay.

From 2010 to 2013, Dr. Selej served as a postdoctoral fellow in pulmonary critical care at the IU School of Medicine. She is also the first M.D. graduate of the school's master's in translational science degree program created three years ago with support from the [Indiana Clinical and Translational Sciences Institute](#).

The program, led by R. Mark Payne, M.D., professor of pediatrics and medical and molecular genetics at the IU School of Medicine, also marked the [graduation of its first Ph.D. student](#) in September 2012.

"When I was serving my internal medicine residency at the University of Arizona, I confirmed my fascination with pulmonary physiology," Dr. Selej said. "IU had everything I wanted in a fellowship program, especially the opportunity to get involved in basic research and pursue a master's degree. Other programs were heavily clinical but really lacked a strong bench research infrastructure and opportunities. The IU program struck a great balance."

Even before enrolling in the new master's program, which launched the second year of her fellowship, Dr. Selej was strongly engaged in research at the IU School of Medicine under the direction of Tim Lahm M.D., assistant professor of medicine, and Irina Petrache, M.D., Dr. Calvin H. English Professor of Medicine and professor of biochemistry and molecular biology.

Dr. Selej's work focuses on pulmonary hypertension. Pulmonary arterial hypertension, a subtype of pulmonary hypertension, disproportionately affects women of childbearing age. Yet women with the condition also tend to experience better prognoses and survival rates compared to men, a phenomenon termed the "Estrogen Paradox," generating interest in the role of estrogen and its protective effects in pulmonary hypertension. In the lab, Dr. Selej's work focused on hypoxic pulmonary hypertension, a form of high blood pressure in the lung vasculature in response to "hypoxia," or oxygen deprivation.

"The 'Estrogen Paradox' continues to be a mystery and we do not fully understand why pulmonary arterial hypertension affects females at higher rates and why females tend to have better survival once they have the disease," she said. "Scientists in the field are looking at the mechanism by which estrogen mediates protection in pulmonary hypertension. Our lab at IU studied the mechanisms of estrogen protection in hypoxia with major emphasis on the role of estrogen receptors as that the main pathway that exerts estrogen protective effects."

Continuing through her enrollment in the master's program, Dr. Selej worked on tasks such as developing an animal model of pulmonary hypertension, including the use of medication to induce low oxygen in the lungs, measuring heart tension and collecting tissue samples for analysis. The lab experience took place alongside her daily clinical work as a pulmonary critical care fellow covering IU Health University Hospital, IU Health Methodist Hospital, Eskenazi Health and the Richard L Roudebush VA Medical Center, where the School's highly ranked pulmonary medicine program provided the opportunity to practice advanced procedures, such as bronchoscopies, many of which were not available to peers in other programs.



Selej, M.D.

Mona

"In addition to my clinical training during my fellowship, I really wanted to develop the skills and learn the language of bench and translational research. Enrolling in the Translational Science Master's, program alongside my time in the lab, was the perfect combination to achieving my goals," she said.

The master's curriculum covered courses on tools and techniques of translational research, grant writing, biostatistics, international research ethics, patient-reported outcome research and other topics to which she had not previously been exposed as a physician. In particular, Dr. Selej pointed to classes such as Quantitative Aspects of Translational Research, in which she and her colleagues learned how to develop computer-simulation of biological systems, as extremely "challenging, educational and memorable."

After graduating from IU, Dr. Selej was accepted as a fellow in Pulmonary Vascular Diseases Program at Stanford University. The program provided the opportunity to work almost exclusively with patients with pulmonary hypertension -- from initial diagnosis to cardiac catheterization to prescribing medical therapy.

"I think my time at IU gave me the crucial background I needed to simply sit through a basic science talk and understand what's under discussion," said Dr. Selej, whose lab work also yielded co-authorships on several academic papers. "Stanford is a very selective program, and they like to recruit physicians who also have a very strong interest in academics and research."

