

Indiana Clinical and Translational Sciences Institute

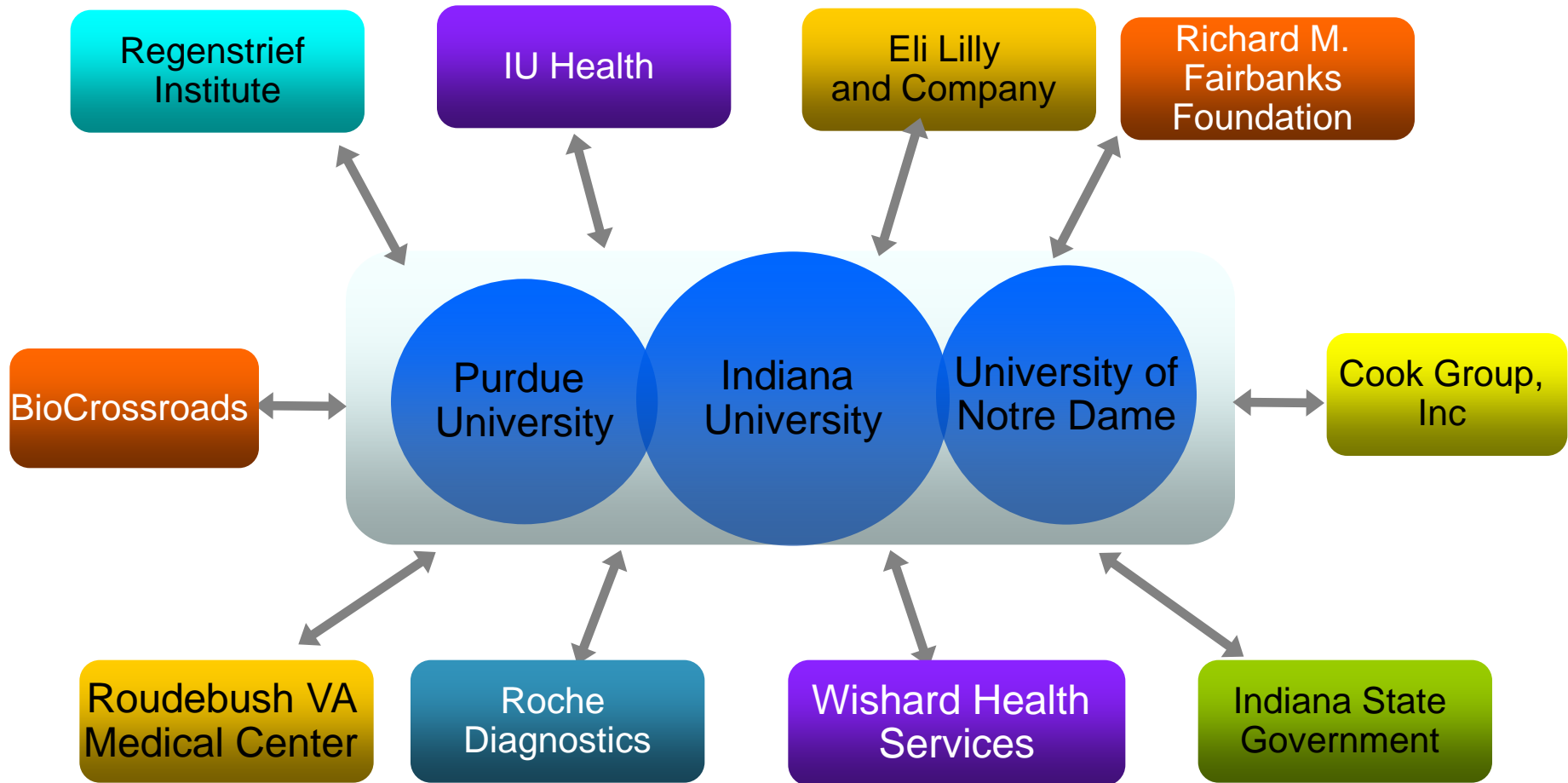
*A statewide Laboratory for accelerating Clinical and
Translational Research*



Indiana CTSI Today

- ❖ State-wide laboratory created to transform health sciences research and health care delivery.
- ❖ A strong Indiana public-private partnership that extends beyond basic research and looks at specific programs to improve the health of Hoosiers and all Americans.
- ❖ Part of a National Consortium of **60** Academic Health Partners working together to accelerate biomedical discoveries across **30** states and DC.

