

2018 ANNUAL REPORT

10 years of
improving health
through research





Message from Indiana CTSI Founding Director

It is my great pleasure to celebrate with you the 10th anniversary of the Indiana Clinical and Translational Sciences Institute (CTSI) and more importantly, a decade of progress towards improving health in Indiana through research.

This milestone provides many reasons to celebrate. Of most significance is the five-year, \$33 million funding renewal award we received from the National Institutes of Health (NIH) in July 2018. Additionally, I am pleased to report that over the past 10 years we have awarded nearly \$14 million in pilot funding to initiate important basic, clinical and translational research projects. Our awardees have used the seed funding to secure more than \$300 million in additional grant funding to bring their research ideas to fruition. The majority of that \$300 million will stay in Indiana and benefit our growing research community and Indiana residents who may unknowingly reap the rewards of research projects every day (some of which you will read about in this report).

Other noteworthy achievements since 2008:

- Our directors, managers and staff have assisted more than 5,000 researchers through 17,000 service offerings.
- We have trained nearly 400 future clinical and translational science investigators.
- Over 1,200 peer-reviewed publications have cited the Indiana CTSI for its support.
- Our ResNet and Clinical Research Center programs have recruited nearly 60,000 research volunteers.

- Our Center for Health Innovation and Implementation Science program has helped more than 100,000 patients receive improved care for chronic conditions such as depression and hypertension.

When I founded the institute as a partnership among the state's preeminent research enterprises of Indiana University, Purdue University and the University of Notre Dame, we utilized our first multimillion-dollar NIH award to build research infrastructure and identify Indiana's greatest health challenges. We maximized the Indiana CTSI's second round of NIH funding to build collaborations and initiate research projects. Now we are seeing the outcomes of those efforts. Improvements in health are being made, with more to come throughout the next five years, as we work to achieve our ambitious vision of making Indiana one of the nation's healthiest states.

CTSI Goals: 2018-2023

- GROW RESEARCH TALENT
- ACCELERATE THE TRANSLATION OF RESEARCH TO THE MARKET
- IMPROVE THE HEALTH OF PEOPLE LIVING IN INDIANA

A key focus of the next five years—what we call Indiana CTSI 3.0—is partnering with the community to improve health. We are asking Indiana residents of all ages and backgrounds to get involved in their own health through programs such as the Community Health Project and All IN for Health. To maximize these efforts, we've added a CTSI navigator in Evansville to facilitate access to approximately one million more people who may be interested in improving their health through research.

On behalf of Indiana CTSI, I'd like to thank you for your dedication to our continued goal of improving health through research. As we celebrate the past 10 years, we look forward to a promising future.

Sincerely,

A handwritten signature in black ink that reads "Anantha Shekhar". The signature is written in a cursive, flowing style.

Anantha Shekhar, MD, PhD
Founding Director
Indiana Clinical and Translational Sciences Institute
Executive Associate Dean for Research Affairs,
Indiana University School of Medicine



Indiana CTSI Awarded Third NIH Grant

The new \$33 million grant renewal is the Indiana CTSI's third, five-year Clinical and Translational Science Award (CTSA) from the NIH's National Center for Advancing Translational Sciences. The CTSA program, which includes a nationwide network of more than 50 academic medical centers, aims to improve the translational research process to accelerate the delivery of treatments to patients.

GROW RESEARCH TALENT

Egan named Indiana CTSI Chief Operating Officer



Carmel Egan, PhD, was appointed COO of Indiana CTSI in 2016.

Carmel Egan, PhD, was appointed chief operating officer of the Indiana CTSI in 2016. Before joining the institute, Egan spent nearly 30 years at Eli Lilly and Company in leadership positions related to pipeline and project management and product development.

“Carmel has helped us recruit additional top talent to the Indiana CTSI; she has helped us streamline our processes and become even more focused and effective at improving health in Indiana,” said Indiana CTSI Founding Director Anantha Shekhar, MD, PhD.

