



November 2015

The Clinical and Translational Science Awards Program

A REPORT ON INDIANA'S POSITION



BioCrossroads



Prologue

Since 2002, BioCrossroads has focused on supporting Indiana's life sciences sector through collaboration, capital formation, talent, and branding. Indiana has a remarkable history and richness of academic and corporate life sciences assets, but we recognized early-on that a deliberate and focused set of actions was needed to continue our leadership in the sector and extend its positive impact on the state's economy, from both a financial and population health perspective. Our shared ability to accelerate research into clinical practice and address items needed for a broader application of discovery to "real world" progress is, and will continue to be, paramount to this strategy.

To address this need, and led by the Indiana University School of Medicine in partnership with Purdue University and the University of Notre Dame, the Indiana Clinical and Translational Science Institute ("CTSI") has emerged as a statewide consortium whose mission is to accelerate the translation of basic, applied, and clinical research discoveries into best practices and solutions to our most pressing health problems. Under its current five-year grant from the National Institutes of Health's National Center for Advancing Translational Sciences, and with the direction of its nationally recognized principal investigator, Dr. Anantha Shekhar, the Indiana CTSI provides the necessary resources, including core laboratory services, to assist in advancing innovative healthcare programs and biomedical research to implementation.

To further understand the development of the CTSI program and to be better able to provide key regional stakeholders and thought leaders with a more accessible vision for the CTSI's mission, and its consequent importance as an effective regional asset, FaegreBD Consulting has detailed the program's history and broad expectations for success moving forward, and compares this Indiana CTSI record against those of five other highlighted sites. The report then identifies common themes and examines how Indiana is situated relative to these peer institutions as well as to the future direction of the CTSI program.

With close to 150 medical schools nationwide, the Indiana University School of Medicine is distinguished by having one of only 62 NIH-funded Clinical and Translational Science Award winning sites. When combined with the fact that it is also the only such NIH-award winner in the state, the Indiana CTSI has a unique opportunity to leverage our highly connected regional life sciences environment to exploit opportunities that are nearly impossible to achieve in other locations around the country. By partnering with industry, the community, and academic institutions, the Indiana CTSI can explore and implement ideas that are truly novel and expose the best the state has to offer. The CTSI has emerged as the principal working mechanism to harness the strengths of Indiana University, Purdue and Notre Dame in shared pursuits for the advancement of clinical discovery. And among the national CTSA institutions, Indiana's CTSI is unique in its success in overcoming the obstacles and barriers typically associated with making university collaborations truly accessible to both community and industry partners.

Moreover, as the report illustrates, the Indiana CTSI does not simply excel against peer institutions that are relatively similar in size. It is positioned to be as effective and instrumental as other academic institutions that generate substantially larger research dollars and are held in high esteem around the country. The Indiana

CTSI is both a differentiator and an integrator for the region's array of health and life sciences assets. It brings widespread recognition to the broader therapy development enterprise, as well as unique opportunities for talent and resource attraction.

The Indiana CTSI has become a core asset for our state since its creation in 2008. As the main portal for sustained collaboration among Indiana's three research universities and in tandem with the strengths of the Indiana Biosciences Research Institute, the 16 Tech Innovation District, and industry partners, our CTSI only holds more potential to realize the full clinical potential of promising research and technology discoveries. Indiana's CTSI has achieved such early success, in part, because of the strong base of collaborative university and industry assets upon which it is based, and through which it achieves its objectives. As such, the CTSI has now become, in its own right, one of our leading drivers for Indiana's next level of success as one of America's leading clusters of healthcare innovation.

Sincerely,

A handwritten signature in black ink, appearing to read "David L. Johnson". The signature is fluid and cursive, with the first name "David" being the most prominent.

David L. Johnson
President and CEO, BioCrossroads
November 2015

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A Report on Indiana's Position

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Introduction

The National Institutes of Health (NIH) launched the groundbreaking Clinical and Translational Science Award (CTSA) program in 2006. It now includes over 60 academic medical institutions across the country, including one in Indiana. Designed to provide a more efficient and effective way to ‘translate’ basic science into therapies, the NIH effort helps to bridge the gap between growing taxpayer investments in basic research and the relatively limited number of therapies being approved by the Food and Drug Administration (FDA). Congress, patient organizations, and other stakeholders have become increasingly vocal in calling for an improved “return-on-investment” from the recent doubling of the NIH budget. This public imperative is the driving force behind the CTSA program, and this report provides an understanding of the CTSA program and examines how the Indiana Clinical and Translational Science Institute (Indiana CTSI) compares to other, selected institutions in the overall CTSA Consortium.

Within this setting, the report details the current structure of the CTSA program and provides insights on how the CTSA program is evolving to respond to a host of factors, both internal to the NIH and external across the scientific community. This information provides a framework for then identifying and examining six of the 62 existing CTSA-funded sites or hubs. Beginning with the Indiana CTSI and moving across five, high-performing peer organizations, the report profiles a diverse array of accomplishments in translational science, community engagement, and education and workforce development. This set of qualitative and quantitative information, in turn, illustrates why the Indiana CTSI is widely recognized as a leading participant in the program today and is positioned well for the future.

In brief, the primary findings are as follows.

- The CTSA program is transforming the organization and conduct of translational science in America while, at the same time, undergoing significant strategic and functional changes itself to build on the foundation of the initiative.
- The Indiana CTSI compares favorably to other CTSA hubs with similar resources and could fairly be characterized as “punching above its weight” when higher-funded institutions are considered.
- A key strength of the Indiana CTSI is its robust network of academic, industry, and non-profit organization partnerships. This collaborative quality sits directly in line with the goals of the CTSA program, particularly the core objective to move more biomedical innovation into clinical application.
- The Indiana CTSI is further strengthened in the evolving CTSA program by its clear emphasis on meaningful community engagement which, when combined with other characteristics, should lead to more powerful impact on health in the region.

As noted, the Indiana CTSI is recognized by leaders across the research and development environment as one of the preeminent sites within the nationwide CTSA Consortium (the CTSA is the NIH’s largest single investment in a program, larger than the consortium of national cancer centers). This conclusion is reinforced by an array of objective indicators, such as the excellent review score received by the Indiana CTSI in the 2013 funding competition cycle, as well as less formal input, such as the opinions of those interviewed in connection with this report.

While having achieved this national recognition, the appreciation of the role and contributions of the Indiana CTSI within the region, both in the Indiana health and life sciences economy and beyond, is only beginning to emerge. Moreover, this rising local recognition comes at a time when the national CTSA program is undergoing significant evolution. As the NIH moves to reshape the national initiative to drive toward even clearer and more compelling value for taxpayer investment, the Indiana CTSI, given its distinguishing elements, is positioned to continue to achieve national prominence and expanded regional impact.

Recognizing this potential and to understand better the convergence of Indiana CTSI's strength with shifting expectations for the CTSA program, BioCrossroads commissioned this external overview of the environment and the Indiana CTSI's position within it.

The structure for this report responds to the following objectives:

1. Outline the history of the CTSA program and the factors that underlie the current transformation;
2. Establish a deeper understanding of the Indiana CTSI's characteristics and standing by profiling it along with five, selected CTSA hubs from across the country; and
3. Distill a set of "Observations and Comparisons" from the quantitative and qualitative CTSA data assembled in this review.

Building on this structure, the report:

- Provides a view for the Indiana community into the Indiana CTSI's strengths and competencies and relative positioning within the CTSA consortium; and
- Examines how the Indiana CTSI is positioned to take advantage of and respond to emerging expectations for the CTSA program, particularly as it prepares to compete for continued funding in 2018.

Section 1– Clinical and Translational Science Awards Background

Clinical and Translational Science Awards – What and Why?

“Consider two numbers: 800,000 and 21,” David Borenstein wrote in the New York Times in 2011. “The first is the number of medical research papers that were published in 2008. The second is the number of new drugs that were approved by the Food and Drug Administration last year. That’s an ocean of research producing treatments by the drop.”

“Over the past 30 or so years, the ecosystems of basic and clinical research have diverged,” science journalist Declan Butler wrote in a 2008 article in *Nature*. “The pharmaceutical industry, which for many years was expected to carry discoveries across the divide, is now hard pushed to do so. The abyss left behind is sometimes labeled the ‘valley of death’ — and neither basic researchers, busy with discoveries, nor physicians, busy with patients, are keen to venture there. ‘The clinical and basic scientists don’t really communicate,’ says Barbara Alving, [then] director of the NIH’s National Center for Research Resources in Bethesda.”¹

The NIH has long sought a solution to this problem. Back in 1959 the NIH established General Clinical Research Centers (GCRCs) at 78 universities and medical centers. The GCRCs, however, tended to focus narrowly on conducting clinical trials and did little to bridge the valley of death.

In fact, the focus on clinical research may have made the problem worse. In his 2008 article, Butler noted that in the 1950s and 1960s basic and clinical research tended to be tightly linked, and both were conducted by the same physician-scientists who treated patients. But this changed in the 1970s with the explosion of molecular biology. In 1970, NIH awarded a roughly equal number of research project grants to MD, MD-PhD, and PhD scientists. But in the ensuing decades, basic scientists with PhDs began winning the lion’s share of research project grants. By 2005, NIH was awarding about 7,000 of these grants to specialized PhD scientists, compared to about 3,000 to MD and MD-PhD scientists combined.

On top of that, many institutions have been organized around functional and disease-specific areas. This is a recipe for creating research silos and for inhibiting the kind of cross-disciplinary collaboration in which translational research thrives.

This situation began to change in 2002 when Elias Zerhouni was appointed NIH director. Soon after, he convened a series of meetings to chart a “Roadmap for Medical Research in the 21st Century.” Released in 2003, the Roadmap identified three major themes: New Pathways to Discovery, Research Teams of the Future, and Re-engineering the Clinical Research Enterprise.

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1. <http://www.nature.com/news/2008/080611/full/453840a.html>

The third theme of re-engineering clinical research eventually led to the creation of the CTSA program as it focused on harmonizing regulatory policies, encouraging multidisciplinary training, and facilitating the establishment of academic homes for clinical and translational research. The CTSA program was intended to transform the way academic biomedical research is conducted by:

- Translating laboratory discoveries into treatments for patients;
- Engaging communities in clinical research efforts; and
- Training a new generation of clinical and translational researchers.

While clearly an ambitious and urgent effort, some early critics of the CTSA program charged that the initial response mostly replicated the GCRC funding, albeit in a new wrapper. Others commented that the CTSA sites would be too big, too complicated, and over-structured, and that host institutions were not being encouraged to develop unique regional strengths. However, despite these initial reservations, leading academic medical centers largely expressed interest in being involved with the NIH plans and eventually flocked to the new program.

Zerhouni formalized the CTSA program in 2006, and it was housed in NIH's National Center for Research Resources (NCRR). Twelve institutions received the first CTSA in that year, and an additional 52 institutions received planning grants, allowing them to prepare applications to join the consortium. The consortium added 12 institutions in 2007, 14 in 2008, 8 in 2009, 9 in 2010, and 5 in 2011. The Indiana CTSA was funded for the first time in 2008.

In 2012 Congress passed and President Obama signed the fiscal year (FY) 2012 Consolidated Appropriations Act, which dissolved the NCRR. The CTSA program was reassigned to the NIH's National Center for Advancing Translational Science (NCATS). Since that time, two additional institutions have been added to the consortium, bringing the total to 62 medical institutions in 31 states and the District of Columbia. In addition, NCATS established the CTSA Consortium Coordinating Center (C4). In FY 2015, CTSA has been allocated \$474,746,000, making it one of the largest, most highly visible NIH programs.