Indiana CTSI Partners – Providing Leveraging Opportunities Throughout the State



Existing Programs

Programs of the Indiana CTSI application	Key function 'Section' of the RFA that is met by this section (Assuming these required elements stay)
1. Administration (Shekhar)	1. Overview
2. Governance (Shekhar)	2. Governance
3. Novel Translational Methodologies and Pilot Studies Lead: Dr. Denne	3. Novel Translational Methodologies and Pilot Studies
4. Biomedical Informatics Lead: Dr. Tierney	4. Biomedical Informatics
5. Biostatistics, Epidemiology and Research Design (BERD) Lead: Dr. Hui	5. Design and Biostatistics
6 & 7. Bioethics, Regulatory Affairs and Subject Safety (BRASS) Lead: Dr. Meslin	6. Regulatory Knowledge and Support
8. Participant and Clinical Interaction Resources (PCIR) Lead: Drs. Shekhar and Denne	7. Participant and Clinical Interaction Resources (PCIR)
9. Community Health Engagement Program (CHEP) Lead: Drs. Marrero and Miller	8. Community Engagement and Research
10. Translational Technologies and Resources (TTR) Lead: Dr. Cornetta	9. Translational Technologies and Resources (TTR)
11. Research Education, Training and Career Development (including disease modeling) Lead: Dr. Kroenke	10. Research Education, Training and Career Development
12. Tracking and Evaluation Lead: TBN and Shekhar	11. Tracking and Evaluation
13. Implementation Plan and Milestones Lead: Dr. Shekhar	12. Implementation Plan and milestones
14. Biomedical Engineering and Nanotechnology Lead: Dr. Wodicka	Optional section

Renewal Strategy

15. Personalized Therapeutic Program (partnership with Institute for Personalized Medicine, Bioinformatics)	Optional section; New Dr. Flockhart to lead
16. Targeted Molecules and Diagnostics Program (partnership with relevant centers at IUSM, Purdue, ND and IUB)	Optional section; New Drs. Zhang and Ratliff to lead
17. Global Health Program (partnership with Center for Global Health)	Optional section; New Dr. Inui and TBN from ND to lead
18. Health Implementation and Innovation Program (in partnership with proposed Innovation and Implementation Sciences Institute, IUH, Wishard, IHIE, etc.)	Optional section; New Drs. Boustani and Beyt to lead

Mission and Goals

*Improve Health and Economy of Indiana
by:*

- 1. Creating Translational Research Acceleration Programs**
- 2. Training a New Cadre of Translational researchers**
- 3. Fostering Robust Community Engagement**
- 4. Streamlining Clinical Research Resources**
- 5. Leveraging Resources of the Greater Indiana Community**

PDT projects



T1
Basic Science



T2
Human Clinical Research



T3
Implementation and Outcomes Research



142



197



20

Goal 2. Training Translational Researchers

Challenge:

- Need to Create Innovative Training Programs and develop future workforce

CTSI Solution:

1. Clinical Faculty Career Development Awards (12 awarded in 2011)
2. Basic Research Faculty career development awards (5 in 2011)
3. Graduate Training (20 awarded)
4. Masters Degrees
 - MS in Clinical research for MD, Nurses, Clinicians
 - MS in Translational Sciences just started this year
5. Program for Research coordinator certification (RCCP)
6. Professional, Undergraduate, and high school Medical Research Fellowships
7. Developing: International Translational Research Programs (Kenya, Australia, others)

Goal 2.

