Indiana CTSI reports a record year for technology transfer

May 8, 2012

The Indiana Clinical and Translational Sciences Institute set a record last year for supported research projects that have reached the technology transfer phase of their development.

Twelve projects supported by the Indiana CTSI in 2011 have filed intellectual disclosures with the Indiana University Research and Technology Corp., a not-for-profit agency affiliated with Indiana University that specializes in moving innovative research into the marketplace. In 2010, no technology transfer projects were reported by IURTC that cited support from the Indiana CTSI.


The Indiana Research and Technology Corp.

“There’s been a significant jump in activity from the Indiana CTSI,” said Bradley Fravel, Ph.D., MBA, business development manager and faculty corporate liaison at the IURTC. Dr. Fravel, in collaboration with Mervin Yoder, M.D., professor of pediatrics at the IU School of Medicine, works to ensure that research results generated by Indiana CTSI support are properly protected. Dr. Yoder was appointed assistant dean for entrepreneurial research at the IU School of Medicine and associate director for entrepreneurship at the Indiana CTSI in June.

The Indiana CTSI and IURTC make “perfect partners” since they focus on two separate but interrelated aspects of the translational research process, Fravel said. “We will provide funds for legal and business costs – but not research dollars – whereas the Indiana CTSI facilitates access to seed funding, lab equipment, research collaborators – all the things that you need to capture larger grants -- but not the business side of the equation.”

Indiana CTSI-support projects to enter the commercialization process over the past year include:

- Autism research by Craig Erickson, M.D., assistant professor of psychiatry at the Indiana University School of Medicine, who has cited the Indiana CTSI on five patents filed by the IURTC in 2011. These include patents for the use of the drugs acamprosate and riluzole as therapeutic agents for Fragile X syndrome and autism, as well as three potential biomarkers -- two to detect biological evidence for improvement after treatment with acamprosate or riluzole and a third to predict in advance whether a patient will react to treatment with these drugs. Initial support for these research projects came from a $17,000 grant from the Indiana CTSI Pediatric Project Development Team as well as support from its bioethics, compliance and biostatistics support programs. Dr. Erickson also serves as clinical director of the Christian Sarkine Autism Treatment Center in the Department of Psychiatry at the IU School of Medicine.
- A new approach to the treatment of bacterial infections by Stan Spinola, M.D., professor and chair of microbiology and immunology, who cited the Indiana CTSI as a contributor to research that recently received a provisional patent through the IURTC. The project has great commercialization potential because the same basic biological pathways have been used in every anti-bacterial product over the past 40 years, Fravel said. In 2011, Dr. Spinola received more than $21,000 from the Indiana CTSI Clinical Project Development Team to support this research as well as services from the Indiana CTSI Clinical Research Center, Bioethics and Subject Advocacy Program, and Design and Biostatics Program.
- A novel method to analyze dental “biofilm” for cavity risk by Dominick Zero, DDS, professor and chair of preventive dentistry and associate dean for research, and Andrea Ferreira-Zandona, DDS, MSD, Ph.D., associate professor of preventive and community dentistry, both of the IU School of Dentistry; and Milos Novotny, Ph.D., Distinguished Professor of

Chemistry, Indiana University Bloomington. This project has significant commercial potential since no reliable method exists to predict whether a dental lesion will develop into a cavity, Fravel said. The project received more than $16,000 from the Pediatric Project Development Team in 2012. Dr. Zero and colleagues also benefited from services from the Design and Biostatistics Program.

- A new method to treat hot flashes developed by Anantha Shekhar, M.D., Ph.D., Raymond E. Houk Professor in Psychiatry, and Philip Johnson, Ph.D., assistant research professor of psychiatry, both of the IU School of Medicine, as well as genetics research related to the treatment of learning disabilities led by Dr. Shekhar and D. Wade Clapp, M.D., Chair and Richard L. Schreiner Professor of Pediatrics at the IU School of Medicine. The first project received about $26,000 in support from the Preclinical Project Development Team in 2010, and the second project received regulatory expertise provided by the Indiana CTSI. Dr. Shekhar also serves as the director of the Indiana CTSI.

