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Indiana CTSI highlights clinical trials to advance research

March 13, 2012

Each year, IU conducts hundreds of clinical trials that need patients. But until recently patients who asked their health care provider if they could get into a study often had to rely on what their doctor or nurse had discovered through word of mouth.

Now all they need to do is point patients to the nearest web browser.

Since its establishment in 2008, the Indiana Clinical and Translational Sciences Institute has made it a part of its mission to highlight clinical trials to advance research. Maintained by the Indiana CTSI Office of Research Recruitment — on the fifth floor of University Hospital — the Indiana CTSI HUB's clinical trials listing provides accurate, up-to-date information on all active research studies at Indiana University.

"Historically it's been very difficult for patients here to even understand what trials they might be eligible for — there simply wasn't a place for them to go to search for research studies relevant to them," said Scott Denne, M.D., professor of pediatrics and associate director of the Indiana CTSI. "Every investigator or clinical research unit has their own little areas of knowledge, but there wasn't a single, simple place for people to go."

The Indiana CTSI clinical trials listing provides a "one-stop shop" for patients — as well as physicians, researchers and others — who want to know what clinical trials are happening across the Indiana CTSI. All trials at IU, including Indiana University-Purdue University Indianapolis, IU School of Medicine and regional campuses, are listed, and officials aim to eventually integrate Purdue University and the University of Notre Dame into the system.

The information is provided to the Indiana CTSI by the IU Institutional Review Board, whose reorganization last year under a central office further streamlined cross-campus information-sharing.

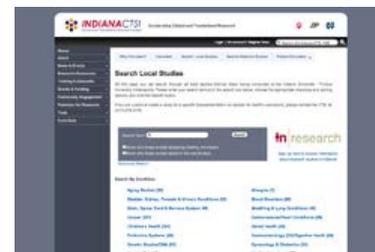
"What [the Indiana CTSI] did was to go to the only place that had all this information — the IRB office — and work together to get permission to list studies on our website," Dr. Denne said. "This information used to be very locked down; searching it was really clunky. The CTSI built a new system from scratch. It's a major accomplishment."

Anyone who conducts research with human subjects at IU passes through the IRB — the primary document they process includes the choice to authorize the Indiana CTSI to publically list the study or opt out — and negotiated deferral agreements between the IU IRB and Purdue and Notre Dame may bring these institutions into the system.

"Our goal is twofold," said Brenda Hudson, MA, CCRP, program manager for the Indiana CTSI Research Recruitment Office. "The first is for the public — to allow people to have a place to go where they can search for research studies that are occurring that they can participate in — and the other is to foster collaboration among researchers."

The clinical trials listings are designed to encourage exploration by both groups with straightforward subject categories such as "infectious disease," "sleep disorders" and "women's health" as well as plain language study descriptions adapted from recruitment materials and patient consent forms. A full-time research assistant with the Research Recruitment Office, Patrick McGuire, enters each trial as it arrives from the IRB office, ensuring each listing remains consistently readable and user-friendly. The system's usability sets the database apart from other resources such as ClinicalTrials.gov, a clinical trial listing established by the National Institutes of Health.

On average, McGuire fields 30 to 40 phone inquiries from patients and community members per month, plus email and Web questions. Last month,



The Indiana CTSI HUB hosts a list of all active clinical trials from the Indiana CTSI partner institutions at indianactsi.org/clinicaltrial

the clinical trials listing Web page received nearly 2,500 page views.

In addition, Hudson notes that the listing attracts a more diverse patient population by reaching beyond the halls of the hospital. It puts information into the community via a medium they're already using — the Internet.

"Nowadays you can't just rely on the patients in the medical center to complete your enrollment," she said. "You've got to have some information outside the system. Previously people would run advertisements in the newspaper or on the radio. That can still work, but investigators can't complete all their recruitment anymore using a single mechanism."

The listing also serves an important internal function as a definitive source for inquiries from patients — and others — regarding clinical research.

"It's easy to identify who's doing what research using the listing, and then ask the investigator if they would be interested in partnering with a specific group," Hudson said. "We get calls all the time from pharmaceutical companies or clinical research organizations looking to connect with a researcher or clinical trial project."

The next step will be to further integrate data from the clinical trial listing into other places patients and researchers go to find information about clinical trials. Currently, Indiana CTSI partners with IU Health to display all clinical research studies conducted by a specific physician under the physician's profile on the IU Health website. Other potential uses include filtering out research studies based on increasingly granular specifications, such as listing only trials related to specific pediatric disorders for parents on the Riley Hospital for Children at IU Health website.