Significant Results to date:

1. 3 K awardees obtained their R01s this year
(1 got 2 R01s)
2. Starting an MD, MS program
3. Planning a DDS, MS program

Goal 3. Robust Community Engagement

Challenge:

- Improve clinical research access through health literacy, research participation and Biobanking in the community
- Increase collaboration among community and research partners throughout Indiana to improve research, health and healthcare

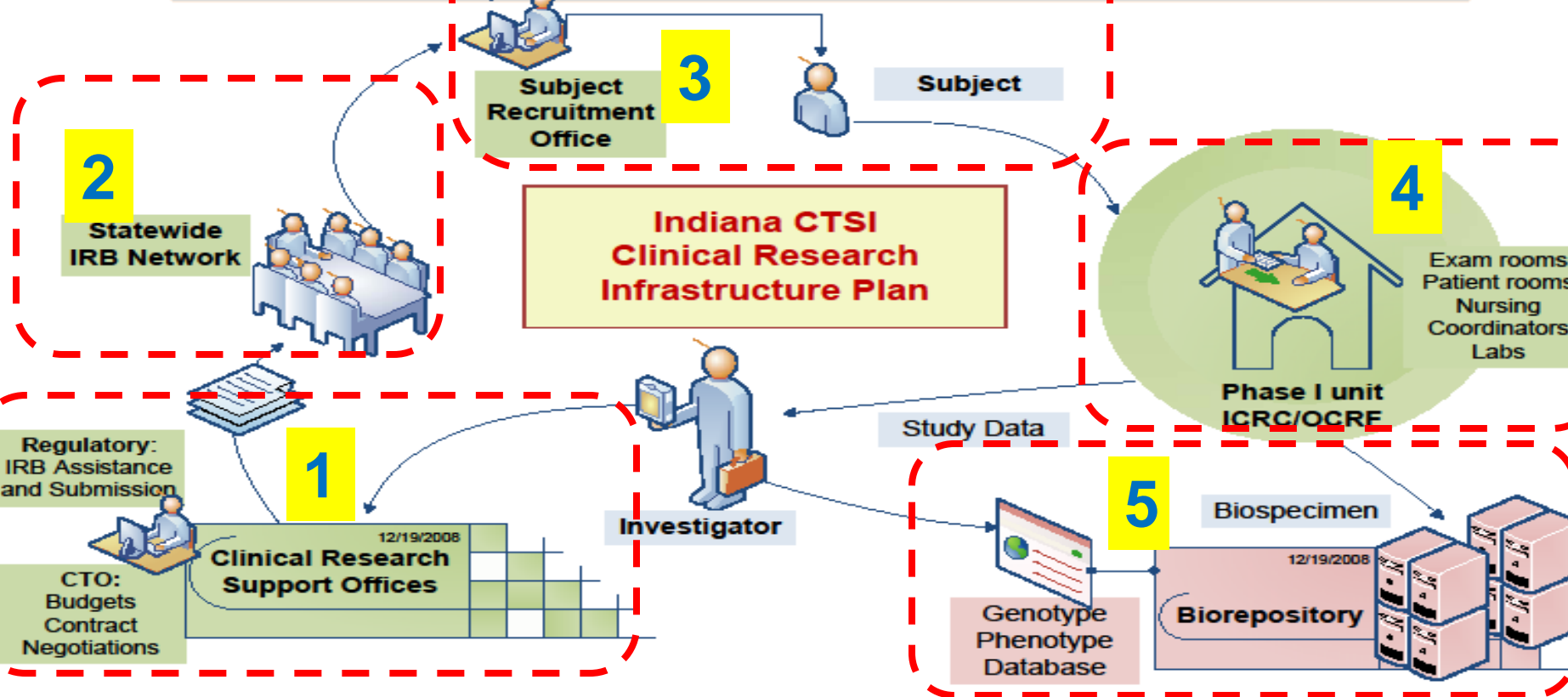
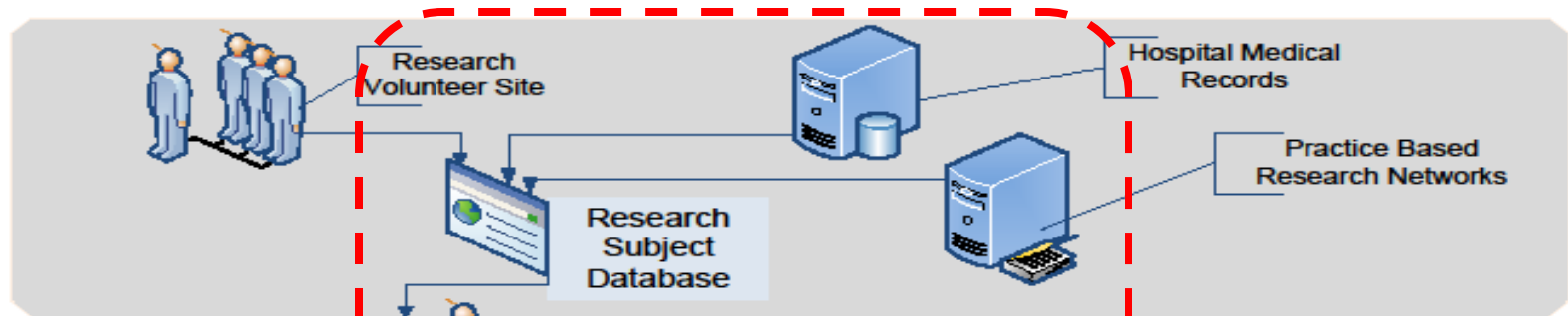
CTSI Solution:

- Community Health Enhancement Program (CHEP)
- Over 280 active Community Partners engaged Community
- Community Advisory Council (CAC) established
 - Focus areas meet monthly, entire group annually
- A New mechanism developed to supplement subject recruitment similar To PDTs

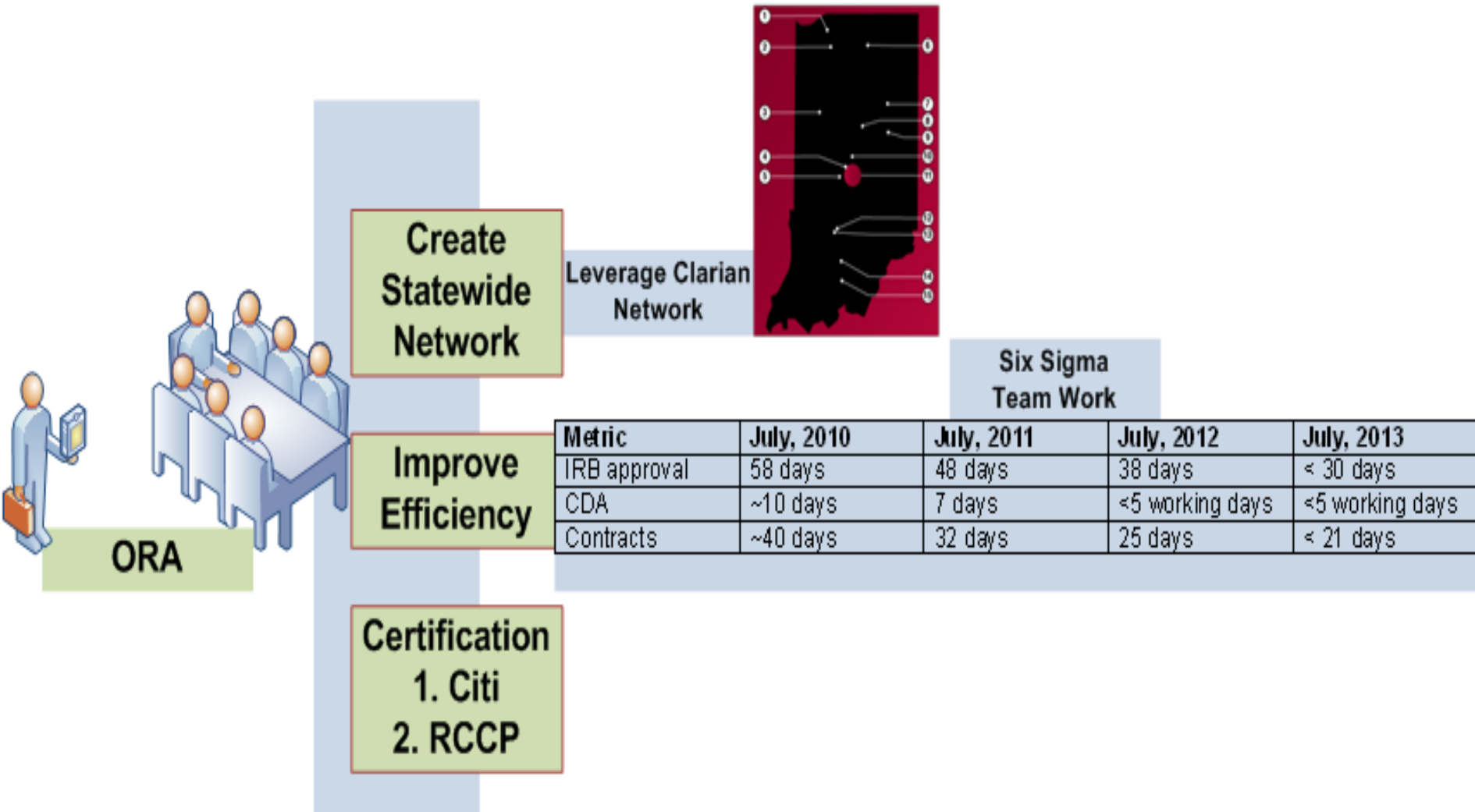
Goal 4. Streamlining and Enhancing Clinical Research Resources