In addition to monitoring pre-publication research for patentable material, a commercialization manager from the IURTC participates in Indiana CTSI Project Development Team meetings to scout for new projects. The Indiana CTSI Project Development Team programs include 10 teams that support and develop research projects aimed at topics such as preclinical research, adult and pediatric clinical trials, behavioral and population science, and urban health.

Fravel added that some researchers approach the center with their projects, whereas others are contacted by technologies managers who have identified their work as possessing commercialization potential.

But no matter how research reaches the tech transfer phase of its development, each receives equal care on its path toward commercialization, said Matt Rubin, MBA, an associate commercialization manager at IURTC.

“In the first year [after a patent filing], the most important step is to put the investigator in touch with a corporate partner and then address what is required to make the research marketable," he said, noting that many challenges identified by business are not easily recognized by investigators.

For example, a corporation might hesitate to develop drugs that are cosmetically unappealing, require injection or produce an unpleasant taste when ingested. Rubin said a recent drug development project being processed by the IURTC met initial resistance because the original compound used to make the medication “druggable” (i.e. water soluble) included a side effect that increased the body’s vulnerability to environmental toxins. Additional work was done to identify a different compound and increase the drug’s changes of being picked up by industry.

“We work together to course correct in the early stages to overcome these issues as well as help forge ties between business and researcher,” said Rubin. “These days industry wants to be fully confident that the early research has been well done before they license a technology; they don’t just want to license a technology, they want to ‘license’ a relationship.”

Fravel, who also ushers many projects through the commercialization process, agrees.

“A lot of the process is about developing relationships – following a researcher’s work, keeping in contact, making sure you work together throughout the process in order to meet deadlines," he said. "It really becomes a partnership between our office and the industrial partner and the faculty member.”

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Collaborative grant supports work toward a blood test for children with cancer

May 8, 2012

Kamnesh Pradhan, M.D., will never forget the moment when the grandmother of one of his patients -- a young girl undergoing yet another MRI scan after a third round of chemotherapy -- asked why they couldn't observe her response to treatment with a blood test rather than another trip to the "scary machine."

Dr. Pradhan, assistant professor of pediatrics at the Indiana University School of Medicine and a pediatric oncologist at Riley Hospital for Children at Indiana University Health, took the grandmother's wisdom to heart by launching a study to find novel biomarkers for treatment response in the blood of children with malignant tumors. The project is the first to receive funding from a pediatric regional collaborative grant program supported by five translational science institutes across the Midwest, including the Indiana Clinical and Translational Science Institute. The goal of this grant is to bring together expertise, scientific resources, patient populations and community resources that are not all available at a single site.

"I realized that little, if any, research exists on observing the effect of cancer treatment on tumors with a simple blood test," said Dr. Pradhan, whose co-investigators include Rachel Egler, M.D., assistant professor of medicine at the Case Western Reserve University School of Medicine, and Vlad Radulescu, M.D., assistant professor of pediatrics at the University of Kentucky College of Medicine. "Had this mechanism not been in place, we might not have been able to pull together enough patients for this research. Pediatric cancers are rare — they are not common like adult cancers — so we needed this support to help us work across multiple institutions."

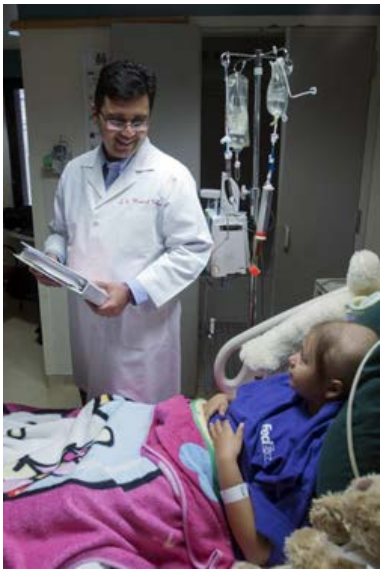
Dr. Pradhan's study examines the level of cells that promote angiogenesis — or the growth of new blood vessels — in tumors from children with malignant tumors. These novel cells, called circulating hematopoietic stem and progenitor cells and endothelial progenitor cells, were identified during an earlier study that revealed tumors possess increased levels of these novel cells. These cells were first characterized by David Ingram, M.D., Hugh McK. Landon Professor of Pediatrics and professor of biochemistry and molecular biology, and Mervin Yoder, M.D., director of the Herman B Wells Center for Pediatric Research and Richard and Pauline Klingler Professor of Pediatrics.

