The Indiana Clinical Translational Science Institute (I-CTSI)

Institute Director:

Anantha Shekhar, MD, PhD Bloomington director: William P. Hetrick, PhD Purdue director: Connie Weaver, PhD Notre Dame director: Gregory Crawford, PhD



IU Health Information and Translational Sciences Building, Indianapolis

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What is clinical translational science?

- Science aimed at:
 - translating discoveries in basic science to the understanding, treatment, and prevention of human disorders (T1)
 - translating discoveries generated during research in the laboratory, and in preclinical studies, to studies in humans and the development of human trials
 - developing and implementing evidence-based standards of practice and public health policy (T2)
 - enhancing the adoption of best practices in the community
 - enhancing cost-effectiveness of prevention and treatment strategies
- More than simply interdisciplinary





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Statement of justification

"At no other time has the need for a robust, bidirectional information flow between basic and translational scientists been so necessary. Advances in our understanding of biologic systems and the development of powerful new tools that can be applied at both the bench and the bedside...offer unprecedented prospects for advancing knowledge of human disorders in a translational context... Today, there is good reason to believe that the scope of knowledge and expertise needed to be an effective translational or clinical scientist can no longer be acquired "on the job," as was done in the past. Although we have made every effort to provide the support functions for translational and clinical research, there is a call for training in a wider range of skill sets that span the biomedical and behavioral sciences and make use of far more advanced and more complex resources and methods than ever before. We may have failed to recognize that clinical and translational science is an emerging discipline that encompasses both the acquisition of new knowledge about health and disease prevention, preemption, and treatment and the methodologic research necessary to develop or improve research tools." — Elias A. Zerhouni (2005)

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IndianaCTSI ACCELERATING CLINICAL AND TRANSLATIONAL RESEARCH

Agenda

- 1. Quick overview of the Indiana CTSI
 - a. What it is?
 - b. Who funds it?
 - c. Who are its partners and users?
 - What is clinical translational science?
 - a. NIH's impetus
 - b. Strategic goals the CTSAs
 - c. Key functions
 - d. Who has a CTSA?
- 3. Indiana CTSI research & training programs
 - a. Research grants
 - b. Education & career development
 - c. Infrastructure and resources
- 4. Translational research & training on the Bloomington campus
 - a. What is its role?
 - b. How do we promote it at IUB?
 - c. How do we increased IUB participation in the I-CTSI?
 - d. How can IUB strengthen the I-CTIS?
 - e. Annual Bloomington InCTSI retreat

Indiana Clinical and Translational Sciences Institute (CTSI) Summary

- A statewide laboratory for transforming health sciences research and health care delivery
- Part of National Institutes of Health new "Roadmap" initiative
- Funded by Clinical Translational Science Awards and leveraged partnerships
- Replaces longstanding General Clinical Research Centers and related awards
- I-CTSI investment scope: NIH \$25 million;
 Partner Institutions \$56 million over 5 years

Indiana CTSI

What is its Funding?

 A CTSA grant from NIH of \$25 Million/5 yrs
 Indiana University, Purdue University and other statewide partners contributed over \$50 Million

Who are its partners?

Providing Leveraging Opportunities Throughout the State



I-CTSI: Institutional Commitment

Type of Commitment	New Funds/5yrs	New Space	New space Costs
IU VP for Life Sci. funds	\$11 million		
IU President's funds	\$5 million		
Purdue President's fund	\$2.5 million		
Indiana legislature	\$15 million		
HITS Building (CTSI home)		169,000 Sq. Ft.	\$42 million
INGEN Core support	\$10 million		
Department of Pediatrics	\$6 million		
IUSM Biostats/Bioethics support	\$2.75 million		
Eli Lilly training support	\$3.15 million		
Translational fellowship	\$600,000		
Research 3 building CTSI space		6000 Sq. Ft.	\$8 million
Totals	\$56 million	175,000 Sq. Ft.	\$50 million

I-CTSI Organizational Principles

- Be inclusive, transparent and collaborative
- All functions are to be metrics driven and continually evaluated
- Enhance collaboration among academic institutions, government and private sector

Indiana CTSI

Who are its users?

Researchers, Trainees, Community members

How can you access its resources? Through the CTSI 'HUB' Log on to: IndianaCTSI.org or Call 317-278-CTSI (2874)



Source: Butler D. Translational research: Crossing the valley of death. Nature. 2008;453:840-2.