"There's real potential to hone this list — to make it more useful for specific populations," said Hudson. "We want everyone to use this resource."

Put simply, Dr. Denne said the work performed by the Indiana CTSI to publically list clinical trials online breaks barriers between researchers and patients that have persisted for decades.

"No question this clinical trials database was made possible by the Indiana CTSI," Dr. Denne said. "This has been an issue as long as I've been here — 25 years — and it didn't happen until the CTSI."

To explore clinical trials, visit www.indianactsi.org/clinicaltrial.

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Indiana CTSI-supported research could lead to risk factor test for rare chest cancers

March 13, 2012

Predicting the risk of recurrence, as well as the best course of post-operative treatment, is a challenge faced by oncologists working on all types of cancers. But research by Indiana University physician-scientists Sunil Badve, MBBS, M.D., Yesim Gökmen-Polar, Ph.D., and Patrick Loehrer Sr., M.D., could result in a genetic test to predict the risk of recurrence for thymoma, a rare tumor of the upper chest.

Castle Biosciences, a cancer-based molecular diagnostics company whose mission is to serve individuals afflicted with rare or orphan cancers, recently announced worldwide exclusive license for the intellectual property and technology rights related to a gene expression profiling test for use in thymoma. The test is based upon research presented by Drs. Badve, Loehrer and Gökmen-Polar at the American Society of Clinical Oncology's annual meeting in 2011. The agreement was made possible by the Indiana University Research and Technology Corp. (IURTC) and the Indiana Clinical and Translational Sciences Institute (CTSI), which provided pilot funds to the project.

"Obtaining objective molecular data to support traditional histological assessment will lead to improved diagnostic accuracy for thymomas and thymic cancers," said Dr. Badve, professor of pathology and laboratory medicine at IU School of Medicine. The test under development, called DecisionDx-Thymoma, could provide an objective, accurate assessment of an individual's risk of metastasis.

This knowledge could assist physicians in developing individualized treatment plans that reduce the amount of painful side effects caused by adjuvant treatments such as radiation and chemotherapy, he said.

Thymomas and thymic cancers are rare, but they are one of the most common types of cancers found in the upper chest. Tumors are often discovered on a chest x-ray when a patient suffers from chest pain, cough or difficulty swallowing — or a previously associated autoimmune disorder — and can spread throughout the chest and body. Treatment consists of surgical removal followed in some cases by radiation or chemotherapy. However, Dr. Badve said that experts are not yet able to accurately assess patients' risk of metastasis or recurrence. While clinical analysis of tumor size, excision and patient symptoms can help determine a tumor's severity, they cannot predict an individual patient's risk.

A more accurate assessment of recurrence risk provided by DecisionDx-Thymoma could reduce or eliminate the need for these painful additional treatments following the tumor removal in patients who test at a low risk for re-developing thymic tumors.

"The ability to accurately assess metastatic risk based upon the thymoma's molecular signature will enable personalizing therapeutic options," said Dr. Loehrer, director of the Indiana University Melvin and Bren Simon Cancer Center and an international expert on thymomas and thymic carcinomas. "This will assist in deciding which patients should receive post-operative therapy."

Dr. Badve said IU is uniquely positioned to collect and analyze thymomas and thymic tumors because of researchers such as Dr. Loehrer, who has been sought by patients for expert care over the past 15 years.

The partnership between Castle Biosciences and the IU investigators was brokered by the IURTC in fall 2011 after the group worked with the IU investigators to file disclosure on the genes used in their research prior to



Sunil Badve, MBBS, M.D.



Patrick Loehrer, M.D.



Yesim Gökmen-Polar, Ph.D.

their poster presentation at ASCO 2011. The partnership with Castle Biosciences provides access to state-of-the-art facilities capable of technical validation of the thymoma test in CAP-accredited, CLIA-certified laboratories. The third investigator on the research that led to partnership with Castle Biosciences, Dr. Gökmen-Polar, is an assistant scientist of medicine at the IU School of Medicine.

The Indiana CTSI was instrumental in providing funding for the initial research, said Dr. Badve. The Indiana CTSI Project Development Team program provided \$19,200 in August 2011 for "Validation of Gene Signature Predicting Metastasis of Thymomas," which supported polymerase chain reaction (PCR) testing and other assays that strengthened the research's validity.