Under the leadership of current NCATS Director Dr. Chris Austin, and through recommendations from the Institute of Medicine (IOM), the CTSA program is evolving to keep pace with the changing translational science landscape. Dr. Austin has made the following observations regarding clinical and translational science:

- While fundamental science has advanced with breathtaking speed, there remains a continued poor transition of basic or clinical observations into interventions that tangibly improve human health.
- The drug/device/diagnostic development system is in crisis, with ever higher investments in R&D returning increasingly poor results.
- Today's clinical trials system operates with inefficiencies, redundancies across differing institutional review systems, and a disturbing lack of reproducibility of results when moving from academic into industry settings.
- Despite a decade of investment in the CTSA infrastructure, there remains a disturbingly poor adoption of demonstrably useful interventions across clinical communities, and this leads to sub-optimal effects on the health of the community that should be served by the academic institution.

In its pivotal 2013 report, *The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research*, the IOM noted that the CTSA program is "contributing significantly to advancing clinical and translational research"² and put forth a series of recommendations intended to strengthen the program. One recommendation implemented immediately was to create a Working Group within NCATS to respond to the IOM's recommendations. The Working Group – comprised of subject matter experts from across the field – issued its report in May 2014. Entitled *NCATS Advisory Council Working Group on the IOM Report: The CTSA Program at NIH*, the report provided a set of measurable goals and objectives for the CTSA program moving forward. Those goals include:

- **Workforce Development:** Building an environment that supports and values translational science as "the place to go" for those who want to pursue high-impact careers in health sciences including training and

2. <http://www.iom.edu/Reports/2013/The-CTSA-Program-at-NIH-Opportunities-for-Advancing-Clinical-and-Translational-Research.aspx>

educating, continuous learning, and developing a translational science workforce that can meet the needs of today and tomorrow.

- Collaboration/Engagement: Engaging stakeholder communities and enabling team science to become a major academic model by ensuring that all translational science is performed in the context of collaborative team science.
- Integration: Integrating translational science across the entire lifespan to attain improvements in health for all and launching efforts to study special population differences in the progress and treatment of disease processes.
- Method/Processes: Enabling CTSA programs to function individually and together as a research engine, transforming the way translational science is conducted while rapidly translating CTSA-generated new knowledge and technologies into health interventions.

The 2014 CTSA request for proposals (RFP) was revised in part to respond to these recommendations and included increased emphasis on patient and community engagement and the need for collaboration between CTSA institutions, now renamed “CTSA hubs.” Specific focus was devoted to network-wide resources that can support multi-site studies in order to add collaborative opportunities to each hub’s areas of strength. In addition, NCATS entered into a wholesale restructuring of its internal committee infrastructure, moving from a byzantine advisory structure to one that’s more strategic and project driven with well-defined, discrete objectives, timelines, and deliverables for every activity. The cornerstone of the new structure is five Domain Task Forces (DTFs), four of which are aligned with the four strategic goals plus one DTF focused on Informatics. To accomplish specific objectives, a DTF can have up to five Working Groups at any given time. Subsequently each Working Group has milestones, deliverables, metrics, and sunset criteria.

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The 2015 CTSA RFP is expected to be refashioned more significantly to respond to the IOM report, the CTSA Working Group analysis, and external feedback received over the past year. While not all of the CTSA hub leaders are embracing these transformational changes, CTSA leadership remains resolute that shifts in the nature of the award and the metrics for performance will continue in response to the input received in 2015.

Anticipated changes include:

- A focus on funding program priorities, rather than infrastructure;
- Expanding to fund more sites with smaller grants;
- An emphasis on inter-disciplinary team science;
- Recognizing the value of the non-traditional and unique contributions of CTSA hubs to the national CTSA platform; and
- Creating new models for patient-oriented clinical research.

Recent signals from the Obama Administration also make it clear just how important this program is to the federal role in biomedical innovation. In President Obama’s FY 2016 budget request, roughly 72% of the entire requested budget for NCATS would go to the CTSA program.³ In the agency’s budget justification, Dr. Austin described the direction of the CTSA program in FY 2016 as continuing to build on its “past accomplishments to form a collaborative, national network to transform the translational science process so that new treatments for disease can be developed in a more systematic and rigorous manner and delivered to patients faster.” Additional insights provided in the budget justification confirm an interest in the CTSA program to:

- Build network capacity for the conduct of multisite clinical trials;
- Support innovative collaborative projects;
- Train for the particular skills required for translation; and
- Diversify project teams.

3. <http://www.ncats.nih.gov/files/NCATS-FY16-justification.pdf>

A Changing Science Landscape

This review is taking place in the context of a dramatically changing external environment where the tools, resources, mechanisms, paths and systems for the conduct of clinical and translational science are in a state of rapid evolution. The infrastructure required to conduct translational research is being redefined. The understanding that translational science must be transdisciplinary team science is rising, and attention is turning to the need for new cultures and reward systems that recognize these essential competencies.

There are ways that CTSA-funded hubs can equip themselves to succeed in this evolving landscape. CTSA hubs must be sure that their culture and academic system do not turn a blind eye toward – or even reward – siloed behaviors. While good investigators can, on their own initiative, reach across the institution and into regional affiliates to create unique cross-disciplinary teams, this ad hoc collaboration will remain just that. In a changing clinical and translational science environment, CTSA infrastructure must provide bridges and paths that invite, support and reward connectivity, both within the hub and across affiliated organizations.

Elias Zerhouni's 2014 editorial in *Science Translational Medicine* provides a glimpse into how the future of translational science is shifting. His definition of key clinical and translational science factors includes several areas of strength, which, when reinforced and leveraged through decisive leadership, can position institutions at the front of this defining curve.

*Society's successes in the past century have transformed medicine—and revealed weaknesses in our approach to the treatment of patients and the development of medical products...**We need a new approach that redirects the research and development (R&D) engine toward deciphering the natural histories of human diseases and using this new understanding to identify therapeutic targets. Such a redesigned drug-development paradigm must begin with the patient.***

Rich patient cohorts coupled with powerful research tools—systems biology, computational modeling, and theragnostic imaging—can illuminate the genetic underpinning of molecular changes associated with human pathophysiology. Only after we lay the groundwork should drug targets be selected for further consideration.

Human tissue samples are crucial in the early validation of one's genetically derived hypothesis, and validation requires precise biopsy methods and serial tissue sampling over the course of the disease. Potent new analytical tools for obtaining and analyzing human materials can facilitate corroboration of ideas: single-cell analyses; clinical-grade liquid chromatography–mass spectrometry; three-dimensional (3D) and 4D cultures; multiplex tissue-based assays and readout capabilities; and next-generation bioinformatics, metabolomics, and proteomics methods.

*...**Better to scrap the linear model of drug development in favor of a network of activities conducted by smaller maneuverable partnerships fueled by diverse stakeholders and a freer, bidirectional flow of scientific information. Deciphering the complexity of human diseases and finding safe, cost-effective solutions that help people live healthier lives requires collaboration across scientific and medical communities throughout the health care ecosystem...***

Turning the Titanic; Elias Zerhouni,
www.ScienceTranslationalMedicine.org
29 January 2014 Vol 6 Issue 221 2.
Emphasis added.

Section 2 – Institutional Profiles

Report Methodology: Examining Six CTSA Hubs

The Indiana CTSI is widely perceived to be a unique and vital element of the Indiana, regional, and national life sciences sector. To validate this perspective, it is useful to provide a clear profile of the Indiana CTSI asset within the context of the broader CTSA program. This section examines the Indiana CTSI alongside five peer CTSA hubs across the nation.

The summaries of the CTSA-funded hubs profiled in this report are built around reliable performance metrics and CTSA site-specific information and commentary. Given that CTSA hubs are announced in different cycles and in response to different RFP's this analysis cannot be based solely on the selection criteria in a given round. As a result, the report uses the following methodology to provide a well-grounded review.

- Several candidate metrics were developed to provide objective measurement of CTSA site performance. This was accomplished through a combination of literature review, interviews with site leaders, and publicly-reported data. Additionally, several (though not all) sites provided access to applications and reports submitted to the NIH. FaegreBD also contacted key opinion leaders outside of the CTSA hubs to provide insights on the state of the CTSA program.
- Six candidate CTSA-funded hubs (including the Indiana CTSI) were selected to inform the report. The candidate sites were chosen through an analysis based on the following factors:
 - a. Geographic Location;
 - b. CTSA Funding Level (FY 2014);
 - c. Total NIH Funding to Host Institution of CTSA (FY 2014);
 - d. Total Bioscience Industry Employment (2014, MSA);
 - e. Population of the Region (MSA, US Census);
 - f. School of Public Health (Yes/No);
 - g. Health System (Yes/No); and
 - h. Health Ranking (2014; State).

To provide a useful base of reference, three “comparable” hubs were chosen which have similar overall NIH funding levels at their host institutions to Indiana University’s. Two “outlier” hubs that sit in institutions (Stanford University and Washington University) with significantly higher NIH funding also were selected to enrich the comparisons.

1. With the six CTSA hubs identified, the report uses three, key areas of CTSA activity to provide a framework for understanding and comparing performance:
 - a. Translational science;
 - b. Community engagement and impact; and
 - c. Education and workforce development.

One or more measurable functional, along with qualitative inputs, is captured in each area to inform the analysis that follows.

A. The Indiana Clinical and Translational Sciences Institute

OVERVIEW

Institution	Indiana University School of Medicine Indianapolis, Indiana https://www.indianactsi.org/
Date Established	2008
Date Renewed; Date of Next Renewal	2013; 2018
Leadership	Anantha Shekhar, MD, PhD, Director
Total NIH Funding (FY14)	\$147,332,684 Indiana University
NIH Funding Level for CTSA Principal Investigator (FY14)	\$6,715,523

Summary

The opportunity to participate in the national CTSA program was compelling for the Indiana University School of Medicine and the region from the earliest stages. Rising investment from both the public and private sectors were creating new areas of research emphasis such as the Indiana Genomics Initiative to fuel innovation. Established centers of excellence such as the Regenstrief Institute with its healthcare informatics competencies, including the Indiana Health Information Exchange, were well positioned to contribute on translation and community impact.

At the same time, IU recognized the fundamental need to improve performance around life sciences commercialization and economic development, particularly as the Central Indiana Life Sciences Initiative, now BioCrossroads, gathered momentum. The Advanced Research and Technology Institute (ARTI) was morphing into the IU Research and Technology Corporation (IURTC) to better support this movement. In many respects, Indiana was as well-prepared to embrace the CTSA model as almost any research environment in the nation.

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One of the most significant, early decisions was to structure the Indiana CTSA as a statewide network led by the IU School of Medicine in partnership with Purdue University and the University of Notre Dame. This array of nationally-prominent institutions is an unusual format for the CTSA hubs and reflects the fundamentally collaborative nature of the Indiana CTSA. While the medical school sits at the center of any CTSA hub, the ability to tap directly into a wider array of basic research disciplines and other science capabilities is a profoundly important characteristic of the Indiana CTSA. It already has over 40 research service cores operating across the participating institutions.