Challenges:

- Regulatory barriers need to be shortened through contracts, IRBs
- Need to engage more patients in clinical studies
- Need a place to conduct pivotal studies faster, better
- Need to establish a statewide Biobank



Regulatory Processes

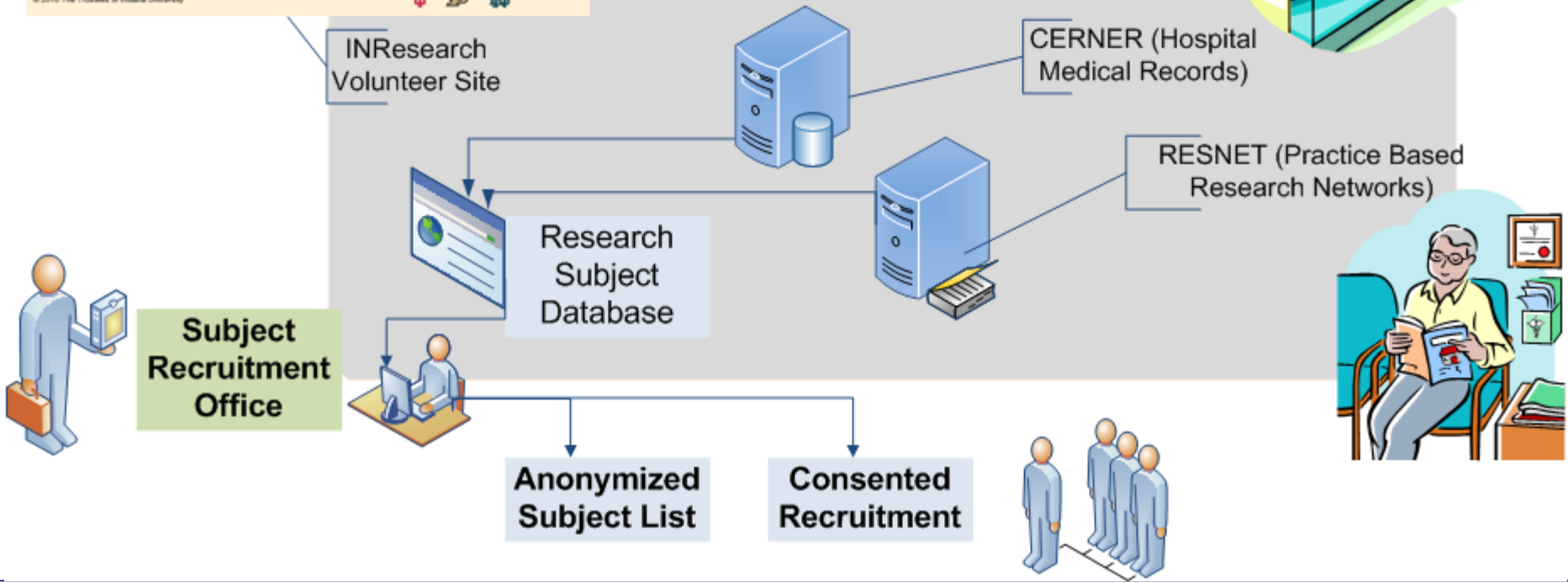


Goal 4.