The Project Development Team Program was eager to support this research on thymoma because it "allowed CTSI to provide seed funding for the thymoma research before Castle stepped in," said Crystal Banks, a translational research coordinator at the IU Simon Cancer Center and Indiana CTSI.

With the drug company's assistance, the clinical validation process will be expedited, said Dr. Badve, and a test could be available to the public sooner than if the work were done within a university laboratory.

If the process is a success, Castle Biosciences stated a commercial test could be available as early as this spring.

"This whole effort has been the perfect combination of a research scientist, clinician and pathologist working together," Dr. Badve said. "Everyone played complimentary research roles to bring about a real change in cancer treatment for patients with thymoma."

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IU MBA Students Provide Business Expertise to Indiana CTSI Scientists, Labs and Clinics

March 13, 2012

As an MBA student learning to provide professional-level business consulting services, it's hard to beat a first client whose ambitions include inventing a new drug to take on breast cancer.

But that's exactly the challenge faced by three students from the IU Kelley School of Business — Eric Laager, Ryan Melnikas and Andy McDonnell — who were among 19 MBA students participating in nine business consultation projects as part of a collaboration project between IU Kelley School of Business and the Indiana Clinical and Translational Sciences Institute Translational Technology Resources program. MBA students from both IU business school campuses — Bloomington and Indianapolis — presented their plans on Feb. 22 at the Health Informatics and Translational Sciences (HITS) Building in Indianapolis.

"This was a big challenge," said Laager, whose Bloomington-based team worked closely with David Flockhart, M.D., Ph.D., Harry and Edith Gladstein Professor of Cancer Epidemiology and Genetics at the IU School of Medicine and director of the Disease and Therapeutic Response Modeling Program at the Indiana CTSI, on investigating potential funding sources for a new breast cancer therapy. "We really got a good feel for drug development, FDA requirements and patent law. It's been great practice doing business evaluations; this is exactly what we're aiming to do in our careers as business people."

Established in 2009, the Indiana CTSI-Kelley School of Business partnership benefits researchers, labs and clinics that engage with the Indiana CTSI in its mission to translate scientific discoveries into new treatments and therapies.

The program aims to bridge the gap between research skills and business acumen that can hamper investigators' ability to advance their work or a lab's ability to provide services at a competitive rate.

"We've got many excellent scientists using or operating some very advanced facilities at the Indiana CTSI," said Lilith Reeves, M.S., chief technology officer at the Indiana CTSI and founder of the Indiana CTSI-IU Kelley School of Business partnership program. "But by definition, scientists aren't business people. We've not only discovered a disconnect between the skill required to advance science and to move it into the clinical sphere, but also between scientists' ability to perform great work and to promote their work."

She also noted that this is the first year the Indiana CTSI program has included a team of students and their mentor from the Kelley School of Business-Indianapolis.

"We were very pleased to get two project teams this year from Indianapolis," said Linda Dunn-Jensen, Ph.D., clinical assistant professor at IU and director of Life Sciences Academy PLUS, an academic program in the Kelley School of Business-Bloomington focused on the health care, pharmaceuticals or life sciences industries. "It really gives a greater depth and breadth to our partnership with the Indiana CTSI."

In general, MBA students from the Bloomington campus are members of the Life Sciences Academy PLUS. Indianapolis MBA students participate with the Indiana CTSI through a pre-existing program that pairs students with life sciences companies ranging from small local startups to global multi-divisional firms.

"We've been partnering for years with companies in the Indianapolis metropolitan area on issues related to supply chain and operations, entrepreneurship and corporate finance, but this is our first year partnering



Mohan Tatikonda (left) and Lilith Reeves (second from right) with MBA students from the IU Kelley School of Business-Indianapolis



Linda Dunn-Jensen (right) with Eric Laager, Ryan Melnikas and Andy McDonnell



Audience members listen to student presentations. Notre Dame, Purdue and Bloomington participated via teleconference.