Equally important as the academic features of the Indiana CTSA are its various and robust relationships beyond the campuses. First and foremost among these is the strategic proximity with several leading life science companies, anchored by Eli Lilly and Company. Very few of the CTSA hubs in any location enjoy this degree of alignment with industry. Corporate participation in the Indiana CTSA operates at a variety of levels from the identification and support of promising basic science, into pre-competitive development of therapeutic targets, through to clinical research, and ultimately bringing the innovation to the patient. Programs such as the Lilly-sponsored fellowships are bringing the academic and industry scientists together to advance this continuum of collaboration.

Around this central partnership between the Indiana CTSI and the region's life science companies, large and small, is an expanding array of community engagement initiatives. This work includes major activities such as the Community Health Engagement Program (CHEP) that links researchers, health providers, and other stakeholders to inform the research agenda and to accelerate clinical applications. The state and local public health community has a seat at the table here and across several Indiana CTSI programs. Additionally, the CHEP patient engagement core represents a powerful move to ensure that the patient perspective is infused across the stages of research and development.

Each of these areas of strength represents a competitive advantage for the Indiana CTSI today and will continue as the CTSA program evolves. While the peer institutions examined in the following section all have distinguishing characteristics as well, the level and depth of strategic collaboration at the Indiana CTSI is truly distinguishing. The balance of this section covers several of these features in more detail.

A. Translational Science

1. Research Partnerships Overview

Internal: INGEN (Indiana Genomics Initiative); Indiana University Melvin and Bren Simon Cancer Center Translational Research Acceleration Collaboration (ITRAC); Indiana University Purdue University Indianapolis (IUPUI); Indiana University at Bloomington; Indiana University School of Dentistry; Indiana University School of Nursing; IU Simon Cancer Center; Fairbanks School of Public Health

Universities: Purdue University; University of Notre Dame; Oregon Clinical & Translational Research Institute; Strategic Pharma-Academic Research Consortium for Translational Medicine (SPARC) with The Ohio State University, Northwestern University, and Washington University at St. Louis; UCSF Clinical & Translational Science Institute; Yale Center for Translational Investigation;

Non-Profits: BioCrossroads; Fairbanks Institute for Healthy Communities; Indiana Biosciences Research Institute; Indiana Health Information Exchange/Indiana Network for Patient Care; Regenstrief Institute

Healthcare Providers: IU Health; Eskenazi Health; Roudebush VA Medical Center

Industry: Anthem; Cook Group; Covance; Eli Lilly and Company; Roche Diagnostics; Takeda

Foundations: Lilly Endowment; Regenstrief Foundation; Richard M. Fairbanks Foundation;

State & Local Governments: Indiana Family & Social Services Administration; Indiana State Department of Health; Indiana Economic Development Corporation (IEDC)

2. Cores/Resources Overview

The Indiana CTSI has created a comprehensive suite of programs called Project Assistance and Resources for Translational Scientists (PARTS) that provides assistance to investigators working across the entire spectrum of clinical and translational research. The scope of supported projects spans a wide range of biomedical research ranging from new biological findings or best practice ideas that require translation from the early phases to the late stages of population and policy level research. Through this comprehensive suite of services, the PARTS initiative provides special assistance to support an effective transition across these phases of translational research.

Additionally, the Indiana CTSI has created a coordinated set of resources and services that address important needs and assist investigators in efficiently overcoming critical barriers, not only of local

constraints in resources and regulatory processes, but also challenges faced by them when conducting studies with national and global collaborators.

Indiana CTSI cores include:

- ***Advanced Biomedical Information Technology Core***
Specializes in supercomputing, medical informatics, applications software, massive storage and advanced visualization services, and collaboration tools.
- ***Biostatistics Core***
Collaborates with investigators in the planning, statistical design, data management, and analysis of health related clinical, laboratory and epidemiological research projects.
- ***Center for Evaluation and Education Policy (CEEP)***
An evaluation and education policy research center that promotes and supports program evaluation and education policy research for educational, human services, and nonprofit organizations. Clients include federal and state agencies, public and private organizations, and foundations and endowments primarily working in the fields of public health, education, and youth development.
- ***Chemical Genomics Core Facility***
Provides investigators with cost-effective access to high throughput screening of structurally-diverse, drug-like small molecules in biological assays to enable investigators to discover small molecule tools for basic research, therapeutic development and diagnostic applications.
- ***Genomics and Bioinformatics Core***
Provides sequencing and microarray services including consulting for appropriate experimental design, use of technology, and data analysis. Computing facilities are equipped with high performance hardware, a collection of software packages and in-house pipelines, and a team of trained bioinformaticians.
- ***Preclinical Histology Core (PHC)***
Provides necropsy, histology and pathology support to researchers who use cell lines, xenografts, animal models, and human tissues in their research at various biosafety levels.

B. Community Engagement & Impact

The Community Health Engagement Program provides infrastructure, assistance, and resources to ensure community engagement for all phases of clinical and translational research for the Indiana CTSI.

One of the primary goals of the Indiana CTSI is to develop better ways to engage the Indiana public towards prevention and treatment of diseases and to educate them about factors that predispose them to the most common diseases including obesity, diabetes, and coronary artery disease.

Since 2008, CHEP has spearheaded the development of a robust structure for community-engaged research on Indiana CTSI campuses and with statewide community partners. There has been an increase in CHEP consultations to academic and community partners, and in academic investigators submitting extramural proposals from these consultations. CHEP partnered with the Purdue Extension Service, Indiana State Department of Health, local health departments, and local health care systems to cultivate county-based health coalitions statewide. Notably, surveys of 348 community partner organizations have shown increasing satisfaction with CHEP's activities from 57% in 2010 to 76% in 2012. CHEP is also making inroads into improving promotion and tenure opportunities for community-engaged researchers.

Indiana CTSI has established a new core specifically on patient engagement. Through this endeavor, patient experts will meet with principal investigators to offer input into improved study design. This program has proved to be extremely successful as witnessed by a high level of interest and demand from the community.

C. Education & Workforce Development

The Indiana CTSI has implemented three major education and workforce development initiatives since 2008. These have included:

1. The design and implementation of new coursework, a new Master of Science, a Graduate Certificate, and a PhD Minor in Translational Research;
2. A new KL2-funded Young Investigator program for junior faculty; and
3. A new TL1-funded predoctoral program.

Additionally, the Clinical Education and Research Training (CERT) program is now a statewide consortium that includes IUPUI, IUB Purdue, and Notre Dame.

The Indiana CTSI continues its focus on expansion. A unique new cluster training project brings three investigators together to be funded for a common research project. The K award mechanism is used for physician-scientist and nursing investigators, and a T Award is used for the postdoctoral investigator. All members of the cluster team are co-authors on all publications with each becoming a first author in the appropriate sub-specialty journal. By supporting a common project with complementary funding, the innovative program builds and rewards team-science endeavors. The goals of the Education, Training and Career Development program are to enhance the current KL2 and TL1 programs, enhance distance-learning modalities, and expand the therapeutics program to include a “discovery to commercialization training track.” Additionally, three new programs--masters and certificate programs in team science, curricular modules in implementation and community-based research, and global training to dispense cross cultural investigational skills--will be added.

Highlights

- Created strong partnerships with corporate, community, and government entities from across the state of Indiana
 - Eli Lilly & Co. partners with Indiana CTSI in a number of innovative public-private initiatives, including a training program for quantitative pharmacology, a Phase 1 unit, drug-discovery programs, and an industry fellowship in which the awardees gain first-hand industry drug-development experience. This relationship is the foundation for a new network of 17 Midwest CTSA hubs, coordinated by IU, known as the Strategic Pharma-Academic Research Consortium for Translational Medicine, or SPARC. Takeda has joined Lilly as an initial corporate participant in SPARC.
 - Cook Group has partnered with Indiana CTSI for device trials across the IU Health statewide hospital network and has created i2iConnect to promote industry-academia collaborations.
 - Indiana CTSI has created a statewide, longitudinal, biospecimen resource called Indiana Biobank which is available to any CTSI investigator.
 - The state supports a high-speed academic network (I-light) and provides \$1 million per year in grants to support spinal cord and brain injury research.
 - The Translational Informatics Program leverages the unusual willingness among the major regional private and public health care systems to collaborate (Ascension Health Network, the Franciscan Alliance, and Community Network).

- A relationship between Covance and the Indiana CTSI has been established to expand early stage (phase 1) clinical research activity.
 - The recently formed Richard M. Fairbanks School of Public Health at IUPUI provides a critical capability for spanning the research to community elements of the CTSA program.
 - The Indiana Network for Patient Care (INPC), a program of the Indiana Health Information Exchange, offers a highly evolved and integrated electronic health records platform.
 - A landmark initiative to bolster the life sciences productivity of the region, the Indiana Biosciences Research Institute (IBRI), is in early stage development with a close connection to the clinical capabilities of the Indiana CTSI.
- Developed several programs with integration of different facilities across the institutions and strong support from the private sector, including Eli Lilly, Roche and other companies
 - Built a statewide infrastructure for research with all sites connected through the Informatics platform of Indiana CTSI's Informatics Data Access Center
 - External advisory board is composed of local corporate and civic leaders, bringing a level of ownership and appreciation from community partners
 - Directly operates the services or resources, but more often, the CTSI supplements or amplifies the existing local institutional resources with additional support

B. National Peers

This section describes five CTSA hubs across the nation using data and insights developed through independent information gathering and interviews with hub leaders. Additional detail on each hub is captured in corresponding appendix. For context, the following table provides a snapshot of various characteristics used in selecting the sites.

Institution	Funding Level for CTSA PIs (FY14)	Total NIH Funding (FY14)	Total Bioscience Industry Employment	Population of the Region	School of Public Health	Health System	Health Ranking*
Indiana University	\$6,715,523	\$147,332,684	57,644	1,953,961	Yes	Yes	41
Albert Einstein College of Medicine	\$5,217,637	\$157,391,499	76,070	19,949,502	No	Yes	15
Emory	\$6,229,144	\$265,282,296	27,667	5,522,942	Yes	Yes	38
University of Texas	\$6,451,913	\$156,565,936	80,792	6,810,913	No	Yes	36
Washington University	\$10,722,640	\$371,946,949	28,109	2,801,056	No	Yes	39
Stanford	\$10,497,336	\$384,340,065	235,864	1,919,641	No	Yes	21

* America's Health Rankings: <http://www.americashealthrankings.org/about/annual>

i. Harold and Muriel Block Institute for Clinical and Translational Research at Einstein and Montefiore

OVERVIEW

Institutions	Albert Einstein College of Medicine Montefiore Medical Center Bronx, New York http://www.einstein.yu.edu/centers/ictr/
Date Established	2008
Date Renewed; Date of Next Renewal	2013; 2018
Leadership	Harry Shamon, M.D., Associate Dean for Clinical & Translational Research, Director of the Harold and Muriel Block Institute for Clinical & Translational Research at Einstein and Montefiore; Brian Currie M.D., M.P.H., Vice President for Medical Research, Assistant Dean for Clinical Research at Montefiore Medical Center, co-director, Harold and Muriel Block Institute for Clinical & Translational Research at Einstein and Montefiore; Paul Marantz, M.D., M.P.H., Associate Dean for Clinical Research Education
Total NIH Funding (FY14)	\$157,391,499
NIH Funding Level for CTSA Principal Investigator (FY14)	\$5,217,637

Summary

The Einstein-Montefiore Institute for Clinical and Translational Research (ICTR) was founded in 2008 through the partnership of the Albert Einstein College of Medicine and Montefiore Medical Center. The ICTR partners with ten local institutions, as well as numerous health care providers. The two institutions recently merged into a single entity.