Now, Dr. Selej's research and clinical work related to pulmonary hypertension, begun at IU, have led to a position with Actelion Pharmaceuticals, a Switzerland-based company in San Francisco's Bay Area and a leader in pulmonary arterial hypertension therapeutics.

Dr. Selej will be working on Actelion's new endothelin receptor antagonist (ERA) medication, Opsumit (Macitentan), for which she will lead the US Opsumit User Registry among other projects as an associate medical director of ERA research.

Without her time as a student in the translational medicine master's program, Dr. Selej isn't sure she would have the tools needed for her current path -- in terms of both a career and a clarity of purpose.

"It improved my credentials, but more importantly it shaped my interest," she said. "Until I did the translational medicine master's program, I wasn't sure what kind of doctor I wanted to be. The whole experience really made me a more complete physician-researcher -- the type who is capable of helping bridge that gap between the bench and the bedside."

By Kevin Fryling

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CHEP pilot grant to support English language training for parents of children with special medical needs

Nov. 11, 2014

An IUPUI center and a local community organization are co-recipients of an Indiana CTSI Community Health Engagement Program grant of nearly \$23,000 to apply academic research to solve a community health issue.

In the pilot project, "Targeted Language Instruction for Limited English Proficiency Latino Families of Infants with Special Needs," the International Center for Intercultural Communication at IUPUI and Family Voices Indiana will develop a program to teach health-related English to Spanish-speaking parents of infants with special medical needs. The International Center for Intercultural Communication, part of the IU School of Liberal Arts at IUPUI, provides educational expertise in English for Specific Purposes. Family Voices Indiana serves parents of children with special health care needs.

As project partners, ICIC and Family Voices Indiana will collaborate to develop and facilitate a targeted English-language curriculum for parents with children admitted to Riley Hospital for Children at IU Health.

"This targeted language instruction is different from the general English language classes typically offered to immigrant populations," said Ulla Connor, Ph.D., director of ICIC, Chancellor's Professor of English, and the Barbara E. and Karl R. Zimmer Chair in Intercultural Communication. "ESP identifies and provides highly specialized language skills needed for communication in particular scenarios to specific communities of learners with similar goals and proficiency levels. ESP courses generally revolve around role-playing, targeted vocabulary and limited time periods in which to achieve language objectives."

Diane Lorant, M.D., associate professor of clinical pediatrics at the IU School of Medicine, has been instrumental in identifying the need for and participating in the development of this project.

"This type of program was successfully implemented with parents in a local school to help with their children's education; however it has not previously been offered to help parents with their children's medical needs," Dr. Lorant said. "The skills parents need include not only instruction on how to communicate with their children's health care providers, but also how to read prescription bottle labels, arrange doctor's appointments and read bus schedules so they can travel to these appointments."

The ICIC/Family Voices Indiana project was one of four selected from the 15 proposals submitted for the 2014-15 awards from Community Health Engagement Program, part of the Indiana Clinical and Translational Sciences Institute.

"This project has the potential to serve as a nationwide model giving non-English-speaking parents the tools they need to successfully participate in the medical care and treatment of their children," said Rylin Rodgers, director of Family Voices Indiana.

By Diane Brown and Rich Schneider

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Ulla

Connor, Ph.D.

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Access Technology Program Updates -- November 2014

Nov. 11, 2014

Access Technology Program News

Study Design and Data Analysis Consulting Center joins Indiana CTSI-designated cores

The Study Design and Data Analysis Consulting Center (SDDACC) in Bloomington is the latest addition to the list of Indiana CTSI-approved core facilities.

The SDDACC is operated by the Department of Epidemiology and Biostatistics at the IU School of Public Health-Bloomington. A core facility that services the IU research community, SDDACC aims to enhance the research portfolio of the school through 1) collaboration among faculty within and outside of the school, 2) student engagement, and 3) by seeking extramural funding. Our mission is to provide biostatistical and epidemiological expertise in support of health-related researchers.