To detect reaction to cancer treatment, Dr. Pradhan and his collaborators are examining patients' bloodstreams for elevated levels of cells with angiogenic potential before, during and after radiation and chemotherapies. Seventeen patients have been enrolled at Riley Hospital, with an additional 12 patients at Rainbow Babies Hospital in Cleveland and the University of Kentucky Medical Center in Lexington made possible by the collaborative grant. The investigators aim to enroll a total of 48 patients over the course of the two-year study.

The team expects to detect elevated levels of these cells during the beginning of treatment — as tumors require an increase in blood vessels to develop — and decrease as treatment progresses. To gauge the levels of cells in the bloodstream, Dr. Pradhan will use a novel method of flow cytometry first developed at the Wells Center.

"The overall goal would be to consider these novel cells as biomarkers to patients' response to treatment," Dr. Pradhan said. "If they turn out to be valid biomarkers, they would be used for predicting response to treatment before treatment is started and describing how a patient is doing in treatment."

In addition to the children's hospitals in Indianapolis, Cleveland and Lexington, the grant mechanism supporting this research includes agreements with Cincinnati Children's Hospital and Nationwide Children's



Kamnesh Pradhan, M.D., meets with Riley Hospital patient Alexis Knight, a participant in his research study.

Hospital in Columbus, Ohio, with each contributing $10,000 per institute engaged in the support project. Due to the co-investigators on Pradhan's study, his project is supported by the Indiana CTSI, the Clinical and Translational Science Collaborative at Case Western Reserve University School of Medicine and the Kentucky Center for Clinical and Translational Sciences at the University of Kentucky College of Medicine.

Moreover, Dr. Pradhan's project received early support from an Indiana CTSI Pediatric Project Development Team program pilot grant, the IU Melvin and Bren Simon Cancer Center and an IU Health Values Grant. These contributions went toward the integration of computer infrastructure to facilitate fast and effective data sharing between the participating institutions, including support for REDCap — managed by the Indiana CTSI — and caTissue Suite, a biorepository tool for biospecimen inventory management, tracking and annotation.

By establishing a strong, virtual biobank across multiple institutes, Dr. Pradhan said he and his collaborators will be well-positioned to expand their work through external funding applications to groups such as the National Institutes of Health.

"The next phase, which I think is the most exciting, will be to explore targets for treatment," Dr. Pradhan said. "When you get such a big, rich data set on what really happens to these cells in the clinical population, the basic scientists can look at why and how these cells varied in people. Can we use these cells as targets with nanoparticles to help in drug delivery to tumor sites, for example? That's a futuristic goal, but clearly one that has implications for basic science and drug development."

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Translational science master's program accepts first fellows

May 8, 2012

The Indiana Clinical and Translational Sciences Institute is supporting a new fellowship program for medical students who want to take a year off from their studies to earn a master's in translational science.

The master's in translational science degree program was established in August 2011 through collaboration between the Indiana CTSI and the Indiana University School of Medicine. The program began by offering degree tracks for postdoctoral students with a medical, dental or doctoral degree in a basic science or engineering, but has expanded to include current medical students with an interest in pursuing translational research.

The new fellowship program, also approved last year, recently accepted its first two members, who will begin classes in the summer.

"We worked with IUSM to obtain approval for their medical students to take a year-off to pursue an expedited version of our master's program," said R. Mark Payne, M.D., director of the masters in translational science program and professor of pediatrics and medical and molecular genetics at the IUSM. "Our overall objective for this program is to jointly train scientists, engineers, and physicians in the methodology of translational research."

R. Mark Payne, M.D., professor of pediatrics and medical and molecular genetics at the IU School of Medicine, is director of the masters in translational science program.

The first students accepted into the fellowship program are **Aisha N. Davis** and **Renecia Watkins**, medical students at IUSM. Davis will be studying the human papillomavirus types and cervical cancer specimens from women in the United States, Jamaica, Botswana and Kenya under the mentorship of Drs. Darron Brown, M.D., and Gregory Zimet, Ph.D. Watkins will be studying the effects of newly diagnosed type I diabetes on endothelial progenitor cell count and function in children under the mentorship of Linda DiMeglio, M.D.; Laura Haneline, M.D., and Janice Blum, Ph.D.