The ICTR provides researchers access to nine services including two Clinical Research Centers, a Biomarker Analytic Research Core, a Biorepository, and a Clinical Trials & Regulatory Support Office. These services provide support for a range of translational sciences including interoperable biomedical informatics, therapeutics development, child health research, and patient- and population-centered outcomes research.

The ICTR has committed space and resources to provide training and career development to:

- Faculty members
- Physicians
- Other health professionals, including nurses, pharmacists, and psychologists
- Post-doctoral fellows and trainees
- Residents
- PhD candidates
- Medical and graduate students

Outside of the ICTR's relationships with universities and health care providers, it does not have independent industry alliances; however, 80% of its clinical trials are industry sponsored. The ICTR is developing partnerships with tech-

nology companies, like Microsoft and IBM, to advance its computational and big data innovations. Additionally, the ICTR is partnering with the New York Genome Center (NYGC), a consortium of academic and medical institutions focusing on translational science.

While the ICTR has demonstrated strengths in their workforce and training functions, leadership points out that 10% of their NIH funding is allocated for this important component of the CTSA. Most CTSA institutions receive more funding.

Appendix A provides additional details of these features.

Highlights

- Strong partnerships with academic and government entities from across the region and state.
- Together, the two entities, officially merged in July 2015, enjoy “a closer working relationship around research and harmonization of resources” as “a joint enterprise.”
- Leaders within ICTR believe their strong informatics and big data capabilities will set them apart during the pending “information revolution.”
- The Accountable Care Organization (ACO) affiliated with medical institutions brought in experts to help with data analytics.
- The ICTR is a member of the New York and Connecticut Consortium (NYCON Consortium) that encourages joint ventures among the New York and Connecticut area CTSA institutions
- The ICTR serves on all five NCATS Advisory Council Working Group Domain Task Forces
- Secured a PatientCentered Outcomes Research Institute (PCORI) clinical data research networks (CDRNs) grant.
- According to ICTR, publications based on ICTR-assisted research exceed 300 papers annually.⁴
- The ICTR cites their biobank as a major asset of their CTSA.

4. <http://www.einstein.yu.edu/docs/centers/ictr/ictr-brochure.pdf>

ii. Atlanta Clinical and Translational Science Institute

OVERVIEW

Institutions	Emory University Morehouse School of Medicine (MSM) Georgia Institute of Technology (Georgia Tech) Atlanta, Georgia http://www.actsi.org/
Date Established	2007
Date Renewed; Date of Next Renewal	2012; 2017
Leadership	David S. Stephens, M.D., Principal Investigator, Emory University
Total NIH Funding (FY14)	\$265,282,296
NIH Funding Level for CTSA Principal Investigator (FY14)	\$6,229,144

Summary

The Atlanta Clinical and Translational Science Institute (ACTSI) is led by Emory University, along with partners Morehouse School of Medicine, Georgia Institute of Technology, and Children’s Healthcare of Atlanta.

ACTSI combines clinical, translational, training, and basic discovery programs at Emory with the health disparities, training, and community outreach focus of Morehouse School of Medicine, the engineering and bioinformatics achievements of Georgia Tech, and the pediatric focus of Children’s Healthcare of Atlanta.

Additionally, ACTSI focuses on research in minority health and addressing health disparities, as well as an emphasis on pediatric research.

Education and workforce development have been areas of success for ACTSI. The Technological Innovation: Generating Economic Results (TI:GER®) program connects law school students with engineers to focus on the commercialization of research and has led to a number of start-up companies. Additionally, the Kids Interested in Discovering Science (K.I.D.S.) Club is a successful community engagement tool that, in partnership with Georgia Tech, encourages interest in science, technology, engineering and mathematics.

Appendix B provides additional details of these features.

Highlights

- ACTSI leaders credit in-person meetings as the key to partnership success. “It takes time” (given that Emory is roughly 6-7 miles away) but well worth the effort to meet face-to-face.
- Several Georgia-based non-profits are actively engaged with ACTSI including Georgia Bio, an industry association, and the Georgia Research Alliance, an independent nonprofit aligned with Georgia’s Department of Economic Development, which provides support to ACTSI outside the CTSA funding.

- ACTSI is a member of the Southeastern CTSA Consortium (SECC), which represents eight CTSA principal investigators from seven states.⁵ The SECC focuses on addressing complex health problems facing the southern region of the country, including stroke, cardiovascular disease, obesity, type 2 diabetes, and low birth weight.
- ACTSI conducts extensive research in minority health and addresses health disparities.
- Emphasis on pediatric research is another distinguishing factor.

5. <https://ctsacentral.org/regional-consortia/southeast-ctsa-consortium>

iii. Center for Translational Medicine at UT Southwestern Medical Center

OVERVIEW

Institution	University of Texas Southwestern Medical Center Dallas, Texas http://www.utsouthwestern.edu/research/translational-medicine/index.html
Date Established	2007
Date Renewed; Date of Next Renewal	2012; 2017
Leadership	Robert D. Toto, M.D., Principal Investigator
Total NIH Funding (FY14)	\$156,565,936
NIH Funding Level for CTSA Principal Investigator (FY14)	\$6,451,913

Summary

The UT Southwestern Center for Translational Medicine, founded in 2007, consists of over 200 established clinical and translational investigators, comprised of faculty and mentors who oversee a large medically diverse patient population in five major teaching hospitals and clinics. The faculty includes five Nobel laureates.

The Center is supported by faculty from UT Southwestern Medical School, School of Public Health, School of Health Professionals, as well as their partner institutions' school of pharmacy, public health, bioengineering, and computer science.

The Center for Translational Medicine focuses on four major areas:

- Catalyzing research that leverages strengths in biological sciences;
- Educating clinical investigators to perform cutting-edge clinical and translational research;
- Developing and implementing new research methods and technologies; and
- Engaging the community in improving the health of the population that they serve.

The Center for Translational Medicine has four cores:

- Target Identification and Validation
- Discovery in Humans
- Interventions in Humans
- Population Science and Community Engagement

The Center's clinical and translational components, such as informatics, education and training, and biostatistics, are structured within and provide support for all four cores.

Appendix C provides additional details of these features.

Highlights

- Center for Translational Medicine's External Advisory Committee (EAC) "provides critical input regarding the organization, scientific and administrative aspects, and progress toward meeting our program goals."
- The EAC conducts a site visit annually for this purpose.⁶ (however, a list of EAC members is not public)
- Center for Translational Medicine is part of the Texas Regional CTSA Consortium (TRCC), along with three other CTSA-funded hubs, that work to facilitate clinical and translational research and dissemination among the Texas CTSA-funded institutions and other interested biomedical research institutions.
- The four core programs are unique in that elements of each can be found in all programs.
- Education and training takes place across all four cores, as does a focus on biostatistics.
- The Center for Translational Medicine prides itself on leveraging resources and infrastructure to enable investigators to perform cutting-edge clinical research.

6. <http://www.utsouthwestern.edu/research/translational-medicine/about/leadership/advisory-boards.html>

iv. Washington University Institute of Clinical and Translational Sciences

OVERVIEW

Institution	Washington University School of Medicine St. Louis, Missouri http://www.icts.wustl.edu/icts-researchers/about
Date Established	2007
Date Renewed; Date of Next Renewal	2012; 2017
Leadership	Dr. Bradley Evanoff
Total NIH Funding (FY14)	\$371,946,949
NIH Funding Level for CTSA Principal Investigator (FY14)	\$10,722,640

Summary

The Washington University Institute of Clinical and Translational Sciences (WU ICTS), established in 2007, includes partnering institutions such as BJC Healthcare, a regional health system, Saint Louis University, and the St. Louis College of Pharmacy. WU ICTS acts as the primary home for intra- and inter-institutional cooperation and collaboration in the region.

The WU ICTS's 22 research cores are supported by the ICTS Administrative Core which provides services and educational opportunities for clinical and translational research to the over 1,000 ICTS members.

One particularly noteworthy core, the Human Imaging Unit (HIU), provides a centralized imaging facility or "portal" that enables investigators with little or no imaging experience to incorporate imaging into their research protocols.

WU ICTS established or facilitated new degree-granting programs in Clinical Investigation, Population Health, and Public Health, and created mentored research and career development programs for faculty, fellows, and students that included a variety of new coursework and seminars focused on clinical and translational research, including technology transfer and intellectual property.

WU ICTS is in the process of merging its clinical data warehouse with BJC Healthcare's Center for Clinical Effectiveness (CCE). The CCE provides clinicians with population, organizational, and patient-level data, as well as analysis and decision support. This collaboration will enhance WU ICTS' impact on technology transfer. Additionally, WU ICTS used to partner with Pfizer until the company left the St. Louis region. WU ICTS is working informally with the Donald Danforth Plant Science Center and is considering formalizing the partnership.

Appendix D provides additional details of these features.

Highlights

- The WU ICTS partners with institutions in the greater St. Louis area to support the overarching goals of the national CTSA consortium and the ICTS regional goals.
- Leaders of these institutions all participate in the oversight of the ICTS through their positions on the Governing Council, and investigators from the institutions may become members of the ICTS.
- The Tracking & Evaluation (T&E) team measures collaboration at three interconnected phases: 1) grant development and submission; 2) active scientific collaboration; and 3) scientific publication.
- The WU ICTS reports a general trend towards greater publication collaboration and interdisciplinary co-authorship teams.
- These collaborations have also become more interdisciplinary, both in terms of grant and journal co-authorship teams.
- There is a robust community engagement program in conjunction with the Institute for Public Health.
- One particularly noteworthy core, the Human Imaging Unit (HIU), provides a centralized imaging facility or “portal” that enables investigators with little or no imaging experience to incorporate imaging into their research protocols. The resources provided by the HIU include: 1) access to imaging technologies, services, expertise, and regulatory support; 2) tailored assistance with experimental design and protocol development; 3) simplification of data acquisition and analysis; 4) customized educational opportunities; 5) and joint pilot funding through a partnership between the WU Mallinckrodt Institute of Radiology (MIR) and WU ICTS.

v. The Stanford Center for Clinical and Translational Education and Research

OVERVIEW

Institution	Stanford University Stanford School of Medicine Stanford, California http://spectrum.stanford.edu/about-spectrum
Date Established	2008
Date Renewed; Date of Next Renewal	2013; 2018
Leadership	Dr. Harry Greenberg
Total NIH Funding (FY14)	\$384,340,065
NIH Funding Level for CTSA Principal Investigator (FY14)	\$10,497,336

Summary

The mission of Stanford Center for Clinical and Translational Research and Education (called Spectrum) is to streamline and support the translation of basic discoveries into practical solutions that maintain and improve human health and to educate the next generation of clinical and translational leaders. Efforts are focused in these three areas:

- **Educate** the next generation of investigators with the multidisciplinary skills required to conduct cutting-edge clinical and translational research, to meet the opportunities and challenges of medicine in the 21st century. Spectrum will facilitate the transformation of medical research training from a narrow focus on discipline-restricted expertise to a more interdisciplinary team approach, where trainees become conversant in the language, processes and tools used across the full extent of the translational pipeline.
- **Create an institutional home** conducive to efficiently translating the most innovative discoveries made by our basic, translational and clinical scientists into products and processes that directly improve human health and well-being. Spectrum is providing the institutional environment to identify and then support those discoveries that are most ready for translation.
- **Develop and implement resources and services** to accelerate the translation of discoveries into better human health, while simultaneously reducing operating costs. Spectrum ensures that investigators receive the necessary clinical trial, informatics, statistics, regulatory, ethics and administrative support to maximize their research productivity and optimize the participation of diverse populations.

