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

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
Conventional Model: Segregated systems of research & training

Mental or Physical Health

- Genetics
- Neuroscience
- Cognitive
- Social
- Psychopathology
- Clinical practice
- Health policy

- Behavioral
- Neuroimaging
- Systems
- Cellular
- Molecular
- Animal models

- Classification
- Diagnosis
- Phenomenology
- Etiology
- Case management
- Psychotherapy
- Neurophysiology
- Pharmacology

- Case management
- Psychotherapy
- Neurophysiology
- Pharmacology

- Case management
- Psychotherapy
- Neurophysiology
- Pharmacology

- Case management
- Psychotherapy
- Neurophysiology
- Pharmacology
Clinical Translational Science Model: Integrated systems of research & training

The Problem Area (e.g., schizophrenia)

Problem focused research & training that facilitates translation

Clinical Translational Science: A subdiscipline to add to the landscape

Mental &/or Physical Health
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)

Agenda

1. Quick overview of the Indiana CTSI
   a. What it is?
   b. Who funds it?
   c. Who are its partners and users?
2. 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

<table>
<thead>
<tr>
<th>Type of Commitment</th>
<th>New Funds/5yrs</th>
<th>New Space</th>
<th>New space Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>IU VP for Life Sci. funds</td>
<td>$11 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IU President’s funds</td>
<td>$5 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purdue President’s fund</td>
<td>$2.5 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indiana legislature</td>
<td>$15 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HITS Building (CTSI home)</td>
<td></td>
<td>169,000 Sq. Ft.</td>
<td>$42 million</td>
</tr>
<tr>
<td>INGEN Core support</td>
<td>$10 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Department of Pediatrics</td>
<td>$6 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IUSM Biostats/Bioethics support</td>
<td>$2.75 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eli Lilly training support</td>
<td>$3.15 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Translational fellowship</td>
<td>$600,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research 3 building CTSI space</td>
<td></td>
<td>6000 Sq. Ft.</td>
<td>$8 million</td>
</tr>
<tr>
<td>Totals</td>
<td>$56 million</td>
<td>175,000 Sq. Ft.</td>
<td>$50 million</td>
</tr>
</tbody>
</table>
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)
2. What is clinical translational science?
   a. NIH’s impetus
   b. Strategic goals the CTSAs
   c. Key functions
   d. Who has a CTSA?
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
Re-engineering Clinical Research

T1 Translation

Bench

Building Blocks and Pathways
- Molecular Libraries
- Bioinformatics
- Computational Biology
- Nanomedicine

T2 Translation

Bedside

Translational Research Initiatives

Community Practice

Integrated Research Networks
- Clinical Research Informatics
- NIH Clinical Research Associates
- Clinical Outcomes

Cross-cutting: Harmonization, Training

Clinical and Translational Science Awards (CTSAs)

- Educate the next generation of clinical researchers
- Improve clinical research management
- Build diversity in leadership
- Assemble interdisciplinary teams
- Enhance public trust
- Forge partnerships with private and public health care organizations

CTSAWeb.org
Key Functions

CTSA Academic Center

- Clinical Research Innovation
- Education and Career Development
- Clinical Research Ethics
- Biomedical Informatics
- Clinical Resources
- Translation
- Community Engagement
- Evaluation
- Comparative Effectiveness
- Public Private Partnerships
- Communication
- Biostatistics
- Regulatory Support

NIH & other government agencies

Industry

Healthcare organizations

Building a National CTSA Consortium

Participating Institutions
- Since 2006
- Since 2007
- Since 2008
- Since 2009
I. Translational research acceleration programs:
   A. Research awards
      1. Collaboration in Translational Research Pilot Grant Program (CTR)
         • Goal: Foster collaborations between investigators at IUB, Purdue, ND, IUSM, and IUPUI in translational research projects with strong potential to develop into externally funded programs or IP.
      2. Project Development Team (PDT) Pilot Funding
         • Goal: Provides funding to support development of preliminary data for external grant submissions.
      3. Pilot Core Funding
         • Promotes use of CTSI cores across CTSI partner institutions and supports science with a high potential for external funding or IP.
      4. Research Inventions and Scientific Commercialization (RISC)
         • Pilot program to support potential gaps in research that leads to IP generation at IU in collaboration with IURTC.

3. Indiana CTSI research & training programs
   a. Research grants
   b. Education & career development
   c. Infrastructure and resources
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.

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.

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.
  4. 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.
  8. Imaging PDT provides expertise in the application of anatomical, functional, and molecular imaging methodologies and technologies.
### Agenda

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
Questions?
Suggestions?
Future directions?