The center will provide a wide range of statistical support and services through collaborative research to IU researchers and other non-university clients, including:

- Designing research studies (experiments and surveys)
- Grant development
- Sample size calculation and power analysis
- Data modeling and statistical analysis of data
- Interpretation of data analysis results
- Professional and scientific report-writing
- Statistical methods translation
- Long-term collaborative work

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Indiana CTSI Opportunities — November 2014

Nov. 11, 2014

A number of programs are offering services to Indiana CTSI investigators. They are:

Access drug development services from the Indiana CTSI and Covance

The Molecular Therapeutics Program, a part of the Indiana Clinical and Translational Sciences Institute, has established a service agreement with Covance, Inc., to support early drug discovery through in vivo assessment.

Indiana CTSI and [Covance, Inc.](#), one of the world's largest and most comprehensive drug development services companies, [formed an alliance last year to conduct early clinical trials](#) on behalf of biotechnology and pharmaceutical companies at clinical research facilities managed by the Indiana CTSI at the IU School of Medicine in Indianapolis -- as well as Covance's clinical research unit in Evansville. Early phase clinical research includes trials in which investigational new drugs are administered to humans for the first time.

The list of drug development services available through the Indiana CTSI-Covance alliance include Ames toxicity screening; Oral Gavage Pilot Toxicity Study; Toxicity and Toxicokinetic study; hERG; Screening Package (Membrane Permeability and P group Assessment, Metabolic Stability, and Rat PK); Membrane Permeability and P-group Assessment; Metabolic Stability; Rat PK; Rat Cassette PK; Dose Formulation Optimization.

These services are available to all three universities partners affiliated with the Indiana CTSI: IU, Purdue and Notre Dame.

For more information about these services, including pricing estimates, contact Padma Portonovo, project manager for the IUSM-Indiana CTSI Industry Collaboration Portal, at pportono@iupui.edu.

Design and Biostatistics Program: free walk-in clinics

The IUSM Department of Biostatistics is now hosting a free weekly walk-in clinic. A biostatistician will be available to provide brief consultations on study design, sample size and power calculations, data analysis advice, interpretation of results and statistical software.

If more in-depth (or potentially fee-based) support is needed, a biostatistician will guide you to the appropriate person.

No reservations are required. This service is provided courtesy of the Department of Biostatistics and the Indiana CTSI Design and Biostatistics Program.

For the time and location of the weekly clinic, visit the [Department of Biostatistics website](#).

Rx-SafeNet seeks translational research collaborators

The Medication Safety Research Network of Indiana (Rx-SafeNet), a community pharmacy practice-based research network (PBRN) administered by the Purdue College of Pharmacy in Indianapolis, is currently seeking to collaborate with translational researchers and community pharmacists to improve medication safety in pharmacy patients.

Established in 2010, Rx-SafeNet was formed in 2010 and has now grown to 168 pharmacies across the state of Indiana including retail chain, independent and health system outpatient pharmacies. Margie E. Snyder, PharmD, MPH, is the director of Rx-SafeNet. Mary Ann Kozak, DrPH, MHSA, is manager.

There are many opportunities for researchers who want to collaboratively partner with outpatient community pharmacies to improve patient quality of care and increase satisfaction among community pharmacists. Partnering with Rx-SafeNet may include identifying a few pharmacies (5-10) to work with on a small to medium-sized project for researchers that are interested in improving population health in real time. Translational research can impact patients with diabetes, heart failure, hypertension and hyperlipidemia, and many other chronic health conditions.

For information about partnering with Rx-SafeNet, contact Mary Ann Kozak at makozak@purdue.edu or 317-880-5411.

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Indiana CTSI Open Requests for Applications — November 2014

Sept. 9, 2014

Several Indiana CTSI-funded programs are accepting applications. They are:

Indiana CTSI-IU Kelley MBA Core and Project Business Management Assistance Program -- due Nov. 21

A good business plan is critical to the success of any research core or program. The [Indiana Clinical and Translational Sciences Institute](#) Access Technology Program, in collaboration with the IU Kelley School of Business, offers access to a team of Kelley MBA students who will receive course credit for partnering with the successful applicants on business solutions for their core or program.