Stanford is well-known for its basic research strengths. The establishment of Spectrum has enabled the institution to expand and enhance its emphasis in translational and clinical sciences, including the launch of the Jill and John Freidenrich Center for Translational Research, designed from the ground up to optimize teamwork and to create a friendly environment for clinical trial subjects and healthy research volunteers.

Moreover, Spectrum has become a significant bridge between the Stanford biomedical research community and its expanding health-care delivery enterprise. Two new major areas of expansion include:

- The Clinical Excellence Research Center (CERC) assembles small teams of physicians, business scholars, engineers, and management and social scientists to redesign care delivery for some of the most expensive

disease conditions in the United States. The CERC fellows vet their new delivery models with disease specialists, hospital administrators and health-care insurers, then recruit hospital partners from around the country to test the models.

- The Stanford Center for Population Health Sciences, as part of the CTSA, brings together scientists and physicians from across the university and its medical institutions to leverage population-level evidence to revolutionize care at the bedside and to improve the overall health of society.

Appendix E provides additional details of Spectrum.

Highlights

- Spectrum leverages its institutional strengths:
 - Excellence in basic biological and computational sciences
 - A single campus that enables all investigators and students to be within walking distance of one another
 - A strong focus on innovation and invention
 - A strong entrepreneurial culture that facilitates interdisciplinary activities.
- Spectrum benefits greatly from being located in the heart of Silicon Valley, a center of innovation in technology and biotechnology.
- Its newly created university-wide Center for Population Health Sciences assembles a diverse group of investigators to complete the “last mile” of the translational pipeline.
- All core services are available to all researchers.
- The Stanford culture encourages and supports innovation

Section 3 – Observations and Comparisons

The research and interviews conducted to inform this report gave rise to several cross-cutting observations regarding the impact and direction of the CTSA program. While the sample is limited and subjective, it is useful to both identify these shared areas of interest and to consider specifically how they may relate to the Indiana CTSI.

Positive shift in relationships within universities

All of the interviewed CTSA representatives identified as a primary CTSA program impact the fundamental and positive change in the way that their host universities connect to the hubs and to the translational science arena more broadly. In particular, several pointed out the extensive interaction and frequent collaboration between the institutional leadership (i.e., President, Provost, Board, etc.) and the CTSA principal investigators and senior staff. This heightened institution-specific collaboration was often cast in terms of an appreciation at the institutional leadership level for the growing importance of translational science and the value of the CTSA program in positioning the institution in this larger shift across the scientific community.

The shift aligns with a fundamental purpose of the CTSA program to reorganize and reform the process of moving biomedical innovation from the lab to the clinic and ultimately into positive impacts on population health. This signal was strong given that the survey of these individuals was constructed to avoid any presumptions in this regard. One interviewee noted that the program was ‘no longer a step-child.’ Several noted that, increasingly, the institution’s basic scientists are ‘becoming more translational.’

For some, the natural bridges formed by the CTSA hubs between their research and clinical colleagues is proving to be a major opportunity for population health management and even competitive advantage in the emerging, value-based approach to health care financing.

While the degree of change and exchange may vary among the three academic institutions participating in the Indiana CTSI, deep, mutual commitment and partnership is well established at Indiana University and its School of Medicine. Moreover, interviews across the Indiana stakeholders, with the other CTSA PIs, and with NIH officials reinforced the view that the Indiana CTSI and in particular its PI, are consistently viewed as a strategic advantage for the Institution.

Blurring of lines between research program and clinical care

The extent to which the CTSA hubs are informing and partnering with local responses to health care reform pressures is striking. This impact is certainly linked to the implementation of the Affordable Care Act but appears to have a broader imperative as the CTSA host institutions partner with health care systems to improve quality and constrain costs. Some of the sites participating in this study have made a strategic decision to direct resources into clinical care improvement well beyond the development and application of new therapies. Several noted the value of these new interactions as a means to tracking community health impact, although all interviewed found this challenge daunting.

For some, the natural bridges formed by the CTSA hubs between their research and clinical colleagues is proving to be a major opportunity for population health management and even competitive advantage in the emerging,

value-based approach to health care financing. Several of the interviews touched on the interdisciplinary relationships supported by the CTSA program that are now providing capacity to accelerate adoption of best practices in both clinical care and, in at least one case, process efficiencies.

This intersection of CTSA investments and related clinical impact also emerged in the review of the Indiana CTSI. A key innovation by the Indiana CTSI was the creation of the Center for Health Innovation and Implementation Sciences (CHIIS) which has created process improvement units within its health care partner hospitals, developed a first in the country certificate and Master's program in implementation sciences, and created several home-based, non-hospital based programs funded by large grants from CMS to improve care delivery. There clearly is a meaningful relationship between the Indiana CTSI and health care delivery.

Concern about the future direction of CTSA program

As noted earlier in the report, the NIH is initiating significant changes in the original construct of the CTSA program. The most recent competitive Request for Applications (RFA) begins to make this evolution more tangible as it lays out several elements that were either less emphasized or largely voluntary in earlier rounds. And while it would be an overstatement to indicate that the CTSA hubs involved in this study were uniformly resistant to these changes, there was clear concern that some of the changes could impose significant limitations on the effectiveness of the program.

Two features of the evolving CTSA requirements provoked particular interest. First was the use of a new CTSA hub funding formula tied to the host institution's overall NIH funding level. For some, this would likely lead to significant funding reductions in future rounds. The second area of shared concern related to the rising emphasis on standardizing processes around translation and especially in the conduct of clinical trials. This trend was seen as fundamentally in tension with the creativity and flexibility encouraged in the early stages of research core activity. Some used the term "unfunded mandates" to refer to the NIH requirements in this area.

Based on the review conducted here, the Indiana CTSI is reasonably well-positioned for many of these new expectations. For example, the robust collaboration with industry suggests a level of readiness to design and deliver clinical trials that meet rigorous expectations. Moreover, the highly networked nature of the Indiana CTSI with three academic organizations, significant industry connectivity, and multi-layered community partnerships is likely a longer-term competitive advantage.

Incentivizing Team Science

The CTSA program has had a consistent emphasis on enabling multi-disciplinary and multi-organizational approaches to research and development. The complexity inherent in improving translation of biomedical innovation demands that investigators work in teams and that recognition in research and publication be given for a distributed network of contributions rather than primary authorship. The CTSI cluster-training program stands out as a creative model to bring trans-disciplinary investigators together to focus on a problem that draws on shared expertise.

While there was a consistent acknowledgement of the need for this strategic shift, the traditional mechanisms for professional promotion and recognition at the hubs remain largely intact. Incentives for team science are slow to emerge. Some experimentation is occurring around early career metrics, but each interview conducted for this report acknowledged the continuing challenges here.

The Indiana CTSI is squarely in line with its peer organizations in this area. The program has significant investments in, and expectations for, the translational science workforce of the future. There is recognition that current professional development systems do not always align with these goals. At the same time, more fundamental changes in how performance is evaluated to recognize team-based contributions is in the pilot stage.

Industry Remains Substantially at Arm's Length

For the majority of sites contacted for this report, external industry relationships do not play a central role in the CTSA hub. And, those who do not enjoy industry relationships view the need for this engagement in the future very differently. One principal investigator stated a clear intent to expand Phase 1 drug trial capacity, with the belief that this is critical given the institution's clinical research assets. In another instance, with expertise and partnerships more firmly planted in bio-engineering and community health, expanding industry partnerships was not on the institution's radar. Technology transfer and commercialization, while not underemphasized, appear to operate in a largely traditional supporting role to the research enterprise, including in the translational phase.

By contrast, the Indiana CTSI enjoys a more integrated position with industry that flows in substantial part from the nature of the central Indiana life sciences sector. The larger industry participants, such as Eli Lilly & Co., have been engaged throughout the history of the Indiana CTSI. In fact, several other CTSA hubs have turned to Indiana to enable a broader regional network to encourage industry collaboration.

By contrast, the Indiana CTSI enjoys a more integrated position with industry that flows in substantial part from the nature of the central Indiana life sciences sector.

Community Engagement

There is no question that the role of community engagement is expected to remain a central, most likely rising, element of the CTSA program. All hub leaders were quick to acknowledge this factor. At the same time, it appears that community engagement is more difficult to plan and execute in a rigorous manner as both the nature and degree of CTSA program expectations are in flux.

Several of the hubs noted that the emerging contours of community engagement are broad, which is helpful for varied, location-specific opportunities, but challenging to ensure that related CTSA program expectations are met. In addition, there was considerable concern that the NIH would prioritize, but not necessarily fund, community engagement activities. In other words, this might be a pivotal area for performance that must be resourced largely from the host institution.

Through the Community Health Engagement Program, the Indiana CTSI has invested robust resources to provide infrastructure, assistance, and resources to facilitate constructive community engagement for all phases of clinical and translational research for the Indiana CTSI.

Conclusion

The NIH Clinical and Translational Science Awards program is entering a pivotal stage of development as it moves from an early definitional phase into a more mature, evolved place in the biomedical research ecosystem. The public clamors for better results from the federal investment in biomedical research. As demands for a demonstration of this “ROI” continue, the expectations for the CTSA program to deliver results will continue to mount, which places new pressures both on the NIH and on the recipient institutions. The unavoidable question will remain: Is the CTSA program bringing more innovation through the “valley of death,” into the clinic and into practice adoption so that the health of the American public is benefited by this investment?

Within this dynamic context, the Indiana CTSI exhibits significant strength as a platform that both drives the development of new therapies and builds collaboration at multiple levels in the region and beyond. These characteristics position the Indiana CTSI as a key asset for the state’s life sciences community. Very few, if any, comparable mechanisms exist in the region with the skills, flexibility, and mission to bridge the academic, industry, and clinical components of the sector.

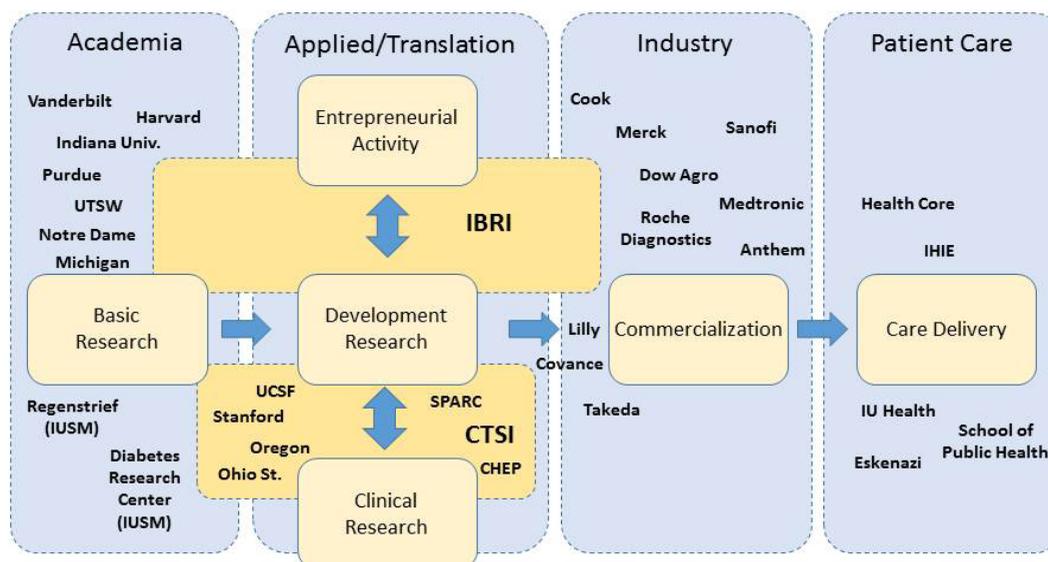
Within this dynamic context, the Indiana CTSI exhibits significant strength as a platform that both drives the development of new therapies and builds collaboration at multiple levels in the region and beyond.