In addition to her responsibilities at CTSI, Egan is chief operating officer of IU's Grand Challenge Precision Health Initiative.

Indiana CTSI maximizes Lilly Endowment's research-focused funding

The Indiana CTSI has helped maximize significant funding from the Lilly Endowment Inc., designed to further elevate Indiana's position as one of the nation's top life science research hubs. The two grants, in excess of \$60 million, support the Physician Scientist Initiative (PSI) and the Indiana Collaborative Initiative for Talent Enrichment (INCITE), both innovative recruitment strategies. The Indiana CTSI has leveraged both to help recruit Peter J. Embi, MD, Chandan Sen, PhD, and Benjamin Gaston, MD, and other prestigious researchers to Indiana.

Embi is an internationally recognized expert in biomedical informatics, and was recruited to Indiana University School of Medicine in 2016, in part through a startup package made possible by the PSI. He also was named president and chief executive officer of the Regeneron Institute Inc., a global leader dedicated to improving health and healthcare through innovations and research in biomedical informatics.



Peter Embi, MD, is associate director for informatics at the Indiana Clinical and Translational Sciences Institute.

Embi is associate dean for informatics and health services research and professor of medicine at the IU School of Medicine and associate director for informatics at the Indiana CTSI.

Embi is developing the Indiana Addictions Data Commons in partnership with Indiana Governor Eric Holcomb, Indiana University and IU Health. The goal of the Addictions Data Commons is to ensure that health care systems, law enforcement and public health professionals have access to a single source of data about the opioid addictions crisis.

As part of INCITE, IU School of Medicine hires biomedical scientists whose work will not only enhance research and education at the school, but also strengthen the economic health of Indiana's broader life sciences community through non-academic INCITE partners such as the Indiana Biosciences Research Institute, Eli Lilly and Company, Roche, Dow, Cook, BioCrossroads, IU Health and Eskenazi Health. Through the Indiana CTSI's involvement, INCITE recruits will also partner with Purdue University and the University of Notre Dame.



Chandan Sen, PhD, will serve as the Indiana CTSI's first associate director of technology and innovation.



Benjamin Gaston, MD, is director of pediatric translational sciences for the Indiana CTSI.

In 2018, Chandan Sen, PhD, was recruited to IU School of Medicine as the inaugural leader of the IU School of Medicine Center for Regenerative Medicine and Engineering and will lead the IU Precision Health Initiative pillar of the same name. His future non-academic partner in Indiana's life sciences community is Cook. Sen will also serve as the first-ever associate director of technology and innovation for the Indiana CTSI.

Sen's research interests include regenerative medicine, cell-based therapies and tissue reprogramming. In a 2017 publication in *Nature Nanotechnology*, the Sen Group reported successful tissue reprogramming in vivo and use of skin-derived reprogrammed neural cells to rescue the stroke-affected brain. His work, cited more than 25,000 times in scientific literature, has the potential to impact people with a variety of health issues, including diabetes and neurodegenerative diseases.

Benjamin Gaston, MD, was also recruited in 2018 as professor of pediatrics at IU School of Medicine. His future non-academic partners in Indiana's life sciences community are Eli Lilly,

Dow Agrosiences, Roche and 16 Tech. He will also serve as director of pediatric translational sciences for the Indiana CTSI.

Gaston is board certified in pediatric pulmonology and focuses on pediatric airway diseases such as asthma and cystic fibrosis. He is currently principal investigator on several related studies in children. Gaston has published more than 125 peer-reviewed journal articles on pediatric pulmonary problems and authored more than a dozen chapters in medical textbooks. His work has the potential to lead to new precision health breakthroughs such as immunotherapies for the treatment of childhood diseases.