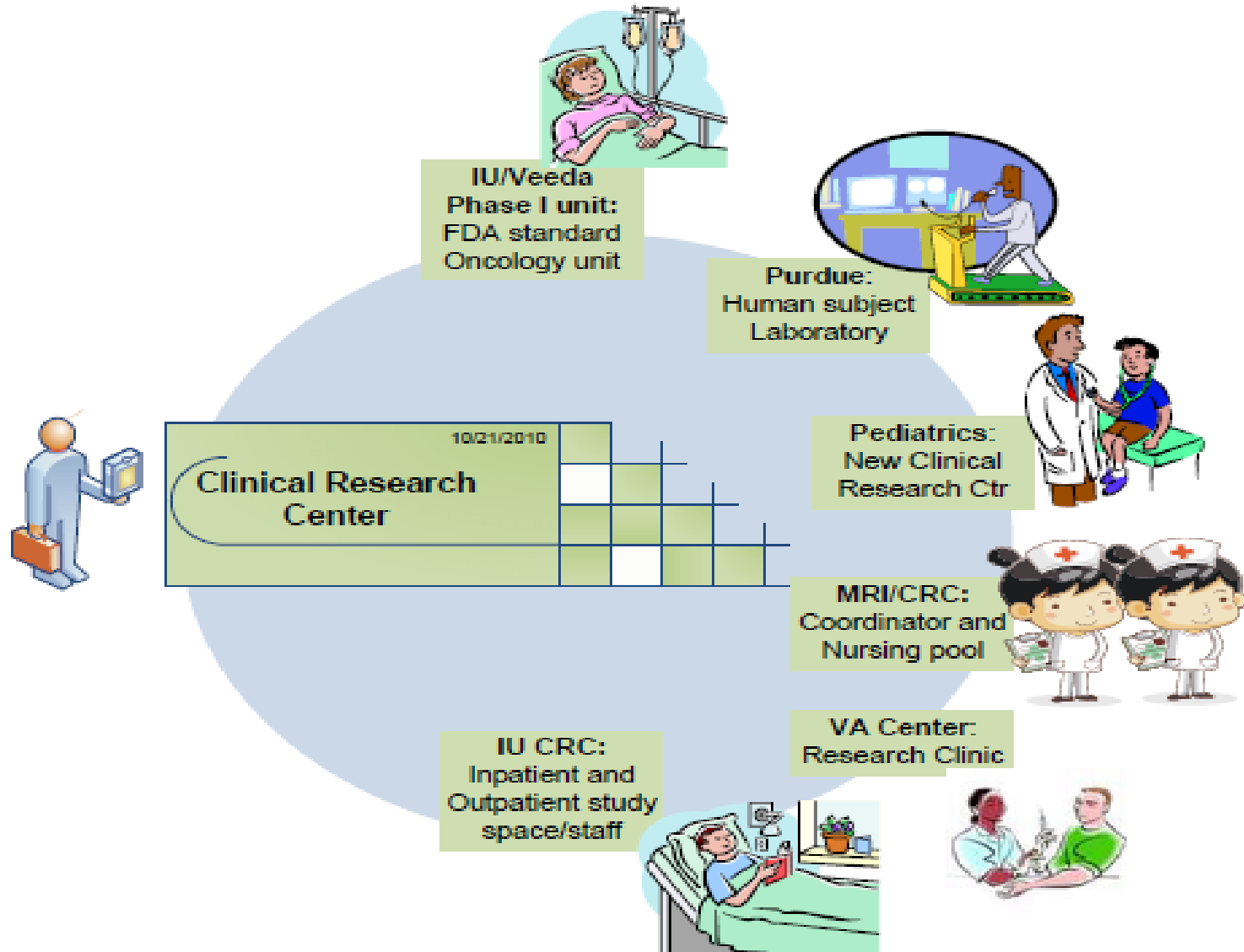
Significant Results to date:

1. Contract time Reduced to <21 days
2. IRB – working on improvements –
Currently around 53 (84) days

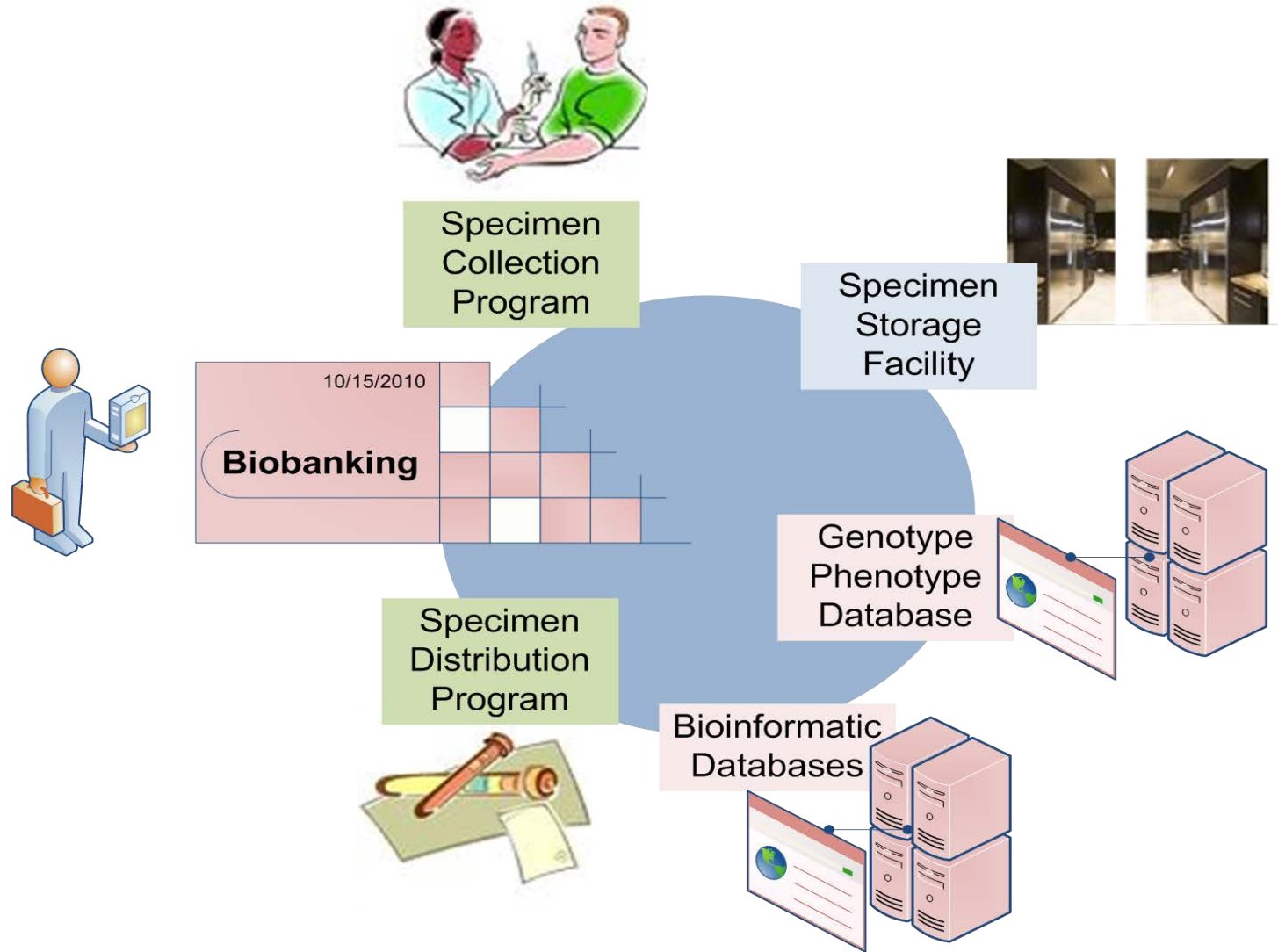
Subject Recruitment Office



Clinical Research Resources



Bio-banking Program

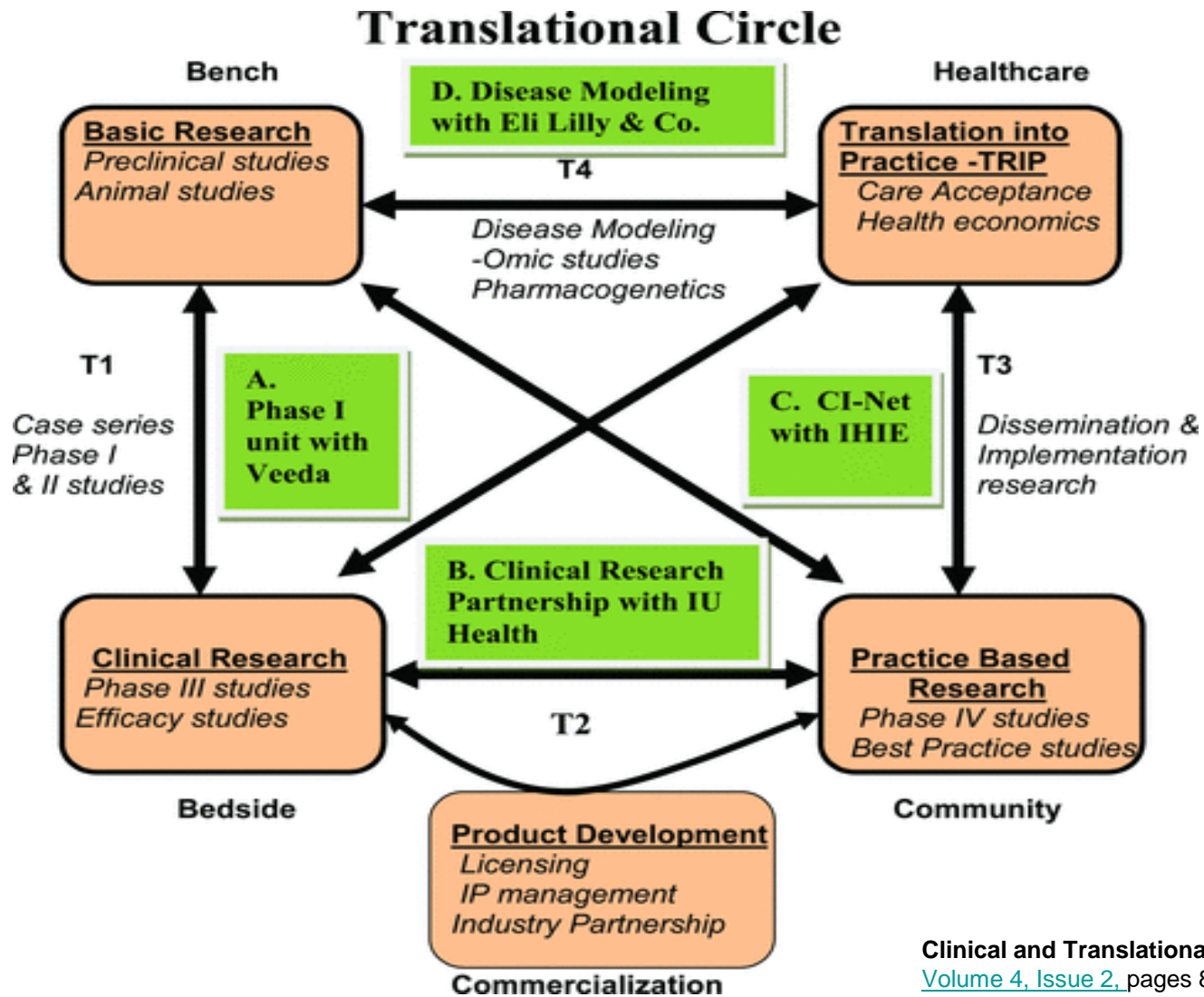


Goal 4. BioBank

1. We now have >4000 annotated samples
2. We have identified have targeted patients with unique phenotypes:
 - a. 30 years of medical records seen last year (6,700)
 - b. 5 years of full pharmacy records (6,000).

HTN (Hypertension)	4699	79.44
DM (Diabetes Mellitus)	2265	38.29
CHF (Congestive Heart Failure)	661	11.17
CAD (Coronary Artery Disease)	838	14.17
RAD (Reactive Airway Disease)	2417	40.86
CVA (stroke)	492	8.32
Renal Disease/Failure	223	3.77
MI (Myocardio Infarction)	829	14.02
Cancer	459	7.76
Liver Problem	162	2.74

Goal 5. Leverage Community Resources



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Other Significant Results to date:

1. Developed “*i2i*” with Cook; Now developing system wide device trial capability
2. Indiana Health Study - Fairbanks Institute for Healthy Communities conducting a longitudinal study of the Indianapolis population