This review also confirms, in a broader sense, what the NIH peer review process suggests: namely, that the Indiana CTSI is a leading CTSA program hub when compared to its peers across the nation. This finding is particularly striking as it holds true even when applied to an institution like Stanford University, which has a considerably higher level of overall NIH funding for biomedical research. The comparative strength is based on several factors including:

- A founding principal investigator who is uniformly recognized as a translational science thought leader and gifted facilitator of complex initiatives;
- Industry commitment at the highest levels to the Indiana CTSI as a means to help transform the area’s research productivity;
- Multiple, significant organizations across the region that are co-invested with the Indiana CTSI across translation, commercialization, and health impact; and
- Perhaps most importantly, a supportive regional life sciences sector that increasingly values and rewards collaboration between and among its participants with the Indiana CTSI positioned in a central, strategic role in this nationally-recognized ecosystem.

This last point, the collaborative and interconnected nature of the Indiana CTSI and the surrounding academic, industry, health care delivery, and public sector organizations, merits special emphasis. It is these characteristics which truly differentiate the Indiana CTSI from most other hubs in both a quantitative and qualitative sense. The

rich array of prominent research and human health-focused organizations working together across the private and public sectors in Indiana is exceedingly rare anywhere. The following graphic depicts the breadth and depth of this network.



This array of relationships also will factor materially in the ability of the Indiana CTSI to sustain itself in future NIH funding competitions and as a magnet for resources coming from within the region and beyond. The CTSA program will continue to evolve towards metrics that emphasize translational productivity – bringing innovation into the clinic. Connection to a robust trans-disciplinary pipeline of basic research opportunities from IU, Purdue, Notre Dame, industry, and a network of allied institutions substantially improves the prospects for specific translational success. The ongoing development of the Indiana Biosciences Research Institute represents a potential inflection point as an industry-led research platform for world class talent, attracting investigators who will inevitably turn to the Indiana CTSI for key development services.

In addition, the Indiana CTSI’s alignment with IU Health, Eskenazi Health, other clinical partners and the public health system helps complete the critical loop of discovery to delivery that changes individual and population health outcomes. Today, the time it takes for evidence-based therapeutic strategies to become widely deployed as standards of care rivals the developmental “valley of death” in terms of delaying the patient benefit. The NIH is responding to this dimension by placing emphasis on community engagement that fosters health impact. Here again, the Indiana CTSI is well-positioned to perform through the extensive network of health care delivery and public health relationships.

Put simply, the Indiana CTSI is both a differentiator and an integrator for the region’s array of health and life sciences assets. It brings widespread recognition to the broader therapy development enterprise, as well as unique opportunities for talent and resource attraction. It bridges the often confounding divide between academic science and industry with purpose. And, it links clinicians and patients to the fruits of this more efficient path to treatments and cures. With continuing commitment across this landscape, the Indiana CTSI will help drive health and economic benefits for generations of Hoosiers.

Appendix A

Harold and Muriel Block Institute for Clinical and Translational Research at Einstein and Montefiore

A. Translational Science

The ICTR provides support for the full range of translational sciences, interoperable biomedical informatics, therapeutics development, child health research, and patient- and population-centered outcomes research. ICTR has expanded its research cores for clinical trials and regulatory support; clinical investigation services; biostatistics, epidemiology and research design; biomarker and analytic research; biospecimen banking; community engagement consultation; research informatics; and project management and acceleration.

1. Research Partnerships Overview⁷

Internal: Einstein-Montefiore Center for Comparative Effectiveness Research (CCER); New York City Clinical Data Research Network (CDRN); Empire Clinical Research Investigator Program (ECRIP); and PCOR-PRIME, a novel training program for comparative effectiveness researchers.

Universities: Columbia University; Mount Sinai; NYU School of Medicine; Rockefeller University; NYU Langone; College of New Rochelle School of Nursing; Lehman College; City University of New York; and Weill Cornell.

Non-Profits: No current partnerships.

Healthcare Providers: Montefiore Medical Center; The Children's Hospital at Montefiore; Bronx Health Link; Clinical Directors Network; Beth Israel Medical Center; North Bronx Health Network/Jacobi Medical Center

Industry: Pfizer Centers for Therapeutic Innovation Program (CITI); Lilly Open Innovation Drug Discovery Program; Novo-Nordisk; AstraZeneca; Microsoft Research, Intel, others.

Foundations: No current partnerships.

State & Local Governments: NY State Department of Health and New York City Department of Health and Mental Hygiene; NYC BioAccelerate and other Technology Development Partners

2. Cores/Resources Overview

The ICTR's core translational science services include:

- **Office of Clinical Trials (OCT)**
The OCT helps researchers sort through the regulatory demands when filing submissions and initiating and conducting clinical trials for potential new therapies, devices and diagnostics.
- **Clinical Investigation Services Core (CISC)**
The CISC provides access to space, staff and resources to enable funded investigation in patients, whether adult or pediatric. Currently the CISC supports more than 75 active protocols in epidemiology, genetics, general medicine, neurology, women's health, pediatrics, psychiatry/

7. <http://www.einstein.yu.edu/centers/ictr/collaborative-initiatives/>

behavioral sciences and surgery. These protocols generate 4,000 outpatient visits annually, including intensive procedures and first-in-human research.

- **Biostatistics, Epidemiology & Research Design (BERD)**
The BERD core provides statistical and epidemiologic support for all phases of clinical and translational research including study design, study conduct, analysis, interpretation and dissemination of results. The core operates a walk-in clinic to provide expertise for new research initiatives including grant applications, pilot studies, and protocols.
- **Biomarker Analytic Research Core (BARC)**
BARC supports investigators at all stages from planning through implementation of sample acquisition, preservation, secure chain of custody with bar codes, quality analysis, and secure data output through vast collection and analytical capabilities. More than 300 investigators are now using BARC.
- **Biorepository (BioR)**
Established in 2007, BioR serves the human research blood and tissue storage needs of the clinical and translational research community. The Biorepository provides banking for more than 200,000 samples of biological fluid and tissue specimens as well as human-subject-derived material.
- **Research Informatics Core (RIC)**
This trans-disciplinary core service provides informatics infrastructure, tools, and standards that optimize collection, retrieval, integration, sharing, processing, and communication of biological, clinical, and environmental data for clinical and translational research. The RIC supports all investigators with the entire life-cycle of information processing for translational research across the diverse spectrum of translational and outcomes research.
- **Project Acceleration Resource (PAR)**
PAR coordinates resources and streamlines and enhances project implementation by integrating expertise and by facilitating efficient access to resources. This core service aims to support investigators throughout the life cycle of a study; to accelerate translational research by identifying potential collaborators and sources of support; to streamline access to core facilities by coordinating resource delivery to investigators; to assist team building, project planning, and project management; and to provide quantification of CTSA support for administrative and study facilitation services.

B. Community Engagement & Impact

The ICTR's Community Engagement Consultation Core (CCEC) provides consultative services that make use of institutional assets, facilitates partnerships with regional community-based organizations and health service cooperatives, accelerates investigator engagement with the Bronx Community Research Review Board, and engages the multi-CTSA consortium with the NYC Department of Health to advance research translation to health. The CCEC facilitates research in health disparities, health outcomes, behavioral interventions, community participatory research, and health services research.

Community-engaged institutional assets include the Montefiore Office of Community Health, the New York City Research and Improvement Networking Group (NYC RING), the Diabetes Prevention & Control Core, the Pediatric Prevention Intervention Research Center, and the Division of Community Collaboration and Implementation Science.

C. Education & Workforce Development

The Research, Education, and Training (RET) Core provides a number of pre-doctoral and post-graduate opportunities to engage faculty and collaborate within peer groups. The ICTR's training and education programs introduce faculty, fellows, residents, PhDs, graduate and medical students and other health professionals to this multidisciplinary field of clinical and translational research. According to ICTR's leadership, their training programs have evolved beyond the core expectations of the CTSA program and funding.

All programs are learner-centered, focus on the core competencies developed by the CTSA, and emphasize methods that promote a team-based approach to scientific inquiry, including:

- **Clinical Research Training Program (CRTP)**

The CRTP is a rigorous and intensive two-year program for individuals who wish to pursue careers in clinical research. The curriculum emphasizes:

- epidemiology,
- biostatistics,
- analytic methods,
- research ethics,
- study design, and
- grant/manuscript writing.

Under the guidance of a mentor, each scholar must also complete a hypothesis-driven research project and a publishable thesis. Enrollment is limited to 10–15 scholars per year, and each participant must have secured a mentor and documentation from his or her department to affirm that the scholar will be given the resources and allocated time required by the program. Between 2000 and 2010, CRTP graduates were awarded 87 research grants as PIs and 46 career development grants.

- **Clinical Research Methods Lecture Series**

The ICTR annually sponsors a series of 10 lectures on the fundamentals of clinical research methods for graduate students, residents, fellows and faculty. The series covers such topics as study design, biostatistics, outcomes research, research ethics, evaluation of diagnostic testing, cost-effectiveness analysis and genetic/genomic issues.

- **PhD and MD/PhD in Clinical Investigation (eCLIPSE)**

In collaboration with Einstein's graduate division for MSTP and PhD students, the ICTR offers a program to students who are interested in obtaining clinical and translational research training and mentorship for their thesis research. This clinical investigation track provides rigorous advanced training to prepare them for independent research careers.

- **MD/MS Program**

Third-year medical students who are interested in clinical research apply to our five-year MD/MS program. If they are accepted, their fourth-year curriculum includes clinical research under the guidance of a faculty mentor as well as CRTP courses. The fifth-year curriculum combines required clerkships, electives, continuing MS course work and completion of the clinical research project, including a defense of a master's thesis.

While the ICTR has demonstrated strengths in their workforce and training functions, leadership points out that 10% of their NIH funding is allocated for this important component of the CTSA. Most CTSA institutions receive more funding.

Appendix B

Atlanta Clinical and Translational Science Institute

A. Translational Science

1. Research Partnerships Overview⁸

Internal: Yerkes National Primate Research Center (Emory); Office of Nursing Research (Emory University Nell Hodgson Woodruff School of Nursing)

Universities: Emory University; Morehouse School of Medicine; Georgia Institute of Technology; Georgia State University*;

Non-Profits: Georgia Bio; Georgia Research Alliance; The Robert W. Woodruff Health Sciences Center; American Cancer Society*; Association of Black Cardiologists*; Georgia Cancer Coalition*; MIT Enterprise Forum of Atlanta*;

Healthcare Providers: Children's Healthcare of Atlanta; Atlanta Veterans Affairs Medical Center; Grady Memorial Hospital and Health System; Atlanta Community Physicians Network; Morehouse Medical Associates; Saint Joseph's Hospital*; Phoebe Putney Memorial Hospital*

Industry: Metro Atlanta Chamber of Commerce*

Foundations: Coulter Foundation

State & Local Governments: Centers for Disease Control and Prevention (Prevention Research Centers)

(* indicates "letter of support for ACTSI")

2. Cores/Resources Overview

Core programs within ACTSI include:

- **Clinical Research Network (CRN)**
The multi-site CRN is a multilayered and geographically distributed network across Atlanta. The network incorporates hospital, medical office, and community-based clinical research sites through integration with the Community Engagement Research Program (CERP). The CRN resources include inpatient/outpatient space, nursing, laboratory, bionutrition and exercise physiology, clinical data extraction, and other types of support.
- **Ethics & Regulatory**
This core program advises and educates researchers on ethical dilemmas specifically involving research; facilitates the regulatory education of researchers; and coordinates the efforts of numerous regulatory offices across multiple institutions in order to streamline the process of initiating clinical and translational research.