STEM and SEED programs build pipeline of future scientists



2018 Project STEM program staff, participants and their families at a recent kick-off meeting.

Established when Indiana CTSI was formed in 2008, the institute's Project STEM and SEED programs provide high school students of all socioeconomic backgrounds hands-on experience in university and industry research labs to learn essential skills needed for future careers in science and related fields. The programs have grown steadily over the past decade with 101 students from Marion and surrounding counties participating in 2018.

"The Indianapolis program alone has hundreds of testimonials from students who have gone on to accomplish great things after their summer internships," said Elmer Sanders, program director.

This past summer, students, who were mentored by professional researchers, engaged in research at IUPUI, IU School of Medicine, Eli Lilly and Company and the Indiana Biosciences Research Institute.

ACCELERATE THE TRANSLATION OF RESEARCH TO THE MARKET

Indiana CTSI-funded research leads to first ever FDA-approved treatment for rare bone disease

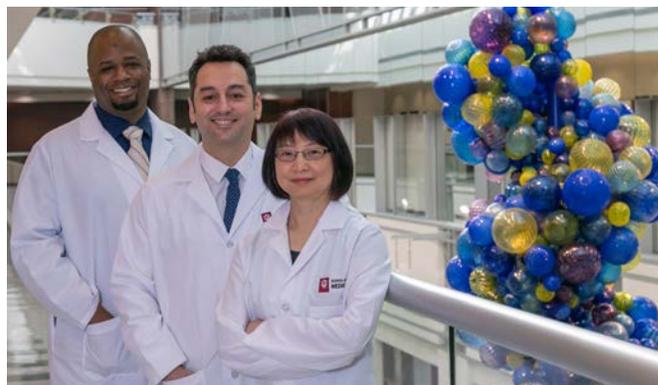


Michael Econs, MD, (left) and Kenneth White, PhD, led research for an FDA-approved treatment for a rare bone disease.

Indiana CTSI-supported research led by two IU School of Medicine researchers—Michael Econs, MD, and Kenneth White, PhD—has culminated in U.S. Food and Drug Administration approval of burosumab to treat X-linked hypophosphatemia, or XLH, a phosphate-wasting disease that causes rickets and osteomalacia (softening of the bones). The disease is typically inherited and affects more than 12,000 patients in the United States and one out of every 20,000 people worldwide. Usually diagnosed as children, those affected by XLH have bowed legs, short stature and experience bone pain and dental abscesses.

The first human dose of burosumab was administered by an Indiana CTSI Clinical Research Center (CRC) nurse in early 2009. CRC staff conducted study procedures for all clinical study visits associated with the Phase I-III studies and continues to support this important work with an upcoming Phase IV study. Burosumab is being brought to market by Ultragenyx Pharmaceutical Inc., in collaboration with Kyowa Hakko Kirin Co., Ltd. and its European subsidiary, Kyowa Kirin International PLC, under the brand name Crysvida.

3D bioprinting core fuels organ transplant research



Lester Smith, PhD, Burcin Ekser, MD, PhD, and Ping Li, PhD, are using 3D printing to develop organ models for xenotransplantation.

IU School of Medicine scientist and transplant surgeon Burcin Ekser, MD, PhD, and his team are using 3D printing to improve the availability of organs for transplant. According to the Organ Procurement and Transplantation Network, there are more than 110,000 people in the United States waiting for a life-saving organ transplant, and each day about 20 people die while waiting for a transplant.

Ekser's team is creating new organ models using the Indiana CTSI-designated 3D Bioprinting Core, a research service core with a 3D bioprinter—one of only two of its kind at academic institutions in the United States. The researchers are printing 3D pig liver tissue from genetically engineered pig liver cells to develop new research models for xenotransplantation.

Ekser is boosting his lab's xenotransplantation, or cross-species transplantation, research program with a four-year, \$9 million research agreement with Lung Biotechnology PBC.

The 3D bioprinter is available to Indiana University, Purdue University and University of Notre Dame scientists who want to advance their research.

Indiana benefits from global health lessons learned



Debra Litzelman, MD (far right), is applying methods she employed in Kenya to develop WeCare Indiana, a program that connects new mothers to health resources.