To view the presentations from this event, please see below:

- Introduction (Lilith Reeves, chief technology officer, Indiana CTSI)
- [Indiana CTSI-TTR and Kelley-Bloomington MBA Student Project Collaboration - Overview](#) (Linda Dunn-Jensen, IU Kelley School of Business-Bloomington)
- [Indiana Center for Biological Microscopy Marketing Plan](#) (Hoa Vo, team leader; Siva Vadlamannati; and Nikhil Singh)
- [Indiana CTSI Clinical Services Core Comprehensive Marketing](#) (Christopher Mahon, team leader; Jennifer Michuda; Lauren Feldman; and Medha Hazari)
- IU School of Medicine Division of Clinical Pharmacology Business Plan (Andy McDonnell, team leader; Ryan Melnikas; and Eric Laager)
- [IU School of Medicine Dean's Office Marketing Training Materials](#) (Natalie Basich, team leader; Julie Huang; and Tom Goodwin)

with the Indiana CTSI to work on nonprofit projects,” said Mohan V. Tatikonda, Ph.D., professor of operations and director of the Global Supply Chain Enterprise at the IU Kelley School of Business-Indianapolis. “It’s been quite a learning experience and an exceptional opportunity.”

He added that startups previously benefitting from the Indianapolis program include ImmuneWorks, a biotechnology company that focuses exclusively on autoimmune diseases of the lung established by David Wilkes, M.D., August M. Watanabe Professor of Medical Research and executive associate dean for research at IUSM.

“Our projects tend to be larger in scope and duration, lasting from three to six months, with each student putting in about 100 hours of time,” Tatikonda said. “We refer to them as management consulting projects because that’s what they are and that’s how we treat them.”

Teams from the Kelley School of Business-Indianapolis were tasked with improving workflow processes at the IU Vector Production Facility and IU National Gene Vector Biorepository, which provide testing and production services to researchers working in the field of gene therapy. Tasks tackled by Kelley School of Business-Bloomington students — in addition to the drug development project under Dr. Flockhart — included creating marketing plans to raise awareness about services provided by the Indiana Center for Biological Microscopy and Indiana CTSI Clinical Research Center as well as a plan to inform users about a new uniform order, management and billing system being implemented at core facilities at IUSM and University of Notre Dame.

In addition to attendees from IUPUI and IUSM, Indiana CTSI partners from IU Bloomington, Purdue and Notre Dame participated by teleconference. Each student presentation was about 15 minutes long and also included a poster presentation.

Now in its third year, the collaboration program with the business school is yielding tangible results, Reeves said. For example, the Indiana CTSI CRC has integrated cost and workflow analyses by previous MBA student teams into their business operating plan, and the Indiana CTSI Specimen Storage Facility has adopted a costing tool developed by the program.

“We had three projects the first year, eight the second year and nine this year,” she added, noting that some programs, such as the CRC, return to benefit from the program each year. “One of the most interesting things about this year’s projects was how many were interrelated, such as systems being implemented at IUSM and Notre Dame, which gave us even more opportunities for coordination and cooperation.”

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- Notre Dame Cores Implementation (Natalie Basich, team leader; Julie Huang; and Tom Goodwin)
- [Indiana CTSI-TTR and Kelley-Indianapolis MBA Student Project Collaboration - Overview](#) (Mohan Tatikonda, IU Kelley School of Business-Indianapolis)
- IU Vector Production Facility (IU VPF) (Aaron Boeke; Patrick Dumas; and Kyle McClurg)
- [IU National Gene Vector Biorepository](#) (Kevin Largent; Sean Seacat; and Peter Tichenor)

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Indiana CTSI Opportunities — March 2012

Indiana CTSI Core Equipment Funding — applications due March 30

The Indiana Clinical and Translational Sciences Institute is seeking proposals from Indiana CTSI-designated cores at the IU School of Medicine to support the purchase of equipment that will enhance the research environment and contribute to the research mission of the school and Indiana CTSI.

Proposals requesting \$5,000 to \$100,000 will be accepted. Requests for equipment costing more than \$100,000 will be entertained if matching funds to cover the balance are identified. Indiana CTSI-designated cores are laboratories whose operational policies have met the standards established by the Indiana CTSI. For more information, visit www.indianactsi.org/servicecores. Only IU School of Medicine cores are eligible for this grant.

The submission deadline is **Friday, March 30**. For 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 CTSI / IUSM Core Equipment Funding -- 2012.03 (COREQ)."

Questions to Liliith Reeves, Translational Technologies and Resources program manager, at info@indianactsi.org.

Indiana CTSI Spring Core Pilot Awards — applications due April 9

The Indiana Clinical and Translational Sciences Institute seeks proposals for its Spring 2012 Core Pilot Grant Program. This opportunity will provide up to \$10,000 for the use of technologies and expertise from Indiana CTSI Core Facilities. Projects are typically one- to two-years in duration.