8. <http://www.actsi.org/about/partners.html>

- **Research Technologies**
This core provides the infrastructure and programmatic foundation to support existing and developing technology resources, with emphasis in the following five areas: genomics, imaging, immunology, molecular screening, and animal models of human disease. The program supports the evaluation and rapid translation of high-impact emerging technologies, enhances collaborative opportunities among translational investigators, provides seed funds to promote novel methodological developments, and co-sponsors biomedical educational symposia.
- **Pilot Grants**
The Pilot Grants program promotes new networks of multidisciplinary research teams by capitalizing currently available resources across multiple institutions to support one to two year pilot projects focused on translational medicine and inter-institutional collaboration.
- **Biostatistics, Epidemiology, & Research Design (BERD)**
The BERD program strengthens the statistical science and rigor of ACTSI-related research by assisting with prospective design of human studies research, statistical methodologies, elements of data collection, and management and analysis of data.
- **Biomedical Informatics Program (BIP)**
The BIP program builds and supports informatics and IT solutions to facilitate research for individual studies and across the ACTSI. BIP also works with partner institutions to develop innovative infrastructure to support collaborative, integrative translational research studies within and between CTSA sites.
- **Pediatrics**
This core program is a collaboration among the Departments of Pediatrics of Emory University, Morehouse School of Medicine, and Children’s Healthcare of Atlanta working with Georgia Tech. This program serves as an academic home for the conduct of pediatric clinical and translational research that effectively reaches the entire Atlanta pediatric community.

B. Community Engagement & Impact

Community Engagement Research Program (CERP)

The CERP supports community-university research partnerships by obtaining community input into university research and responding to the health needs of the community. It connects existing academic community research programs from Morehouse School of Medicine (MSM) and Emory University’s Robert W. Woodruff Health Sciences Center and seeks to address health disparities in the community. Specific efforts to address health disparities include:

- Creating a continuous community involvement process to reach communities and practitioners, share findings, and engage communities;
- Generating new research programs;
- Conducting courses and seminars on community-based participatory research; and
- Building community capacity to generate research questions and work toward the improvement of community health.

Three specific CERP research projects include:

- **I-Adapt** – A project that tests an intervention to improve diabetes self-management implemented by community health workers using motivational interviewing techniques. West End Medical Center, a federally funded community health center, is the community partner.
- **e-Healthy Strides** – A project testing an intervention employing lay health coaches and utilizing a web-based program to improve diabetes self-management. The original community partner was Big Bethel AME Church; the program is now offered to City of Atlanta employees.

- **EPICS (Educational Program to Increase Colorectal Cancer Screening)** –A project testing several approaches to disseminate an evidence-based colorectal cancer screening intervention. It was developed in a community-based participatory research project and then demonstrated in practice with cooperation from the Fulton County Department of Health and Wellness.

C. Education & Workforce Development

Research Education, Training, & Career Development (RETCD)

The RETCD program focuses on long-term didactic and mentored clinical and translational research training through a variety of initiatives. It provides clinical and translational research training opportunities including Master of Science in Clinical Research (MSCR), KL2 Mentored Clinical & Translational Research Scholars Program for junior faculty, TL1 Medical Scientist Training (PhD graduate students and medical students), and a Certificate Program in Translational Research (CPTR) for PhD students. RETCD also enhances clinical and translational research activities for doctoral and non-doctoral level trainees through short course training.

The Technological Innovation: Generating Economic Results (TI:GER®) program is connecting law school students with engineers to tackle problems in a nontraditional way. This legal support is noted as an important component in leading to new start-ups. Additionally, the Kids Interested in Discovering Science (K.I.D.S.) Club has been a successful tool for community engagement. It is a partnership with Georgia Tech to encourage interest in science, technology, engineering and mathematics.

Appendix C

Center for Translational Medicine at UT Southwestern Medical Center

A. Translational Science

1. Research Partnerships Overview

The Center for Translational Medicine created a Council of Institutional Partners to ensure effective and efficient integration of the partnering institutions in their collaborative functions and to promote synergy with the CTSA's programs in translation medicine, specifically NIH-funded activities.

Internal: In recent years, the Bio-Center has spun out small bio and pharma companies.

Universities: Seton / UT Southwestern Clinical Research Institute of Austin, Southern Methodist University, University of North Texas Health Sciences Center, Fort Worth, University of North Texas Health Sciences Center, Fort Worth, University of Texas at Arlington, University of Texas at Dallas, University of Texas Health Science Center at Houston School of Public Health, Dallas Regional Campus.

Non-Profits: No current partnerships.

Healthcare Providers: Children's Medical Center Dallas, Dallas Veterans Affairs Medical Center, Moncrief Cancer Institute, Parkland Health & Hospital System, Texas Scottish Rite Hospital for Children, Texas Tech University Health Sciences Center.

Industry: No current partnerships.

Foundations: No current partnerships.

State & Local Governments: No current partnerships.

2. Cores/Resources Overview

The Center for Translational Medicine has four core focuses:

- **Core 1 – Target Identification and Validation**
This core program exists to organize, enhance, and increase partnerships with external cores on campus and to provide state-of-the-art technologies, assistance with statistical analyses, and development/validation of assays to measure clinically relevant metabolites and biomarkers.
- **Core 2 – Discovery in Humans**
This core program incorporates highly phenotyped human cohorts into the Center for Translational Medicine to facilitate human discovery, using centralized human specimen procurement and sample management, state-of-the-art imaging and physiological assay, and provision of a clinical research unit specific to translational science.
- **Core 3 – Interventions in Humans**
This core program helps investigators build capacity for early and later-phase multi-site clinical trials through strategic partnerships. Resources include technologies in imaging, genomic research, biomarkers, and informatics. In addition, this core program leverages existing partnerships to form

and support a Phase 1 clinical testing facility. The Principal Investigator is currently expanding the program's Phase 1 trial capacity.

- **Core 4 – Population Science and Community Engagement**

This core program supports observational and interventional patient-centered outcomes and comparative effectiveness research by accelerating methods for electronic-health-record-supported projects and expanding several highly successful community-based research programs. This core program also provides the link between research findings from previous cores and population health outcomes.

B. Community Engagement & Impact

The focus of the Community Engagement Program is to develop means of reducing disease causality in under-served communities by integrating, supporting, and expanding existing and developing new collaborative relationships between researchers and communities. This includes the following activities:

- Partnering with various community constituencies to identify and address health needs by:
 - Helping community-based organizations assess needs among their constituencies;
 - Providing technical assistance for planning interventions and evaluation designs;
 - Partnering with new organizations to expand community-engaged work, especially reaching out to English- and Spanish-speaking Hispanic populations; and
 - Setting up mechanisms to share research results with community members while continuing and extending their ongoing partnerships and projects.
- Linking community members' need for health promotion with community-based health care services by:
 - Facilitating members' access to sources of primary care;
 - Enabling community clinics to participate in health promotion efforts such as vaccine promotion or smoking cessation interventions; and
 - Providing follow-up care for people whose research participation may lead to identification of a medical problem.
- Enhancing fair and equitable opportunities for community members' participation in translational research by:
 - Launching new initiatives to expand a community-based research registry, including under-served groups in research; and
 - Deploying a Spanish-language validation system to expand research participation opportunities.
- Building capacity for culturally sensitive, community-engaged research by:
 - Expanding training for Clinical Scholars;
 - Enhancing opportunities for pre- and postdoctoral students' summer research and practica;
 - Facilitating and funding pilot applications for community-engaged research; and
 - Providing consultation and technical assistance for investigators seeking to conduct research that addresses the three above-listed goals.

C. Education & Workforce Development

The Education and Career Development program provides a multidisciplinary program that trains predoctoral, doctoral, and postdoctoral level trainees across all disciplines and all partnering institutions of the Center for Translational Medicine.

Degree and certificate programs offered through the UT Southwestern Graduate School of Biomedical Sciences include:

- Postdoctoral Programs
 - **Clinical and Translational Research Scholar Program**
Sponsored in part by the National Institutes of Health (NCATS CTSA grant mechanism), this two-year track is designed for postdoctoral fellows and junior faculty who are on course to obtain extramural grant funding and show great promise toward becoming independently funded investigators.
 - **Master of Clinical Science**
Designed for postdoctoral fellows and junior faculty, the Master of Clinical Science is a three-year track for training in clinical/translational research.
 - **Graduate Certificate in Clinical Science**
The Graduate Certificate track involves basic training in clinical/translational research for postdoctoral fellows and junior faculty.
- Predoctoral Programs
 - **TL1 Predoctoral Training Award and Basic Certificate in Clinical Science**
This track supports early career development of predoctoral trainees, including medical students and Ph.D. students, by providing interdisciplinary training in clinical and translational research.
 - **Mechanisms of Disease and Translational Science Track (MoDTS)**
This is an enrichment program overlaid on all Division of Basic Science Graduate Programs. The MoDTS Program is supported by the Howard Hughes Medical Institute's Med into Grad Initiative and the State of Texas Innovative Graduate Program Initiative.

Education programs and policies are established by a steering and oversight committee, the Career Development Committee (CDC). The CDC evaluates the continuous development and implementation of Education and Career Development Program, which includes making final decisions on degree completion.

Appendix D

Washington University Institute of Clinical and Translational Sciences

A. Translational Science

1. Research Partnerships Overview

Internal: College of Arts & Sciences, George Warren Brown School of Social Work, School of Engineering, School of Law, School of Medicine

Universities: St. Louis College of Pharmacy, Southern Illinois University Edwardsville School of Nursing, University of Missouri - St. Louis College of Nursing, Saint Louis University: Albert Gnaegi Center for Health Care Ethics, Doisy College of Health Sciences, School of Medicine, School of Nursing, College for Public Health & Social Justice

Non-Profits: Danforth Plant Science Center

Healthcare Providers: BJC HealthCare: Barnes-Jewish Hospital, Goldfarb School of Nursing, St. Louis Children's Hospital

Industry: CORTEX District

Foundations: Missouri Foundation for Health

State & Local Governments: No current partnerships.

2. Cores/Resources Overview

The WU ICTS has 22 research cores, including:

- **Center for Biomedical Informatics (CBMI)**
The CBMI focuses on Biomedical Informatics (BMI) as an academic discipline and as a facilitator of a broad range of research projects and their application to evidence-based changes in the treatment and management of patients.
- **Pediatric Clinical Research Unit (PCRU)**
PCRU provides space and nursing and bionutritional support for clinical research projects conducted with children at Washington University in St. Louis. The bionutritional support includes dietary analysis of food records and dietary histories and the development of educational materials.
- **Research Design and Biostatistics Group (RDBG)**
RDBG guides clinical study design, data collection and data analysis and provides services such as triage requests to other appropriate methodological and quantitative WU ICTS investigators and coordination for multi-institutional studies.