After working with doctors and patients in Kenya to provide health services to rural and resource-constrained populations, Debra Litzelman, MD, is applying that knowledge to help reduce risk factors for infant mortality in Indiana—ranked among the 10 worst states for infant mortality in the country.

“My work in Kenya was pivotal in seeing the effectiveness of community health workers doing door-to-door screening,” said Litzelman, who worked to build medical education and workforce development programs in Kenya as part of AMPATH, an IU-led, international consortium dedicated to improving health in the African country. “Find, link, treat, retain—that is the AMPATH model for caring for HIV patients in sub-Saharan Africa. I’ve seen that in action, so I thought, ‘why couldn’t we do that here?’”

In 2015, Litzelman and her team were awarded a two-year, \$500,000 IU Health Values Grand Challenge grant—funded in partnership with the Indiana CTSI—to make that idea a reality. Her project, WeCare Indiana, began in January 2016 at two health centers. Community health workers are trained by WeCare Indiana to connect new mothers and mothers-to-be with local health resources to reduce infant mortality risk factors, including obesity, smoking, mental health issues,

substance abuse, lack of breastfeeding and unsafe sleeping environments for babies. WeCare Plus was launched in October 2016 with an additional \$4 million in funding provided by the Indiana State Department of Health and more than \$800,000 from the Richard M. Fairbanks School of Public Health. This program expands the initiative to include postpartum mothers dependent on opioids and their babies.

All IN for Health aims to get Hoosiers involved in improving the state’s health



Indiana State Fair visitors at the Indiana CTSI’s All IN for Health booth.

A critical piece of improving health in Indiana is engaging its residents. The All IN for Health initiative, developed and funded by the Indiana CTSI, aims to improve health in Indiana by increasing health literacy and connecting Hoosiers to health resources. The initiative offers opportunities for Indiana residents to become research volunteers and be matched to any of the 1,000 active Indiana-based research studies, made possible through Indiana University, Purdue University and the University of Notre Dame. So far more than 6,000 people have signed up to participate as research volunteers.



Indiana is home to hundreds of health studies and clinical trials; however, only 30 percent of Hoosiers report being involved in a research study or knowing someone who has participated in a research study.
—allin4health.info

Indiana CTSI launches project to identify gaps and improve health in Marion County

As part of its vision to make Indiana one of the nation's healthiest states, the Indiana CTSI has launched a community health project to determine the geographic areas in Marion County most vulnerable to health disparities, such as limited access to health care. After analyzing data from all 99 Marion County neighborhoods, Community Health Partnerships (CHeP), Indiana CTSI's community engagement arm, is partnering with the community to develop community-based health research projects in targeted areas of need.

"Indiana is home to one of the nation's top life sciences ecosystems, and yet still suffers from poor population health," said Sarah Wiehe, MD, MPH, CHeP director. "By partnering with those directly affected and leveraging the vast assets of the Indiana CTSI and our statewide collaborators, we will work as hard as we can to tackle health inequity in Indiana."

