Indiana Clinical and Translational Sciences Institute (I-CTSI)

Anantha Shekhar, MD, PhD
Indiana CTSI

What is it?
An NIH funded institute established at Indiana University with Purdue University and other statewide partners

What is its Mission?
Increase translational research to improve the health (and economy) of Indiana
What is Translational Research?

Translational Circle

Bench

Basic Research
- Preclinical studies
- Animal studies

T1
- Case series
- Phase I & II studies

Clinical Research
- Phase III studies
- Efficacy studies

T2
- Meta-analyses
- Systematic Reviews

Bedside

Product Development
- Licensing
- IP management
- Industry Partnership

Commercialization

Healthcare

Translation into Practice - TRIP
- Care Acceptance
- Health economics

T3
- Dissemination & Implementation research

Community

Practice Based Research
- Phase IV studies
- Best Practice studies

T4
- Disease Modeling
- -Omic studies
- Pharmacogenetics

Phase I & II studies

Phase III studies

Best Practice studies

Case series

What is Translational Research?
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?
Indiana CTSI partners

To increase translational biomedical research and improve the health of the people of Indiana and beyond.
## 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>
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<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>
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<tr>
<td>Indiana legislature</td>
<td>$15 million</td>
<td></td>
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<tr>
<td>HITS Building (CTSI home)</td>
<td></td>
<td>169,000 Sq. Ft.</td>
<td>$42 million</td>
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<tr>
<td>INGEN Core support</td>
<td>$10 million</td>
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<td></td>
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<tr>
<td>Department of Pediatrics</td>
<td>$6 million</td>
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<tr>
<td>IUSM Biostats/Bioethics support</td>
<td>$2.75 million</td>
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<tr>
<td>Eli Lilly training support</td>
<td>$3.15 million</td>
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<tr>
<td>Translational fellowship</td>
<td>$600,000</td>
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<td></td>
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<tr>
<td>Research 3 building CTSI space</td>
<td></td>
<td>6000 Sq. Ft.</td>
<td>$8 million</td>
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<tr>
<td><strong>Totals</strong></td>
<td><strong>$56 million</strong></td>
<td><strong>175,000 Sq. Ft.</strong></td>
<td><strong>$50 million</strong></td>
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</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)
I - CTSI: Structure and Goals

I. Create Translational Research Acceleration Programs
II. Train a New Cadre of Translational Researchers
III. Foster Robust Community Engagement
IV. Build Facile and Comprehensive Research Resources and Technologies
V. Leverage Resources of the Greater Indiana Community

Indiana University
1. Overview
2. Governance
3. Novel Clinical & Translational Methodologies
4. Informatics Program
5. Study Design Biostatistics
6. Regulatory Knowledge Support
7. PCIR
8. Community Health Enhancement Program (CHEP)
9. TTR Cores
10. Education, Training & Career Development CITE- K30, K12, T32
11. Tracking & Evaluation
12. Milestones & Implementation

Purdue University
13. Bioethics Advocacy
14. Bio medical & Nanotechnology
15. Disease Modeling Eli Lilly & Co
16. Future Directions Global Health WellPoint

Improved Health of Indiana & Beyond

Trainee
Researcher
Community
Indiana CTSI Goals

1. Create Translational Research Acceleration Programs
I-CTSI Goal 1

What are the translational research acceleration programs?

- Project Development Teams (PDT)
- Pilot grants (solicited & unsolicited)
- Greater access to core facilities

How will this work?
Mapping and Oversight Program (MOP)

- Pilots project mapping
- Mapping sets metrics and milestones
- Milestone driven access to funds

How will this work?
Indiana CTSI Goal 2

Train a new cadre of Translational Researchers

What about the ‘K 30’ program?
What new training programs are there?
Medical Students
Pilot Program
Curriculum
MS in Clinical Research
MS in Translational Research
PhD in Translational Research
CITE Core Program
Scholars
K-12 postdoctoral
T-32 predoctoral
Others (K-23, other T-32)
Indiana University Bloomington
Purdue University
PhDs
Minor in Clinical or Translational Research
Residents
Research Electives
Medical Students
Pilot Program
College Students
Summer Internships
Translational Scholars
Informed Consumers
PI E L
PI E L
PI E L
Indiana CTSI

Goals

3. Foster Robust Community Engagement

Create ‘CHEP’ (community health enhancement program)
Community Health Engagement Program

Administrative oversight and management of community engagement, practice & community data integration, communications, technical assistance, training in community

CHEP Executive Committee

Community Advisory Board

CHEP Project Coordination Teams

Community Population Engagement

Community Provider Engagement

Advancing Community Research Methods
Indiana CTSI

Goals

4. Build Facile and Comprehensive Research Resources and Technologies

How is this done?
Indiana CTSI

Comprehensive Resources

- Build new programs such as
  - Participant and clinical interaction resources (PCIR)
  - Translational technology resources (TTR)
  - Study Design and Biostatistics
  - Research ethics support and education
  - Regulatory support office
  - Central IRB
PCI R- Indiana CTSI

What about the GCRC?
Will continue as a CRC, will have Clarian nursing, plus research nurses

Can you access OCRF resources?
Yes, the OCRF services will continue as the CTSI’s consolidated CRO

Log on to: IndianaCTSI.org
or Call 317-278-CTSI (2874)
Participant and clinical interaction resources (PCIR)

Office of VP for Research Administration
OVPRA

Clinical and Translational Sciences Institute
CTSI

Patient and Clinical Interaction Resources
PCIR

Clinical Trials Office
CTO

Clinical Research Office
CRO

Clinical Research Center
CRC

Subject Recruitment Office
SRO
What will change with cores?
Uniform access and utilization procedures across all campuses for core facilities

How about core utilization grants?
Will continue through the CTSI ‘HUB’ or TTR helpdesk

How about GCRC Labs?

Log on to: IndianaCTSI.org
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Indiana CTSI

Governance

1. Internal organizational chart
2. External Advisory Board
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