Cores, resources and units at IU, Purdue or Notre Dame providing a central service to Indiana CTSI investigators are eligible. Priority will be given to proposals that will lead to improvements in organizational efficiency, speed of service, and/or quality; and have the potential to be extrapolated and benefit other cores, resources or units. The proposal must request and define a need for assistance in one or at most two of these following: project management, marketing, financial management and resource efficiency management.

Successful applications to this program will receive business management assistance from teams of Kelley MBA students. Project durations vary from eight to 12 weeks, depending on project scope, starting in February or March and completing anywhere from mid-May to July.

Selected cores will be expected to engage with the MBA students for initial project scope (two hours), additional follow-up or onsite meetings (eight to 12 hours) and a final project close-out (one to two hours). The MBA students will contribute 30 to 100 hours each (depending on the project scope, number of team members and course credit assignment) to the project progression in turn.

Applications are due **Friday, Nov. 21**. [More on this program and access to the application](#) are available online. Log in using your institutional username and password. Application instructions are under "CTSI - IU Kelley MBA Core and Project Business Management Assistance - 2014.11."

For more information, contact Lilith Reeves at ictsi@iu.edu.

Pre-doctoral training awards in translational research -- Applications due Dec. 8

The Indiana Clinical and Translational Sciences Institute is seeking applicants for special predoctoral training awards in translational research.

In biomedical terminology translational research refers to what is popularly termed "bench to bedside," the process by which research in the lab "translates" into patient treatment. Translation may involve applying discoveries made during research (in the lab, through animal studies, etc.) to the development of clinical trials and studies in humans, or carrying out research aimed at enhancing the adoption of best practices, or both.

These two types of translational research are usually described as consisting of either "T1 research" (basic biomedical research, e.g. study disease at a molecular or cellular level, as it progresses to the development of new treatment options at the clinical level) or "T2 research" (enhancing access to and the adoption of evidence-based strategies in clinical and community practice, institutionalizing programs, products, and services to improve health). These awards are aimed at predoctoral students whose research is at any point along this spectrum.

Funding is available for pre-doctoral graduate students. Criteria for application include:

- Candidates must have completed at least one year of a pre-doctoral training program but cannot have completed more than their third year (i.e., applicants must be in the second or third year of their pre- doctoral program when they apply).
- Co-mentorship by faculty investigators from at least two different disciplines (preferably a clinician and a non-clinician scientist).
- Research that is translational in nature and takes advantage of the synergism that comes from working at this basic/clinical interface or clinical/community interface.
- U.S. citizen or permanent resident status.

Funding is for two years (with the second year of funding contingent upon satisfactory progress). Benefits include a stipend as well as health insurance and partial coverage of tuition and fees.

Trainees will be required to participate in a translational science course, attend a National CTSA meeting and present their work at several Indiana CTSI pre-doctoral gatherings during the academic year.

Completed applications must be submitted by **Monday, Dec. 8**, with awards starting July 1. Interested candidates must be prescreened for eligibility by submitting a copy of their CV to Colleen Gabauer by **Monday, Nov. 24**, at ictsi@purdue.edu. You can also contact Gabauer at 765-496-1016.

Fall 2014 Core Pilot Grants -- Due Sept. 29

Spinal Cord and Brain Injury Research Fund -- Open December 2014

In 2007, the State of Indiana established the [Indiana Spinal Cord and Brain Injury Research Fund](#) (login required), which releases a request for proposals (RFP) each December.

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The overall objective of this RFP is to foster and encourage research for the prevention, treatment and cure of spinal cord and brain injuries, including acute management, medical complications, rehabilitative techniques, and neuronal recovery.