The program is also supported by matching funds from IUSM. Participants are medical students who have completed at least one year of medical school, in good academic standing, and must work with co-mentors from clinical and non-clinical fields.

"This program is a natural outgrowth of the planning and implementation of the Indiana CTSI," Dr. Payne said. "It was jointly designed by basic and physician scientists who realized that all the best major medical centers in the country have a very valued group of physicians who work at the interface of basic science and human health."

Since its establishment in August 2011, Dr. Payne adds the program has enrolled four students, including **Xiaodong Peng**, Ph.D., a biomedical informatics fellow at Regenstrief Institute, who will graduate this fall.

"Through this program, I realized that there is a huge demand for collaboration between the scientific and medical communities," Dr. Peng said. "These groups really need to work together to turn innovative discoveries in the lab into new therapeutic interventions or services that improve health care delivery, and patient quality of life."

During the two-year program, Dr. Peng noted that the degree program covered all aspects of translational science, including cutting-edge genomic research, regulatory and ethical issues in basic biomedical and clinical research, clinical study design, data analysis, and statistical and mathematical modeling.

"My most interesting experience was the clinical rotation," he added. "We learned how clinicians treat the patients, how do they ask questions for themselves and scientists to answer, how do they think about research, including clinical and basic research. I also learned how translational research proposals are discussed and approved by the Indiana CTSI project

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development teams, and saw how pharmaceutical companies engage in the translational research process by sponsoring clinical trials.”

Understanding the interconnections between basic and clinical research is imperative for research to make the leap from the bench to the bedside,” Dr. Payne added, noting too many discoveries are failing to make the leap into the “real world.”

“This master’s program was designed to bridge this gap,” he said. “Translational research doesn’t always take place inside a laboratory. Overcoming these changes requires a new training paradigm in which scientists, engineers and physicians are trained together and understands the others’ language and methodology.”

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Indiana CTSI Opportunities — May 2012

Indiana Spinal Cord and Brain Injury Fund — applications due May 21

The state of Indiana is seeking applications for its 2012 Spinal Cord and Brain Injury Fund research award program. This program supports research for the prevention, treatment and cure of spinal cord and brain injuries, including acute management, medical complications, rehabilitative techniques and neuronal recovery.

The maximum amount for these grants is $60,000 per year for up to two years. Applicants must be affiliated with an Indiana-based research institution or organization, but national and international collaborations are encouraged. This grant is administered for the state of Indiana by the Indiana Clinical and Translational Sciences Institute.

Application deadline is **5 p.m. Monday, May 21**.

To access complete application information, including eligibility guidelines, submission forms and a proposals presentation checklist, visit www.indianactsi.org/grants. Log in using your institutional username and password and select “Indiana Spinal Cord and Brain Injury Research Fund Grant Program - 2012.05 (SCBI).”

Application are also available at www.in.gov/isdh/23657.htm.

For more information, contact Lisa Dinsmore at info@indianactsi.org.

Center of Excellence in Cardiovascular Research grants – applications due July 2

The Center of Excellence in Cardiovascular Research (CECARE) is seeking application for grants to support clinical and translational cardiovascular research projects. The research projects must be relevant to cardiovascular disease and provide information to enhance an application for a larger extramurally funded research activity.

The maximum amount for this grant is $80,000 per year for up to two years. Applicants must have an Indiana University faculty appointment, or demonstrate a close link to the IU Health Cardiovascular Programs. IU Health physicians with affiliate appointments are eligible to apply.

Faculty from Indiana CTSI partner institutions (Indiana University, Purdue University and the University of Notre Dame) are eligible to apply if the study is linked to IU Health facilities. The submission deadline for letters of intent is **5 p.m. Monday, June 18**, and applications are due **5 p.m. Monday, July 2**.

To access complete application information, including eligibility guidelines, submission forms and a proposals presentation checklist, visit www.indianactsi.org/grants. Log in using your institutional username and password and select “Center of Excellence in Cardiovascular Research: Research Grants - 2012.07.”