Impetus for the CTSA Program







Integrative

- Across health disciplines
- Between scientific areas
- Into the community
 - engagement/participation

Translational

Laboratory to Clinic to Community to Laboratory

Educational

- Scientists
- Health care providers
- Community

Provides resource infrastructure

- NIH funded research
- Non-NIH funded research
- Public-private partnership

CTSA Strategic Goals

(1) Enhancing National Clinical and Translational Research Capability

- Clinical research management
- Research infrastructure
- Phenotyping human and preclinical models

(2) Enhancing the Training and Career Development of Clinical and Translational Scientists

(3) Enhancing Consortium-Wide Collaborations

- Social networking
- Inventory of resources
- Data sharing

(4) Enhancing the Health of Our Communities and the Nation

- National Model for Community Engagement
- Inform Public Health Policy Through Research







Building a National CTSA Consortium





I. Translational research acceleration programs:

- B. Education & career development awards
 - 1. T Trainee awards
 - The T32 focuses on pre-doctoral training in translational research.
 - 2. K Clinical Scholar awards
 - The K12 program focuses on junior faculty pursuing clinical or translational research.
 - 3. K Basic Science Scholar awards
 - The K12 program focuses on junior faculty pursuing Basic Science research.
 - 4. Notre Dame Innovation Postdoc (ND only)
 - Post-doc funding to facilitate movement of research inventions/concepts to commercialization.
 - 5. Purdue's Trask Venture Fund (Purdue only)
 - *Goal*: To assist faculty to further clinical commercial potential of IP disclosed to the Office of Technology Commercialization.

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I-CTSI programs that facilitate research:

- Novel Translational Methodologies and Pilot Studies Program, Project Development Teams (PDTs)
- Biomedical Informatics Program
- Design and Biostatistics Program (DBP)
- Regulatory Knowledge and Support (RKS)
- Clinical Research Resource Center (CRRC)
- Community Health Engagement Program (CHEP)
- Translational Technologies and Resources (TTR) Cores Program
- Research Education, Training and Career Development
- Bioethics and Subject Advocacy Program (BSAP)
- Disease and Therapeutic Modeling Program
- Biomedical Engineering and Bionanotechnology Program
- Indiana CTSI HUB (http://www.indianactsi.org)

Project Development Teams:

- Purpose:
 - "one-stop shop" for study development by providing investigators access to multidisciplinary research expertise, biostatistics, IRB/regulatory services, nursing support, and pilot funds
 - Comprised of experienced researchers who discuss ideas and concepts with investigators to assist in developing high quality, feasible, fundable clinical/translational research projects.

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Project Development Teams:

- Eight PDTs address a broad spectrum of research focuses
 - 1. **Preclinical PDT (TRAC1)** focuses on translational studies in animal and cellular models.
 - 2. Pediatric PDT (PRAT) facilitates research in children with emphasis on interactions with basic scientists to design and implement bench-to-bedside studies.
 - 3. Adult PDT (TRAC2) focuses on early translational studies related to adult medicine.
 - Behavioral/Population Science PDT (BEHV) helps investigators design and implement epidemiological and behavioral research.
 - 5. Purdue PDT has particular strengths in assisting investigators with a special emphasis on bioengineering, nutritional, and veterinary medicine.
 - 6. Translating Research into Practice PDT (TRIP) focuses on projects that evaluate and implement evidence-based practice and other health services research.
 - 7. Notre Dame PDT provides access to broad biomedical expertise particularly in basic research.
 - Imaging PDT provides expertise in the application of anatomical, functional, and molecular imaging methodologies and technologies.

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IndianaCTSI ACCELERATING CLINICAL AND PDT projects - portfolio by stage

	BENCH	L Basic Science Research Preclinical Studies Animal Research Model	Ta Case 5 Phase 1 Clinical	eries and 2 Trials BEDSIDE Human Clinical Research Controlled Observational Studies Phane 3 Clinical Controlled Observational Studies	T2 P R A C T I C E teta-analyses ematic Reviews T3 ssemination & sentation Research Systems Redesign plied Health IT Clinical Practice Delivery of Care Identification of New Clinical Questions and Gaps in Care
	Concept	Dev	Dev	Trials	
TRAC1					Ť
			<u></u>		
TRAC2	40 49 04	44	53	26 27 29 31 33 35 37 39 41 43 4 51 23 30 32 34 36 38 40 42 47 50 52	5 48105 123
<u>PRAT</u>	73 81	63		5 5 9 6 6 6 7 7 7 5 5 9 6 6 6 6 6 6	6 6 6 7 7 8
<u>Beh/Pop</u>	97			06	63 65 67 69 99 99 99 99 69 69 69 69 69 69 69 69 69 69 69 69 69 69
TRIP					
<u>Imaging</u>			108	07	
<u>Purdue</u>	109 13114 122	1017		1	⁰ 0 ⁰ 0 ⁰ 0 ²
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Questions? Suggestions? Future directions?