B. Community Engagement & Impact

WU ICTS expanded its community engagement with the CORTEX District (Center of Research, Technology and Entrepreneurial Exchange), which was started in 2002 by WU, BJC HealthCare, Saint Louis University (SLU), University of Missouri - St. Louis, and the Missouri Botanical Garden, and is located in the business corridor between WU and SLU; both WU ICTS institutions continue to work to capitalize on this environment to grow industry translational partners. The Cortex CEO was invited to join the WU ICTS Governing Council, to formally interact with key leaders from all of the ICTS partner institutions.

Additionally WU ICTS maintains a significant relationship with Integrated Health Network, the regional safety net clinic organization. WU ICTS also has facilitated the merger of the Washington University and the BJC HealthCare System clinical data warehouse.

C. Education & Workforce Development

WU ICTS established or facilitated new degree-granting programs in Clinical Investigation, Population Health, and Public Health, and created mentored research and career development programs for faculty, fellows, and students, as well as a variety of new coursework and seminars focused on clinical and translational research, including technology transfer and intellectual property.

WU ICTS offers multiple predoctoral and postdoctoral program opportunities through the Center for Clinical Research Training (CRTC). The CRTC expanded predoctoral offerings for PhD students to include a joint MSCI/PhD degree and an MD/PhD track developed in conjunction with WU's medical scientist training program, which is one of the largest in the country. WU ICTS is working with the Division of Biology and Biomedical Sciences to further develop training tracks to produce more MD/PhD and PhD graduates devoted to translational research.

Trainees have begun to make independent and team-based contributions in clinical and translational investigation, as measured by their record of publications and grant funding, which has led to ten WU ICTS Members noted on the 2014 Highly Cited Researchers list.

Appendix E

The Stanford Center for Clinical and Translational Education and Research

A. Translational Science

1. Research Partnerships Overview

Internal: Stanford University Schools: Business; Earth, Energy & Environmental Sciences; Education; Engineering; Humanities & Sciences; Law; and Medicine.

Outside Universities: No formal partnerships but numerous individual research collaborations. Within the University, there are collaborations with virtually every other school and with several other independent centers including Bio-X, Freeman Spogli Institute for International Studies, the Stanford Center on Longevity, the Stanford Woods Institute for the Environment, Institute for Research in the Social Sciences, and the Center for Healthy Weight at Lucile Packard Children's Hospital.

Non-Profits: Kaiser Permanente Division of Research; Community Partners; YMCA of the USA Activate America Program; Mountain View-Los Altos Challenge Team; Adolescent Pregnancy Prevention Network.

Health-care Providers: Veterans Affairs Palo Alto Health Care System; Northern California Cancer Center; Santa Clara Valley Medical Center; Gardner Family Health Network; Community Health Partnership of Santa Clara County; Stanford Health Care; and Lucile Packard Children's Hospital Stanford.

Industry: Multiple industry collaborations, including a cardiovascular mobile health study (MyHeart Counts) with Apple Computer and the Google baseline study, in which daily health information is being collected from healthy people in Southern California via a Google-designed web portal and with biometrics devices.

Foundations: The Palo Alto Medical Foundation for Health Care, Research, and Education, and many others.

State & Local Governments: Santa Clara County data-sharing for discovering, designing, implementing and testing novel interventions to improve population health.

2. Cores/Resources Overview

The role of Spectrum's Enabling Technologies Resource is to provide investigators with a comprehensive directory and access to best tools. In addition, Spectrum provides direct financial support to supplement charge-back costs to a few selected cores that have been judged to be uniquely valuable to the clinical and translational science enterprise. Before the CTSA funding started, many useful assay devices, analyzers and databases were buried in basements and scattered through labs across the institution – unknown or unusable to many of the CTR investigators. The formation of Spectrum has created centralized oversight and management, enabling these resources to be identified, cataloged and publicized.

Stanford hosts over 36 enabling technologies, supporting a full range of biomedical research. A select subset of core resources receives direct support from Spectrum and provides unique facilities to CTR researchers at subsidized rates:

- **Human Immune Monitoring Center** – provide comprehensive immune monitoring for studies in humans including sample banking and assays at the genomic and proteomic and bulk and single-cell levels.
- **Human Genomics Core** – provides basic, translational and clinical research with integrated genomics services from blood sample to interpreted genomic sequence.

Additional core resources include:

- Biomaterials and Advanced Drug Delivery facility
- Fluorescence-Activated Cell Sorting facility
- High-Throughput Bioscience Center
- Microfluids Foundry
- Richard M. Lucas Center (experimental human MRI)
- Stanford Behavioral and Functional Neuroscience Laboratory
- Stanford Center for Innovation and In vivo Imaging
- Stanford Functional Genomics Facility
- Stanford Magnetic Resonance Laboratory
- Stanford University Mass Spectrometry Laboratory
- Transgenic and Animal Tumor Models facility

B. Community Engagement & Impact

The Community Engagement Program, now part of the Population Health Science Center brings together community health professionals and the public in Spectrum’s clinical and translational research activities through the development of long-term, trusted, and meaningful partnerships in the unique local communities surrounding Stanford University Medical Center. The local communities offer an unusual blend of diverse populations from all socioeconomic levels and ethnic groups, including people of African, Asian, Pacific Islander, Latin, American Indian, and Caucasian descent. This diversity, which mirrors the breadth of diversity across California, provides Spectrum with a valuable opportunity to conduct population health science research relevant to the changing demographics across the U.S.

The Community Engagement program consists of five main components:

- **Community partnerships** link Stanford researchers with community partners to ensure that translational discoveries support advancements in public health, clinical medicine and basic science. Using Community Based Participatory Research (CBPR), the community engagement program has been highly successful in developing over 40 trusted partnerships with community organizations over the past 4.5 years.
- **Education and training** of faculty, students, trainees and community partners builds capacity and continues to foster growth and development of a cadre of leaders within the Stanford community who are skilled and committed to conducting effective translational research in our diverse communities. In the past 4.5 years, the program has provided training to more than 1,000 individuals from Stanford and community-based organizations.
- **Individual and group** consultation and technical assistance supports Stanford investigators engaged in population and community-based research. The program staff has provided technical assistance to over 200 investigators and community partners on community-based research design and methods, proposal development and implementation, evaluation and tracking tools, partner capacity building and the ethical conduct of research.

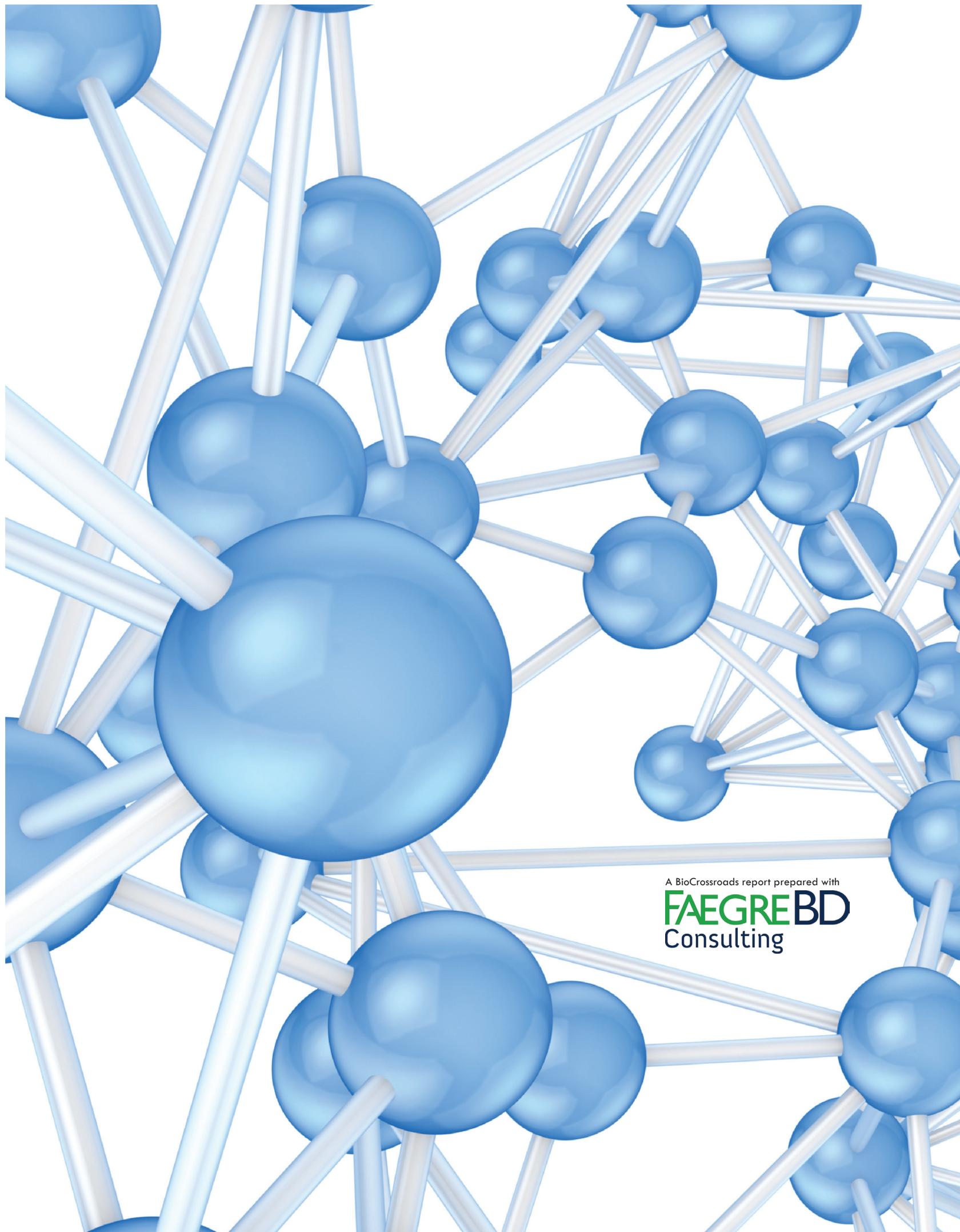
- **Seed funding** for academic-community partnerships helps accelerate the development of research partnerships and the collection of pilot data to support larger studies. The program has awarded 29 seed grants to Stanford faculty working directly with community partners.
- **Partnerships** with other CTSA Institutions have been formed to further develop collaborative partnerships with local public health departments, establish regional community-based participatory training programs and foster collaborative relationships with faculty investigators.

C. Education & Workforce Development

Spectrum's core educational mission is to provide intensive, supervised, high-quality clinical and translational research training toward producing a cadre of successful CTR investigators.

To that end, Spectrum both offers and facilitates several state-of-the-art educational programs for a diverse set of trainees — medical and doctoral students, residents and fellows. Principal components of our offerings include: advanced didactic instruction, tailored career plans, coordinated and closely monitored mentorship, and high-quality translational research in interdisciplinary teams. Offerings include:

- Epidemiology and Clinical Research (MS/PhD)
- Biomedical Informatics (MS/PhD)
- Health Services Research (MS/PhD)
- Biomedical PhD Training for Personalized Medicine
- Genetics (MD/PhD)
- Bioengineering (MS/PhD)
- Master of Medicine (MOM, MS)
- Biostatistics (MS, PhD)
- Masters of Public Health (through UC Berkeley)



A BioCrossroads report prepared with
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