The Indiana CTSI supports this initiative for PIs and/or collaborators from its affiliated institutions (IU, Purdue and Notre Dame) by providing assistance with successful proposal development via its Project Development Team program. The PDTs are teams comprised of members with a wide variety of expertise who can provide feedback on study design, protocol development, biostatistical design and grantsmanship, as well as facilitating collaborations and networking.

For more information on how the PDTs can assist with your ISCBIRF proposal prior to submission, please contact Julie Driscoll at judrisco@iu.edu.

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On the Horizon — November 2014

Indiana CTSI Fourth Annual Disease and Therapeutic Response Modeling Symposium -- Nov. 12-13

The Indiana Clinical and Translational Sciences Institute Fourth Annual Disease and Therapeutic Response Modeling Symposium will be Nov. 12 and 13 at the IUPUI Campus Center.

Speakers include Jamie Dananberg, Ph.D., executive vice president at Takeda Pharmaceuticals; Nick Holford of the University of Auckland, New Zealand; John Urquhart, M.D., of the AARDEX Group, Switzerland; Mark Sale, M.D., of Next Level Solutions, LLC; Sean Mooney, Ph.D., of the Buck Institute for Research on Aging; Stephen Hall, Ph.D., of Eli Lilly and Co.; and Benjamin Ribba, Ph.D., of the French Institute for Research in Computer Science and Automation (INRIA), France.

Academic, government and Eli Lilly and Co. employees may register for free at <http://operations.medicine.iu.edu/index.php?CID=163>. Other guests must pay a fee of \$250 to register at <http://go.iu.edu/e0J>.

A limited number of hotel rooms have been arranged at a discounted rate at the Omni Severin Hotel in Indianapolis for \$159 per night.

For questions or more information, contact Ayman Akil at aakil@iupui.edu, Abhishek Gulati at agulati@iupui.edu or Cheryl Weatherholt at weather@iu.edu.

National Science Foundation educational proposal workshops -- Nov. 13, 18 & 20

The Office of the Vice Chancellor for Research and the IUPUI STEM Education Research Institute will host several National Science Foundation-sponsored STEM (Science, Technology, Engineering and Math) Interactive Web-Based Workshops from Nov. 6 to 20 at IUPUI.

These workshops are primarily intended for STEM faculty members who are interested in NSF educational proposals or already have a funded project. These programs are designed to engage local participants in discussions related to the workshop topic, interdisciplinary collaboration and will enable local sites to interact with the entire virtual group. Attending some or all of these workshops may give faculty a competitive edge in developing STEM educational projects and writing successful NSF proposals.

Each session will be presented by former program directors in the Directorate for Education and Human Resources at the National Science Function and is facilitated by an IUPUI faculty member.

All sessions are scheduled from 2 to 4 p.m. in the IUPUI Library. Workshop topics are:

- **Nov. 13:** "Project Evaluation," Room 1126. The goal of this workshop is to enhance the participants' understanding of evaluation concepts and methods so that they can more effectively work with an evaluator in addressing this important component in preparing proposals or in implementing funded efforts.
- **Nov. 18:** "Impact and Transportability," Room 2115E. The goal of this workshop is to enhance the participants' understanding of strategies for developing a project that is adaptable and potentially transformative so that they can more effectively address transportability and dissemination in preparing proposals or in implementing funded efforts.
- **Nov. 20:** "Broader Impacts," Room 2115E. The goal of this workshop is to enhance the participants' understanding of strategies for dealing with broader impacts in an NSF educational project so that they can more effectively address this issue in preparing proposals or in implementing funded efforts. The discussion of the broader impacts criterion has changed substantially in the latest version of the [Grant Proposal Guidelines](#).

Space is limited. To RSVP, email Etta Ward at emward@iupui.edu.

Workshop questions to Yolanda George at ygeorge@aaas.org.

Submit your events!

Other events will be listed as they are scheduled on the Indiana CTSI's newly upgraded [events calendar](#). To submit an event, email date, time, location, description and contact information to info@indianactsi.org.

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