This opportunity will support the use of Indiana CTSI-designated core facilities at the three Indiana CTSI partner institutions only. Successful proposals will demonstrate outstanding scientific merit that can be linked to generating extramural funding or novel intellectual property. Proposals will be judged with equal measure on scientific merit and the likelihood of generating new intellectual property or extramural grant support.

Faculty from IU, Purdue and Notre Dame are eligible to apply. For more information on available core services, visit www.indianactsi.org/servicecores. (Eligible cores are denoted by the Indiana CTSI logo.)

For 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 "Pilot Funding for Research Use of Core Facilities — 2012.04." Applications are due **5 p.m. Monday, April 9**.

Questions to Liliith Reeves, Translational Technologies and Resources program manager, at info@indianactsi.org.

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On the Horizon — March 2012

Community Health Engagement Program Annual Meeting — March 20

The Indiana Clinical and Translational Sciences Institute's Community Health Engagement Program will host its Fourth Annual CHEP Community Advisory Council Forum on Tuesday, March 20, at the Indianapolis Museum of Art, 4000 Michigan Road, Indianapolis.

CHEP's mission is to promote collaboration among community partners throughout Indiana to improve research, health and health care. This free event is open to anyone interested in community research in Indiana.

A complete agenda is to be announced. To register, visit <http://www.indianactsi.org/events/details/461>.

For more information on CHEP, visit www.indianactsi.org/chep.

Metabolomics Symposium and Working Group Discussion — March 22

The Indiana Clinical and Translational Sciences Institute will host a symposium and working group discussion on establishing a Regional Comprehensive Metabolomics Resource Core from 1:30 to 4:30 p.m. Thursday, March 22, in the Cancer Research Institute (R4), room 101.

The National Institutes of Health recently released a [Request for Applications](#) to address the increasing need for metabolomics research capacity in different regions of the country. The goal of this symposium and working group is to bring together "omics" experts from across Indiana to facilitate collaborative efforts that will lead to a proposal submission to NIH early next year in response to this RFA.

This event will include a presentation on the need for metabolomics analyses capacity in Indiana as well as an overview of available metabolomics instrumentation and capabilities at the IU School of Medicine, IU Bloomington, Purdue University and University of Notre Dame. Working group moderators will include Mu Wang, Ph.D., associate professor of biochemistry and molecular biology.

All IU, Purdue and Notre Dame faculty interested in participating in the submission or learning more about the "omics" expertise available across the CTSI institutions are encouraged to attend.

Pre-registration is not required, and all presentations will be available via Breeze at breeze.iu.edu/metabolomics.

For a complete agenda, see the [event flier](#).

NIH Regional Seminar on Program Funding and Grants Administration — April 16 to 18

The NIH has begun taking reservations for its Regional Seminar on Program Funding and Grants Administration to be held April 16 to 18 at the JW Marriott in Indianapolis. About 35 NIH and Health and Human Services staff will be on hand to:

- Demystify the application and review process
- Clarify federal regulations and policies
- Highlight current areas of special interest or concern

The workshops are appropriate for grants administrators, new and early-stage investigators, researchers, graduate students and anyone interested in the grants administration process. Topics include fundamentals of the NIH grants process, successful grant writing, the peer review process, career development awards, the Small Business Innovation Research and Small Business Technology Transfer programs and much more.

The main seminar will take place April 17 to 18, with registration costing \$475 to \$550 depending on time of registration. April 16 will be devoted to optional electronic research administration (eRA) hands-on computer workshops costing \$250.

For full conference and program details, and to register, visit grants.nih.gov/grants/regionalseminars/Indiana_2012/index.html.

Note: Volunteers needed! As the host institution, the IU School of Medicine will be soliciting volunteers to help with registration, serve as room monitors and perform other tasks at the seminar. Volunteers will be able to attend sessions for free on the day they volunteer and at a sharply reduced cost on the other day of the seminar. To volunteer, contact Eric Schoch at eschoch@iu.edu.

Fourth Annual Indiana CTSI Meeting — May 7

The Fourth Annual Indiana CTSI Meeting will be **Monday, May 7**, at the University Place Conference Center and Hotel at IUPUI. This annual event provides an opportunity to learn more about the Indiana CTSI and its programs from local-, state- and national-level representatives, as well as hear from researchers supported by the institute, explore poster presentations, and meet new colleagues and collaborators. Information about previous annual events is available on the Indiana CTSI HUB [under the drop down menu labeled "Meetings."](#)

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