For more information, email info@indianactsi.org.

Fairbanks Institute for Health Communities – biospecimen funding

The Fairbanks Institute for Healthy Communities is seeking applications for the purchase of phenotypic-rich biospecimens from INbank®. Awards for the purchase of specimens is based out scientific funding that could generate extramural funding or novel intellectual property (IP).

The maximum amount for this award is $50,000, with several awards to be distributed based on the number and type of biospecimens requested. Full-time faculty with a rank of assistant professor and above from Indiana University, Purdue University, or the University of Notre Dame are eligible to apply.

The submission deadline for letters of intent **5 p.m. Friday, June 29**, and applications are due **5 p.m. Monday, Oct. 1**.

To access complete application information, including eligibility guidelines, submission forms and a proposals presentation checklist, visit www.indianactsi.org/grants. Log in using your institutional username and password and select “Fairbanks Institute: Funding for the Purchase of Phenotypic-rich Biospecimens - 2012.10.”

More information about the Fairbanks Institute is available at www.fairbanksinstitute.org.

For more information, email info@indianactsi.org.

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Anantha Shekhar elected president of Association for Clinical and Translational Science

Anantha Shekhar, M.D., Ph.D., director of the Indiana Clinical and Translational Sciences Institute, has been named president of the Association for Clinical and Translational Science at the group's annual meeting in Washington, D.C. April 18 to 20. Dr. Shekhar also serves as associate dean for translational research and Raymond E. Houk Professor of Psychiatry and Professor of Neurobiology and Pharmacology at the Indiana University School of Medicine.

Anantha Shekhar, M.D., Ph.D., director of the Indiana Clinical and Translational Sciences Institute, is president of the Society for Clinical and Translational Science

"I'm honored to be selected as the president of the Association for Clinical and Translational Science," Dr. Shekhar said. "Our goal over the next year will be to continue to create a greater awareness about the power of translational medicine, the impact it could have on our nation's health, and attract more young investigators into working in the translational aspects of biomedical research."

ACTS was formed this year following the merger of three scientific societies: the Society for Clinical and Translational Science, the Association for Clinical Research Training and the Association for Patient-Oriented Research. The merger of these three prestigious organizations, which are focused on various aspects of translational science, will help the translational medicine community speak with a louder, more unified voice on policy issues, such as encouraging continued government support of scientific research.

Dr. Shekhar previously served as president-elect of the Society for Clinical and Translational Science, a national organization with a mission to advance research and education in clinical and translational science to improve human health. The society was founded in 2008 to enhance the goals set by the National Institutes of Health after the establishment of its Clinical and Translational Science Award to support 60 centers focuses on clinical and translational research across the United States.

ACTS has more than 6,000 members, including directors and investigators from all 60 CTSA centers as well as representatives from the NIH and industrial partners such as Merck and Pfizer.

As president of ACTS, Dr. Shekhar aims to increase the diverse types of researchers and young investigators engaged in the ACTS mission, with an emphasis on mentorship and research excellence. He also expects to encourage greater international participation in the group, noting that the U.S. model of re-engineering translational medicine is being emulated by other countries. The Australian government has begun to develop a national network akin to the CTSA Consortium in the United States, and the European Union, China and the United Kingdom are implementing similar projects, or channeling funds into translational science.

"Large investments are being put into biomedical research across the globe, and many countries are considering how to reorganize to emphasize those things supported by translational science, such as commercialization and accelerating the process by which new research makes an impact on human health," he said.

ACTS membership is free to members of all institutions within the CTSA Consortium, including Indiana University, Purdue University and University of Notre Dame. To learn more or to join, visit www.indianactsi.org/memberopp.

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On the Horizon — May 2012

The Indiana Clinical and Translational Science Institute will host an online workshop from 2 to 4 p.m. Thursday, May 24, for investigators who wish to learn more about **MetaMiner**, a product from GeneGo designed for disease-specific analysis of metabolic pathway information. For more information, visit www.indianactsi.org/events/details/490.

In addition, Indiana CTSI will cosponsor the **Second Annual American Delirium Society Conference** June 3-5 in Indianapolis. For more information, see the event flier or visit www.americandeliriumsociety.org.

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