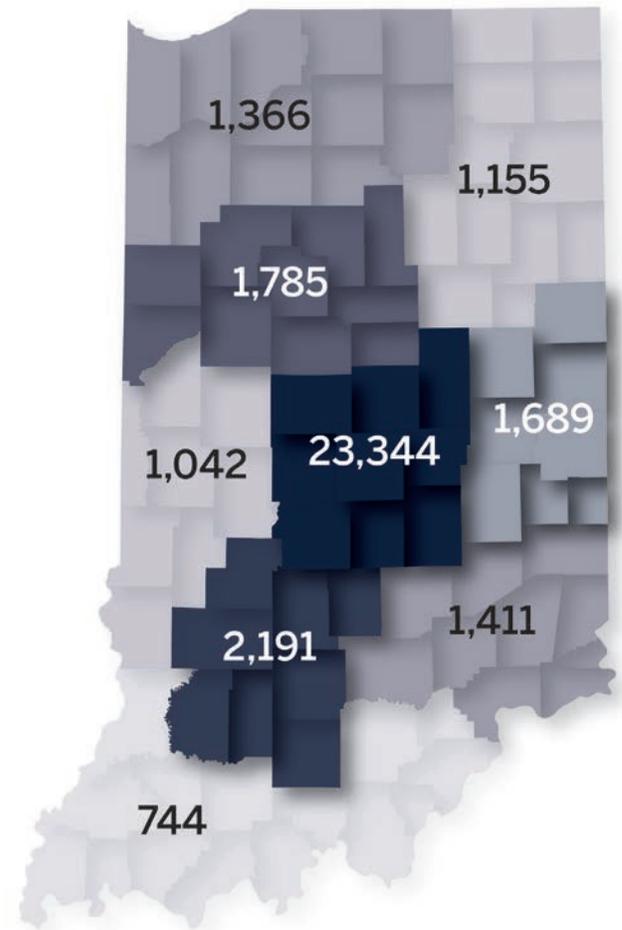
Field study aims to protect South Bend kids from lead poisoning

Lead levels were recently discovered to be extremely high in children living in downtown South Bend, and in some cases, the levels were five times higher than those reported in Flint, Michigan. Lead-based paint is a major source of lead exposure for toddlers, who often chew painted surfaces, eat paint chips or lick lead-based paint dust from their hands. The problem extends across the U.S., so finding lead-based paint in spaces occupied by small children is important for controlling and mitigating lead exposure.

Commercially available home screening tests are expensive and show false positive or negative results with dark paint colors. University of Notre Dame faculty, staff and students, supported by the Indiana CTSI, the City of South Bend and numerous community partners, are working together to develop and validate a quick field test for lead-based paint that works on any paint color and tests soil and dust. To date, scientists have enrolled and tested 46 homes.

Hoosiers across the state contribute to the Indiana Biobank

This heat map shows the statewide reach of the Indiana Biobank, a key program of the Indiana CTSI. Since its creation in 2010, the Indiana Biobank has collected biosamples, such as blood and saliva, from 35,000 residents representing every county in Indiana.



Collected biosamples are linked to an individual's electronic medical record and shared in a de-identified manner with researchers in pursuit of treatments, cures and prevention of diseases prevalent in the Hoosier state.

THE ROLE OF INDIANA CTSI

FUNDING

The Indiana CTSI provides research funding through its member institutions and public/private partnerships for a variety of community projects, collaborative grants, core services and training.

Eligibility: Faculty from all participating institutions, community and academic partners. For more information: Visit indianactsi.org/funding.

PROJECT DEVELOPMENT ASSISTANCE

Project Development Teams help advance translational research projects for individuals and/or teams by providing the resources, services and training needed for external submissions.

Eligibility: Researchers in translational and clinical research at all Indiana CTSI institutions. For more information: Visit indianactsi.org/project-development.

EDUCATIONAL OPPORTUNITIES

The Indiana CTSI's educational opportunities facilitate the next generation of researchers, beginning with high school students and continuing with undergraduates, medical students and other postgraduate students.

Degree/certificate programs:

- MS/Graduate Certificate in Clinical Research
- MD/MS Program
- Graduate Certificate in Innovation and Implementation Science
- Pre- and post-doctoral training
- Early career investigator training
- Independent Investigator Incubator
- Research coordinator training

Learn more about these opportunities online at indianactsi.org/education.



RESEARCH NAVIGATORS

Scientists by training, Indiana CTSI navigators are located at each partner institution to help researchers and other interested people successfully navigate and engage with the many programs and services the Indiana CTSI has to offer. Navigators can point to potential collaboration partners, pilot funding, grant reviews and much more.

To connect with a navigator, use the contact information provided below. If your inquiry is not location specific, email navigate@indianactsi.org.

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